

# **Merus** *closing in on cancer*

**Merus N.V.**

**Dutch statutory board report and financial statements  
for the fiscal year ended December 31, 2022**

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# **1 INTRODUCTION**

## **1.1 Preparation**

In this report, the terms "we", "us", "our" and "the Company" refer to Merus N.V. and, where appropriate, its subsidiaries.

This report has been prepared by the Company's board of directors pursuant to Section 2:391 of the Dutch Civil Code, or DCC, and also contains (i) the Company's financial statements within the meaning of Section 2:361(1) DCC and (ii) to the extent applicable, the information to be added pursuant to Section 2:392 DCC. This report relates to the fiscal year ended December 31, 2022 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2022. Section 10 of this report contains our consolidated financial statements and our Company financial statements.

## **1.2 Cautionary Statement Regarding Forward-Looking Statements**

This report contains forward-looking statements. All statements other than statements of historical facts contained in this report are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "forecast," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this report, include without limitation statements regarding our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials, the timing of and our ability to obtain and maintain regulatory approvals, the clinical utility of our product candidates, our commercialization, marketing and manufacturing capabilities and strategy, our expectations surrounding our collaborations, our expectations about the willingness of healthcare professionals to use our product candidates, the sufficiency of our cash, cash equivalents and investments, and the plans and objectives of management for future operations and capital expenditures.

The forward-looking statements in this report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this report and are subject to a number of known and unknown risks, uncertainties and assumptions and other important factors, including those described under the sections in this report entitled "Summary Risk Factors," "Risk Factors" and elsewhere in this report.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving

environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this report to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

## **2 INFORMATION ON THE COMPANY**

### **2.1 Business Overview**

We are a clinical-stage oncology company developing innovative antibody therapeutics. Our pipeline of full-length, human, multispecific antibody candidates is generated from our proprietary technology platforms, which are able to generate a diverse array of antibody binding domains, or Fabs, against virtually any target. Each antibody binding domain consists of a target-specific heavy chain paired with a common light chain. Multiple binding domains can be combined to produce novel multispecific antibodies that bind to a wide range of targets and display novel and innovative biology. These platforms, referred to as Biclonics® and Triclonics®, allow us to generate large numbers of diverse panels of bispecific and trispecific antibodies, respectively, which can then be functionally screened in large-scale cell-based assays to identify those unique molecules that possess novel biology, which we believe are best suited for a given therapeutic application. Further, by binding to multiple targets, Biclonics® and Triclonics® may be designed to provide a variety of mechanisms of action, including simultaneously blocking receptors that drive tumor cell growth and survival and mobilizing the patient's immune response by engaging T cells, and/or activating various killer cells to eradicate tumors.

Our technology platforms employ an assortment of patented technologies and techniques to generate human antibodies. We utilize our patented MeMo® mouse to produce a host of antibodies with diverse heavy chains and a common light chain that are capable of binding to virtually any antigen target. We use our patented heavy chain and CH3 domain dimerization technology to generate substantially pure bispecific and trispecific antibodies. We also employ our patented Spleen to Screen® technology to efficiently screen panels of diverse heavy chains, designed to allow us to more rapidly identify Biclonics® and Triclonics® therapeutic candidates with differentiated modes of action for pre-clinical and clinical testing.

Using our Biclonics® platform we have produced, and are currently developing, the following candidates: MCLA-128 (zenocutuzumab or Zeno) for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions as a monotherapy, for the potential treatment of non-small cell lung cancer (NSCLC) harboring NRG1 gene fusions in combination with afatinib, and for the potential treatment of castration resistant prostate cancer (CRPC) in combination with an androgen deprivation therapy (ADT); MCLA-158 (petosemtamab) for the potential treatment of solid tumors; MCLA-129, for the potential treatment of lung and other solid tumors; and MCLA-145 for the potential treatment of solid tumors. Furthermore, we have a pipeline of proprietary antibody candidates in pre-clinical

development and intend to further leverage our Biclomics® and Triclomics® technology platforms to identify multiple additional antibody candidates and advance them to clinical development.

## 2.2 Our Strategy

Our goal is to become a leading oncology company developing innovative multispecific antibodies to treat various types of cancer. Our business strategy comprises the following components:

- **Successfully develop our most advanced bispecific antibody candidate, zenocutuzumab, for the treatment of NRG1 fusion solid tumors, and explore other potential indications in non-NRG1 fusion cancers by targeting both HER2 and HER3.** We are developing our most advanced bispecific antibody candidate, zenocutuzumab, for the potential treatment of solid tumors that contain NRG1 gene fusions. The NRG1 protein is the ligand for the HER3 receptor—a known cause of cancer cell growth. The gene encoding NRG1 can form genetic rearrangements referred to as NRG1 gene fusions. The protein product of the NRG1 gene fusion can drive signaling through the HER3 receptor and thus drive cancer cell growth. NRG1 gene fusions (NRG1+) occur infrequently in a wide range of different cancer types. Zenocutuzumab has been shown pre-clinically to potently disrupt binding of NRG1 (and NRG1-fusion proteins) to HER3 and halt NRG1-stimulated tumor cell growth. In July 2020, the FDA granted zenocutuzumab orphan drug designation for the treatment of patients with pancreatic cancer and in January 2021, the FDA granted Fast Track Designation to zenocutuzumab for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy. We plan to provide an update on the potential registrational path and timeline in NRG1+ cancer in the first half of 2023 and a clinical update on zenocutuzumab in NRG1+ cancer at a major medical conference in 2023. Further, we are evaluating a cohort exploring the combination of zenocutuzumab with enzalutamide or abiraterone, an androgen deprivation therapy (ADT) in castration resistant prostate cancer (CRPC), and we plan to provide an initial clinical data update on zenocutuzumab in CRPC in the second half of 2023. Further, we are evaluating a cohort exploring the combination of zenocutuzumab and afatinib for patients with NRG1+ non-small cell lung cancer (NSCLC).
- **Successfully develop our bispecific antibody candidate MCLA-158, petosemtamab.** We are developing petosemtamab for a potential dual EGFR/LRG5 blockade for the treatment of solid tumors. Our phase 1/2 clinical trial of petosemtamab is ongoing in the dose expansion phase. In April 2023, we announced initiation of a cohort in the petosemtamab trial, investigating petosemtamab in combination with Keytruda in patients with untreated head and neck squamous cell carcinoma, or HNSCC, designed to evaluate safety and clinical activity in this population. In April 2023, we further announced interim clinical data as of a February 1, 2023 data cutoff, from the ongoing phase 1/2 trial of petosemtamab in previously treated HNSCC during a plenary session presentation at the AACR Annual Meeting. As of the February 1, 2023 data cutoff date, 49 previously treated HNSCC patients were treated with petosemtamab at the recommended phase 2 dose of 1500 mg intravenous (IV) every two weeks, 6 patients excluded per protocol (5 withdrew due to infusion-related reactions, or IRRs, on day 1 and 1 patient with exclusion

criterion). Below is a summary of the interim clinical data as of the February 1, 2023 data cutoff date:

- Patient population:
  - Median age was 63 (range of 31-77); 78% were male;
  - Median prior lines of systemic therapy was 2 (range 1-4); including PD-(L)1 inhibitor in 96% of patients, chemotherapy in 94% and platinum-based chemotherapy in 92% of patients; 2 patients received prior cetuximab; and
  - Most frequent primary tumor locations were oropharynx (35%), oral cavity (31%), and larynx (16%).
- 43 patients were evaluable for efficacy, receiving  $\geq 2$  treatment cycles ( $\geq 8$  weeks) with  $\geq 1$  post-baseline tumor assessment or experiencing early progressive disease:
  - Antitumor activity among 43 patients:
    - Overall response rate was 37.2% (16/43; 95% CI 23%-53.3% ) by RECIST 1.1 per investigator assessment, including 15 confirmed partial responses, or PRs, and 1 confirmed complete response, or CR (ongoing after 20 months);
    - Disease control rate (CR + PR + stable disease) was 72.1% (31/43; 95% CI 56.3%-84.7%);
    - Median time to response was 1.8 months (range 0.8-3.5);
    - Median duration of response was 6.0 months (95% CI 3.7-NC), with 10 of 16 (62.5%) responders ongoing, and 12 of 43 (27.9%) patients overall ongoing at the time of the data cutoff;
    - Median progression free survival was 5.3 months (95% CI 3.7-6.8); with 29 of 43 patients progressing and 14 of 43 patients censored; and
    - Median overall survival was 11.5 months (95% CI 7.2-20.6); with 29 of 49 patients still alive at the data cutoff date.

Petosemtamab continued to demonstrate manageable safety results:

- 80 patients were treated with 1500 mg petosemtamab every two weeks across dose escalation and expansion cohorts of the study;

- Gastrointestinal and skin toxicities were mostly mild to moderate;
- No treatment-related Grade 5 adverse events, or AEs:
  - Most frequent related AEs were signs and symptoms of IRRs;
  - 74% Grade 1-4, 21% Grade 3-4 (as grouped term);
  - Mainly occurred during first infusion;
  - 6 of 80 patients discontinued on Day 1 due to a Grade 3-4 IRR;
  - For all patients rechallenged after an IRR, rechallenge was successful; and
  - IRRs were manageable with prophylaxis/prolonged infusion (necessary on day 1 only).

Further, in April 2023, we announced the publication of an abstract for a poster presentation of early clinical data on petosemtamab in advanced gastric/esophageal adenocarcinoma, or GEA, at the AACR Annual Meeting. Although petosemtamab has demonstrated encouraging clinical activity among GEA patients having EGFR gene amplification and/or overexpression, we have decided to pause further clinical exploration of the GEA cancer cohort at this time, with plans to prioritize investigating petosemtamab in HNSCC. Further, in April 2023, we provided an update concerning our meeting with the U.S. Food and Drug Administration, or the FDA, in an end-of-phase meeting to discuss interim results from the previously treated HNSCC cohort of the petosemtamab phase 1/2 trial. The FDA recognized recurrent or metastatic HNSCC represents an area of unmet medical need, and provided clear recommendations for the path to potential registration. Based on the strong clinical data and discussions with the FDA, we believe a randomized clinical trial in previously treated (2L/3L) or untreated (front-line) HNSCC may support a possible registration. Additionally, we believe a randomized registration trial in HNSCC with an overall response rate endpoint could potentially support accelerated approval and the overall survival results from the same study could potentially verify its clinical benefit to support regular approval. We also plan to continue to acquire data to confirm a suitable dose for future randomized clinical trials. Further, we plan to provide an update in Q3 2023 on our potential registrational path for this program.

- **Successfully develop our bispecific antibody candidate MCLA-129.** We are developing MCLA-129 as a potential treatment for solid tumors, including NSCLC. In May 2021, we announced that the first patient was treated in the phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced NSCLC and other solid tumors. The MCLA-129 trial is ongoing in the dose expansion phase, treating patients with MCLA-129 monotherapy in c-MET exon 14 mutant (mt) NSCLC, exon 20 insertion (EGFRex20) NSCLC, HNSCC, as well as in combination with Tagrisso (osimertinib) a third generation EGFR tyrosine kinase inhibitor (TKI) in treatment naive EGFRmt NSCLC and in patients with EGFRmt NSCLC that have progressed on Tagrisso. We plan to provide an initial clinical data update from the expansion cohorts, and a further clinical development strategy



update in the second half of 2023. MCLA-129 is subject to a collaboration and license agreement between Merus and Betta Pharmaceuticals Co. Ltd. (Betta), whereby Merus exclusively licensed Betta to develop MCLA-129 in China, while Merus retains full ex-China rights.

- **Successfully develop our bispecific antibody candidate MCLA-145.** We are developing MCLA-145 in an ongoing phase 1 trial for the potential treatment of solid tumors. MCLA-145 is designed to recruit, activate and prevent the exhaustion of tumor-infiltrating T-cells. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. In December 2021, we presented interim clinical data on MCLA-145 from the phase 1 trial dose escalation study in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021. As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors had been treated at eight dose levels ranging from 0.4-75mg every two weeks. Preliminary evidence of antitumor activity was observed at doses  $\geq 25$  mg biweekly. We have also initiated a cohort combining MCLA-145 with Keytruda (pembrolizumab) a PD-1 blocking antibody, with enrollment on-going.
- **Accelerate the discovery and development of additional internal and collaboration-related bispecific antibody candidates and internal trispecific antibody candidates.** We believe we are well positioned to expand our pipeline of Biclomics® and Triclomics® molecules for the potential treatment of cancer and potentially other forms of disease. We are conducting pre-clinical studies for our internal proprietary bispecific and trispecific pipeline as well as leveraging our bispecific platform with our collaborators including Incyte, Eli Lilly and Company (Eli Lilly) and Betta.
- **Seek strategic collaborations.** We intend to seek strategic collaborations to facilitate the capital-efficient development of our pipeline and to maximize the value of our Biclomics® and Triclomics® technology platforms and to access unique partner capabilities and capacity. We have entered into collaborations with Incyte, Eli Lilly, and Betta to develop bispecific antibody candidates based on our Biclomics® technology platform. We plan to work with other potential future collaborators to further validate and expand the use of our Biclomics® and Triclomics® platforms in developing bispecific and trispecific antibody candidates. We have also worked with Ono Pharmaceutical Co., Ltd., under a research license agreement to generate bispecific antibodies, including for indications in and outside oncology, which further underscore the breadth of the Merus platform. We believe these collaborations, license and future agreements could potentially provide significant funding to advance our pipeline and allow us to benefit from the additional resources, development and commercialization expertise of our collaborators.

### 2.3 Organizational Structure

We have one wholly owned subsidiary, Merus US, Inc., which is incorporated in the United States in the State of Delaware.

## 2.4 Summary of Key Risk Factors

Our business is subject to numerous risks and uncertainties, including those described here and in this report under the section entitled “Risk Factors”. You should carefully consider these risks and uncertainties when investing in our common shares. The principal risks and uncertainties affecting our business include the following:

- We have incurred significant net losses since our inception and we expect to continue to incur significant expenses and operating losses for the foreseeable future.
- We have a limited operating history, have not completed any registrational clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.
- The clinical trial and regulatory approval processes are lengthy, time consuming and inherently unpredictable, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our antibody candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our antibody candidates or following approval, if any, we may need to abandon our development of such antibody candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.
- We have never commercialized an antibody candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable collaborators.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations or CROs, to conduct our pre-clinical studies, clinical trials, chemistry, manufacturing and controls and potential development of a companion diagnostic. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or perform at reasonable cost, we may not be able to obtain regulatory approval for or commercialize our antibody candidates or we may be subject to other significant negative consequences following marketing approval, if any, and our business could be substantially harmed.

- Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain antibody candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.
- We operate in highly competitive and rapidly changing industries, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we are unable to adequately protect our intellectual property and our proprietary technologies or obtain and maintain issued patents which are sufficient to protect our product candidates and proprietary technologies, or if others do not respect our intellectual property rights and exclusivity, others could compete against us more directly, which would negatively impact our business.
- Our existing collaboration agreements are important to our business and potential future collaborations and licenses may also be important to us, and if we are unable to maintain any of these collaborations or execute new collaborations or licenses, or if these arrangements are not successful, our business could be adversely affected.
- The trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of disruptions and extreme volatility in the global economy, including rising inflation and interest rates, declines in economic growth, the conflict between Russia and Ukraine and the COVID-19 pandemic, which have and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition, our ability to raise capital and results of operations.

### **3 RISK FACTORS**

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this report. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

#### **Risks Related to Our Business and Industry**

*We are a clinical-stage company and have incurred significant losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.*

We are a clinical-stage oncology company with a limited operating history. We have incurred net losses of €125.5 million and €56.5 million for the years ended December 31, 2022 and 2021, respectively. As of

December 31, 2022, we had an accumulated deficit of €428.2 million. Our losses have resulted principally from expenses incurred in research and development of our antibody candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we continue to advance our antibody candidates from discovery through pre-clinical development and into clinical trials and seek regulatory approval and pursue commercialization of any approved antibody candidates. We anticipate that we will continue to incur significant expenses as we:

- conduct our ongoing, single agent, Phase 1/2 eNRGy clinical trial of zenocutuzumab, our most advanced bispecific antibody candidate, for the potential treatment of solid tumors harboring neuregulin 1 (NRG1) gene fusions, our ongoing Phase 2 clinical trial of zenocutuzumab in combination with an androgen deprivation therapy for the potential treatment of CRPC, and for the potential treatment of NSCLC harboring neuregulin 1 (NRG1) gene fusions in combination with afatinib;
- conduct our ongoing Phase 1/2 clinical trial of MCLA-158 or petosemtamab for the treatment of solid tumors;
- conduct our ongoing Phase 1/2 clinical trial for MCLA-129 for the treatment of solid tumors, which is subject to a collaboration with Betta, whereby Betta has exclusive rights to develop MCLA-129 in China, and Merus retains all rights ex-China;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors;
- continue the research and development of our other pre-clinical antibody candidates;
- expand our clinical programs to explore new potential combination therapies or indications;
- expand and enhance our technology platforms, including our Biclomics® technology platform which generates our pipeline of bispecific product candidates, our Triclomics® technology platform, which generates pre-clinical trispecific candidates and generate and develop additional multispecific antibody candidates;
- seek regulatory approvals for any antibody candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approvals;
- maintain, expand and protect our intellectual property portfolio;
- secure, maintain and/or obtain freedom to operate for our technologies and products;
- add clinical, scientific, operational, financial, information technology and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operation as a public company; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing, potential commercialization challenges, safety issues or other regulatory challenges.

We have financed our operations primarily through public offerings and private placements of our common shares and our collaboration and license agreement with Incyte and Eli Lilly. We have devoted a significant portion of our financial resources and efforts to developing our full-length bispecific antibody therapeutics, which we refer to as Biclomics®, our technology platforms, identifying potential antibody candidates, conducting pre-clinical studies of a variety of candidates, and conducting our clinical trials of zenocutuzumab, petosemtamab, MCLA-129 and MCLA-145. We have not completed development of any Biclomics® or any other drugs or biologics.

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 pre-clinical testing and clinical trials of our antibody candidates, discovering and developing additional antibody candidates, obtaining regulatory approval for any antibody candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of many of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the U.S. Food and Drug Administration (FDA), or the European Medicines Agency (EMA), or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our antibody candidates, our expenses could increase and commercial revenue could be further delayed.

Even if we do generate product royalties or product sales, we may never achieve or sustain profitability on a quarterly or annual basis. Our failure to sustain profitability could depress the market price of our common shares and could impair our ability to raise capital, expand our business, diversify our product offerings or continue our operations.

***We will need additional funding in order to complete development of our antibody candidates and commercialize our products, if approved. If we are unable to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.***

We expect to continue to incur significant expenses in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of zenocutuzumab, petosemtamab, MCLA-129, MCLA-145 and continue to research, develop and conduct pre-clinical studies of our other antibody candidates. In addition, if we obtain regulatory approval for any of our antibody candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of disruptions and extreme volatility in the global economy, including rising inflation and interest rates, declines in economic growth, the conflict between Russia and Ukraine and the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2022 will be sufficient to fund our operations into the second half of 2025. We maintain the majority of our cash and cash equivalents in accounts with major U.S. and multi-national financial institutions, and our deposits at these institutions exceed insured limits. Market conditions can impact the viability of these institutions. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we would be able to access uninsured funds in a timely manner or at all. Any inability to access or delay in accessing these funds could adversely affect our business and financial position. 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. Our future capital requirements will depend on many factors, including:

- the cost, progress and results of our ongoing clinical trials of zenocutuzumab and petosemtamab, MCLA-129 and MCLA-145;
- the success of our collaborations with Incyte and with Lilly to develop antibody candidates;

- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of potential future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our antibody candidates to the extent any receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any potential future claims by third parties that we are alleged to be infringing upon their intellectual property rights;
- the costs and timing of securing, maintaining and/or obtaining freedom to operate for our technologies and products;
- the revenue, if any, received from commercial sales of our antibody candidates to the extent any receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including our existing collaborations and any other future licensing or collaboration arrangements for any of our antibody candidates.

***We depend heavily on the success of our antibody candidates, and we cannot give any assurance that any of our antibody candidates will receive regulatory approval, which is necessary before they can be commercialized. If we, any of our collaborators, or any other strategic partners we may enter into collaboration agreements with for the development and commercialization of our antibody candidates, are unable to commercialize our antibody candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.***

We have invested a significant portion of our efforts and financial resources in the development of bispecific antibody candidates using our Biclomics® technology platform and in development of multi-specific antibody candidates using our Triclomics® technology platform. Our ability to generate royalty and product revenues, which we do not expect will occur for at least the next year, if ever, will depend heavily on the successful development and eventual commercialization of these antibody candidates, which may never occur. We currently generate no revenues from sales of any products, and we may never be able to develop or commercialize a marketable product. Each of our bispecific antibody candidates and pre-clinical antibody candidates will require additional clinical development, management of clinical, pre-clinical and manufacturing activities, regulatory approval in multiple jurisdictions, obtaining manufacturing supply, including commercial manufacturing supply, building of a commercial organization, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote any of our antibody candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our antibody candidates. The success of our antibody candidates will depend on several factors, including the following:

- for antibody candidates which we may license to others, such as to our collaborators, the successful efforts of those parties in completing clinical trials of, receipt of regulatory approval for and commercialization of such antibody candidates;

- for the antibody candidates to which we retain rights, completion of pre-clinical studies and clinical trials of, receipt of marketing approvals for, establishment of commercial manufacturing supplies of and successful commercialization of such antibody candidates; and
- for all of our antibody candidates, if approved, acceptance of our antibody candidates by patients, the medical community and third-party payors, effectively competing with other therapies, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.
- If we or our collaborators, as applicable, do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our antibody candidates, which would materially adversely affect our business, financial condition and results of operations.

We have not previously submitted a Biologics License Application (BLA), to the FDA, a marketing authorization application (MAA) to the EMA, or similar regulatory approval filings to comparable foreign authorities, for any antibody candidate, and we cannot be certain that any of our antibody candidates will be successful in clinical trials or receive regulatory approval. Further, our antibody candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our antibody candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market one or more of our antibody candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our antibody candidates both in the United States and the European Union (EU), and potentially in additional foreign countries. While the scope of regulatory approval is similar in other countries, to obtain separate regulatory approval in many other countries we must comply with the numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our antibody candidates, and we cannot predict success in these jurisdictions.

***The Biclomics® technology platform and Triclomics® technology platform are unproven, novel approaches to the production of biologics for therapeutic intervention.***

We have not received regulatory approval for a therapeutic based on a full-length human bispecific or trispecific IgG approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Biclomics® and Triclomics® may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA, the EMA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on Biclomics® and Triclomics® therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our antibody candidates.

Our Biclomics® and Triclomics® technology platforms rely on third parties for biological materials. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. Although we have control processes, auditing and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper filling or storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or antibody candidates.

***Failure to successfully validate, develop and obtain regulatory approval or certification for companion diagnostics could harm our development strategy.***

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the antibody candidates we are developing. Through collaborations or license agreements, companion diagnostics may help us to more accurately identify patients within a particular subset, both during our clinical trials and in connection with the commercialization of our antibody candidates, if approved. Companion diagnostics are subject to regulation by the FDA, and comparable foreign regulatory authorities as medical devices and typically require separate regulatory approval (or clearance, or certification) prior to commercialization. The development of companion diagnostics in collaboration with or via license agreements with third parties, may make us potentially dependent on the scientific insights and sustained cooperation and effort of any third-party collaborators in developing and obtaining approval (or clearance, or certification) for companion diagnostics. Difficulties in developing and obtaining approval or certification for any companion diagnostics may be encountered, including as it concerns issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure to develop or obtain regulatory approval (or clearance, or certification) of companion diagnostics could delay or prevent approval of our antibody candidates. In addition, production difficulties may be encountered that could constrain the supply of the companion diagnostics, and difficulties may arise in gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it could have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our antibody candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative companion diagnostic test for use in connection with the development and commercialization of our antibody candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our antibody candidates.

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

Since our inception in 2003, we have devoted a significant portion of our resources to developing zenocutuzumab, petosemtamab, MCLA-129, MCLA-145 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, generating and enhancing our Biclomics® and Triclomics® technology platforms, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for zenocutuzumab, petosemtamab, MCLA-129 and MCLA-145, we have not successfully completed any clinical trials for any antibody candidate. We have not yet demonstrated our ability to successfully complete any Phase 3 or registrational trials or address other registrational risks related to our clinical trials, to obtain regulatory approvals, to manufacture a commercial scale product or arrange for a third party to do so on our behalf or to conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

***Raising additional capital may cause dilution to our holders, restrict our operations or require us to relinquish rights to our technologies or antibody candidates.***

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity or debt financings and upfront and milestone payments, if any, received under our existing collaborations and any other future licenses or collaborations, together with our existing cash and cash equivalents. In order to accomplish our business objectives and further develop our product pipeline, we will, however, need to seek additional funds. If we raise additional capital through the sale of equity or convertible debt securities, our existing shareholders' ownership interests will be diluted, and the terms of



these securities may include liquidation or other preferences that adversely affect our existing shareholders' rights as holders of our common shares. In addition, the possibility of such issuance may cause the market price of our common shares to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling or licensing intellectual property rights, which could adversely impact our ability to conduct our business.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, technologies, future revenue streams or antibody candidates or grant licenses on terms that may not be favorable to us. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable. Any of these occurrences may have a material adverse effect on our business, operating results and prospects.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our antibody candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of disruptions and extreme volatility in the global economy, including rising inflation and interest rates, declines in economic growth, the conflict between Russia and Ukraine and the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our antibody candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

***Our business may become subject to economic, political, regulatory and other risks associated with international operations***

As a company based in the Netherlands, our business is subject to risks associated with conducting business internationally. Many of our suppliers and collaborative and clinical trial relationships are located outside the United States. Accordingly, our future results could be harmed by a variety of factors, including:

- economic weakness, including inflation, or political instability, in particular, in non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining and/or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;

- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with international privacy regulations, including the General Data Protection Regulation (GDPR);
- negative consequences from the United Kingdom's withdrawal from the EU, and its potential impact on supply-chain and our personnel;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, riots and terrorism, as well as the conflict between Russia and Ukraine, or natural disasters including earthquakes, typhoons, floods, fires, epidemics or public health emergencies and U.S. or non-U.S. governmental actions or restrictions related thereto.

***Exchange rate fluctuations or abandonment of the euro currency may materially affect our results of operations and financial condition.***

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the euro and the U.S. dollar, may adversely affect us. Although we are based in the Netherlands, we source research and development, manufacturing, consulting and other services from several countries. Further, potential future revenue may be derived from abroad, particularly from the United States. Additionally, our funding has mainly come from investors and collaborators mainly in the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

In addition, the possible abandonment of the euro by one or more members of the EU could materially affect our business in the future. Despite measures taken by the EU to provide funding to certain EU member states in financial difficulties and by a number of European countries to stabilize their economies and reduce their debt burdens, it is possible that the euro could be abandoned in the future as a currency by countries that have adopted its use. This could lead to the re-introduction of individual currencies in one or more EU member states, or in more extreme circumstances, the dissolution of the EU. The effects on our business of a potential dissolution of the EU, the exit of one or more EU member states from the EU or the abandonment of the euro as a currency, are impossible to predict with certainty, and any such events could have a material adverse effect on our business, financial condition and results of operations.

***Risks from improper conduct by our employees, agents, contractors, or collaborators could adversely affect our reputation, business, prospects, operating results, and financial condition.***

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, health care, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, import and export requirements, competition, patient privacy and other privacy laws and regulations. Such improper actions

could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are subject to a number of anti-corruption laws, including the Foreign Corrupt Practices Act (FCPA) in the United States, the Bribery Act in the United Kingdom and the anti-corruption provisions of the Dutch Criminal Code in the Netherlands. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of improperly or corruptly obtaining or keeping business, obtaining preferential treatment and/or other undue benefits or advantages. The FCPA also requires public companies to maintain accurate books and records and devise a system of sufficient internal accounting controls. We regularly review and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, distributors and other intermediaries comply with the anti-corruption laws to which we are subject. However, there are inherent limitations to the effectiveness of any policies, procedures and internal controls, including the possibility of human error and the circumvention or overriding of the policies, procedures and internal controls. There can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, distributors and other intermediaries with respect to our business.

The Securities and Exchange Commission (SEC) and Department of Justice continue to view FCPA enforcement activities as a high priority. There is no certainty that all of our employees, agents, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could materially damage our reputation, our brand, our international operations, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

***The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions and financial markets, which could materially affect our financial condition and results of operations.***

Since the end of the Brexit transition period on January 1, 2021, Great Britain (England, Scotland and Wales) has not been directly subject to EU laws, however under the terms of the Ireland/Northern Ireland Protocol, EU laws generally apply to Northern Ireland. The EU laws that have been transposed into United Kingdom (UK) law through secondary legislation remain applicable in Great Britain. However, under the Retained EU Law (Revocation and Reform) Bill 2022, which is currently before the UK parliament, any retained EU law not expressly preserved and “assimilated” into domestic law or extended by ministerial regulations (to no later than June 23, 2026) will automatically expire and be revoked by December 31, 2023. In addition, new legislation such as the EU Clinical Trials Regulation (CTR) is not applicable in Great Britain. The UK government has passed the Medicines and Medical Devices Act 2021, which introduces delegated powers in favor of the Secretary of State or an ‘appropriate authority’ to amend or supplement existing regulations in the area of medicinal products and medical devices. This allows new rules to be introduced in the future by way of secondary legislation, which aims to allow flexibility in addressing regulatory gaps and future changes in the fields of human medicines, clinical trials and medical devices.

The EU-UK Trade and Cooperation Agreement (TCA), came into effect on January 1, 2021. The TCA includes provisions affecting pharmaceutical businesses (including on customs and tariffs). In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of Good Manufacturing Practice (GMP) inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards, and it can be expected that there may be divergent

local requirements in the UK from the EU in the future, which may impact clinical and development activities that occur in the UK in the future. Similarly, clinical trial submissions and data for activity in the UK will not be able to be bundled with those of EU member states within the EMA Clinical Trial Information System (CTIS), adding further complexity, cost and potential risk to future clinical and development activity in the UK.

Significant political and economic uncertainty remains about how much the relationship between the UK and EU will differ as a result of the UK's withdrawal.

***The COVID-19 pandemic has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations.***

The COVID-19 pandemic and government measures taken in response have had a significant impact, both direct and indirect, on businesses and commerce. As a result of the COVID-19 pandemic, certain of our contract research organizations (CROs) and third-party suppliers, as well as collaborators in the U.S., Europe and China that are developing or collaborating with us to develop certain of our pre-clinical and clinical-stage antibody candidates have been affected. As a result of such impact, we may face difficulties with and delays in performance of certain chemistry, manufacturing and controls associated with our clinical candidates, including as it relates to challenges for sourcing materials required for such manufacture that may be diverted for other purposes associated with COVID-19 or due to supply chain issues related to the COVID-19 pandemic, or difficulties or delays associated with testing of our pre-clinical antibody candidates associated with our collaborations with Incyte and Eli Lilly, which may delay or prevent their potential clinical development. Additionally, our collaborators, CROs and third-party suppliers may in the future experience closures and labor shortages, reagent or materials shortages which may delay or prevent our development of our antibody candidates, including zenocutuzumab, petosemtamab, MCLA-129 and MCLA-145. Moreover, although our collaborators based in China and elsewhere have resumed operations, we may experience labor, reagent or material shortages associated with these chemistry, manufacturing and controls, or pre-clinical development activities due to the periodic restrictions on travel and work globally and staff shortages, which may force us to reduce related workflows until such work and travel restrictions are lifted or staff issues resolved. Also, there can be no assurances that the applicable governments will not renew or extend these closures.

With respect to our clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials and source verification of clinical data required for presentation of clinical data for zenocutuzumab, petosemtamab, MCLA-129 and MCLA-145. Over the quarter ended December 31, 2022 and to date, we have observed a low to moderate impact on clinical trial enrollment and operations, and a moderate impact on patient monitoring visits as a consequence of the COVID-19 pandemic, with adjustments made to allow remote visits for some patient follow-up, and reduced onsite monitoring by the sponsor or CRO and insufficient source verification of clinical data required for presentation of clinical data. We may further experience shortages of reagents or supplies necessary for certain clinical trial activities as a result of disruptions caused by COVID-19 associated supply chain issues. The extent of the impact to our overall clinical development timeline is uncertain at this time and we continue to monitor this impact on a regular basis. As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- 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;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, operations, source data verification, and other clinical trial activities such as clinical trial site patient visits, patient and data monitoring, due to limitations on travel imposed or recommended by national, state or local governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or EMA or comparable foreign regulatory authorities, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA or EMA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies;
- interruption or delays in our collaborations, including with Incyte, Eli Lilly, Betta Pharma and our license agreements with Ono and our academic collaborators, which may experience laboratory closures causing delays in preclinical, translational and development studies that support our clinical programs and potential IND-enabling studies or those of our collaborators and licensees, from which we may receive milestones or royalties;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common shares and any such sales may be on unfavorable terms. The COVID-19 pandemic continues to evolve. The extent to which the pandemic may further impact our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the spread and potential resurgence of the disease, the duration of the pandemic, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States, the Netherlands and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, the Netherlands and other countries to contain, treat and function with the disease.

### **Risks Related to the Development and Clinical Testing of Our Antibody Candidates**

*All of our antibody candidates are in pre-clinical or early-to-mid-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes.*

***If clinical trials of our antibody candidates, particularly zenocutuzumab, petosemtamab, MCLA-129 or MCLA-145, are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our antibody candidates on a timely basis or at all.***

To obtain the requisite regulatory approvals to market and sell any of our antibody candidates, we or any collaborator for such candidates must demonstrate through extensive pre-clinical studies and clinical trials that such candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early-stage clinical trials of our antibody candidates may not be predictive of the results of later-stage clinical trials. Antibody candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful. To date, we have not completed any registrational clinical trials required for the approval of any of our antibody candidates. Although we are conducting ongoing clinical trials for zenocutuzumab, petosemtamab, MCLA-129, and MCLA-145 and pre-clinical studies for other antibody candidates, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to reach 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;
- delays in or failure to recruit suitable patients to participate in a trial;
- delays in or failure to establish the appropriate dose and schedule for antibody candidates in clinical trials;
- the difficulty in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- investigator-sponsored studies of our product candidates, including expanded or early access protocols, may identify safety or efficacy concerns associated with our antibody candidates, or otherwise negatively affect patient enrollment in our ongoing and planned clinical trials;
- delays in, inability or failure to add new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or regulatory authorities, as applicable, to pause, suspend or terminate a trial if we or our collaborators or regulatory authorities, find that the participants are being exposed to unacceptable health risks or during evaluation of safety signals;
- failure to observe a meaningful clinical benefit;
- delays in or failure to obtain regulatory approval or authorizations to commence a trial;

- delays in or failure to obtain institutional review board (IRB) or ethics committee approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or applicable law, or to meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of antibody candidate for use in clinical trials;
- the quality or stability of an antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our antibody candidates no longer relevant;
- third party actions claiming infringement by our antibody candidates in clinical trials outside of the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires, epidemics or public health emergencies and U.S. or non-U.S. governmental actions or restrictions related thereto.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, reporting on or completing our planned and ongoing clinical trials. We could encounter delays if a clinical trial is paused, suspended or terminated by us, by the IRBs or ethics committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, the competent authorities of the European Economic Area (EEA) member states (the 27 EU member states plus Iceland, Liechtenstein and Norway) and the UK, or other regulatory authorities. Such authorities may impose such a suspension or termination due to 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, EEA competent authorities or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our antibody candidates, the commercial prospects of our antibody candidates will be harmed, and our ability to generate product revenues from any of these antibody candidates, if approved, will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our antibody candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our antibody candidates and impair our ability to commercialize our antibody candidates, if approved, and may harm our business and results of operations.

Any of these occurrences may harm our business, financial condition and prospects significantly. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our antibody candidates.

Clinical trials must be conducted in accordance with the FDA, EU, EEA member states, and other applicable regulatory authorities' legal requirements, other regulations or guidelines, and are subject to oversight by these governmental agencies and ethics committees or IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our antibody candidates produced under current good manufacturing practice (cGMP), or similar foreign requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice (GCP)

requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the EEA and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EEA and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EEA competent authorities, and may use different standards of diagnosis, screening and medical care.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. Clinical trials for which an application was submitted (i) prior to January 31, 2022 under the Clinical Trials Directive, or (ii) between January 31, 2022 and January 31, 2023 and for which the sponsor has opted for the application of the Clinical Trials Directive remain governed by said Directive until January 31, 2025. After this date, all clinical trials (including those which are ongoing) will become subject to the provisions of the CTR. Compliance with the CTR requirements by us, our collaborators and third-party service providers, such as CROs, may impact our developments plans.

It is currently unclear to what extent the UK will seek to align its regulations with the EU. The UK regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the UK MHRA launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closed on March 14, 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the UK chooses to align with the CTR or diverge from it to maintain regulatory flexibility. Under the terms of the Protocol on Ireland/Northern Ireland, provisions of the CTR which relate to the manufacture and import of investigational medicinal products and auxiliary medicinal products apply in Northern Ireland. A decision by the UK government not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the UK as opposed to other countries. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

***Interim, preliminary, and “top-line” 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, preliminary or “top-line” data from our clinical trials. Interim 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.



Preliminary and top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. Further, as a result of the COVID-19 pandemic or for other reasons, we may not be able to collect accurate or complete data at the time we collect such preliminary data, including as a result of the inability of sites to properly record data due to staffing limitations or the inability of patients to visit sites at scheduled times, the inability of CROs to access site data or for other reasons. In addition, we may decide to report interim or preliminary analyses of only certain endpoints (e.g., primary subject to investigator review) rather than all endpoints (e.g., including secondary subject to central review). As a result, interim, preliminary and top-line data should be viewed with caution until the final data are available.

Furthermore, the information we choose to publicly disclose regarding a particular study or clinical trial is based on more extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to disclose. 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 antibody candidate or our business. 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 particular programs, the approvability or commercialization of the particular antibody candidates, and our business in general. As a result, interim, preliminary or top-line data and analyses should be viewed with caution. Adverse differences between preliminary, top-line or interim data and final data or changes in what is material information regarding the results from a particular study or clinical trial could significantly harm our clinical development and business prospects and cause volatility in the price of our common shares. If the interim, top-line, or preliminary data that we report differ from actual or final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

***Our antibody candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our antibody candidates or following approval, if any, we may need to abandon our development of such antibody candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.***

Undesirable side effects that may be caused by our antibody candidates 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, the EMA or other comparable foreign authorities. In February 2015, we commenced a Phase 1/2 clinical trial in Europe of our most advanced antibody candidate, zenocutuzumab, for the treatment of various solid tumors, which was amended to treat patients having solid tumors harboring a NRG1 gene fusion. Additionally, in January 2018 we commenced a Phase 2 clinical trial in Europe and the United States exploring zenocutuzumab, in combination with other agents, in patients with metastatic breast cancer. Patients treated with zenocutuzumab have experienced adverse reactions that may be related to the treatment with a safety update provided for zenocutuzumab on June 5, 2022, at the American Society of Clinical Oncology, or ASCO, 2022 Annual Meeting, with a safety cut-off date of April 12, 2022. In May 2018 we commenced a Phase 1/2 clinical trial of our bispecific antibody petosemtamab in patients with solid tumors. Patients treated with petosemtamab have experienced adverse reactions that may be treatment related, with a safety update provided for petosemtamab in April 2023 at AACR, with a safety data cutoff date of February 1, 2023, and on January 15, 2021, at ASCO GI, with a safety data cutoff date of September 7, 2020, where safety events were reported for patients treated with petosemtamab as a single agent across 11 dose levels (5 to 1500mg), and at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, on October 7-10, 2021, with a data cutoff date of August 9, 2021. In May 2021, we commenced a Phase 1/2 clinical trial in the United States of our bispecific antibody MCLA-129 in patients with advanced NSCLC and other solid tumors. Patients treated with MCLA-129 have experienced adverse events, with an initial safety update provided for MCLA-129 in October 2022 at the 34th

EORTC/NCI/AACR Symposium on Molecular Targets and Cancer Therapeutics, with a data cutoff date of August 15, 2022. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 in patients with solid tumors. Patients treated with MCLA-145 have experienced adverse events that may be related to the treatment, with a safety update provided for MCLA-145 on December 8-11, 2021 at the 2021 European Society for Medical Oncology-Immuno-Oncology (ESMO-IO) Congress, with a data cutoff date of July 14, 2021.

Results of our trials could reveal a high and unacceptable severity and prevalence of adverse events or side effects, including those that may be new or unexpected. In such an event, our trials or enrollment could be paused, suspended or terminated and the FDA, EEA competent authorities, or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our antibody candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment, investigator engagement and commitment and perception of the clinical candidate or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if any of our antibody candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products and require us to take our approved product off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- regulatory authorities may require a medication guide outlining the risks of such side effects for distribution to patients, or that we implement a risk evaluation and mitigation strategy plan to ensure that the benefits of the product outweigh its risks;
- we may be required to change the dose or the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected antibody candidate, if approved, or could substantially increase commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our antibody candidates, if approved.

***We depend on enrollment of patients in our clinical trials for our antibody candidates. If we are unable to enroll patients in our clinical trials, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.***

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For our Phase 1/2 clinical trial of zenocutuzumab in solid tumors, we are enrolling up to 250 patients with tumors harboring NRG1 gene fusions (NRG1+). Solid tumors with NRG1 gene fusions occur infrequently, which could result in slow enrollment of clinical trial participants. For our Phase 2 clinical trial of zenocutuzumab in patients with CRPC in combinations with an ADT, and patients with NRG1+ NSCLC in combination with afatinib, we are enrolling up to 90 patients. In the Phase 2 clinical trial of MCLA-129, we plan to enroll up to 400 adult patients with solid tumors. In the Phase 1/2 clinical trial of petosemtamab, we plan to enroll up to 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll up to 118 adult patients with solid tumors. These trials and other

trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

Our clinical trials will also compete with other clinical trials for antibody candidates that are in the same therapeutic areas as our antibody candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators and clinical trial sites is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites.

Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our antibody candidates will increase our costs, slow down our antibody candidate development and approval process, delay or potentially jeopardize our ability to commence product sales and generate revenue and harm our reputation and ability to obtain financing. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our antibody candidates.

***We may become exposed to costly and damaging liability claims, either when testing our antibody candidates in the clinic or at the commercial stage; and our product liability insurance may not cover all damages from such claims.***

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the current and future use of antibody candidates by us and our collaborators in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies, our collaborators or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our antibody candidates or any prospects for commercialization of our antibody candidates, if approved.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our antibody candidates were to cause adverse side effects during clinical trials or after approval of the antibody candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our antibody candidates.

Although we maintain adequate product liability insurance for our antibody candidates, it is possible that our liabilities could exceed our insurance coverage. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our antibody candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

***The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our antibody candidates, our business will be substantially harmed.***

The time required to obtain approval by the FDA and comparable foreign authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of an antibody candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any antibody candidate and it is possible that none of our existing antibody candidates or any antibody candidates we may seek to develop in the future will ever obtain regulatory approval.

Our antibody candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that an antibody candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that an antibody candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our antibody candidates may not be sufficient in amount or quality to support the submission of a BLA or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities and notified bodies may fail to approve (or to clear or to certify) the companion diagnostics we contemplate developing with collaborators; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.
- for instance, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. A proposal for revision of several legislative instruments related to medicinal products (including potentially revising the duration of regulatory exclusivity and eligibility for expedited pathways) is expected to be adopted by the European Commission during the first half of 2023. The proposed revisions, once they are agreed and adopted by the European Parliament and European Council (not expected before the end of 2024 or early 2025) may have a significant impact on the biopharmaceutical industry in the long term.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our antibody candidates, which would significantly harm our business, results of operations and prospects. The FDA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether

regulatory approval will be obtained for any of our antibody candidates. Even if we believe the data collected from clinical trials of our antibody candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our antibody candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve an antibody candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that antibody candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our antibody candidates and have a material adverse effect on our business, financial condition and results of operations.

***Fast Track designation by the FDA for zenocutuzumab or potential future Fast Track designation of our other antibody candidates may not actually lead to a faster development or regulatory review or approval process.***

We have been granted a Fast Track designation for zenocutuzumab in the United States for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy, and we may seek additional Fast Track designations for zenocutuzumab or for our other antibody candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing therapeutic candidates that meet certain criteria. Specifically, new biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, 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 candidate and the specific indication for which it is being studied. With a Fast Track designation for an antibody candidate, 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.

Obtaining a Fast Track designation does not change the standards for product approval but may expedite the development or approval process. Even though the FDA has granted such designation for zenocutuzumab for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that zenocutuzumab or any other antibody candidate that may be granted Fast Track designation will receive marketing approval in the United States.

***Even if our antibody candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, our antibody candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we may receive for our antibody candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy in order to approve our antibody candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Similar risk management measures may be required by foreign regulatory authorities. In addition, if the FDA or foreign regulatory authorities approve our antibody candidates, the manufacturing processes, labeling, packaging,

distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs or similar foreign requirements, and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP or similar foreign regulations and standards.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

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. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also 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.

***We may not be successful in our efforts to use and expand our Biclomics® technology platform to build a pipeline of antibody candidates or to use our Triclomics® technology platform to build a pipeline of trispecific antibody candidates.***

A key element of our strategy is to use and expand our Biclomics® technology platform to build a pipeline of antibody candidates and progress these antibody candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of antibody candidates directed at various cancers, we may not be able to develop antibody candidates that are safe and effective.

Another important element of our strategy is to develop, use and exploit our Triclonics® technology platform to build a pipeline of trispecific antibody candidates and collaborate with third parties in potentially researching and developing these trispecific antibody candidates through pre-clinical and clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in proof of concept pre-clinical candidates, we may not be able to develop or monetize these trispecific antibody candidates or demonstrate in the clinic that they are safe and effective. Even if we are successful in continuing to build our bispecific and trispecific pipelines, the potential antibody candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize our bispecific antibody candidates or if we do not successfully develop, collaborate, license or begin to commercialize our trispecific antibody candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

***Even if we obtain marketing approval of any of our antibody candidates in a major pharmaceutical market such as the United States or the EU, we may never obtain approval or commercialize our products in other major markets, which would limit our ability to realize their full market potential.***

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We currently do not have any antibody candidates approved for sale in any jurisdiction, whether in the Netherlands, the United States or any other international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products, if any, will be harmed.

***Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain antibody candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.***

Because we have limited resources and access to capital to fund our operations, we must decide which antibody candidates to pursue and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, antibody candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. Similarly, our decisions to delay, terminate or collaborate with third parties in respect of certain antibody development programs may also prove not to be optimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the market potential of our antibody candidates or misread trends in the biopharmaceutical industry, in particular for our lead antibody candidates, our business, financial condition and results of operations could be materially adversely affected.

***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 importation, storage, 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, animal byproducts, genetically modified organisms, 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, or fail to obtain or maintain relevant permits, we could be subject to fines or other sanctions or work stoppages, which could have a material adverse effect on our business, financial condition and results of operations.

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.

***Our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaborators may engage in misconduct or other improper activities, including noncompliance with applicable law, regulatory standards and requirements, which could have a material adverse effect on our business.***

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaborators may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include fraudulent, intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA and other regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; (iv) laws that require the reporting of true, complete and accurate financial information and data; or (v) their representations or commitments to us regarding their capabilities and performance under existing or future agreements. Specifically, 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, 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 governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our



business and our results of operations. Additionally, we are subject to the risk that misrepresentations regarding an independent contractors, principal investigators, CROs, consultants, vendors and collaborators' capabilities and performance under existing or future agreements may lead us to rely upon them for important strategic or operational matters, which could have a significant adverse impact on our business and results of operations.

***Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.***

Certain laws and regulations require us to test our antibody candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

**Risks Related to Regulatory Approval of Our Antibody Candidates**

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our antibody candidates and may affect the prices we may set. The successful commercialization of our antibody candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.***

In the United States, the EU, and other foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively the ACA) was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- 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;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing 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; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes include the American Rescue Plan Act of 2021, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, beginning January 1, 2024. Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. In addition, recently 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 legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Most recently, in August 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning 2025). The IRA permits the Secretary of the Department of Health and Human Services (HHS) to implement many of these provisions through guidance, as opposed to regulation, for the initial years. For that and other reasons, it is currently unclear how the IRA will be effectuated. 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 antibody candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing 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, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for any future products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our antibody candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

Finally, policies of the individual government agencies, including the FDA or similar regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our antibody candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***If we are required by the FDA or similar authorities to obtain approval (or clearance, or certification) of a companion diagnostic test in connection with approval of any of our antibody candidates, and we do not obtain or face delays in obtaining approval (or clearance, or certification) 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 antibody candidates depends on a diagnostic that is not otherwise commercially available, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our antibody candidates, if at all or as a post-marketing commitment. 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 develop or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time consuming and costly and associated with numerous risks and uncertainties.

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 generally required premarket approval of companion diagnostics labeled for use with 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 or a comparable regulatory authority requires approval (or clearance, or certification) of a companion diagnostic for any of our antibody candidates, whether before or after such candidate obtains marketing approval, difficulties may be encountered in developing and obtaining approval for such antibody candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval (or clearance, or certification) of a companion diagnostic could delay or prevent approval or continued marketing of such antibody 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.

Approval, clearance or certification of companion diagnostics may be subject to further legislative or regulatory reforms notably in the EU. On May 25, 2017, the new In Vitro Medical Devices Regulation (2017/746) (IVDR) entered into force. The IVDR repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, regulations are directly applicable, i.e., without the need for adoption of EEA member states laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member states. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The IVDR became applicable on May 26, 2022. However, on October 14, 2021, the European Commission proposed a “progressive” roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. The European Parliament and Council adopted the proposed regulation on December 15, 2021. Therefore, the IVDR has applied since May 26, 2022 but there is a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The regulation of companion diagnostics is subject to further requirements since the IVDR became applicable and introduced a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue an EU certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from national competent authorities or the EMA. These modifications may make it more difficult and costly for us to obtain regulatory clearances, approvals or certifications for our companion diagnostics or to manufacture, market or distribute our products after clearance, approval or certification is obtained.

***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 developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA and foreign regulatory authorities to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA’s or foreign regulatory authorities’ ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s or foreign regulatory authorities’ ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities 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, such as the EMA following its relocation to Amsterdam and resulting staff changes, may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, 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, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic, and any resurgence of the virus or emergence of new variants may lead to further inspectional delays. Regulatory authorities outside the United States have adopted 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.

***We may be subject to healthcare laws, regulation and enforcement; our failure to comply with these laws could harm our results of operations and financial conditions.***

Although we do not currently have any products on the market, if we obtain FDA approval for any of our antibody candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers and third-party payors, subject to various U.S. federal and state healthcare laws and regulations, including, without limitation, the U.S. federal Anti-Kickback Statute. Healthcare providers, physicians and others play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. These laws may impact, among other things, our proposed sales, marketing and education programs and constrain our financial arrangements and relationships with healthcare providers, physicians and other parties through which we market, sell and distribute our products for which we obtain marketing approval. In addition, we may be subject to additional healthcare, statutory and regulatory requirements and enforcement by foreign regulatory authorities in jurisdictions in which we conduct our business. The laws that may affect our ability to operate include:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid; 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 U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or

entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the FD&C Act which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals including physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, and that require the tracking and reporting of gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance 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 the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government funded healthcare programs, such as Medicare and Medicaid, disgorgement, individual imprisonment, contractual damages, reputational harm, diminished profits, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs and imprisonment. If any of the above occur, it could adversely affect our ability to operate our business and our results of operations. Further, defending against any such actions can be costly, time-consuming and may require significant personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

***We face potential liability related to the privacy of health or other personal information we obtain from clinical trials sponsored by us or our collaborators, from research institutions, and directly from individuals.***

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. HIPAA imposes privacy, security and data breach reporting obligations with respect to individually identifiable health information upon “covered entities” (health plans, health care clearinghouses and certain health care providers), and their respective “business associates” (individuals or entities that create, receive, maintain or transmit individually identifiable health information in connection with providing a service for or on behalf of a covered entity, as well as their covered subcontractors). Entities that are found to be in violation of HIPAA as the result of a breach of unsecured PHI, a complaint about privacy practices, or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations. Any person may be prosecuted under HIPAA’s criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA’s requirements for the disclosure of such information.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers’ personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company’s data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC’s guidance for appropriately securing consumers’ personal information is similar to what is required by the HIPAA Security Rule. As such, we, our collaborators, research institutions, health care providers and other entities that provide personally identifiable information to us may be subject to state information security laws, and state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

The United States and global data protection landscape is rapidly evolving, and we may be affected by or subject to new or amended laws and regulations in the future. Certain states have also adopted privacy and security laws and regulations governing the privacy, processing and protection of personal information. For example, the CCPA went into effect on January 1, 2020. The CCPA, among other things, creates data privacy obligations for covered companies and provides individual privacy rights to California residents, including the right to delete and to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, and has increased the risks associated with a data breach. Although the law includes limited exceptions, including for “protected health information” maintained by a covered entity or business associate, it may regulate or impact our processing of certain personal information depending on the context. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023. The CPRA significantly amends the CCPA and imposes additional data protection obligations on covered businesses, including additional consumer rights, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and which could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may also be required.

On March 2, 2021, Virginia enacted the Consumer Data Protection Act (CDPA) and, on July 8, 2021, Colorado’s governor signed the Colorado Privacy Act (CPA) into law. The CDPA and the CPA went into effect on January 1, 2023. In addition, Connecticut enacted the Connecticut Data Privacy Act, effective July 1, 2023, and Utah enacted the Utah Consumer Privacy Act, effective December 31, 2023, Virginia enacted the Virginia Consumer Data Protection Act, effective January 1, 2023. While these laws incorporate many similar concepts of the CCPA and CPRA, there are also several key differences in the

scope, application, and enforcement of the law that will change the operational practices of regulated businesses. The new laws will, among other things, impact how regulated businesses collect and process personal data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests. Similar laws have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition, our ability to operate in certain jurisdictions and our reputation.

Our and our collaborators' clinical trial programs and research collaborations outside the U.S. may implicate international data protection laws, including, in Europe, the GDPR and local laws further implementing or supplementing the GDPR. The GDPR imposes more stringent operational requirements for processors and controllers of personal data including requirements for such companies to be able to ensure and be able to demonstrate compliance with the GDPR. If our or our collaborators' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher. In addition to statutory enforcement, a non-compliance can lead to compensation claims by affected individuals, negative publicity and a potential loss of business.

Further, following the withdrawal of the UK from the EU on January 31, 2020, and the expiration of the transition period, from January 1, 2021, we have had to comply with the GDPR and separately the GDPR as implemented in the UK (UK GDPR), with 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 UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the UK, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision. In September 2021, the UK government launched a consultation on its proposals for wide-ranging reforms of UK data protection laws following Brexit and the response to this consultation was published in June 2022. There is a risk that any material changes that are made to the UK data protection regime could result in the European Commission reviewing the UK adequacy decision, and the UK losing its adequacy decision if the European Commission deems the UK to no longer provide adequate protection for personal data.

We are also subject to EU/national laws on personal data export, as we may transfer personal data from the EU/EEA to other jurisdictions which are not considered by the European Commission to offer "adequate" protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. In addition, in July 2020, the Court of Justice of the EU (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative mechanisms to lawfully transfer data to the US). In March 2022, the US and EU announced a new regulatory regime intended to replace the invalidated regulations; however, this new EU-US Data Privacy Framework has not been implemented beyond an executive order signed by President Biden on October 7, 2022 on Enhancing Safeguards for United States Signals Intelligence Activities. 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 geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.



Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner among jurisdictions in which we operate. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations regardless of merit and even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Claims that we or any collaborators fail to comply with applicable federal, state, or local, legal or regulatory requirements, could subject us to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our antibody candidates, if approved. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business.

### **Risks Related to Commercialization of Our Antibody Candidates**

*We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.*

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our antibody candidates.

With the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Any antibody candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. The highly competitive nature of and rapid technological changes in the biotechnology and pharmaceutical industries could render our antibody candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

- have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do;
- develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe side effects;
- obtain quicker regulatory approval;
- establish superior proprietary positions covering our products and technologies;
- implement more effective approaches to sales and marketing; or
- form more advantageous strategic alliances.

Should any of these factors occur, our business, financial condition and results of operations could be materially adversely affected.

In addition, existing and future collaborators may decide to market and sell products that compete with the antibody candidates that we have agreed to license to them. While we have agreements governing their committed activities, we have limited influence over their actual performance, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition and results of operations.

Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, retaining manufacturers to produce clinical trial materials, as well as in acquiring technologies complementary to, or necessary for, our programs.

***If we fail to obtain orphan drug designation for our antibody candidates, or obtain or maintain orphan drug exclusivity for our products, or lose or fail to add to such designation for zenocutuzumab in the United States, our competitors may sell products to treat the same conditions and our revenue will be reduced.***

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that during this period, the regulatory authorities cannot accept another application for a marketing authorization (MA) or grant a MA or accept an application to extend an existing MA for the same indication, in respect of a similar medicinal product. The application for orphan designation must be submitted before the MA application (MAA). The applicant will receive a fee reduction for the MAA if the orphan designation has been granted, but not if the designation is still pending at the time the MA is submitted. Orphan designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to potential financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. In the EU, orphan designation entitles a party to potential financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the orphan designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold.

We have obtained orphan drug designation from the FDA for zenocutuzumab for the treatment of patients with pancreatic cancer and potentially may seek that or a similar designation from the EMA for

zenocutuzumab or additional orphan drug designations for zenocutuzumab, and we may seek such designation from the FDA and foreign regulatory authorities for other clinical assets, where supported by data in the appropriate indications that meet the criteria for orphan status. Even though we obtained orphan designation in the United States for zenocutuzumab for treatment of patients with pancreatic cancer and may obtain additional designations for zenocutuzumab, or orphan designations for other antibody candidates in the United States and/or the EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or 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. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or foreign regulatory authorities can subsequently approve the same drug with the same active moiety for the same condition if the FDA or foreign regulatory authorities concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation, when appropriate, we may not receive such designation.

***The successful commercialization of our antibody candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain adequate coverage and reimbursement for our antibody candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.***

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our antibody candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaborators to invest in the development of our antibody candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our antibody candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our antibody candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us 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 our antibody candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for

how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our antibody candidates, if approved.

Obtaining and maintaining reimbursement status is time-consuming and costly. No uniform policy for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of any future products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases at short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada, and other countries has and will continue to put pressure on the pricing and usage of our antibody candidates, if approved. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our antibody candidates, if approved. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our antibody candidates, if approved. We expect to experience pricing pressures in connection with the sale of any of our antibody candidates that are approved due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

In addition, even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

***Our products may not gain market acceptance, in which case we may not be able to generate product revenues, which will materially adversely affect our business, financial condition and results of operations.***

Even if the FDA or any other regulatory authority approves the marketing of any antibody candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients or the medical community may not accept or use them. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from operations. The degree of market acceptance of any of our antibody candidates that are approved will depend on a variety of factors, including:

- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;

- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- availability of adequate coverage, reimbursement and adequate payment from health maintenance organizations and other insurers, both public and private; and
- other potential advantages over alternative treatment methods.

Failure of our antibody candidates, if approved, to gain market acceptance will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow us to generate significant revenues.

***We currently have limited marketing, sales or distribution infrastructure. If we are unable to adequately develop sales, marketing and distribution capabilities on our own or through collaborations, we will not be successful in commercializing our antibody candidates.***

While we have hired a Chief Commercial Officer and certain personnel to support market access and supply chain, we currently have only limited marketing, and distribution capabilities, and no sales force, because all of our antibody candidates are still in clinical or pre-clinical development. If any of our antibody candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our antibody candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our antibody candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure, delay or inadequacy in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any approved products.

To the extent that we enter into collaboration agreements with respect to marketing, sales or distribution, our product revenue may be lower than if we directly marketed or sold any approved products. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third-party collaborators, which may not be successful and are generally not within our control. If we are unable to enter into these arrangements on acceptable terms or at all, we may not be able to successfully commercialize any approved products. If we are not successful in commercializing any approved products, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***We have never commercialized an antibody candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize our products on our own or together with suitable collaborators.***

We have never commercialized an antibody candidate. While we have hired a Chief Commercial Officer and certain personnel to support market access and supply chain, we currently have only limited marketing or distribution capabilities, and no sales force. To achieve commercial success for our antibody candidates, if approved, which we may license to others, we will rely on the assistance and guidance of those collaborators. For antibody candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. Outside consultants may be relied upon to provide advice on commercialization strategies, which may fail to deliver or provide effective guidance to maximize any commercial opportunity, if any, that may arise from our antibody candidates.

Factors that may affect our ability to commercialize our antibody candidates on our own include obtaining effective advice from consultants on commercialization strategy, recruiting and retaining adequate numbers of effective sales and marketing personnel, having adequate numbers of physicians decide to prescribe our antibody candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our antibody candidates, if approved. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our antibody candidates, we may not generate revenues from them or be able to reach or sustain profitability.

***Our antibody candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.***

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved 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 approved. 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 the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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.

We believe that any of our antibody candidates approved 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. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our 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.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our antibody candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

### **Risks Related to Our Dependence on Third Parties**

***We rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our antibody candidates and our business could be substantially harmed.***

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our pre-clinical studies and clinical trials and to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities.

Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the competent authorities of the member states of the EEA, and comparable foreign regulatory authorities for all of our antibody candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities, who may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with the antibody candidate produced under cGMP or similar foreign regulations. Our failure to comply with these regulations may require us 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 antibody candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our antibody candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any antibody candidates that we develop. Moreover, as a result of the COVID-19 pandemic, certain of our third-party CROs have been affected and in some instances have experienced cessation or mitigation of activity and may experience closures and labor shortages, which may negatively affect our pre-clinical and clinical development activities. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for 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 our antibody candidates. As a result, our results of operations and the commercial prospects for our antibody candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional 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 materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***The collaboration and license agreement, or the Collaboration Agreement, with Incyte Corporation (Incyte) is important to our business. If suitable monospecific or bispecific antibody candidates are not***

***identified for further development and commercialization activities under the Collaboration Agreement, or if we or Incyte fail to adequately perform under the Collaboration Agreement, or if we or Incyte terminate the Collaboration Agreement, the development and commercialization of our antibody candidates would be delayed or terminated and our business would be adversely affected.***

The Collaboration Agreement may be terminated:

- in its entirety or on a program-by-program basis by Incyte for convenience;
- in its entirety or on a program-by-program basis by either party due to a material breach of the Collaboration Agreement, or any one or more programs under the Collaboration Agreement, as applicable; and
- on a program-by-program basis (but not in its entirety), by either party if the other party challenges the terminating party's patents for such program, and such challenge is not withdrawn within 30 days.

If the Collaboration Agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to us, subject to payment to Incyte of a reverse royalty of up to 4% on sales of future products, depending on the stage of development as of the date of termination, if we elect to pursue development and commercialization of monospecific or bispecific antibody candidates arising from the terminated programs.

Termination of the Collaboration Agreement could cause significant delays in our antibody candidate development and commercialization efforts, which could prevent us from commercializing our antibody candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us. In addition, under the Collaboration Agreement, Incyte agreed to conduct certain clinical development activities. If the Collaboration Agreement were to be terminated, and whether or not we identify another suitable collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

Under the Collaboration Agreement, we are dependent upon Incyte to successfully develop and commercialize any antibody candidates that are identified for further development under the Collaboration Agreement. With the exception of those programs where we retain certain co-development rights, we have limited ability to influence or control Incyte's development and commercialization activities or the resources it allocates to development of product candidates identified under the Collaboration Agreement. Our interests and Incyte's interests may differ or conflict from time to time, or we may disagree with Incyte's level of effort or resource allocation. Incyte may internally prioritize programs under development within the collaboration differently than we would, or it may not allocate sufficient resources to effectively or optimally develop or commercialize antibody candidates arising from such programs. If these events were to occur, our ability to receive revenue from the commercialization of products arising from such programs would be reduced, and our business would be adversely affected.

***The collaboration and license agreement, or the Lilly Collaboration Agreement, with Eli Lilly is important to our business. If suitable monospecific or bispecific antibody candidates are not identified for further development and commercialization activities under the Lilly Collaboration Agreement, or if we or Eli Lilly fail to adequately perform under the Lilly Collaboration Agreement, or if we or Eli Lilly terminate the Lilly Collaboration Agreement, the development and commercialization of our antibody candidates would be delayed or terminated and our business would be adversely affected.***

The Lilly Collaboration Agreement may be terminated:

- in its entirety or on a program-by-program basis by Eli Lilly for convenience;



- on a product-by-product basis (but not in its entirety), by Merus if Lilly challenges the Merus patents for such product and
- in its entirety or on a program-by-program basis by either party due to a material breach of the Lilly Collaboration Agreement, or any one or more programs under the Lilly Collaboration Agreement, as applicable.

If the Lilly Collaboration Agreement is terminated with respect to one or more programs, depending on the stage of development, certain rights in the terminated programs revert to us.

Termination of the Lilly Collaboration Agreement could cause significant delays in our antibody candidate development and commercialization efforts, which could prevent us from commercializing our antibody candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us. In addition, under the Lilly Collaboration Agreement, Eli Lilly agreed to conduct certain pre-clinical and clinical development activities. If the Lilly Collaboration Agreement were to be terminated, and whether or not we identify another suitable collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

Under the Lilly Collaboration Agreement, we are dependent upon Eli Lilly to successfully develop and commercialize any antibody candidates that are identified for further development under the Lilly Collaboration Agreement. We have limited ability to influence or control Eli Lilly's development and commercialization activities or the resources it allocates to development of product candidates identified under the Lilly Collaboration Agreement. Our interests and Eli Lilly's interests may differ or conflict from time to time, or we may disagree with Eli Lilly's level of effort or resource allocation. Eli Lilly may internally prioritize programs under development within the collaboration differently than we would, or it may not allocate sufficient resources to effectively or optimally develop or commercialize antibody candidates arising from such programs. If these events were to occur, our ability to receive revenue from the commercialization of products arising from such programs would be reduced, and our business would be adversely affected.

***The collaboration and license agreement with Betta Pharma, and the research and license agreements with Ono are important to our business. If our Biclomics® antibodies licensed in these collaboration and license agreements fail to advance or experience unacceptable safety or efficacy results if clinically developed, this could adversely impact the reputation of our platform and our ability to engage in future collaborations.***

If our collaboration and license agreement with Betta Pharma or our research and license agreements with Ono are terminated with respect to one or more programs, or the pre-clinical assets associated with the Ono license agreements fail to advance into the clinic, or experience negative results with respect to safety, efficacy, manufacturability, or other features of research and development, this could adversely affect the reputation of our Biclomics® technology platform and our ability to engage in future collaborations or licensing agreements. While we have certain contractual provisions in place in our collaboration and license agreement with Betta Pharma that permit us to supervise its development efforts for MCLA-129, for which it has development and product rights in China, we cannot guarantee that this clinical antibody candidate will be developed in China in accordance with our standards as applied to our wholly owned programs or in a manner suitable for ex-China development or in a manner that does not detract from our development of MCLA-129 outside of China. Ono is currently clinically developing at least one antibody program generated by us under a license agreement with Merus through use of our proprietary Biclomics® platform. To the extent this asset does not successfully advance through clinical development, this may impair our ability to leverage our platform in future license agreements to further expand the use of our platform and generate future revenue. Should the Betta Pharma collaboration or Ono

license agreements fail or be terminated, any suitable alternative collaboration or license agreement would take considerable time to negotiate, if at all, and could also be on less favorable terms to us. If these agreements were to be terminated, and whether or not we identify a suitable alternative collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could, depending on the stage of development and investment, have a material adverse effect on our business.

***If we fail to enter into new strategic relationships our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.***

Our product development programs and the potential commercialization of our antibody candidates will require substantial additional cash to fund expenses. Therefore, for some of our antibody candidates and with respect to our Triclonics® technology platform, we may decide to enter into new collaborations with pharmaceutical or biotechnology companies for the development and potential commercialization of those bispecific and trispecific antibody candidates. For instance, we have license and collaboration agreements with Ono, Incyte, Eli Lilly and Betta Pharma, under which we have licensed certain development and commercialization rights of certain of our monospecific or bispecific antibody candidates.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, we may have to curtail the development of a particular bispecific or trispecific antibody candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our antibody candidates to market, further research and develop new trispecific antibody candidates, enhance our Biclomics® and Triclonics® technology platforms and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;
- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator may experience technical, clinical, intellectual property, manufacturing or other setbacks in the research or development of a product program arising from our collaboration adversely affecting the financial return of our collaboration or the reputation of our technology platform;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

***We currently rely on third-party suppliers and other third parties for production of our antibody candidates and our dependence on these third parties may impair the advancement of our research***

***and development programs and the development of our antibody candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved antibody candidate and our commercialization of any of our antibody candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities following inspection of their facilities and procedures to manufacture our antibody candidates and products, fail to provide us with sufficient quantities of antibody product or fail to do so at acceptable timing, quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.***

We rely on and expect to continue to rely on third-party contract manufacturing organizations (CMOs) for the supply of cGMP-grade clinical trial materials and commercial quantities of our antibody candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture antibody candidates ourselves. The facilities used by our CMOs to manufacture our antibody candidates must be approved by the FDA foreign regulatory authorities pursuant to inspections that will be conducted after we submit our BLA to the FDA, or similar applications to foreign regulatory authorities. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP or similar foreign requirements for the manufacture of our antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities or may result in delay of our ability to obtain marketing authorization, if any, of our antibody candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our antibody 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 antibody candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our antibody candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our antibody candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials or scarcity that may arise as a result of the COVID-19 pandemic 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.

We rely on our CMOs to purchase from third-party suppliers the materials necessary to produce our antibody candidates for our clinical trials, and will rely on our existing and future collaborators to purchase from third-party suppliers the materials necessary to develop and produce our antibody candidates for future clinical trials and, upon approval, our products for commercialization. There are a limited number of suppliers for raw materials that we use to manufacture our antibody candidates and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our antibody candidates for our clinical trials, and if approved, ultimately for commercial sale. Apart from contractual measures, we do not have any control over the process or

timing of the acquisition of these raw materials by our manufacturers or manufacturers paid by our collaborators. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of an antibody candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of an antibody candidate, or the raw material components thereof, for a planned or 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 antibody candidates. If our manufacturers,

collaborators or we are unable to purchase these raw materials after regulatory approval has been obtained for our antibody candidates, the commercial launch of our antibody candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our antibody candidates. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers have been affected, which could disrupt or delay their activities or ability to source materials and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our pre-clinical and clinical development activities.

We rely on our manufacturers and other subcontractors to comply with and respect the proprietary rights of others in conducting their contractual obligations for us. If our manufacturers or other subcontractors fail to acquire the proper licenses or otherwise infringe third party proprietary rights in the course of completing their contractual obligations to us, we may have to find alternative manufacturers or defend against claims of infringement, either of which would significantly impact our ability to develop, obtain regulatory approval for or market our antibody candidates, if approved.

### **Risks Related to Intellectual Property and Information Technology**

*We rely on patents and other intellectual property rights to protect our technology, including antibody candidates and our Biclomics® technology platform and Triclomics® technology platform, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.*

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our Biclomics® technology platform, Triclomics® technology platform, our common light chain transgenic technology, our dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody pre-clinical and clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our platform technologies, and antibody candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' 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. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and

patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, or have issued and even if such patents cover our Biclomics® technology platform, Triclomics® technology platform, our common light chain transgenic technology, our dimerization technology our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody pre-clinical and clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical antibody and antibody clinical candidates, the methods for treating patients using those candidates, and other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology in the relevant jurisdiction.

Because patent applications 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 any patent application related to our technology, including our antibody candidates. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs.

***Issued patents covering one or more of our products or the Biclomics® technology or Triclomics® technology platforms could be found invalid or unenforceable if challenged in court.***

To protect our competitive position, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being enjoined, required to pay us any license fees, or compensate us for lost profits or reasonable royalty. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize technology covered by our patents we seek to enforce, such as those covering our antibody candidates or methods, our Biclomics® technology and Triclomics® technology platforms, our common light chain transgenic technology, or our dimerization technology, among other technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering our technology, one of our products or methods, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements for patentability, for example, lack of utility, novelty, obviousness, non-enablement or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the U.S. Patent and Trademark Office (USPTO) or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the USPTO. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on

one or more of our technologies, products, methods or certain aspects of our Biclomics® technology and Triclomics® technology platforms. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our antibody candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our antibody candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms or at all.***

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our technology platforms, methods or candidates or elements thereof, our manufacture or uses relevant to our development, or other attributes of our antibody candidates or our Biclomics® technology platform or Triclomics® technology platform. In such cases, we may not be in a position to develop or commercialize products or antibody candidates unless we successfully pursue litigation, opposition, inter partes, or related post-grant proceedings to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. In addition, we are aware of issued patents and/or pending patent applications held by third parties that could be alleged as covering some of our antibody candidates, irrespective of the merits. We believe that if such patents or patent applications (if issued as currently pending) were asserted against us, we would have counterclaims and defenses against such claims, including non-infringement, the affirmative defense of safe harbor designed to protect activity undertaken to obtain federal regulatory approval of a drug, including under 35 U.S.C. § 271(e) and similar foreign exceptions to infringement, and defenses concerning patent invalidity and/or unenforceability. However, if such counterclaims and defenses were not successful and such patents were successfully asserted against us such that they are found to be valid and enforceable, and infringed, unless we obtain a license to such patents, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our technology. We could also be required to pay substantial damages.

It is also possible that in our evaluation of third party intellectual property, we failed to identify relevant patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technologies could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, antibody candidates or the use of our bispecific and trispecific antibody candidates.

Third party intellectual property right holders, including our competitors, may actively bring infringement claims against us. The granting of orphan drug status in respect of any of our antibody candidates does not guarantee our freedom to operate and is separate from our risk of possible infringement of third parties' intellectual property rights. We may not be able to successfully settle or otherwise resolve such potential infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing any approved products.

If we fail in any such dispute, in addition to being forced to potentially pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our antibody candidates that are held to be infringing or be forced to redesign antibody candidates so that we no longer infringe the

third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our present or future licensors', collaborators' or partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future antibody candidates. 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.

***Our ability to compete may be adversely affected if we are unsuccessful in defending against any claims by competitors or others that we are infringing upon their intellectual property rights.***

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including those producing therapeutic candidates or products to treat and potentially cure cancer, have employed intellectual property litigation as a means to gain an advantage over their competitors. As a result, we may be required to defend against claims of intellectual property infringement that may be asserted by our competitors against us and, if the outcome of any such litigation is adverse to us, it may affect our ability to compete effectively.

Our involvement in litigation, and in any interferences, opposition, pre and post-grant administrative proceedings or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any potential intellectual property litigation successfully adjudicated against us could also force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our products, if approved, in the United States and/or other jurisdictions that are covered by the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those technologies, products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

We are aware that significant number of patents and patent applications may exist relating to aspects of therapeutic antibody technologies filed by, and issued to, third parties.

We cannot assure you that we will ultimately prevail if any of this third-party intellectual property is asserted against us.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Where we are asserting our intellectual property against third parties, or defending against an allegation of infringement, even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims 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 and if

securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings and the legal costs associated with them, could substantially increase our operating losses and reduce our resources available for development activities. 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 substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***We may not be successful in obtaining or maintaining necessary rights to our antibody candidates through acquisitions and in-licenses.***

We currently have rights and own our intellectual property, including issued patents and pending patent applications, relating to and covering our Biclomics® technology and Triclomics® technology platforms, our common light chain transgenic technology, our dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and pre-clinical antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we may identify as necessary for our antibody candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash 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. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of an antibody candidate or program, we may have to abandon development of that antibody candidate or program and our business and financial condition could suffer.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

We currently have trademark and service mark rights relating to and covering our Biclomics® technology and Triclomics® technology platforms, zenocutuzumab and other aspects of our company, its services and activities used in commerce. Our registered or unregistered trademarks, trade names or service marks may be challenged including during prosecution or through opposition proceedings, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks, trade names, and service marks, which we need to build name recognition by potential collaborators, partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names and service marks then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks, trade names or service marks similar to ours in different jurisdictions, or have senior rights to ours, or prevail in any opposition proceedings, it could interfere with our use of our current trademarks, trade names or service marks throughout the world.



***If we do not obtain protection under the Hatch-Waxman Amendments and similar non-U.S. legislation for extending the term of patents covering each of our antibody candidates, our business may be materially harmed.***

Patents typically 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, not including potential patent term extensions or adjustments that may be available in the U.S., and under comparable laws applicable outside the U.S., where certain conditions are met. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our antibody candidates are obtained, once the patent life has expired for a candidate, we may be open to competition from competitive medications, including biosimilar or generic medications. Given the amount of time required for the development, testing and regulatory review of new antibody candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, causing our revenue from applicable products to be reduced, possibly materially, and potentially harming our ability to recover our investment in such product or obtain a reasonable return on that investment.

Depending upon the timing, duration and conditions of FDA marketing approval of our antibody candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

***We enjoy only limited geographical protection with respect to certain patents and may face difficulties in certain jurisdictions, which may diminish the value of intellectual property rights in those jurisdictions.***

We generally file our first patent application (i.e., priority filing) in the Netherlands. International applications under the Patent Cooperation Treaty (PCT) are usually filed within 12 months after the priority filing, where we pursue patent applications in the U.S., across the E.U., and other PCT participating jurisdictions, as based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our antibody candidates may be marketed or manufactured or our platform technologies may be utilized. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same antibody candidate and/or technology.

Competitors may use our and our existing or future licensors', collaborators' or partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our existing or future licensors, collaborators or partners have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our antibody candidates or our platform technologies, and our

and our existing or future licensors', collaborators' or partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and the EU, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our existing or future licensors, collaborators or partners encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some 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 existing or future licensors, collaborators or partners 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 and results of operations may be adversely affected.

***Intellectual property rights do not necessarily address all potential threats to our competitive advantage.***

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. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to our antibody candidates but that are not covered by the claims of the patents that we own or have exclusively licensed;
- the patents of third parties may have an adverse effect on our business;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our antibody candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- we may not develop additional technologies that are patentable.

***Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our antibody candidates and technology platforms.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involve both technological complexity and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain.

In September 2011, the America Invents Act (AIA) was enacted in the United States, resulting in significant changes to the U.S. patent system. An important change introduced by the AIA was a transition to a “first-to-file” system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention, which went into effect on March 16, 2013. Therefore, a third party that now files a patent application in the USPTO before we do could be awarded a patent covering an invention of ours even if we created the invention before it was created by the third party. While we are cognizant of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

Among some of the other changes introduced by the AIA were changes that limit where a patentee may file a patent infringement suit and providing opportunities for third parties to challenge any issued patent in the USPTO. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower burden of proof in USPTO proceedings compared to the burden of proof in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. The AIA and its continued implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, and the patent applications of our existing and future collaborators or licensors and the enforcement or defense of our issued patents.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Similarly, there is complexity and uncertainty related to European patent laws. For example, the European Patent Convention was amended in April 2010 to limit the time permitted for filing divisional applications. In addition, the EPO patent system is relatively stringent in the type of amendments that are allowed during prosecution. These limitations and requirements could adversely affect our ability to obtain new patents in the future that may be important for our business.

***Confidentiality agreements with employees, contractors, agents, consultants, collaborators and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.***

We consider proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to our business. We may rely on trade secrets and/or confidential know-how to protect our technology, especially where patent protection is believed to be of limited value. However, trade secrets and/or confidential know-how are difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, collaborators and advisors to enter into confidentiality agreements with us, our practice is to provide regular trainings on the importance of maintaining confidentiality, to promulgate a business code of conduct requiring confidentiality, and prohibit the use of non-sanctioned devices with company confidential information. However, current or former employees, consultants, contractors, collaborators and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements and other precautions taken may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or we

may be unaware of such disclosure to enforce our confidentiality agreements and other remedies. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements and theft of trade secret claims may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

Failure to obtain or maintain trade secrets and/or confidential know-how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

Under certain circumstances and to guarantee our freedom to operate, we may also decide to publish some know-how to prevent others from obtaining patent rights covering such know-how.

***We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.***

Many of our employees, including our senior management, were previously employed at universities or at pharmaceutical or biotechnology companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we take measures including by policy, procedure and contract to try to ensure that our employees do not improperly use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed confidential information or intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we successfully prosecute or defend against such claims, litigation could result in substantial costs and distract management.

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The 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. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our existing or future licensors or collaborators fail to maintain the patents and patent applications covering our antibody candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

***Use of social media could give rise to liability, breaches of data security, or reputational harm.***

We and our employees use social media to communicate internally and externally, as do our contractors, consultants, CROs, and third parties, including clinical trial participants. While we have policies and procedures in place governing employee use of social media, there is risk that the use of social media by us or our employees or third parties to communicate about our antibody candidates, technologies or business may give rise to liability, lead to the loss of trade secrets or other intellectual property, or result in public exposure of personal information of our employees, clinical trial patients, customers, and others. Furthermore, negative posts or comments about us, our clinical trials, or our antibody candidates, our technologies, and company generally in social media could seriously damage our reputation, brand image, and goodwill. Any of these events could have a material adverse effect on our business, prospects, operating results, and financial condition and could adversely affect the price of our common shares.

***Our information technology systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.***

Despite the implementation of security measures, our information technology systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, computer viruses, and malware (e.g., ransomware malicious software), fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in frequency and sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. While we continue to make investments to improve the protection of data and information technology, including in the hiring of IT personnel, periodic cyber security awareness trainings, and improvements to IT infrastructure and controls, and conduct regular testing of our systems, there can be no assurance that our efforts will prevent service interruptions or security breaches.

We and certain of our service providers are from time to time subject to cyberattack attempts or incidents and security incidents. Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others.

Although to our knowledge we have not experienced any significant cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to breach notification requirements, regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties, result in substantial costs and distract

management. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price and shareholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs and distract management.

### **Risks Related to Employee Matters and Managing Growth**

***Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.***

Our success depends upon the contributions of our senior leaders, including our board of directors, our senior management, and other key scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our antibody candidates and related technologies. The loss of key senior management, managers and senior scientists could delay our research and development and clinical trial activities or impair our ability operate the company effectively. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is increasingly intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

***We expect to expand our development, regulatory and sales and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.***

We expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug and clinical development, regulatory affairs, medical affairs, commercialization, sales and marketing. To manage our 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 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.

## **Risks Related to Our Common Shares**

***Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of the shares.***

Sales of a substantial number of our common shares in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common shares. We have registered and intend to continue to register all common shares that we may issue under our equity compensation plans. Once registered, these common shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates who hold such shares. In addition, in connection with entering into the Collaboration Agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which we issued and sold to Incyte 3,200,000 of our common shares. Incyte's ability to sell these common shares may be subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. Subject to that, these shares can be freely sold in the public market. In addition, in connection with entering into the Lilly Collaboration Agreement, we entered into a Lilly Share Subscription Agreement with Eli Lilly, pursuant to which we issued and sold to Eli Lilly 706,834 of our common shares.

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

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 our board of directors.

These provisions include:

- the authorization of a class of preferred shares that may be issued to an independent special purpose foundation;
- the possibility to appoint our board members for staggered terms;
- a provision that our board members may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast representing more than 50% of our outstanding share capital (unless the removal was proposed by the board of directors); and
- a requirement that certain matters, including an amendment of our articles of association, may only be brought to our shareholders for a vote upon a proposal by our board of directors.

The board of directors can invoke a statutory cooling-off period of up to 250 days in situations described below. When such cooling-off period is invoked, our general meeting of shareholders cannot dismiss, suspend or appoint members of the board of directors (or amend the provisions in our articles of association dealing with those matters) unless those matters would be proposed by the board of directors. This cooling-off period could be invoked by the board of directors in case:

- a) shareholders, using either their shareholder proposal right or their right to request a general meeting of shareholders, propose an agenda item for the general meeting of shareholders to dismiss, suspend or appoint a member of the board of directors (or to amend any provision in the articles of association dealing with those matters); or
- b) a public offer for the company is made or announced without the company's support, provided, in each case, that the board of directors believes that such proposal or offer materially conflicts with the interests of the company and its business.

Under the Dutch Corporate Governance Code (DCGC), the board of directors may also invoke a response period of up to 180 days in case shareholders, using either their shareholder proposal right or their right to

request a general meeting of shareholders, propose an agenda item for the general meeting of shareholders which may result in a change in our strategy (including through the dismissal of one or more of our board members). If this response period is invoked, the shareholders concerned must give the board of directors the opportunity to respond to their intentions before their request is dealt with at a general meeting of shareholders

***Our anti-takeover provision may prevent a beneficial change of control.***

We adopted an anti-takeover measure pursuant to which our board of directors may, without shareholder approval, issue (or grant the right to acquire) preferred shares. Pursuant to a call option agreement entered into with an independent special purpose foundation, we may issue an amount of preferred shares up to 100% of our issued capital held by third parties immediately prior to the issuance of such preferred shares.

The preferred shares will be issued to the foundation for their nominal value, of which only 25% will be due upon issuance. The voting rights of our shares are based on nominal value and as we expect our shares to continue to trade substantially in excess of nominal value, preferred shares issued at nominal value can obtain significant voting power for a substantially reduced price and thus be used as a defensive measure. These preferred shares will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate. Subject to the foundation exercising its call option under the call option agreement, the board may issue these preferred shares to protect us from influences that we believe do not serve our best interests and threaten to undermine our continuity, independence and identity. These influences may include a third-party acquiring a significant percentage of our common shares, the announcement of a public offer for our common shares, other concentration of control over our common shares or any other form of pressure on us to alter our strategic policies. The foundation's articles of association provide that it will act to serve the best interests of us, our associated business and all parties connected to us, by opposing any influences that conflict with these interests and threaten to undermine our continuity, independence and identity. This foundation is structured to operate independently of us.

***Holders of our common shares outside the Netherlands may not be able to exercise preemptive rights.***

In the event of an increase in our share capital, holders of our common shares are generally entitled under Dutch law to full preemptive rights, unless these rights are excluded either by a resolution of the general meeting of shareholders, or by a resolution of the board (if the board has been designated by the general meeting of shareholders for this purpose). Certain holders of our common shares outside the Netherlands, in particular U.S. holders of our common shares, may not be able to exercise preemptive rights unless a registration statement under the Securities Act is declared effective with respect to our common shares issuable upon exercise of such rights or an exemption from the registration requirements is available.

***The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.***

We are a Dutch public company with limited liability (naamloze vennootschap). Our corporate affairs are governed by our articles of association and by the laws governing companies incorporated in the Netherlands. The rights of shareholders and the responsibilities of members of our board 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, the members of our board are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders.

***We are not obligated to and do not comply with all the best practice provisions of the Dutch Corporate Governance Code. This may affect the rights of our shareholders.***



We are subject to the DCGC. The DCGC contains both principles and best practice provisions for board of directors, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. The principles and best practice provisions apply to our board (in relation to role and composition, conflicts of interest and independence requirements, board committees and remuneration), shareholders and the general meeting of shareholders (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best practice provisions of the DCGC. As a result, the rights of our shareholders may be affected and our shareholders may not have the same level of protection as a shareholder in another Dutch public company with limited liability (naamloze vennootschap) listed in the Netherlands that fully complies with the DCGC.

***Claims of U.S. civil liabilities may not be enforceable against us.***

We are incorporated under the laws of the Netherlands. Most of our assets are located outside the United States. The United States and the Netherlands currently 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, we note that the Hague Convention on Choice of Court Agreements of 30 June 2005 has entered into force for the Netherlands, but has not entered into force for the United States. The Hague Convention of 2 July 2019 on the Recognition and Enforcement of Foreign Judgments in Civil or Commercial Matters has not entered into force for either the Netherlands or the United States. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the Dutch court the final judgment rendered by the U.S. court. If and to the extent that the Dutch court finds that the jurisdiction of the U.S. court has been based on grounds which are generally acceptable according to international standards and that proper legal procedures have been observed, the court of the Netherlands will, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of the Netherlands or is irreconcilable with a judgement of a Dutch court or foreign court that is acknowledged in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (Wetboek van Burgerlijke Rechtsvordering). As a result of the above, it may not be possible for investors to effect service of process within the United States upon us or members of our board or certain experts named herein who are residents of the Netherlands or countries other than the United States or to enforce any judgments against the same obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

***Our articles of association include a U.S. federal forum selection clause designating federal courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.***

Our articles of association provide that, unless we consent in writing to an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act, to the fullest extent permitted by applicable law, shall be the federal district courts of the United States of America (the "Federal Forum Provision"). The Federal Forum Provision in our articles of association may impose additional litigation costs on shareholders in pursuing any such claims. Additionally, the forum

selection clause may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

***We are no longer an "emerging growth company" or a "smaller reporting company", and as a result we are subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.***

We are no longer an "emerging growth company" or a "smaller reporting company," and as a result, we are required to comply with various disclosure and compliance requirements that did not previously apply, such as the auditor attestation requirements of The Sarbanes-Oxley Act of 2002 (SOX) Section 404(b), the requirement that we hold a nonbinding advisory vote on executive compensation and obtain shareholder approval of any golden parachute payments not previously approved, and the requirement to provide full and more detailed executive compensation disclosure. Compliance with these additional requirements increases our legal and financial compliance costs and causes management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the stock exchange on which our common shares are listed, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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

Based on the value of our assets, including goodwill, and composition of our income, assets and operations for the taxable year 2022, we do not believe we were a PFIC for U.S. federal income tax purposes for that taxable year. A non-U.S. company generally 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 (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. 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. It is possible the Internal Revenue Service could determine that we were a PFIC for the taxable year 2022. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. Once treated as a PFIC, for any taxable year in which a U.S. Holder owns equity in such foreign corporation, a foreign corporation will generally continue to be treated as a PFIC for all subsequent taxable years with respect to such U.S. Holder. If we were to be a PFIC, "excess distributions" (as such term is defined in the United States Internal Revenue Code of 1986, as amended (U.S. Tax Code)) to a U.S. Holder, and any gain recognized by a U.S. Holder on a disposition of our common shares would be taxed in potentially unfavorable ways. Among other consequences, our dividends would be taxed at the regular rates applicable to ordinary income, rather than the 20% maximum

rate applicable to certain dividends received by an individual from a qualified foreign corporation, and, to the extent that they constituted excess distributions, certain interest charges may apply, and gains on the sale of our shares would be treated in the same way as excess distributions. In addition, the U.S. Holder would be subject to detailed reporting obligations. The tests for determining PFIC status are applied annually and it is difficult to make accurate predictions of future income and assets, which are relevant to the determination of any future PFIC status. As such, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. Further, we cannot provide any assurances that we will furnish to any U.S. Holder information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares, including the potential availability and advisability of an election to treat us as a qualified electing fund or a mark-to-market election. A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our common shares and is:

- (1) a citizen or individual 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 that (a) is subject to the primary supervision of a U.S. court and the control of one or more “United States persons” (within the meaning of Section 7701(a)(30) of the U.S. Tax Code) or (b) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

***If a U.S. Holder is treated as owning at least 10% of our common shares, such holder may be subject to adverse U.S. federal income tax consequences.***

If a U.S. Holder 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) as such term is defined in the Tax Code. A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income, as ordinary income, its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may extend the statute of limitations with respect to such United States shareholder’s U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether we or any of our future non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares. The risk of being subject to increased taxation may deter our current shareholders from increasing their investment in us and others from investing in us, which could impact the demand for, and value of, our common shares.

## General Risk Factors

***The price of our common shares may be volatile and may fluctuate due to factors beyond our control.***

The share price of publicly traded emerging biopharmaceutical and drug discovery and development companies has been highly volatile and is likely to remain highly volatile in the future. The market price of our common shares may fluctuate significantly due to a variety of factors, including:

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our antibody candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our antibody candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole;
- political instability in the United States, including the failure of the federal government to raise the federal debt ceiling; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their common shares and may otherwise negatively affect the liquidity of our common shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

***Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.***

The global economy, including credit and financial markets, has recently experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, rising interest and inflation rates, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. If the equity and credit markets continue to deteriorate or the Netherlands or the United States enters a recession, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive. In addition, there is a risk that one or more of our CROs, suppliers or other third-party providers may not survive an economic downturn or recession. As a result, our business, results of operations and price of our common shares may be adversely affected.

***Because we do not expect to pay cash dividends for the foreseeable future, any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares, which is uncertain.***

We have not paid any cash dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that cash dividends will not be paid until we have an established revenue stream to support continuing cash dividends. Payment of any future dividends to shareholders will in addition effectively be at the discretion of the general meeting, upon proposal of the board of directors, after taking into account various factors including our business prospects, cash requirements, financial performance and new product development. In addition, payment of future cash dividends may be made only if our shareholders' equity exceeds the sum of our paid-in and called-up share capital plus the reserves required to be maintained by Dutch law or by our articles of association. Accordingly, investors cannot rely on cash dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares. In addition, the low trading volume of our common shares may adversely affect the trading price of our common shares, and our shareholders may not be able to sell their common shares for a price higher than the price they paid for our common shares.

***If securities or industry analysts publish inaccurate or unfavorable research about our business, the price of our common shares and our trading volume could decline.***

The trading market for our common shares depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause the price of our common shares and trading volume to decline.

***We will continue to incur increased costs as a result of operating as a public company with limited liability (naamloze vennootschap), and our management team is required to devote substantial time to new compliance initiatives and corporate governance practices.***

As a public company, and particularly now that we no longer qualify as an emerging growth company or a smaller reporting company, we will continue to incur significant legal, accounting and other expenses related to our operation as a public company. The Sarbanes-Oxley Act of 2002 (SOX), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel continues to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and make some activities more time-consuming and costly.

These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404(a) of SOX (Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K. Additionally, we are no longer an emerging growth company or smaller reporting company and are required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404(a), we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources and have engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of our 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 we will not be able to maintain effective internal control over financial reporting as required by Section 404. Material weaknesses or significant deficiencies in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

***The increasing focus on environmental sustainability and social initiatives could increase our costs, harm our reputation and adversely impact our financial results.***

There has been increasing public focus by investors, patients, environmental activists, the media and governmental and nongovernmental organizations on a variety of environmental, social and other sustainability matters. We may experience pressure to make commitments relating to sustainability matters that affect us, including the design and implementation of specific risk mitigation strategic initiatives relating to sustainability. Expectations regarding the management of ESG initiatives continues to evolve rapidly. While we may from time to time engage in various initiatives (including but not limited to voluntary disclosures, policies, or goals) to improve our ESG profile or respond to stakeholder expectations, we cannot guarantee that these initiatives will have the desired effect. If we are not effective in addressing environmental, social and other sustainability matters affecting our business, or setting and meeting relevant sustainability goals, our reputation and financial results may suffer. In addition, even if we are effective at addressing such concerns, we may experience increased costs as a result of executing upon our sustainability goals that may not be offset by any benefit to our reputation, which could have an adverse impact on our business and financial condition.

In addition, this emphasis on environmental, social and other sustainability matters has resulted and may result in the adoption of new laws and regulations, including new reporting requirements. If we fail to comply with new laws, regulations or reporting requirements, our reputation and business could be adversely impacted.

#### **4 LEGAL PROCEEDINGS**




From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings, which could be deemed to be material.

## 5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

### 5.1 Operating Results

#### Our Bionics® and Trionics® Candidate Portfolio

We currently have bispecific candidates in clinical development, with a variety bispecific and trispecific candidates in pre-clinical development. The following table summarizes our development candidate pipeline:

PROGRAM	BISPECIFIC TARGETS	INDICATION(S)	PRECLINICAL	PHASE 1	PHASE 1/2	STATUS
Zenocutuzumab (Zeno) (MCLA-128)	HER2 x HER3	NRG1+ cancer with afatinib in NRG1+ NSCLC with androgen deprivation therapy (ADT) in castration-resistant prostate cancer (CRPC) Other cancers				<ul style="list-style-type: none"> <li>Phase 1/2 registration-directed trial ongoing in NRG1+ cancer</li> <li>Clinical update on Zeno monotherapy in NRG1+ cancer planned 2023</li> <li>Initial clinical data update in CRPC planned 2H23</li> </ul>
Petosemtamab (MCLA-158)	EGFR x LGR5	Solid tumors				<ul style="list-style-type: none"> <li>Phase 1 trial ongoing</li> <li>Clinical update planned 1H23</li> </ul>
MCLA-129	EGFR x c-MET	Solid tumors with a 3rd gen EGFR TKI in NSCLC	 (China)			<ul style="list-style-type: none"> <li>Phase 1/2 trial ongoing</li> <li>Clinical update planned 2H23</li> </ul>
MCLA-145	CD137 x PD-L1	Solid tumors with a PD1 inhibitor in solid tumors				Phase 1 trial ongoing
ONO-4685 <sup>1</sup>	PD-1 x CD3	Relapsed/Refractory T Cell Lymphoma; Psoriasis				Phase 1 trial ongoing
INCA32459 <sup>1</sup>	LAG3 x PD-1	Not disclosed				Phase 1 trial ongoing <sup>2</sup>

<sup>1</sup> If commercialized, Merus to receive royalties  
<sup>2</sup> Incyte February 7, 2023 10K

**Merus**

### Results of Operations for the Years Ended December 31, 2022 and 2021

#### Collaboration Revenue

The following is a comparison of collaboration revenue for the years ended December 31, 2022 and 2021:

	<b>Year Ended December 31,</b>		<b>Change</b>	<b>%</b>
	<b>2022</b>	<b>2021</b>		
	<b>(In euros thousands)</b>			
Incyte	25,068	25,063	5	0.0%
Lilly	12,984	14,762	(1,778)	-12.0%
Other	1,239	1,713	(474)	-27.7%
Total revenue	<u>39,291</u>	<u>41,538</u>	<u>(2,247)</u>	<u>-5.4%</u>

Our revenue from each collaboration partner consists of revenue recognized from the amortization of deferred revenue related to upfront payments for licenses or options to obtain licenses in the future, research and development services, reimbursement revenue earned and milestone payments earned under collaboration and license agreements with our collaboration partners.

Collaboration revenue for the year ended December 31, 2022 decreased €2.2 million as compared to the year ended December 31, 2021, primarily as a result of decreases in Lilly revenue of €1.8 million and Other revenue of €0.5 million. The decrease in Lilly revenue was primarily due to a decrease in upfront payment amortization of €2.4 million, partially offset by an increase in reimbursement revenue of €0.6 million. The decrease in Lilly upfront payment amortization is the result of a change in estimate related to the program target substitution of one of the Lilly programs which reduced the percent complete and resulted in a reversal of a portion of the cumulative amount of revenue recognized. The decrease in Other revenue is primarily the result of a decrease in reimbursement revenue of €0.9 million and a decrease upfront payment amortization of €0.2 million partially offset by an increase in milestone revenue of €0.6 million.

As of December 31, 2022, we have total deferred revenue of €63.9 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and Lilly collaboration agreement. The remaining deferred revenue of €48.8 million from the Incyte collaboration agreement is expected to be recognized over the next three years. The remaining deferred revenue of €15.1 million from the Lilly collaboration agreement is expected to be recognized over time using a cost-to-cost measure of progress toward the development of a lead compound for each respective target.

### *Operating Expenses*

The following is a comparison of operating expenses for the years ended December 31, 2022 and 2021:

	<b>Year Ended December 31,</b>		<b>Change</b>	<b>%</b>
	<b>2022</b>	<b>2021</b>		
	<b>(In euros thousands)</b>			
Research and development costs	142,230	83,225	59,005	70.9%
General and administrative costs	49,008	34,580	14,428	41.7%
<b>Total operating expenses</b>	<b>191,238</b>	<b>117,805</b>	<b>73,433</b>	<b>62.3%</b>

### *Research and Development Expense*

Research and development costs consist principally of the costs associated with our research and development activities, conducting pre-clinical studies and clinical trials, and activities related to our regulatory filings. Our research and development expenses consist of:

- salaries for research and development staff and related expenses, including share-based compensation expenses;
- expenses incurred under agreements with contract research organizations (CROs) contract manufacturing organizations, and consultants that conduct and support clinical trials and pre-clinical studies;
- costs to enhance our platform technologies, develop product candidates, including raw materials and supplies, product testing, and facility related expenses; and
- amortization and depreciation of tangible and intangible fixed assets used to develop our product candidates.

Note that we do not allocate employee-related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple programs under research and development and, as such, are separately classified as unallocated research and development expenses.



Research and development expense for the year ended December 31, 2022 increased €59.0 million as compared to the year ended December 31, 2021, primarily as a result of increases in external clinical services and drug manufacturing costs, including costs to fulfill our obligations under our collaboration agreements, related to our programs of €40.9 million, personnel related expenses including stock-based compensation of €12.5 million due to an increase in employee headcount, facilities cost of €2.4 million, and consultancy costs of €2.1 million.

Research and development activities are central to our business model. We expect to continue to incur significant research and development costs for the foreseeable future as we continue to enhance our platform technologies, our development programs progress, as we continue to support the clinical trials of our antibody candidates as treatments for various cancers and as we move these candidates into additional clinical trials. There are numerous factors associated with the successful commercialization of any of our antibody candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development programs and plans.

#### *General and Administrative Expense*

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, legal and intellectual property, business development and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services, including intellectual property and general legal services.

General and administrative expense for the year ended December 31, 2022 increased €14.4 million as compared to the year ended December 31, 2021, primarily as a result of increases in consultancy costs of €4.0 million, stock-based compensation of €3.8 million, personnel related costs of €3.6 million, and finance costs of €1.2 million.

We expect general and administrative expenses to increase as we grow as a company, driven by the need to support a growing workforce, engaging in financing transactions, establishing and maintaining our intellectual property rights, fulfilling our compliance requirements as a public company and related legal, regulatory and potential commercialization costs.

#### *Net Finance Income (Costs)*

The following is a comparison of net finance income (costs), for the years ended December 31, 2022 and 2021:

	<b>Year Ended</b>		<b>Change</b>	<b>%</b>
	<b>December 31,</b>			
	<b>2022</b>	<b>2021</b>		
	<b>(In euros thousands)</b>			
Finance income	27,982	21,111	6,871	32.5%
Finance costs	(567)	(1,366)	799	-58.5%
Net finance income (costs)	<u>27,415</u>	<u>19,745</u>	<u>7,670</u>	38.8%

Net finance income (costs) consists of finance income from interest earned on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains on our foreign denominated cash, cash equivalents and marketable securities.

### ***Tax Expense***

The following is a comparison of income tax expense for the years ended December 31, 2022 and 2021:

	<b>Year Ended</b>		<b>Change</b>	<b>%</b>
	<b>December 31,</b>			
	<b>2022</b>	<b>2021</b>		
	<b>(In euros thousands)</b>			
Current	(2,500)	(207)	(2,293)	1107.7%
Deferred	1,571	6	1,565	26083.3%
<b>Tax expense</b>	<b>(929)</b>	<b>(201)</b>	<b>(728)</b>	<b>362.2%</b>

We are subject to income taxes in the Netherlands and the U.S. Our current and deferred tax provision represents taxable income attributed to our U.S. operations as a consequence of allocating income to that jurisdiction. No current or deferred provision for income taxes has been made for income taxes in the Netherlands due to losses for tax purposes. Further, given a history of losses in the Netherlands, no deferred tax assets in excess of deferred tax liabilities are recognized as it is not more likely than not that they will be recovered.

The Tax Cuts and Jobs Act of 2017 (“TCJA”), which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 effective January 1, 2022. The amended provision under Section 174 requires us to capitalize and amortize these expenditures over five years (for U.S.-based research). As of December 31, 2022, we recorded an increase to net deferred tax assets of a €1.3 million and an increase to income taxes payable of a similar amount. We are monitoring legislation for any further changes to Section 174 and the potential impact to our financial statements in 2023.

Income tax expense increased primarily due to an increase in book income before tax and an increase in temporary differences due to the inclusion of Section 174 expenses due to the TCJA.

## **5.2 Liquidity and Capital Resources**

### ***Funding Our Operations***

We are a clinical-stage company and have not generated any revenue from product sales. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our antibody candidates from discovery through pre-clinical development and into clinical trials and seek regulatory approval and pursue commercialization of any approved antibody candidate. In addition, if we obtain regulatory approval for any of our antibody candidates, if appropriate, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

We anticipate that we will require additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which

may include collaborations, business development and licensing opportunities with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Risk Factors—Risks Related to Our Business and Industry—The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations." in this report. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so. Based on our current operating plan, we expect that our existing cash, cash equivalents and marketable securities of €306.3 million as of December 31, 2022 will be sufficient to fund our operations and capital expenditure requirements into the second half of 2025. Our cash and cash equivalents are maintained at financial institutions in amounts that exceed federally insured limits. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all.

### ***Cash Requirements***

We require external sources of financing to fund our operations. Since inception through December 31, 2022, we have raised an aggregate of \$932.7 million or €820.0 million, of which \$165.4 million or €153.4 million was non-equity funding through our collaboration agreements, \$656.6 million or €575.6 million was from the sale of common shares and \$110.7 million or €91.0 million was from private funding sources prior to our initial public offering. These amounts include aggregate immediate proceeds from the closing of the collaboration and license agreement and share purchase agreement with Eli Lilly in January 2021 of \$60.0 million or €49.7 million, the aggregate net proceeds from the January 2021 follow-on offering of \$129.7 million or €106.5 million, the aggregate net proceeds from the November 2021 follow-on offering of \$118.7 million or €102.5 million, and the aggregate net proceeds during the year ended December 31, 2022 from the "at the market" offering program pursuant to an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC (Jefferies) of \$57.5 million, or €54.8 million. As of December 31, 2022, we had €306.3 million in cash, cash equivalents and marketable securities that are available to fund our current and future operations.

In May 2021, we entered into the Sales Agreement with Jefferies, to sell from time to time up to \$125.0 million of our common stock through an "at the market" offering program under which Jefferies acts as the sales agent. During the year ended December 31, 2021, we did not sell any ordinary shares under the Sales Agreement. During the year ended December 31, 2022, we had \$59.5 million or €56.6 million of gross proceeds from sales of our ordinary shares under the Sales Agreement.

In addition to our existing cash, cash equivalents and marketable securities, we may receive research and development co-funding and are eligible to earn a significant amount of milestone payments under our collaboration agreements. Our ability to earn these payments and the timing of earning these payments is dependent upon the outcome of our research and development activities and is uncertain at this time. Our collaboration and license agreements may require payment of milestones to third parties contingent on future events.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaboration arrangements, licensing, other business development opportunities and government grants. Except for any obligations of our collaborators to make license, milestone or royalty payments under our agreements with them, and government grants, we do not have any committed external sources of liquidity.

To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our shareholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common shareholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through collaboration arrangements, licensing or other business development opportunities in the future, we may have to relinquish valuable rights to our technologies or intellectual property, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise any additional funds that may be needed through equity or debt financings 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 prefer to develop and market ourselves.

Our primary uses of capital are: clinical trial costs, third-party research and development services, personnel, laboratory and related supplies, legal, intellectual property and other regulatory expenses and general overhead costs. Because our product candidates are in various stages of clinical and pre-clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. In addition, our expenditures as reported in our financial statements may be expected to be variable due to that uncertainty. We enter into contracts in the normal course of business with CROs for clinical and pre-clinical research studies, external manufacturers for product candidates for use in our clinical trials, and other research supplies and other services as part of our operations. These contracts generally provide for termination on notice, and therefore are cancelable contracts and are not contractual obligations. Our material contractual obligations, if any, are described elsewhere in this Annual Report, including Notes 5 and 10 of the attached Consolidated Financial Statements.

Based on our current operating plan, research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash, cash equivalents and marketable securities as of December 31, 2022, will be sufficient to fund our planned operating expenses and capital expenditure requirements into the second half of 2025. We have based this estimate on assumptions that may prove to be wrong, particularly as the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain. Our cash and cash equivalents are maintained at financial institutions in amounts that exceed federally insured limits. In the event of failure of any of the financial institutions where we maintain our cash and cash equivalents, there can be no assurance that we will be able to access uninsured funds in a timely manner or at all. As a result, we could use our capital resources sooner than we expect.

### ***Cash Flows***

The following is a summary of cash flows for the years ended December 31, 2022 and 2021:

	<b>Year Ended</b>		<b>Change</b>	<b>%</b>
	<b>December 31,</b>			
	<b>2022</b>	<b>2021</b>		
	<b>(In euros thousands)</b>			
Net cash used in operating activities	(145,100)	(49,777)	(95,323)	192%
Net cash provided by (used in) investing activities	4,885	(122,895)	127,780	-104%
Net cash provided by financing activities	53,030	235,777	(182,747)	-78%

### *Operating Activities*

Net cash used in operating activities for the year ended December 31, 2022 increased €95.3 million as compared to the year ended December 31, 2021, primarily as a result of a decrease in operating cash receipts related to collaboration arrangements (upfront payments, milestones, and research and development reimbursements) of €29.3 million, an increase in operating cash out flows related to operating expenses and taxes of €72.5 million partially offset by cash inflows related to other income increasing by €6.5 million.

### *Investing Activities*

Net cash provided by investing activities for the year ended December 31, 2022 increased €127.8 million as compared to the year ended December 31, 2021, primarily as a result of increases in cash provided by proceeds from maturities of investments of €163.6 million and interest received of €1.3 million partially offset by increases in cash used in purchases of investments of €30.6 million and purchases of property and equipment of €6.5 million.

### *Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2022 decreased €182.7 million as compared to the year ended December 31, 2021, primarily as a result of the decrease in receipt of proceeds from our equity issuances of €167.9 million and decreases in proceeds received from option exercises of €13.5 million.

## **5.3 Off-Balance Sheet Arrangements**

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

## **5.4 Market Risk**

We refer to Note 19 to the consolidated financial statements for further information on our exposure to market risks, our policy and objectives in hedging market risks, if any, and the use of financial instruments.

## **5.5 Transactions with Major Shareholders**

We refer to Note 12 to the consolidated financial statements for further information on our transactions with major shareholders. A major shareholder is an entity holding more than 10% of our common shares.

# **6 CONTROLS AND PROCEDURES**

## **6.1 Risk Management and Control Systems**

### **Limitations on Effectiveness of Controls and Procedures**

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

### **Management's Report on Controls and Procedures**

On the basis of reports and information provided to our board of directors, our board of directors is of the opinion that:

- a. this report provides sufficient insight into any failings in the effectiveness of the Company's risk management and control systems;
- b. the Company's risk management and control systems provide reasonable assurance that the Company's financial reporting does not contain material inaccuracies, except as described above;
- c. based on the Company's state of affairs as at the date of this report, it is justified that the Company's financial reporting is prepared on a going concern basis; and
- d. this report states those material risks and uncertainties that are relevant to the expectation of the Company's continuity for a period of twelve months after the date of this report.

Any material failings in, material changes to, and/or material improvements of the Company's risk management and control systems which have been observed, made and/or planned, respectively, during the fiscal year to which this report relates, have been discussed with our audit committee and with our non-executive directors.

## **7 DIRECTORS AND EMPLOYEES**

### **7.1 Directors**

Our executive director is charged primarily with the Company's day-to-day business and operations and the implementation of the Company's strategy. Our non-executive directors are charged primarily with the supervision of the performance of the duties of our board of directors. Each director is charged with all tasks and duties of our board of directors that are not delegated to one or more other specific directors by virtue of Dutch law, the Company's articles of association or any arrangement catered for therein (e.g., the internal rules of our board of directors). In performing their duties, our directors shall be guided by the interests of the Company and of the business connected with it.

Our executive director has developed a view on sustainable long-term value creation by the Company and has formulated a strategy consistent with that view, see "Our Strategy" in section 2.2 of this report. The non-

executive directors have been actively engaged at an early stage in formulating the Company's strategy and supervise the manner in which the strategy is implemented.

As at December 31, 2022, our board of directors was composed as follows:

Name and age	Gender	Nationality	Date of initial appointment	Expiration of current term of office	Attendance rate at meetings of the board
Sven (Bill) Ante Lundberg, M.D. (59)*	M	U.S. and Swedish	December 31, 2019**	2023 AGM	100%
Mark Iwicki (56)***	M	U.S.	June 4, 2015	2024 AGM	100%
Len Kanavy (61)***	M	U.S.	July 20, 2018	2026 AGM	100%
Anand Mehra, M.D. (47)***	M	U.S.	August 21, 2015	2023 AGM	100%
Gregory Perry (62)***	M	U.S.	May 19, 2016	2024 AGM	100%
Victor Sandor, M.D.C.M. (56)***	M	U.S. and Canadian	June 12, 2019	2023 AGM	100%
Paolo Pucci (61)***	M	U.S.	June 30, 2020	2024 AGM	100%
Maxine Gowen, Ph.D. (65)***	F	U.S.	May 28, 2021	2025 AGM	100%

\*Executive director

\*\*Before December 31, 2019, Bill Lundberg served as non-executive director as from June 12, 2019.

\*\*\*Non-executive director

On March 29, 2023, our board of directors nominated Bill Lundberg, M.D., for re-appointment at the AGM in 2023 as executive director for a term ending immediately after the AGM to be held in 2027, our board of directors nominated Victor Sandor, M.D.C.M., for re-appointment at the AGM in 2023 as non-executive director for a term ending immediately after the AGM to be held in 2027, and our board of directors nominated Anand Mehra, M.D., for re-appointment at the AGM in 2023 as executive director for a term ending immediately after the AGM to be held in 2025.

**Bill Lundberg, M.D.** has served as a non-executive of our board of directors from June 2019 to December 2019, and as an executive director since December 2019. Since December 2019, Dr. Lundberg has served as our President, Chief Executive Officer and Principal Financial Officer. From January 2015 to February 2018, Dr. Lundberg was Chief Scientific Officer of CRISPR Therapeutics AG (CRISPR), a biotechnology company, where he was responsible for establishing and growing research and development in the United States and oversaw CRISPR's first CRISPR-based product from inception to regulatory filing for clinical trials. From February 2011 to January 2015, Dr. Lundberg was Vice President and Head of Translational Medicine at Alexion Pharmaceuticals, Inc. (Alexion), where he oversaw research and development from discovery through early-stage development, and prior to that, he was Director and Chief Medical Officer of Taligen Therapeutics, Inc. (Taligen), a biotechnology company, which was acquired by Alexion in 2011. Prior to Taligen, he held roles of increasing responsibility in clinical drug development and medical affairs

at Xanthus/Antisoma, Wyeth (now Pfizer), and Genzyme. Dr. Lundberg currently serves on the board of directors of the publicly traded life science company Vor Biopharma. Dr. Lundberg received an M.D. from Stanford University and M.B.A. from the University of Massachusetts. He completed post-doctoral training at the Whitehead Institute/M.I.T., and clinical training in Medicine and Medical Oncology from Harvard and the Dana-Farber Cancer Institute.

**Mark Iwicki** has served as a non-executive director of our board of directors since June 2015. From June 2015 until July 2018, Mr. Iwicki served as the Chairperson of our board of directors. Mr. Iwicki currently serves as the Chairperson and Chief Executive Officer of Kala Pharmaceuticals, Inc., a pharmaceutical company, where he has been employed since April 2015. From February 2014 to November 2014 Mr. Iwicki served as President and Chief Executive Officer of Civitas Therapeutics. From December 2012 to January 2014, Mr. Iwicki served as President and Chief Executive Officer and director at Blend Therapeutics, Inc. From 2007 to June 2012, Mr. Iwicki served in several roles, including Chief Commercial Officer, President and Chief Operating Officer and Director and Chief Executive Officer at Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Iwicki held executive positions, including Vice President and Business Unit Head, at Novartis Pharmaceuticals Corporation, a pharmaceutical company. Mr. Iwicki currently serves on the boards of directors of publicly held life science companies Akero Therapeutics, Inc. and Kala Pharmaceuticals, Inc. Within the past five years, he also served on the board of directors of the publicly held life science company Aimmune Therapeutics Inc. and Pulmatrix, Inc. Mr. Iwicki received a B.A. in business administration from Ball State University and an M.B.A. from Loyola University.

**Len Kanavy** has served as a non-executive director of our board of directors since July 2018. Mr. Kanavy most recently served as Senior Vice President, Commercial Business Operations at Genentech, a biotechnology company, from September 2006 to September 2016, where he was responsible for strategic decisions for the U.S. commercial business, including product launches, valuation of business development opportunities, clinical development plan options and pricing. From 2014 to 2016, he was a board member of the Genentech Access to Care Foundation. Prior to joining Genentech, Mr. Kanavy was Vice President, Commercial Operations at Novartis Pharmaceuticals, where he led teams in business analytics, strategy, and product launches. Mr. Kanavy holds a B.S. in Business Administration and an M.B.A. with a specialization in Finance from the University of Scranton.

**Anand Mehra, M.D.** has served as a non-executive director since August 2015 and as Chairperson of our board of directors effective since June 2020. Dr. Mehra held various positions at Sofinnova Investments (f.k.a. Sofinnova Ventures) from 2007 to January 2020, most recently holding the position of a managing general partner, where he focused on working with entrepreneurs to build drug development companies. He led the firm's investments in Vicept Therapeutics (acquired by Allergan), Aerie Pharmaceuticals, Inc., Aclaris Therapeutics, Inc. (Aclaris), and Spark Therapeutics. Prior to joining Sofinnova, Dr. Mehra worked in J.P. Morgan's private equity and venture capital group and as a consultant at McKinsey & Company. He currently serves as a member of the board of directors of the publicly held life science company Aclaris. Within the past five years, he also served on the boards of directors of the publicly held life science companies Marinus Pharmaceuticals, Inc., Spark Therapeutics, Inc. and Aerie Pharmaceuticals. Dr. Mehra received a B.A. degree in political philosophy from the University of Virginia and an M.D. degree from Columbia University's College of Physicians and Surgeons.



**Gregory D. Perry** has served as a non-executive director of our board of directors since May 2016 and Vice Chairperson of our board of directors since August 2018. Mr. Perry served as the Chief Financial Officer at Finch Therapeutics Group, a microbiome therapeutics company from May 2018 until his retirement in April 2022. Mr. Perry served as the Chief Financial and Administrative Officer of Novelion Therapeutics Inc., a biopharmaceutical company (Novelion), from November 2016 to December 2017. Prior to Novelion, Mr. Perry was Chief Financial Officer of Aegerion Pharmaceuticals Inc., a biopharmaceutical company from July 2015 until its merger with Novelion in November 2016. Prior to that, he served as Chief Financial and Business Officer of Eleven Biotherapeutics, Inc., now Sensen Bio, a fusion-protein therapeutics company, from January 2014 to June 2015. Prior to that, Mr. Perry served as the Interim Chief Financial Officer of InVivo Therapeutics Holdings Corp., a biomaterials and biotechnology company, from September 2013 to December 2013, and prior to that he served as Senior Vice President and Chief Financial Officer of ImmunoGen, Inc., a biotechnology company, from 2009 until he was promoted in 2011 to Executive Vice President and Chief Financial Officer, a role he held until 2013. Before that, he was the Chief Financial Officer of Elixir Pharmaceuticals and, prior to that Senior Vice President and Chief Financial Officer of Transkaryotic Therapies. He has also held various financial leadership roles within PerkinElmer Inc., Domantis Ltd., Honeywell and General Electric. Since February 2018, Mr. Perry has served on the board of directors of the publicly held life science company Kala Pharmaceuticals, including as chairperson of its audit committee. From December 2011 to February 2016, Mr. Perry served on the board of directors of Ocata Therapeutics, including as chairperson of its audit committee and a member of its compensation committee, until it was acquired by Astellas Pharma Inc. Mr. Perry received a B.A. in Economics and Political Science from Amherst College.

**Victor Sandor, M.D.C.M.** has served as a non-executive director of our board of directors since June 2019. From September 2014 to December 2019, Dr. Sandor was the Chief Medical Officer at Array BioPharma (Array), a pharmaceutical company, where he oversaw clinical development through regulatory approval of Braftovi® and Mektovi® for the treatment of BRAFV600E/K mutant melanoma and Braftovi for the treatment of BRAFV600E mutant colorectal cancer. Prior to joining Array, from February 2010 to September 2014, he was Senior Vice President for Global Clinical Development at Incyte Corporation (Incyte), a pharmaceutical company, where he oversaw clinical development through regulatory approval of Jakafi® for the treatment of myelofibrosis and polycythemia vera. Prior to joining Incyte, Dr. Sandor was Vice President and Chief Medical Officer for oncology at Biogen Idec and, prior to that held positions of increasing responsibility in oncology product development at AstraZeneca, where he played a lead role in the registration of Arimidex® (anastrozole) for adjuvant use and the development of early stage programs through proof-of-concept. Dr. Sandor received his M.D.C.M. from McGill University in Montreal, Canada, and completed his Fellowship in Medical Oncology at the National Institutes of Health in Bethesda, Maryland. He currently serves on the boards of directors of publicly held life sciences companies ADC Therapeutics, Prelude Therapeutics and Kymera Therapeutics.

**Paolo Pucci**, has served as a non-executive director of our board of directors since June 2020. Mr. Pucci served as the Chief Executive Officer of ArQule, Inc. (ArQule), a biopharmaceutical oncology company engaged in the research and development of targeted therapeutics, from June 2008 until its acquisition by Merck Inc. in January 2020. Prior to joining ArQule, Mr. Pucci worked at Bayer AG from 2001 to 2008, where he served in a number of leadership capacities including President of the Oncology & Global Specialty Medicines Business Units and was a member of the Bayer Pharmaceuticals Global Management

Committee. Before Bayer, Mr. Pucci held positions of increasing responsibility with Eli Lilly and Company from July 1991 to April 2001, culminating with his appointment as Managing Director, Eli Lilly Sweden AB. Mr. Pucci earned an M.S. in economics and accounting from Università degli Studi di Napoli Federico II and an M.B.A. in marketing and finance from the University of Chicago. Within the past five years, Mr. Pucci previously served on the boards of directors of Algeta ASA, until its acquisition by Bayer AG, and Dyax Inc., until its acquisition by Shire Plc (which was subsequently acquired by Takeda Pharmaceutical Company Ltd.), New Link Genetics Inc, ArQule Inc., until its acquisition by Merck Inc., and Trillium Therapeutics Inc., until its acquisition by Pfizer Inc. He currently serves on the boards of directors of publicly held life sciences companies West Pharmaceuticals Services, Inc., and Replimmune Group Inc.

**Maxine Gowen, Ph.D.**, has served as a non-executive director of our board of directors since May 2021. Dr. Gowen was the founding President and Chief Executive Officer of Trevena, Inc. (Trevena), from 2007 to October 2018. Prior to this position, Dr. Gowen held a variety of leadership roles at GlaxoSmithKline (GSK) over a period of 15 years. As Senior Vice President for the company's Center of Excellence for Drug Discovery, she developed an innovative new approach to externalizing drug discovery. Dr. Gowen was previously President and Managing Partner at SR One, the venture capital subsidiary of GSK, where she led its investments in and served on the boards of directors of numerous companies. Dr. Gowen also previously served as Vice President, Drug Discovery, Musculoskeletal Diseases at GSK, where she was responsible for drug discovery and early development for osteoporosis, arthritis and metastatic bone disease. Dr. Gowen currently serves on the boards of directors of publicly held life science companies Aclaris, Aceragen, Inc., and Passage Bio, and served on the boards of directors of publicly held life science companies Akebia Therapeutics (Akebia) and Trevena until May 2021. Dr. Gowen holds a B.Sc. in biochemistry from the University of Bristol, U.K., received a Ph.D. in cell biology from the University of Sheffield, U.K., and received an M.B.A. from the Wharton School of the University of Pennsylvania.

Currently, all of our non-executive directors are independent within the meaning of the DCGC.

## **7.2 Compensation**

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

See Notes 14 and 18 to our consolidated financial statements (included in section 10.1 of this report) for further information concerning the implementation of our remuneration policy in the fiscal year to which this report relates. In determining the level and structure of the compensation of the directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered.

### **Short-Term Incentive Plan**

We maintain a short-term incentive plan pursuant to which we may grant our employees, including our senior management, incentive cash bonuses based upon corporate and/or individual performance. We generally pay annual cash bonuses based upon the achievement of set financial targets, non-financial and personal goals and company milestones for the period. Achievement of the targets is measured following year-end and the actual bonus amounts paid to our senior management, including our executive officers, are determined by our board of directors.

The corporate objectives set for 2022 pursuant to our short-term incentive plan accounted for 90% of the President, Chief Executive Officer and Financial Officer's bonus opportunity, and 70% of the other senior management's bonus opportunity and were generally related to clinical developments, intellectual property, business developments and preclinical pipeline development. Individual objectives are established annually for each member of the senior management and, in 2022, accounted for 10% of the President, Chief Executive Officer and Financial Officer's bonus opportunity, and 30% of the other senior management's bonus opportunity. The board of directors determined that the Company achieved the corporate objectives at the 100% level. The actual bonus amounts paid to our senior management for 2022 are set forth in the table above entitled "Senior Management Remuneration".

See Notes 14 and 18 to our consolidated financial statements (included in section 10.1 of this report) for further information concerning the implementation of our remuneration policy in the fiscal year to which this report relates. In determining the level and structure of the compensation of executive directors in the fiscal year to which this report relates relevant scenario analyses carried out in advance have been considered.

### **7.3 Pay Ratio**

The DCGC recommends that the Company provide a ratio comparing the compensation of our executive directors and that of a "representative reference group" determined by the Company. We have chosen to compare the cash compensation of our President, Chief Executive Officer and Principal Financial Officer to that of an average full-time permanent employee. Our methodology for producing this ratio excludes employees employed on a non-permanent or part-time basis. We have used the aggregate cash compensation over the fiscal year concerned as a reference amount (i.e., excluding the value of equity incentive awards and other non-cash compensation components). To calculate the ratio, we have annualized the salaries of employees who had worked with us for less than a year as of December 31, 2022. Based on this methodology, the ratio between the cash compensation of our President, Chief Executive Officer and Principal Financial Officer and an average full-time permanent employee for the fiscal year to which this report relates is 6 to 1 (rounded to the nearest integer).

## 7.4 Board Practices

On May 29, 2017, upon approval by our shareholders, our corporate governance structure changed from a two-tier model with a management board under the supervision of a supervisory board to a one-tier model with a unitary board of directors. As of December 31, 2022, our board of directors was comprised of eight members. Each member of our board of directors, except for Dr. Mehra, Mr. Iwicki, Mr. Perry and Mr. Kanavy is appointed for an initial term of up to four years. Dr. Mehra has been re-appointed as non-executive director at the 2019 AGM, but only for one subsequent four-year term after serving one four-year term. Mr. Iwicki and Mr. Perry have been re-appointed as non-executive director at the 2020 AGM, but only for one subsequent four-year term after serving one four-year term. Mr. Kanavy has been re-appointed as non-executive director at the 2022 AGM, but only for one subsequent four-year term after serving one four-year term. A non-executive director may be re-appointed for up to one subsequent term of up to four years followed by up to two subsequent terms of up to two years. An executive director may serve for an unlimited number of consecutive four-year terms of up to four years.

The expiration of the current terms of the members of our board of directors and the period each member has served in that term are as follows:

Name	Year Current Term Began	Year Current Term Expires
Sven (Bill) Ante Lundberg, M.D..	2019	2023
Mark Iwicki .....	2020	2024
Len Kanavy .....	2022	2026
Anand Mehra, M.D.....	2019	2023
Gregory Perry .....	2020	2024
Victor Sandor, M.D. ....	2019	2023
Paolo Pucci .....	2020	2024
Maxine Gowen, Ph.D. ....	2021	2025

Our articles of association provide that the number of executive and non-executive directors may only be determined by our board of directors. Our directors are appointed on the basis of a binding nomination prepared by our board of directors. Our general meeting of shareholders may overrule the binding nomination by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital, in which case our board of directors shall be allowed to make a new binding nomination. Our directors may be dismissed only by a resolution at a general meeting of shareholders. Dismissal of a director by our general meeting of shareholders requires a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital, unless the dismissal is proposed by the board of directors, in which latter case a simple majority of votes cast will suffice to pass the resolution.

There are no family relationships among any of our executive officers or directors.

### Committees of the Board of Directors

Our board of directors has established an Audit Committee, Compensation Committee, Nomination and Corporate Governance Committee and a Research and Development Committee, which operate pursuant to written charters adopted by our board of directors.

Due to the sometimes ad-hoc nature of committee meetings and the developing phase the Company is in, an exact attendance rate for the committee meetings is difficult to determine. Generally, committee meetings in the year under review were well attended.

### *Audit Committee*

The audit committee, which consists of Gregory Perry, Maxine Gowen and Paolo Pucci, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Mr. Perry serves as Chairman of the audit committee.

The audit committee's responsibilities include:

- overseeing the responsibilities of the board of directors with respect to: our relationship with, and compliance with recommendations and follow-up of comments made by, our independent auditor, our funding, the application of information and communication technology by us, including risks relating to cybersecurity, operation of our Code of Business Conduct and Ethics and other internal policies, and our tax policy;
- preparing our internal audit plan for approval by the board of directors;
- reviewing and discussing our independent auditor's audit plan with our independent auditor;
- reviewing and discussing our internal audit results, including (i) any material weaknesses, significant deficiencies or other deficiencies in our internal controls, (ii) any findings and observations with a material impact on our risk profile; and (iii) any failings in the follow-up of recommendations made previously;
- at least annually, reviewing and discussing with our independent auditor the scope of the independent auditor's audit plan and the principal risks of our financial reporting identified in the audit plan and the findings and outcome of our independent auditor's audit of our financial statements and our management letter;
- determining whether and, if so, how our independent auditor should be involved in the content and publication of financial reports other than our financial statements;
- reviewing and discussing the effectiveness of the design and operation of our internal controls over financial reporting with the board of directors, including (i) any identified material failings in the internal controls; and (ii) any material changes made to, and any material improvements planned for, the internal controls;
- taking, or recommending that the board of directors take, appropriate action to oversee the independence of our independent auditor, including obtaining and reviewing a formal statement from the independent auditor delineating all relationships between the auditor and us, including written disclosures and the letter from the independent auditor required by the Public Company Accounting Oversight Board (PCAOB) regarding the independent auditor's communications with the audit committee concerning independence, and actively engaging in

dialogue with the independent auditor concerning any disclosed relationships or services that might impact the objectivity and independence of the independent auditor;

- advising the board of directors regarding nominating for appointment or reappointment the independent auditor and preparing the selection of the independent auditor for such purpose;
- setting the compensation of our independent auditor subject to further approval by the board of directors, retaining our independent auditor subject to further approval by the board and overseeing the independent auditor, and, when necessary, recommending the termination of the engagement of the independent auditor to the board of directors;
- reviewing and discussing with our management and the independent auditor our audited financial statements and receiving and considering the reports and other communications required to be made by the independent auditor;
- requesting the independent auditor to provide relevant information about any inspections of the firm by the PCAOB;
- considering whether to recommend to the board of directors that our audited financial statements be included in our annual report on Form 10-K;
- preparing an annual committee report for inclusion where necessary in our proxy statement relating to our annual general meeting of shareholders;
- directing the independent auditor to use its best efforts to perform all reviews of interim financial information prior to disclosure by us of such information and to discuss promptly with the audit committee and our principal financial officer any matters identified in connection with the independent auditor's review of interim financial information, and directing management to advise the audit committee in the event that we propose to disclose interim financial information prior to completion of the independent auditor's review of interim financial information;
- establishing procedures for (i) the receipt, retention and treatment of complaints regarding accounting, internal accounting controls or auditing matters; and (ii) the confidential, anonymous submission by our employees concerns regarding questionable accounting or auditing matters;
- periodically reviewing our policies and procedures for reviewing and approving or ratifying related person transactions, including our Related Person Transaction Policy, and recommending any changes to the board of directors, and conducting appropriate review and oversight of all related person transactions for potential conflict of interest situations on an ongoing basis;
- engagement of such independent legal, accounting and other advisors as the audit committee deems necessary or appropriate to carry out its responsibilities, including causing us, without further action by the board of directors, to pay the compensation of such advisors as approved

by the audit committee; and causing us to pay, without further action by the board of directors, the ordinary administrative expenses of the audit committee that are necessary or appropriate in carrying out its duties; and

- conducting or authorizing investigations into any matters within the scope of the audit committee's responsibilities as it shall deem appropriate, including the authority to request any of our officers, employees or advisors to meet with the audit committee or any advisors engaged by the audit committee.

The audit committee meets as often as one or more members of the audit committee deem necessary, but in any event, meets at least four times per year. The audit committee meets at least once per year with our independent accountant, without our executive director being present.

During the fiscal year to which this report relates, our audit committee met several times in order to carry out its responsibilities. The main items discussed at those meetings included the engagement (appointment, compensation, retention, oversight and plan) of the Company's independent auditor and auditor of the statutory consolidated and Company financial statements; Merus' quarterly financial reports; Merus' annual report on Form 10-K; this report; Merus' accounting, legal, and tax matters; certain accounting highlights; risks associated with its business, including IT and cybersecurity risks, and our internal risk management and control systems.

#### ***Compensation Committee***

The compensation committee, which consists of Mark Iwicki, Len Kanavy, Gregory Perry and Paolo Pucci, assists our board of directors in determining management compensation. Mr. Iwicki serves as Chairman of the committee.

The compensation committee's responsibilities include:

- submitting clear and understandable proposals to the board of directors concerning changes to our compensation policy;
- submitting proposals to the board concerning the compensation of individual directors and our Chief Executive Officer and other executive officers at least covering: the compensation structure; the amount of the fixed and variable compensation components; the applicable performance criteria, if any; the scenario analyses that have been carried out; the pay ratios within our group; and with respect to a director, the relevant director's views with regard to the amount and structure of his or her own compensation;
- preparing of our compensation report for the board of directors;
- reviewing and discussing with management the Compensation Discussion and Analysis ("CD&A") included in our proxy statement and considering whether it will recommend to the board of directors that the CD&A be included in the proxy statement; and
- preparing the annual compensation committee report pursuant to the rules of the US Exchange Act.

During the fiscal year to which this report relates, our compensation committee met several times in order to carry out its responsibilities. The main items discussed at those meetings included the Company's compensation philosophy; the Company's short term incentive policy, the Company's hiring process policy, director and executive officer cash and equity compensation; non-executive equity compensation and compensation-related disclosure included in the Company's annual report on Form 10-K and in this report.

#### ***Nomination and Corporate Governance Committee***

The nomination and corporate governance committee, which consists of Anand Mehra, Len Kanavy and Mark Iwicki, assists our board of directors in identifying individuals qualified to become members of our board and part of our management consistent with criteria established by our board and in developing our corporate governance principles. Dr. Mehra serves as Chairman of the nomination and corporate governance committee.

The nomination and corporate governance committee's responsibilities include:

- drawing up selection criteria and appointment procedures for the directors;
- reviewing the size and composition of the board and submitting proposals for a composition profile of the board;
- reviewing the functioning of individual directors and reporting on such review to the board;
- overseeing the process on annual self-evaluation of the Board to determine whether it and its committees are functioning effectively;
- drawing up a plan for the succession of directors;
- targeting an annual review to work with our Chief Executive Officer to evaluate our succession plans for our Chief Executive Officer and other executive officers, including an emergency succession plan for our Chief Executive Officer;
- submitting proposals for the appointment or reappointment of directors;
- supervising the policy of the board of directors regarding the selection criteria and appointment procedures for our senior management;
- reviewing the Company's practices, goals and risk management regarding sustainability, climate-related, environmental, social and governance matters, and the Company's public reporting concerning such matters; and
- conducting or authorizing investigations into any matters within the scope of its the responsibilities as it shall deem appropriate, including the authority to request any of our officers, employees or advisors to meet with the nomination and corporate governance committee or any advisors engaged by the nomination and corporate governance committee.

During the fiscal year to which this report relates, our nomination and corporate governance committee met several times in order to carry out its responsibilities. The main items discussed at those meetings included potential new director candidates; succession planning; qualifications, diversity and independence of



directors and committee members; reviewing the Company's practices, goals and risk management regarding sustainability, climate-related, environmental, social and governance matters, and the Company's public reporting concerning such matters and the board of director and committee self-assessment process.

### ***Research and Development Committee***

The research and development committee, which consists of Anand Mehra, Maxine Gowen and Victor Sandor, assists our board of directors in setting the Company's strategy on technology, research and development. Dr. Sandor serves as Chairman of the research and development committee.

The research and development committee's responsibilities include oversight and evaluation of (i) the Company's technology, research and development strategy, (ii) the Company's pipeline, (iii) the Company's platform, and (iv) the operations and effectiveness of the research, development and clinical departments.

During the fiscal year to which this report relates, our research and development committee met several times in order to carry out its responsibilities. The main items discussed at those meetings included the Company's technology, research and development strategy and the Company's performance thereof.

## **7.5 Employees**

As of January 1, 2023, we had 164 full-time employees and 57 part-time employees, 90 of whom hold M.D. or Ph.D. degrees. 157 of our employees work in research and development and 64 work in management and administrative areas. All of our employees are located in the Netherlands, except 2 employees located in Spain, 2 employees located in Italy, 1 employee located in France and 1 employee located in Germany, and 45 employees of Merus US, Inc., located in the United States. None of our employees are subject to a collective bargaining agreement or represented by a trade or labor union. We have established a works council for our employees, effective as of January 1, 2019.

## **8 CORPORATE GOVERNANCE**

### **8.1 Dutch Corporate Governance Code**

For the fiscal year to which this report relates, the Dutch Corporate Governance Code 2016 (the **DCGC**) applied to the Company. The text of the DCGC can be accessed at <http://www.mccg.nl>. The DCGC has been updated in the course of 2022, with effect from January 1, 2023 and therefore the updated DCGC will only apply to us as from the fiscal year 2023.

Except as set out below, during the fiscal year to which this report relates, the Company complied with the principles and best practice provisions of the DCGC, to the extent that these are directed at our board of directors.

#### *Risk management and internal audit function (best practice provisions 1.3.1, 1.3.2, 1.3.3, 1.3.4 and 1.3.5)*

The Company has not established an internal audit department. Our board of directors has considered this in 2022 whether setting up an internal audit department would be advisable and is of the opinion that

adequate alternative measures have been taken in the form of the Company's risk management and control systems, as outlined elsewhere in this report, and that it is presently not necessary to establish an internal audit function.

*Remuneration (best practice provisions 3.1.2, 3.2.3, 3.3.2 and 3.3.3)*

The options granted under the 2010 Option Plan vest in instalments over a four-year period from the grant date. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly instalments 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. Options will lapse on the eighth anniversary of the date of grant. The options granted under the 2016 Plan will be subject to vesting in accordance with the applicable award agreement and will be exercisable upon vesting. The term of options granted under the 2016 Plan may not be longer than ten years. We do not intend to comply with all of the above requirements as we believe it is in the best interest of the company to attract and retain highly skilled management board members on conditions based on market practice, as we believe these are.

Consistent with market practice in the U.S., the primary trading jurisdiction of our common shares, and in order to further support our ability to attract and retain the right highly qualified candidates for a position on our board of directors, options awarded to our directors as part of their remuneration are subject to time-based vesting. The 2016 Plan under which shares may be granted (including to the executive directors) provides for the retention of shares for the time period specified in the applicable award agreement. We believe that shares held by the members of our board of directors should be retained for a certain period; however, such period may be shorter than five years.

Consistent with market practice in the U.S., our non-executive directors receive rights to acquire common shares in our capital as part of their remuneration and may also receive other equity-based remuneration. We believe that such remuneration structure is appropriate due to our listing on NASDAQ.

Under circumstances, the severance payment to which our President, Chief Executive Officer and Principal Financial Officer might become entitled could exceed the maximum recommended by the DCGC. This deviation from the DCGC is justified as it is consistent with market practice in the U.S.

*Majority requirements for dismissal and setting-aside binding nominations (best practice provision 4.3.3)*

Our directors are appointed by our general meeting of shareholders upon the binding nomination by our board of directors. Our general meeting of shareholders may only overrule the binding nomination by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. In addition, except if proposed by our board of directors, our directors may be suspended or dismissed by our general meeting of shareholders at any time by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. The possibility to convene a new general meeting of shareholders as referred to in

Section 2:120(3) DCC in respect of these matters has been excluded in our articles of association. We believe that these provisions support the continuity of the Company and its business and that those provisions, therefore, are in the best interests of our shareholders and our other stakeholders.

## **8.2 General Meeting of Shareholders**

### **8.2.1 Functioning of Our General Meeting of Shareholders**

Annually, at least one general meeting of the Company must be held. This annual general meeting of shareholders must be held within six months after the end of the Company's fiscal year. A general meeting of shareholders must also be held within three months after our board of directors has decided that it is likely that the Company's equity has decreased to or below 50% of its paid up and called up share capital. In addition, without prejudice to the relevant best practice provisions of the DCGC with respect to invoking a 'response period' or the provisions under Dutch law with respect to invoking a 'cooling-off period', a general meeting of shareholders must be held when requested by one or more shareholders and/or others with meeting rights under Dutch law collectively representing at least 10% of the Company's issued share capital, provided that certain criteria are met. Any additional general meeting of shareholders shall be convened whenever our board of directors would so decide. Each general meeting of Shareholders must be held in Utrecht, Amsterdam, Rotterdam, Haarlemmermeer (Schiphol) or The Hague, the Netherlands.

For purposes of determining who have voting rights and/or meeting rights under Dutch law at a general meeting of shareholders, our board of directors may set a record date. The record date, if set, shall be the 28th day prior to that of our general meeting of shareholders. Those who have voting rights and/or meeting rights under Dutch law on the record date and are recorded as such in one or more registers designated by our board of directors shall be considered to have those rights at our general meeting of shareholders, irrespective of any changes in the composition of the shareholder base between the record date and the date of our general meeting of shareholders. The Company's articles of association require shareholders and others with meeting rights under Dutch law to notify the Company of their identity and their intention to attend our general meeting of shareholders. This notice must be received by the Company ultimately on the seventh day prior to our general meeting of shareholders, unless indicated otherwise when such meeting is convened.

### **8.2.2 Powers of Our General Meeting of Shareholders**

All powers that do not vest in our board of directors pursuant to applicable law, the Company's articles of association or otherwise, vest in the Company's general meeting of shareholders. The main powers of our general meeting of shareholders include, subject in each case to the applicable provisions in the Company's articles of association:

- a. the appointment, suspension and dismissal of our directors;
- b. the approval of certain resolutions of our board of directors concerning a material change to the identity or the character of the Company or its business;

- c. the reduction of the Company's issued share capital through a decrease of the nominal value, or cancellation, of shares in its capital;
- d. the adoption of the Company's statutory annual accounts;
- e. the appointment of the Dutch independent auditor to examine the Company's statutory annual accounts;
- f. amendments to the Company's articles of association;
- g. approving a merger or demerger by the Company, without prejudice to the authority of our board of directors to resolve on certain types of mergers and demergers if certain requirements are met; and
- h. the dissolution of the Company.

In addition, our general meeting of shareholders has the right, and our board of directors must provide, any information reasonably requested by our general meeting of shareholders, unless this would be contrary to an overriding interest of the Company.

### **8.2.3 Shareholder Rights**

Each share in the Company's capital, irrespective of its class, carries one vote. Shareholders, irrespective of whether or not they have voting rights, have meeting rights under Dutch law (including the right to attend and address our general meeting of shareholders, subject to the concept of a record date as described in section 8.2.1). Furthermore, each share in the Company's capital carries an entitlement to dividends and other distributions as set forth in the Company's articles of association. Pursuant to the Company's articles of association, any such dividend or other distribution shall be payable on such date as determined by our board of directors and our board of directors may also set a record date for determining who are entitled to receive any such dividend or other distribution (irrespective of subsequent changes in the shareholder base). The record date for dividends and other distributions shall not be earlier than the date on which the dividend or other distribution is announced. In addition, shareholders have those rights awarded to them by applicable law.

Subject to any provision of mandatory Dutch law and any higher quorum requirement stipulated by our articles of association, if and for as long as we are subject to the rules and requirements of a securities exchange and such securities exchange requires us to have a quorum for the general meeting of shareholders (which is presently the case), then the general meeting of shareholders can only pass resolutions if at least one third of the issued and outstanding shares in the Company's capital are present or represented at such general meeting of shareholders. A second meeting as referred to in Section 2:120(3) DCC cannot be convened.

### **8.3 Evaluation**

Our board of directors regularly evaluates its own functioning, the functioning of the committees of our board of directors and that of the individual directors, including on the basis of self-evaluation form distributed to the directors. As part of these evaluations, our board of directors considers (i) substantive aspects, mutual interaction, (ii) events that occurred in practice from which lessons may be learned and (iii) the desired profile, composition, competencies and expertise of our board of directors. These evaluations are intended to facilitate an examination and discussion by our board of directors of its effectiveness and areas for improvement. Our board of directors performed such evaluation in relation to the fiscal year to which this report relates in the fourth quarter of 2022.

### **8.4 Diversity**

The Company has a diversity policy with respect to the composition of our board of directors. The Company is committed to supporting, valuing and leveraging the value of diversity. However, the importance of diversity, in and of itself, should not set aside the overriding principle that someone should be recommended, nominated and appointed for being "the right person for the job". The Company believes that it is important for our board of directors to represent a diverse composite mix of personal backgrounds, experiences, qualifications, knowledge, abilities and viewpoints. The Company seeks to combine the skills and experience of long-standing members of our board of directors with the fresh perspectives, insights, skills and experiences of new members. To further increase the range of viewpoints, perspectives, talents and experience within our board of directors, the Company strives for a mix of ages in the composition of those bodies. Under the Company's diversity policy, to the extent possible and practicable, the Company intends for the composition of our board of directors to be consistent with applicable Nasdaq Rule 5605(f), at least two members of our board of directors are Diverse within the meaning of Nasdaq Rule 5605(f). Other than the aforementioned intention of the Company that at least two members of our board of directors are Diverse within the meaning of Nasdaq Rule 5605(f), the Company has not set specific targets with respect to particular elements of diversity and inclusion. In addition to age and gender, the Company recognizes and welcomes the value of diversity with respect to race, ethnicity, nationality, sexual orientation and other important cultural differences. The Company is committed to seeking broad diversity in the composition of our board of directors and will consider these attributes when evaluating new candidates in the best interests of the Company and its stakeholders. In terms of experience and expertise, the Company intends for our board of directors to be composed of individuals who are knowledgeable in one or more specific areas detailed in the Company's diversity policy.

The Company believes that the composition of our board of directors is such, that the Company's diversity objectives, as outlined above, have been achieved, except for the Company's diversity targets in term of gender. This is primarily due to the selection of the current members of our board of directors based on the required profile and their backgrounds, experiences, qualifications, knowledge, abilities and viewpoints without positive or negative bias on gender. In the future, this will continue to be the Company's basis for selection of new members of our board of directors.

With respect to gender diversity, the Company set appropriate and ambitious targets with respect to the

board of directors and senior management as required by applicable law.

## **8.5 Corporate Values and Code of Business Conduct and Ethics**

We have adopted a written Code of Business Conduct and Ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions and others temporarily assigned to perform work or services for us. The Code of Business Conduct and Ethics is available on our website, [www.merus.nl](http://www.merus.nl). Our board of directors is responsible for administering the Code of Business Conduct and Ethics. The board of directors is allowed to amend, alter or terminate the Code of Business Conduct and Ethics. In addition, we intend to post on our website all disclosures that are required by law or the rules of Nasdaq, concerning any amendments to, or waivers from, any provision of the Code of Business Conduct and Ethics.

## **8.6 Large Company Regime**

On July 28, 2021, we filed a statement, as referred to in section 2:153 of the Dutch Civil Code, that we meet the legal requirements of the large company regime (structuurregime). If the legal criteria to qualify for the large company regime continue to be met by us for an uninterrupted term of three years from the date of such filing, the large company regime will become applicable to us by operation of law as of July 28, 2024 and we will propose to our general meeting an amendment to our articles of association to reflect the large company regime.

## **9 PROTECTIVE MEASURES**

Established Dutch law allows Dutch companies to have certain protective measures in place, in order to safeguard the interests of a company, its business and its stakeholders. We adopted an anti-takeover measure pursuant to which our board of directors may issue preferred shares without shareholder approval pursuant to a call option agreement with a special purpose foundation, or the protective foundation. We may issue an amount of preferred shares up to the lesser of (i) the total number of shares (of whichever class) comprised in the Company's issued share capital when the call option is exercised pursuant to the call option agreement on the relevant occasion, less the number of preferred shares already held by the protective foundation at that time (if any) and less one (1); or (ii) the maximum number of preferred shares that may be issued under the Company's authorized share capital as included in the Company's articles of association when the call option is exercised. The protective foundation has been structured to operate independently of us.

In addition, our articles of association contain certain provisions which might have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us. These provisions include:

- requirements that certain shareholder matters, including the amendment of our articles of association may only be voted on by the general meeting of shareholders at the proposal of our board of directors;

- a provision that our directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital if such removal is not proposed by our board of directors; and
- our directors being appointed on the basis of a binding nomination by our board of directors, which can only be overruled by the general meeting of shareholders 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 (in which case the board of directors shall make a new nomination).

Also, we have implemented staggered terms of our directors, as a result of which our directors are not all subject to election in any one year.

**10 FINANCIAL INFORMATION**

**10.1 Consolidated Financial Statements**

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**MERUS N.V.**  
**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
(All amounts in euro thousand)

	Note	As at December 31,	
		2022	2021
<b>Non-current assets</b>			
Property and equipment	3	11,459	3,133
Intangible assets	4	1,829	2,073
Right-of-use assets	5	12,539	3,894
Deferred tax assets	6	1,913	368
Investments	7	34,181	17,921
Other assets		4,511	1,835
		<u>66,432</u>	<u>29,224</u>
<b>Current assets</b>			
Trade receivables	12	3,798	5,570
Investments	7	133,583	149,205
Other assets	8	11,404	6,576
Cash and cash equivalents	16	138,523	213,169
		<u>287,308</u>	<u>374,520</u>
<b>Total assets</b>		<u><u>353,740</u></u>	<u><u>403,744</u></u>
<b>Shareholders' equity</b>			
	9		
Issued and paid-in capital		4,168	3,912
Share premium account		655,849	600,213
Accumulated loss		(428,197)	(325,308)
Translation reserve		288	163
Total shareholders' equity		<u>232,108</u>	<u>278,980</u>
<b>Non-current liabilities</b>			
Lease liabilities	5	11,218	2,315
Deferred revenue	12	36,353	58,490
		<u>47,571</u>	<u>60,805</u>
<b>Current liabilities</b>			
Trade payables		9,220	11,686
Accrued liabilities	11	33,368	19,871
Taxes payable		2,250	—
Lease liabilities	5	1,642	1,801
Deferred revenue	12	27,581	30,601
		<u>74,061</u>	<u>63,959</u>
<b>Total liabilities</b>		<u><u>121,632</u></u>	<u><u>124,764</u></u>
<b>Total shareholders' equity and liabilities</b>		<u><u>353,740</u></u>	<u><u>403,744</u></u>

*After appropriation of the result for the year*

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

**MERUS N.V.**  
**CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE  
LOSS**

(All amounts in euro thousands except per share data)

	Note	<b>Year ended December 31,</b>	
		<b>2022</b>	<b>2021</b>
Collaboration revenue	12	39,291	41,538
Research and development costs	13	(142,230)	(83,225)
General and administrative costs	13	(49,008)	(34,580)
<b>Total operating expenses</b>		<b>(191,238)</b>	<b>(117,805)</b>
<b>Operating result</b>		<b>(151,947)</b>	<b>(76,267)</b>
Finance income	15	27,982	21,111
Finance costs	15	(567)	(1,366)
<b>Net finance income (costs)</b>	15	<b>27,415</b>	<b>19,745</b>
<b>Result before taxation</b>		<b>(124,532)</b>	<b>(56,522)</b>
Tax (expense) benefit	6	(929)	(201)
<b>Result after taxation</b>		<b>(125,461)</b>	<b>(56,723)</b>
<b>Other comprehensive income</b>			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences - foreign operations		125	206
<b>Total comprehensive loss</b>		<b>(125,336)</b>	<b>(56,517)</b>
Basic and diluted loss per share	17	(2.79)	(1.47)

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

**MERUS N.V.**  
**CONSOLIDATED STATEMENT OF CHANGES IN EQUITY**  
(Amounts in euro thousands except share data)

	Note	Common shares	Common share capital	Common share premium	Accumulated loss	Translation reserve	Total equity
Balance at January 1, 2021		31,602,953	2,844	363,773	(283,271)	(43)	83,303
Transactions with owners of the Company:							
Issuance of shares, net	9	10,014,354	901	208,067	—	—	208,968
Issuance of shares, net - Lilly	12	706,834	64	13,594	—	—	13,658
Exercise of stock options and vesting of restricted stock units		1,142,911	103	14,541	—	—	14,644
Short-swing profit disgorgement		—	—	238	—	—	238
Equity settled share-based payments	14	—	—	—	14,686	—	14,686
Total contributions by and distributions to owners of the Company		11,864,099	1,068	236,440	14,686	—	252,194
Result after taxation		—	—	—	(56,723)	—	(56,723)
Other comprehensive income – foreign currency translation differences		—	—	—	—	206	206
Balance at December 31, 2021		43,467,052	3,912	600,213	(325,308)	163	278,980
Transactions with owners of the Company:							
Issuance of shares, net	9	2,720,846	245	54,510	-	-	54,755
Issuance of shares, net - Lilly	12	-	-	-	-	-	-
Exercise of stock options and vesting of restricted stock units		122,691	11	1,126	-	-	1,137
Short-swing profit disgorgement		—	—	—	-	-	-
Equity settled share-based payments	14	-	-	-	22,572	-	22,572
Total contributions by and distributions to owners of the Company		2,843,537	256	55,636	22,572	-	78,464
Result after taxation		-	-	-	(125,461)	-	(125,461)
Other comprehensive income – foreign currency translation differences		-	-	-	-	125	125
Balance at December 31, 2022		<b>46,310,589</b>	<b>4,168</b>	<b>655,849</b>	<b>(428,197)</b>	<b>288</b>	<b>232,108</b>

*After appropriation of the result for the year*

**MERUS N.V.**  
**CONSOLIDATED STATEMENT OF CASH FLOWS**  
(All amounts euros in thousands)

	Note	<b>Year Ended December 31,</b>	
		<b>2022</b>	<b>2021</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>			
Result after taxation		(125,461)	(56,723)
Adjustments for:			
Depreciation and amortization of property and equipment	3,5	3,546	2,710
Amortization of intangible assets	4	294	244
Foreign exchange loss (gain)		(22,771)	(23,365)
Stock-based compensation expense	14	22,572	14,686
Deferred tax benefit	6	(1,571)	(6)
Net finance income		(2,105)	(521)
Changes in working capital	16	(19,037)	14,065
		<u>(144,533)</u>	<u>(48,910)</u>
Interest paid	15	(567)	(343)
Taxes paid		—	(524)
<b>Net cash used in operating activities</b>		<u>(145,100)</u>	<u>(49,777)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>			
Purchases of investments		(212,648)	(182,041)
Proceeds from maturities of investments		222,753	59,112
Interest received		2,172	864
Purchases of property and equipment	3	(7,342)	(830)
Purchases of intangible assets	4	(50)	—
<b>Net cash provided by (used in) investing activities</b>		<u>4,885</u>	<u>(122,895)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>			
Proceeds from issuance of common stock, net of issuance costs	9	54,755	208,968
Proceeds from issuance of common stock - Lilly		—	13,658
Proceeds from stock options exercised		1,137	14,644
Payment of lease liabilities	5	(2,503)	(1,631)
Short-swing profit disgorgement		—	238
Changes in restricted cash		(359)	(100)
<b>Net cash provided by financing activities</b>		<u>53,030</u>	<u>235,777</u>
Foreign exchange impact on cash and cash equivalents		12,539	17,164
Net (decrease) increase in cash and cash equivalents		(74,646)	80,269
Cash and cash equivalents, beginning of period		<u>213,169</u>	<u>132,900</u>
Cash and cash equivalents, end of period	16	<u><u>138,523</u></u>	<u><u>213,169</u></u>
Supplemental disclosures	16		

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

## MERUS N.V.

### NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

#### 1. The Company

Merus N.V. is a clinical-stage oncology company developing innovative antibody therapeutics, headquartered in Utrecht, the Netherlands. Merus US, Inc. is a wholly-owned subsidiary of Merus N.V. located at 139 Main Street, Cambridge, Massachusetts, United States (Merus N.V. and Merus US, Inc. collectively, the “Company”). Merus N.V. is registered with the Trade Register of the Chamber of Commerce under file number 30189136.

Since inception, the Company has generated an accumulated loss of €428.2 million as of December 31, 2022. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its antibody candidates advance through discovery, pre-clinical development and clinical trials and as it seeks regulatory approval and pursues commercialization of any approved antibody candidate.

As a result, the Company may need additional financing to support its continuing operations. Until the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through public equity offerings, debt financings, or other sources, which may include collaborations, business development and licensing opportunities with third parties. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company’s inability to raise capital as and when needed would have a negative impact on its financial condition and ability to pursue its business strategy. The Company will need to generate significant revenues to achieve profitability and may never do so.

Based on the Company’s current operating plan, the Company expects that its existing cash, cash equivalents and marketable securities of €306.3 million as of December 31, 2022, will fund the Company’s operations into the second half of 2025.

#### 2. Summary of Significant Accounting Policies

##### *Basis of Preparation*

The consolidated financial statements of the Company are part of the statutory financial statements of the Company. These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRSs) and with Section 2:362(9) of the Dutch Civil Code. Except as otherwise noted, the Company has consistently applied the accounting policies to all periods presented in these consolidated financial statements.

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2022. None of these have a significant effect on the financial statements of the Company.

The financial statements of the Company have been prepared on a going concern basis and under the historical cost convention unless otherwise stated in the accounting policies below.

These consolidated financial statements have been authorized for issuance on May 8, 2023.

##### *Principles of Consolidation*

Subsidiaries are entities controlled by the Company, consisting of Merus N.V.’s wholly owned subsidiary Merus US, Inc. The Company controls an entity when it 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. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases. All significant intercompany balances and transactions have been eliminated in consolidation.

### ***Functional and Presentation Currency***

Items recorded in each of the Company's entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). Merus US, Inc.'s functional currency is the U.S. dollar. The functional and presentation currency of Merus N.V. is the euro. After measuring foreign currency denominated transactions into an entity's functional currency, to the extent that a subsidiary's functional currency differs from its parent, a subsidiary's financial position and results of operations are translated into its parent's functional currency.

### ***Use of Estimates***

The preparation of these consolidated financial statements in accordance with IFRS requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities, as of the date of the consolidated financial statements, and the reported amounts of revenue and expenses during the reporting period. Actual results and outcomes may differ materially from management's estimates, judgments and assumptions.

### ***Revenue Recognition***

Pursuant to the Company's research, collaboration and license agreements the Company has received or will receive upfront nonrefundable payments and milestones for certain rights granted under the respective agreements. The applicable period over which to recognize these upfront or milestone payments requires significant judgment, see Note 12.

### ***Equity Settled Share-Based Payments***

Share options granted to employees, consultants and directors 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 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 Company's share options. These assumptions and estimates are further discussed in Note 14 to the consolidated financial statements.

### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk include cash, cash equivalents, marketable securities and accounts receivable. The Company attempts to minimize the risks related to cash, cash equivalents and marketable securities by working with highly rated financial institutions that invest in a broad and diverse range of financial instruments as defined by the Company. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The Company maintains its funds in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and is designed to limit the Company's credit exposure to any single issuer.

Accounts receivable represent amounts due from collaboration partners. The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection.

### ***Cash and Cash Equivalents***

The Company considers all highly liquid debt securities with original final maturities of three months or less from the date of purchase to be cash equivalents. Instruments subject to restrictions are not included in cash and cash equivalents.

### ***Foreign Currency***

#### ***Foreign currency transactions***

Transactions in foreign currencies are translated to the functional currency of the Company at exchange rates at the dates of the transactions. Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Non-monetary assets and liabilities that are measured at fair value in a foreign currency are translated into the functional currency at the exchange rate when the fair value was determined. Non-monetary items that are measured based on historical cost in a foreign currency are translated at the exchange rate at the date of the transaction. Foreign currency differences are generally recognized in profit or loss and presented within finance costs.

#### ***Foreign operations***

The assets and liabilities of foreign operations are translated into euro at exchange rates at the reporting date. The income and expenses of foreign operations are translated into euros at the exchange rates at the dates of the transactions. Foreign currency differences are recognized in other comprehensive income and accumulated in the translation reserve.

### ***Property and Equipment***

The Company records property and equipment at cost. The Company calculates depreciation and amortization using the straight-line method over the following estimated useful lives:

<b><u>Asset Category</u></b>	<b><u>Useful Lives</u></b>
Laboratory equipment	5 years
Office furniture and equipment	5 years
Leasehold improvements	Shorter of useful life or term of lease

The Company capitalizes expenditures for new property and equipment and improvements to existing facilities and charges the cost of maintenance to expense. The Company eliminates the cost of property retired or otherwise disposed of, along with the corresponding accumulated depreciation or amortization, from the related accounts, and the resulting gain or loss is reflected in the results of operations.

### ***Intangible Assets***

Intangible assets are identifiable non-monetary assets without physical substance. An asset is a resource that is controlled by the enterprise as a result of past events (for example, purchase or self-creation) and from which future economic benefits (inflows of cash or other assets) are expected. The useful lives of intangible assets are assessed to be definite-lived and amortized over the useful economic life. The Company's intangible assets are comprised of purchased licenses to intellectual property and software licenses.

### ***Impairment***

#### ***Financial Assets Measured at Amortized Cost***

The Company evaluates its cash equivalents, trade receivables and held-to-maturity investment financial assets for expected credit losses. Expected credit losses represent the portion of the amortized cost basis of a financial asset that an entity does not expect to collect. An allowance for expected credit losses is meant to reflect a risk of loss even if remote, irrespective of the expectation of collection from a particular issuer or debt security. The Company has not historically experienced any credit losses on any of its financial assets.

With respect to cash equivalents and trade receivables, given consideration of their short maturity, historical losses and the current environment, the Company concluded there is generally no expected credit losses for these financial assets. With respect to held-to-maturity investments which are comprised of debt securities, the Company evaluates expected credit losses on a pooled basis based on issuer-type which have similar credit risk characteristics. The allowance for credit losses is immaterial for all periods presented.

#### *Non-Financial Assets*

At each reporting date, the Company reviews the carrying amounts of its non-financial assets to determine whether there is any indication of impairment. If any such indication exists, then the asset's recoverable amount is estimated. For impairment testing, assets are grouped together into the smallest group of assets that generates cash inflows from continuing use that are largely independent of the cash inflows of other assets or cash generating units ("CGU"). The recoverable amount of an asset or CGU is the greater of its value in use and its fair value less costs to sell. Value in use is based on the estimated future cash flows, discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset or CGU. An impairment loss is recognized if the carrying amount of an asset or CGU exceeds its recoverable amount. Impairment losses are recognized in profit or loss. They are allocated first to reduce the carrying amount of any goodwill allocated to the CGU, and then to reduce the carrying amounts of the other assets in the CGU on a pro rata basis.

An impairment loss is reversed only to the extent that the asset's carrying amount does not exceed the carrying amount that would have been determined, net of depreciation or amortization, if no impairment loss had been recognized.

#### *Financial Instruments*

The Company classifies non-derivative financial assets as either financial assets at fair value through profit or loss, financial assets at amortized cost or financial assets at fair value through other comprehensive income or loss. The Company classifies non-derivative financial liabilities into either financial liabilities at fair value through profit or loss or the other financial liabilities category.

#### *Non-Derivative Financial Assets and Financial Liabilities*

The Company initially recognizes receivables and investments at fair value on the date when they are originated. Subsequent to initial recognition, they are measured at amortized cost using the effective interest rate method. All other financial assets and financial liabilities are initially recognized on the trade date.

The Company derecognizes a financial asset when the contractual rights to the cash flows from the asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred, or it neither transfers nor retains substantially all of the risks and rewards of ownership and does not retain control over the transferred asset. Any interest in such derecognized financial assets that is created or retained by the Company is recognized as a separate asset or liability.

The Company initially recognizes non-derivate financial liabilities at fair value less any directly attributable transaction costs. Subsequent to initial recognition, these liabilities are measured at amortized cost using the effective interest method.

The Company derecognizes a financial liability when its contractual obligations are settled or cancelled, or expire.



Financial assets and financial liabilities are offset and the net amount presented in the statement of financial position when, and only when, the Company has a legal right to offset the amounts and intends either to settle them on a net basis or to realize the asset and settle the liability simultaneously.

### *Investments*

Investments are classified and accounted for at amortized cost and initially measured at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest rate method. Investments are classified as amortized cost as the Company has the positive intent and ability to hold them until maturity. Interest income from these securities is included in finance income. Current investments include investments with a maturity date of greater than three months at the date of settlement. Investments with a maturity of 12 months or more from the balance sheet date are classified as non-current. Cash and cash equivalents include investments with a three month or less maturity, callable on demand.

### *Receivables*

These assets are initially recognized at fair value plus any directly attributable transaction costs, if any.

### *Leases*

#### *Determining Whether an Arrangement Contains a Lease*

At inception of an arrangement, the Company determines whether the arrangement conveys the right to control the use of an identified asset for a period in exchange for consideration, in which case the arrangement is, or contains, a lease.

At inception or on reassessment of an arrangement that contains a lease, the Company allocates the consideration in the arrangement to each lease component on the basis of the relative stand-alone price of the lease component and the aggregate stand-alone price of the non-lease components. However, for non-real estate leases, the Company has elected not to separate non-lease components and accounts for the lease and non-lease components as a single lease component.

#### *Lease Assets and Lease Liabilities*

The Company recognizes a right-of-use asset ("lease asset") and a lease liability at the lease commencement date. The lease asset is initially measured at cost, which comprises the initial amount of the lease liability adjusted for any lease payments made at or before the commencement date, plus any initial direct costs incurred and an estimate of costs to restore the underlying asset, less any lease incentives received. Subsequent to initial recognition, the lease asset is depreciated from the commencement date to the earlier of the end of the useful life of the lease asset or the end of the lease term. Lease asset depreciation expense is recognized as an operating expense in the consolidated statement of profit or loss and comprehensive loss.

The lease liability is initially measured at the present value of outstanding lease payments, discounted using the interest rate implicit in the lease or, if that rate cannot be readily determined, the Company's incremental borrowing rate. The lease liability is measured at amortized cost using the effective interest method and is remeasured when there is a change in future lease payments arising from a change in an index or rate. A corresponding adjustment is made to the carrying amount of the lease asset. Interest expense related to the Company's lease liabilities is recognized as a finance expense in the consolidated statement of profit or loss and comprehensive loss.

#### *Short-Term Leases and Low Value-Leases*

The Company has elected not to recognize lease assets and lease liabilities for short-term leases (leases with a term of 12 months or less) and leases of low-value assets. The Company recognizes the lease payments associated with these leases as an operating expense in its consolidated statement of profit or loss and comprehensive loss over the lease term.

## ***Taxes***

Tax expense comprises current and deferred tax. It is recognized in the consolidated statement of profit or loss and comprehensive loss except to the extent that it relates to a business combination, or items recognized directly in equity or in other comprehensive income or loss. 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 Company expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities. Deferred tax assets and liabilities are offset only if certain criteria are met.

## ***Revenue Recognition***

The terms of the contracts within the scope of IFRS 15, *Revenue from Contracts with Customers* (“IFRS 15”), may contain multiple promised goods and services, which often include license rights to certain of the Company’s product candidates and R&D activities. Payments under such agreements include: (i) upfront nonrefundable license fees; (ii) payments for R&D services performed by the Company, including reimbursement for certain external costs; (iii) payments based upon the achievement of certain development, regulatory and commercial milestones; and (iv) royalties on net product sales, if any.

Under IFRS 15, the Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services. The Company recognizes revenue following the five-step model prescribed under IFRS 15: (i) identification of the contract(s) with the customer; (ii) identification of the performance obligations; (iii) determination of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations in the contract; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

In order to account for contracts with customers, the Company identifies the promised goods or services in the contract and evaluates whether such promised goods or services represent performance obligations. The Company accounts for those components as separate performance obligations when the following criteria are met: (i) the customer can benefit from the good or service either on its own or

together with other resources that are readily available to the customer, and (ii) the Company's promise to transfer the good or service to the customer is separately identifiable from other promises in the contract. This evaluation requires subjective determinations and requires the Company to make judgments about the promised goods and services and whether such goods and services are separable from the other aspects of the contractual relationship. In determining the performance obligations, the Company evaluates certain criteria, including whether the promised good or service is capable of being distinct and whether such good or service is distinct within the context of the contract, based on consideration of the relevant facts and circumstances for each arrangement. Factors considered in this determination include the research, manufacturing and commercialization capabilities of the partner; the availability of research and manufacturing expertise in the general marketplace; and the level of integration, interrelation, and interdependence among the promises to transfer goods or services.

The transaction price is allocated among the performance obligations using the relative selling price method and the applicable revenue recognition criteria are applied to each of the separate performance obligations. At contract inception, the Company determines the standalone selling price for each performance obligation identified in the contract. If an observable price of the promised good or service sold separately is not readily available, the Company utilizes assumptions that require judgment to estimate the standalone selling price, which may include development timelines, probabilities of technical and regulatory success, reimbursement rates for personnel costs, forecasted revenues, potential limitations to the selling price of the product, expected technological life of the product and discount rates.

#### *Up-front License Payments*

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. For licenses that are not distinct and bundled with other performance obligations, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue from the combined performance obligation. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

#### *Milestones*

At the inception of each arrangement that includes pre-commercial milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant cumulative revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control, such as regulatory approvals, are not considered probable of being achieved until the uncertainty related to the milestone is resolved. The transaction price is then allocated to each performance obligation on a relative selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. Any such adjustments are recorded on a cumulative catch-up basis, which affects revenue in the period of adjustment. At the end of each subsequent reporting period, the Company reevaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price.

#### *Royalties*

For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and where the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of: (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue.

### *R&D Cost Reimbursement*

R&D cost reimbursement revenue, which is typically related to reimbursements from customers for the Company's performance of R&D services under the respective agreements, is recognized on the basis of labor hours valued at a contractually agreed rate. R&D cost reimbursement revenue also includes reimbursements for related out-of-pocket expenses and third-party costs. R&D cost reimbursement revenue is recognized in the same period as the costs for which they are intended to compensate. The Company typically acts as the principal under such arrangements and, therefore, records these reimbursements on a gross basis.

### *Costs of Obtaining a Contract with a Customer*

The Company capitalizes the incremental costs of obtaining a contract with a customer if it expects to recover those costs. To date, the Company has not capitalized any incremental costs for obtaining a contract.

### **Research and Development Costs**

Research and development costs are expensed as incurred. Research and development expenses are comprised of costs incurred in providing research and development activities, including salaries and benefits, facilities costs, overhead costs, contract research and development services, and other outside costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

When third-party service providers' billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those third parties, including clinical trial and pharmaceutical development costs, contractual services costs and costs for supply of its product candidates incurred in a given accounting period and record accruals at the end of the period. The Company bases its estimates on its knowledge of the research and development programs, services performed for the period, past history in conducting similar activities and the expected duration of the third-party service contract, among other considerations.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to vendors will exceed the level of services provided and result in a prepayment of research and development expenses.

### **Employee Benefits**

#### *Short-term Employee Benefits*

Short-term employee benefits are expensed as the related service is provided. A liability is recognized for the amount expected to be paid if the Company has a present legal or constructive obligation to pay this amount as a result of past service provided by the employee and the obligation can be estimated reliably.

#### *Share-Based Payment Transactions*

The grant-date fair value of equity-settled share-based payment awards granted to employees including grants of employee options, restricted share units, and modifications to existing instruments, is recognized as an expense, net of an estimated forfeiture rate, with a corresponding increase in equity (accumulated loss), over the vesting period of the awards. Service conditions and non-market related conditions are not taken into account in determining the fair value. The amount recognized as an expense is adjusted to reflect the number of awards for which the related service and non-market performance conditions are expected to be met, such that the amount ultimately recognized is based on the number of awards that meet the related service and non-market performance conditions at the vesting date. For any share-based payment awards with market conditions or non-vesting conditions,

the grant-date fair value of the share-based payment is measured to reflect such conditions and there is no true-up for differences between expected and actual outcomes.

### *WBSO*

The WBSO (*afdrachtvermindering speur- en ontwikkelingswerk*) is a Dutch fiscal facility that provides subsidies to companies, knowledge centers and self-employed people who perform R&D activities (as defined in the WBSO Act). Under this act, a contribution is paid towards the labor costs of employees directly involved in R&D and other related expenditures. The contribution is in the form of a reduction of payroll taxes. Subsidies relating to labor costs are deferred and recognized in the consolidated statement of profit or loss and comprehensive loss as negative labor costs over the period necessary to match them with the labor costs that they are intended to compensate (see Note 13).

### *Post-Employment Benefit Plans*

The Company contributes to a post-employment benefit plan that entitles executive officers and other staff members to retire at the age of 67 and receive annual payments based upon the average salary earned during the service period. The Company has insured the liabilities from the post-employment benefit plan with an insurance company and has no other obligation than to pay the annual insurance premiums to the insurance company. The annual pension payments are conditional; the Company will have no further obligation (legal or constructive) to pay further amounts if the insurance fund has insufficient assets to pay all employee benefits relating to current and prior service. Based on its characteristics, the Company's post-employment benefit plan is classified as a defined contribution plan.

Obligations for contributions to defined contribution plans are expensed as the related service is provided. Prepaid contributions are recognized as an asset.

### *Finance Income and Finance Costs*

The Company's finance income and finance costs include: interest and related income, interest expense, financing costs, and the foreign currency gain or loss on financial assets and financial liabilities. Interest income or expense is recognized using the effective interest method.

### *Earnings (Loss) per Share*

The Company computes basic earnings (loss) per share by dividing income (loss) allocable to common shareholders by the weighted average number of shares of common stock outstanding. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The Company computes diluted earnings (loss) per share after giving consideration to the dilutive effect of stock options and restricted stock units ("RSU") that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

### *Segment Information*

The Company operates in one reportable segment, which comprises the discovery and development of innovative antibody therapeutics.

### *Recently Adopted Accounting Pronouncements*

From time to time, new accounting pronouncements are issued by the IASB or other standard-setting bodies that are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial position or results of operations upon adoption. The Company did not adopt any new accounting pronouncements during the year ended December 31, 2022 which had a material impact on its financial position or results of operations upon adoption.

### 3. Property and Equipment

Movements in property and equipment, net were as follows:

<b>For the Year Ended December 31, 2022</b>					
<b>(In euro thousands)</b>					
	<b>Office Furniture &amp; Leasehold Improvements</b>			<b>Assets under construction</b>	<b>Total</b>
<b>Cost</b>	<b>Laboratory Equipment</b>	<b>Equipment</b>	<b>Improvements</b>	<b>construction</b>	<b>Total</b>
Balance at January 1, 2022	4,930	1,079	98	933	7,040
Additions	1,023	664	7,642	—	9,329
Transfers between categories	—	—	863	(863)	—
Disposals	—	—	(63)	—	(63)
Effect of movements in exchange	—	13	2	—	15
Balance at December 31, 2022	<u>5,953</u>	<u>1,756</u>	<u>8,542</u>	<u>70</u>	<u>16,321</u>
	<b>Office Furniture &amp; Leasehold Improvements</b>			<b>Assets under construction</b>	<b>Total</b>
<b>Accumulated Depreciation</b>	<b>Laboratory Equipment</b>	<b>Equipment</b>	<b>Improvements</b>	<b>construction</b>	<b>Total</b>
Balance at January 1, 2022	(3,086)	(771)	(50)	—	(3,907)
Depreciation	(829)	(144)	(20)	—	(993)
Disposals	—	—	45	—	45
Effect of movements in exchange	—	(7)	—	—	(7)
Balance at December 31, 2022	<u>(3,915)</u>	<u>(922)</u>	<u>(25)</u>	<u>—</u>	<u>(4,862)</u>
Carrying amount at December 31, 2022	<u>2,038</u>	<u>834</u>	<u>8,517</u>	<u>70</u>	<u>11,459</u>

**For the Year Ended December 31, 2021**

(In euro thousands)

Cost	Office Furniture & Leasehold Improvements				Assets under construction	Total
	Laboratory Equipment	Equipment	Leasehold Improvements	Assets under construction		
Balance at January 1, 2021	4,641	1,060	95	404	6,200	
Additions	298	3	—	529	830	
Disposals	(9)	—	—	—	(9)	
Effect of movements in exchange	—	16	3	—	19	
Balance at December 31, 2021	<u>4,930</u>	<u>1,079</u>	<u>98</u>	<u>933</u>	<u>7,040</u>	

Accumulated Depreciation	Office Furniture & Leasehold Improvements				Assets under construction	Total
	Laboratory Equipment	Equipment	Leasehold Improvements	Assets under construction		
Balance at January 1, 2021	(2,227)	(592)	(28)	—	(2,847)	
Depreciation	(868)	(172)	(19)	—	(1,059)	
Disposals	9	—	—	—	9	
Effect of movements in exchange	—	(7)	(3)	—	(10)	
Balance at December 31, 2021	<u>(3,086)</u>	<u>(771)</u>	<u>(50)</u>	<u>—</u>	<u>(3,907)</u>	

Carrying amount at December 31, 2021	<u>1,844</u>	<u>308</u>	<u>48</u>	<u>933</u>	<u>3,133</u>
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Assets under Construction primarily relates to certain ongoing development and construction costs related to the office lease the Company entered into with Kadans Science Partner XII B.V. that was capitalized during 2022. Property and equipment are primarily located in the Netherlands for all periods presented.

#### 4. Intangible Assets

Movements in intangible assets, net were as follows:

Cost	For the Year Ended December 31, 2022		
	(In euro thousands)		
	Patents & Licenses	Software Licenses	Total
Balance at January 1, 2022	3,176	235	3,411
Additions	50	—	50
Balance at December 31, 2022	<u>3,226</u>	<u>235</u>	<u>3,461</u>
Accumulated Depreciation	Patents & Licenses	Software Licenses	Total
Balance at January 1, 2022	(1,221)	(117)	(1,338)
Amortization	(247)	(47)	(294)
Balance at December 31, 2022	<u>(1,468)</u>	<u>(164)</u>	<u>(1,632)</u>
Carrying amount at December 31, 2022	<u>1,758</u>	<u>71</u>	<u>1,829</u>

	<b>For the Year Ended December 31, 2021</b>		
	<b>(In euro thousands)</b>		
<b>Cost</b>	<b>Patents &amp; Licenses</b>	<b>Software Licenses</b>	<b>Total</b>
Balance at January 1, 2021	3,176	235	3,411
Additions	—	—	—
Balance at December 31, 2021	<u>3,176</u>	<u>235</u>	<u>3,411</u>
	<b>Patents &amp; Licenses</b>	<b>Software Licenses</b>	<b>Total</b>
<b>Accumulated Depreciation</b>			
Balance at January 1, 2021	(1,024)	(70)	(1,094)
Amortization	(197)	(47)	(244)
Balance at December 31, 2021	<u>(1,221)</u>	<u>(117)</u>	<u>(1,338)</u>
Carrying amount at December 31, 2021	<u>1,955</u>	<u>118</u>	<u>2,073</u>

Amortization of intangible assets are recorded in operating expenses in the consolidated statement of profit or loss and comprehensive loss. Intangible Assets are predominantly located in the Netherlands.

## 5. Leases

The Company has noncancelable operating leases for offices and lab spaces expiring at various dates through 2032.

Merus N.V. has non-cancellable operating leases for its corporate headquarters in Utrecht, the Netherlands. In December 2022, the Company moved into its new headquarters called the "Accelerator" in the Utrecht Science Park, at 17 Uppsalalaan, 3rd and 4th floor, 3583 CT, Utrecht.

On July 19, 2019, Merus N.V. entered into a lease agreement with Kadans Science Partner XIII B.V. ("Kadans") for the Accelerator headquarters. In April 2022, the Accelerator lease between the Company and Kadans commenced. In accordance with the accounting requirements under IFRS 16, the right-of-use asset and lease obligation were not recorded until the lease commenced. In December 2022, the Company completed the fit-out construction on approximately 4,957 square meters of office and laboratory space in the premises. The lease provides for a base rent of approximately €1.4 million per annum. The rent amount is subject to adjustment based on the consumer price index (the "CPI") annually, beginning one year after the lease commencement date, subject to certain limitations if the CPI is greater than 3.0%. The initial term of the lease is ten years with two 5-year renewal options following the initial term, unless earlier terminated by the Company or Kadans, except that the earliest Kadans may terminate the lease is 20 years from the completion date of the premise construction. The Company expects the lease to end as of April 4, 2032. On April 5, 2022, the Company recognized a right-of-use asset of \$11.5 million, or €10.5 million, and a lease liability of \$12.4 million, or €11.3 million, on the consolidated balance sheets. In connection with signing the lease, the Company received a lease incentive of \$0.9 million, or €0.8 million. To measure the lease liability at the commencement date, the Company discounted the outstanding lease payments using an incremental borrowing rate of 4.85%.

During the year ended December 31, 2021, the Company signed a lease amendment (the "Amendment"), which extended the term of the lease for its former corporate headquarters with Stichting Incubator Utrecht by approximately 1.5 years ending at the end of March 2023. The Amendment did not include additional right-of-use other than the extended lease term. There is no additional renewal term included in the Amendment to consider in the estimate of the lease term. On



December 7, 2022, the Company signed a second lease amendment terminating the lease for the former corporate headquarters as of January 1, 2023. The Company continued to make payments through mid-February 2023. The Company accounted for the second amendment as a lease modification and reduced the lease liability and right-of-use asset by approximately €0.2 million to equal to the remaining lease payments.

In March 2019, Merus US, Inc. entered into a non-cancellable operating lease agreement for office space in Cambridge, Massachusetts. The lease commenced in the second quarter of 2019 and has a term of seven years, and may be extended for another five years. Given the Company's current plans, the renewal term has not been included in the estimate of the lease term. Fixed lease payments increase annually and include an increase on an inflationary measure. Variable payments include amounts due to the lessor for additional services and cost reimbursements.

Movements in right-of-use assets were as follows:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Opening balance January 1	3,894	3,533
Additions to right-of-use assets	11,275	1,812
Modification	(200)	—
Depreciation	(2,596)	(1,651)
Foreign exchange	166	200
Closing balance December 31	<u>12,539</u>	<u>3,894</u>

The schedule of lease payments and balance of lease liabilities as of December 31, 2022 was as follows:

<b>Year</b>	<b>Payments (In euro thousands)</b>
2023	2,205
2024	2,092
2025	2,109
2026	1,648
2027	1,414
Thereafter	6,030
Total lease payments	<u>15,498</u>
Less: amount representing interest	<u>(2,638)</u>
Total lease liabilities	<u>12,860</u>
Current lease liabilities	1,642
Non-current lease liabilities	<u>11,218</u>
Total lease liabilities	<u>12,860</u>

Amounts recognized in the consolidated statement of profit or loss and cash flows were as follows:

	<b>For the Year</b>	
	<b>Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Variable lease payments not included in the measurement of lease liabilities	519	497
Interest on lease liabilities	528	165
Expense from low-value leases	54	42
Cash outflow for leases	2,503	1,631

## 6. Taxes

Amounts recognized in the consolidated statement of profit or loss and comprehensive loss were as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Current year tax expense		
Current year	(2,440)	(269)
Changes related to prior years	(60)	62
	<u>(2,500)</u>	<u>(207)</u>
Deferred tax benefit		
Origination and reversal of temporary differences	1,571	6
Tax (expense) benefit	<u>(929)</u>	<u>(201)</u>

The parent company is subject to income tax in the Netherlands where a greater proportion of economic activity is attributed. A reconciliation of the Netherlands statutory income tax rate to the Company's effective income tax rate is as follows:

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Netherlands statutory income tax rate	25.8%	25.0%
Changes in tax rates	—	5.2
Non-deductible expenses	(4.4)	0.8
Current year losses for which no deferred tax asset was recognised	(22.0)	(31.4)
Other	(0.1)	0.1
Effective income tax rate	<u>(0.7)%</u>	<u>(0.3)%</u>

In 2020 and 2021, Dutch tax authorities enacted new tax rates applicable to future periods which impact the measurement of deferred income taxes.

The movement of deferred tax balances are as follows:

	<b>For the Year Ended December 31, 2022</b>			
	<b>(In euros thousands)</b>			
	<b>Net balance at January 1</b>	<b>Recognized in profit or loss</b>	<b>Foreign exchange</b>	<b>Net balance at December 31</b>
<b>Deferred tax assets</b>				
Lease liability	608	(136)	42	514
Accrued liabilities	421	212	19	652
Section 174 Expenses	—	1,373	(43)	1,330
Total deferred tax assets	<u>1,029</u>	<u>1,449</u>	<u>18</u>	<u>2,496</u>
<b>Deferred tax liabilities</b>				
Operating lease right-of-use assets	611	(143)	42	510
Other	50	21	2	73
	<u>661</u>	<u>(122)</u>	<u>44</u>	<u>583</u>
Total, net	<u>368</u>	<u>1,571</u>	<u>(26)</u>	<u>1,913</u>

	<b>For the Year Ended December 31, 2021</b>			
	<b>(In euros thousands)</b>			
	<b>Net balance at January 1</b>	<b>Recognized in profit or loss</b>	<b>Foreign exchange</b>	<b>Net balance at December 31</b>
<b>Deferred tax assets</b>				
Lease liability	667	(110)	51	608
Accrued liabilities	402	(14)	33	421
Total deferred tax assets	<u>1,069</u>	<u>(124)</u>	<u>84</u>	<u>1,029</u>
<b>Deferred tax liabilities</b>				
Operating lease right-of-use assets	680	(120)	51	611
Other	55	(10)	5	50
	<u>735</u>	<u>(130)</u>	<u>56</u>	<u>661</u>
Total, net	<u>334</u>	<u>6</u>	<u>28</u>	<u>368</u>

The Tax Cuts and Jobs Act of 2017 (“TCJA”), which was signed into U.S. law in December 2017, eliminated the option to immediately deduct research and development expenditures in the year incurred under Section 174 effective January 1, 2022. The amended provision under Section 174 requires us to capitalize and amortize these expenditures over five years (for U.S.-based research). As of December 31, 2022, the Company recorded an increase to net deferred tax assets of a €1.3 million and an increase to income taxes payable of a similar amount. Income tax expense increased primarily

due to an increase in book income before tax and an increase in temporary differences due to the inclusion of Section 174 expenses due to the TCJA.

After consideration of all positive and negative evidence, the Company believes that it is probable that the Netherlands deferred tax assets that are not supported by reversing temporary differences will not be realized. As a result, deferred tax assets and liabilities associated with the Netherlands have not been recognized.

At of December 31, 2022 and 2021, the Company did not have any net operating losses for U.S. federal or state income tax purposes. U.S. deferred tax assets of Merus US, Inc. have been recognized as future taxable profits in excess of the reversal of taxable temporary differences are expected given its intercompany arrangement with Merus N.V. The Company had net operating loss carryforwards for Dutch income tax purposes of €402.3 million and €268.8 million as of December 31, 2022, and 2021, respectively. Under Dutch tax law, net operating loss carryforwards may be used to offset future taxable income in full up to €1.0 million and 50% of taxable income that exceeds €1.0 million. Effective as of January 1, 2022, these losses can be carried forward indefinitely.

As of December 31, 2022 and December 31, 2021, the Company had no unrecognized tax benefits. As of December 31, 2022 and December 31, 2021, the Company had no accrued interest or penalties related to underpayments of income taxes and no amounts have been recognized in the consolidated statements of operations. The Company will recognize interest and penalties related to an underpayment of income taxes in income tax expense.

The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions as well as in the Netherlands. The statute of limitations for assessment by the Internal Revenue Service (IRS), and Massachusetts tax authorities is closed for tax years prior to 2019. The statute of limitations for assessment by the Netherlands tax authorities is closed for tax years prior to 2017. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

## 7. Investments

Cash equivalents and investments as of December 31, 2022 and 2021 consisted of the following:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(in euro thousands)</b>	
Corporate paper and notes	101,129	119,919
U.S. treasuries	17,318	28,391
U.S. government agency securities	15,136	895
Current investments	133,583	149,205
Corporate paper and notes	17,098	16,968
U.S. government agency securities	17,083	953
Non-current investments	34,181	17,921
Total investments	<u>167,764</u>	<u>167,126</u>

## 8. Other Assets, Current

The components of other assets are as follows:

	<u>December 31,</u>	
	<u>2022</u>	<u>2021</u>
	<u>(In euros thousands)</u>	
Prepaid clinical and manufacturing costs	5,974	1,895
Prepaid general and administrative expenses	2,756	2,437
VAT receivable, net	1,575	724
Interest receivable	607	324
Other	492	1,196
Total	<u>11,404</u>	<u>6,576</u>

## 9. Shareholders' Equity

### *Common Shares*

All common shares in the periods presented were issued and fully paid in cash. Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Common shareholders are entitled to dividends when and if declared by the board of directors. As at December 31, 2022, 67,500,000 shares were authorized for issuance (2021: 67,500,000). Common shares have a par value of €0.09. Shares issued and outstanding in the periods presented are disclosed in the statement of changes in equity.

On November 7, 2019, the Company completed an underwritten public offering in which the Company sold 5,462,500 common shares, including 715,500 common shares pursuant to the underwriters' option to purchase additional shares, at a price to the public of \$14.50 for aggregate gross proceeds of \$79.2 million, or €71.3 million. The Company incurred transaction costs of \$5.2 million, or €4.7 million.

During 2020, the Company completed additional share offerings for a total of 2,451,281 common shares, at a weighted average price of \$16.10, or €13.38, for aggregate gross proceeds of \$39.5 million or €32.8 million. The Company incurred transaction costs of \$1.3 million or €1.2 million.

On January 18, 2021, the Company sold 706,834 common shares, at a price of \$28.295, or €23.45, for aggregate proceeds of \$16.5 million or €13.7 million as part of the Share Subscription Agreement with Lilly. Additional details of the Agreement is more fully described in Note 12.

During 2021, the Company completed additional share offerings for a total of 10,014,354 common shares, at a weighted average price of \$26.41, or €22.25, for aggregate gross proceeds of \$264.5 million or €222.9 million. The Company incurred transaction costs of \$16.4 million or €13.9 million.

In May 2021, the Company entered into an Open Market Sale Agreement (the "Sales Agreement") with Jefferies LLC ("Jefferies") to sell from time to time up to \$125.0 million of the Company's common stock through an "at the market" offering program under which Jefferies acts as the sales agent. Subject to the terms and conditions of the Sales Agreement, Jefferies can sell the common stock by any method deemed to be an "at-the-market" offering as defined in Rule 415 promulgated under the Securities Act of 1933, as amended (the "Securities Act").

Jefferies will be entitled to compensation at a commission rate of up to 3.0% of the gross proceeds of shares sold under the Sales Agreement. In connection with the sale of the common shares on our behalf, Jefferies will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Jefferies will be deemed to be underwriting commissions or discounts. The Company agreed to provide indemnification and contribution to Jefferies with respect to certain liabilities, including liabilities under the Securities Act or the Securities Exchange Act of 1934, as amended, or the Exchange Act.

As of December 31, 2022, the Company, pursuant to the Sales Agreement, had issued and sold an aggregate of 2,720,846 shares of its common stock resulting in gross proceeds of €56.6 million, before deducting sales agent commissions of €1.6 million.

#### *Share Premium Reserve*

The share premium reserve relates to amounts contributed by shareholders at the issue of shares in excess of the par value of the shares issued. All share premium can be considered as free share premium as referred to in the Netherlands Income tax act.

#### *Translation Reserve*

The translation reserve comprises all foreign currency differences arising from the translation of the financial statements of foreign operations.

#### *Equity Compensation Plan*

As of January 1, 2023, a total of 2,810,025 shares of common stock were reserved for additional grants of stock awards under the Company's 2016 Incentive Award Plan. Stock-based compensation expense related to the equity compensation plan is more fully described in Note 14.

#### *Capital Risk Management*

The Company's objectives in managing capital are to safeguard the Company's ability to continue as a going concern and to minimize the cost of capital to provide returns for shareholders and benefits for other stakeholders.

The Company has no firm sources of additional financing other than its collaboration agreements. Until such time, if ever, as the Company can generate substantial cash flows from successfully commercializing its product candidates, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution and licensing arrangements.

The total amount of equity as recorded on the consolidated statement of financial position is managed as capital by the Company.

## **10. Commitments and Contingencies**

#### *Commitments Related to the Collaboration and License Agreements*

Under the collaboration and license agreements, the Company has agreed to collaborate with Lilly and Incyte, separately, respect to the research, discovery and development of bispecific antibodies utilizing the Company's proprietary bispecific technology platform. The actual amounts that the Company may pay to Lilly or Incyte or that Lilly or Incyte may pay to the Company will depend on numerous factors outside of the Company's control, including the success of certain clinical development efforts.

In addition, the Company has commitments to make potential future milestone payments to third parties under certain of its license arrangements. These milestones primarily relate to the initiation and results of clinical trials, obtaining regulatory approval in various jurisdictions and the future commercial success of development programs, the outcome and timing of which are difficult to predict and subject to significant uncertainty. In addition to the milestones discussed above, the Company is obligated to pay royalties on future sales, which are contingent on generating levels of sales of future products that have not been achieved and may never be achieved.

#### *Other Funding Commitments*

As of December 31, 2022, the Company had several ongoing clinical and nonclinical studies for its various pipeline programs. The Company enters into contracts in the normal course of business with contract research organizations and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services.

These contracts are generally cancellable, with notice, at the Company's option and do not have significant cancellation penalties.

### *Guarantees*

The Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that is intended to limit its exposure and enable it to recover a portion of any future amounts paid.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, landlords, clinical sites and customers. Under these provisions, the Company may indemnify and holds harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities, such as gross negligence, willful misconduct or at times, other activities. These indemnification provisions may survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions may be unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of December 31, 2022 and 2021.

### *Litigation*

On August 19, 2022, Kymab Limited, a subsidiary of Sanofi, filed a notice of opposition against the Company's EP3456190 patent (the "'190 patent"), entitled "Antibody Producing Transgenic Murine Animal," in the European Opposition Division of the European Patent Office (EPO). The notice asserted, as applicable, the '190 patent is contrary to the provision of Article 123(2) EPC, Article 75(1) EPC and Article 100(c) EPC, and alleges the '190 patent lacks novelty and/or is obvious contrary to the provisions of Articles 54 and/or 56 EPC, and Article 100(a) EPC, and that the specification of the '190 patent does not provide sufficient disclosure of the subject matter of the inventions contravening Article 83 EPC and Article 100(b). On January 17, 2023, the Company timely filed a response before the European Opposition Division of the EPO contesting each of these assertions, with further proceedings to follow.

From time to time, the Company may be involved in various other claims and legal proceedings relating to claims arising out of the Company's operations. The Company is not currently a party to any material legal proceedings.

## **11. Accrued Liabilities**

The components of accrued liabilities are as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Accrued research and development expenses	24,526	13,397
Accrued personnel costs	5,418	4,292
Accrued general and administrative expenses	3,389	1,203
Other	35	979
<b>Total accrued liabilities</b>	<b>33,368</b>	<b>19,871</b>

The increase in accrued research and development expenses during 2022 is attributable to the increase in research and development activities.

## **12. Collaboration Revenue**

### *Lilly*

On January 18, 2021, Eli Lilly and Company (“Lilly”) agreed to pay the Company a \$40.0 million, non-refundable upfront payment, and purchased 706,834 common shares at a stated price per share of \$28.295, for an aggregate purchase price of \$20.0 million. The Company and Lilly agreed to collaborate with respect to the discovery and research of bispecific antibodies utilizing the Company’s proprietary Biclomics® bispecific technology platform. The collaboration encompasses up to three (3) independent programs directed to the generation of T-cell re-directing bispecific antibodies that bind CD3 and a tumor associated antigen target selected by Lilly to be the subject of each program.

The objective of each program is to develop a lead compound that Lilly would be able to continue to develop through clinical trials. Lilly agreed to fund the research activities the Company conducts for each program under an agreed research plan and budget. Lilly receives an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights and know-how to exploit certain compounds and products directed to designated targets in combination with targeting CD3, or directed to such designated target(s) alone as a monospecific antibody or monospecific antibody drug conjugate, subject to rights granted by Merus to third parties under one or more existing third party agreements. Merus retains all rights not granted to Lilly. Lilly has certain rights to replace selected targets, including the right to substitute a target selection after initial selection for a period of time. The Company may be entitled to further milestones and royalties in the future dependent on development and commercialization of any resulting product.

The initial term of the arrangement includes a three-year research term for the Company to perform research and development activities, subject to two extension terms of six months at Lilly’s discretion. While the arrangement may be terminated in its entirety or on a program-by-program basis at will by Lilly, there are no direct costs or penalties to Lilly to terminate the arrangement prior to the end of the initial term.

At inception of the arrangement, the Company identified a single performance obligation comprised of a combined delivery of a license and related activities, including research activities associated with a product candidate against the first target and the activities of the joint steering committee. The Company also identified two other combined performance obligations relating to options exercisable by Lilly to select a second and third target to advance a second and third product candidate against the selected targets through discovery and research.

The transaction price at inception was comprised of fixed consideration of \$43.5 million that was derived from the \$40.0 million upfront payment and \$20.0 million share purchase proceeds, net of the fair value of shares of the shares delivered to Lilly of \$16.5 million, and variable consideration associated with the funding of research services for the product candidate against the first target at inception. All other consideration under the arrangement was determined to be variable consideration and fully constrained at inception.

The fixed consideration was allocated equally amongst the three performance obligations and the variable consideration associated with each target was allocated to the performance obligation of each respective target. The equal allocation of the fixed consideration was based on the estimated standalone selling price of each performance obligation as each was materially the same.

On February 12, 2021, the Company and Lilly completed the initial exchange of fixed consideration and transfer of common shares. The Company initially deferred \$43.5 million allocated to the performance obligations to be recognized as revenue over time using a cost-to-cost measure of progress toward the development of a lead compound for each respective target, anticipated to be recognized as revenue within the initial research term, along with research funding. Development milestones, commercialization milestones and royalties are variable consideration, fully constrained, to be included in the transaction price for each performance obligation and recognized in future periods in accordance with the Company’s revenue recognition policy. The revenue recognized relating to each combined performance obligation is presented in the notes according to the source of consideration received (upfront, reimbursement revenue, milestone), reflective of their differing timing of receipt.



During the year ended December 31, 2022, Lilly substituted one of the target programs. The program timeline is expected to extend beyond the original research term. Under the current research plan, for the program to be completed in collaboration with Merus, Lilly would be required to extend the research term to 2025, subject to its discretion. The fee associated with an extension into 2025 is \$0.5 million or €0.5 million. As a result, the Company increased the transaction price for one of the programs by \$0.5 million or €0.5 million. The decrease in Lilly upfront payment amortization is the result of a change in estimate related to the program target substitution of one of the Lilly programs which reduced the percentage complete and resulted in a reversal of a portion of the cumulative amount of revenue recognized.

As of December 31, 2022, research activities were on-going and no milestones have been achieved to date.

### *Incyte*

In December 2016, pending regulatory clearance, Incyte Corporation ("Incyte") agreed to pay the Company a \$120.0 million, non-refundable upfront payment, and purchased 3.2 million common shares at a stated price per share of \$25.00, for an aggregate purchase price of \$80.0 million. In exchange, the Company granted Incyte with a license to certain of its intellectual property and committed to collaborate with Incyte to research, discover and develop monospecific or bispecific antibodies utilizing the Company's proprietary bispecific technology platform. The collaboration is managed by a joint steering committee in which both parties are represented and is tasked with overseeing the activities which significantly contributes to the collaboration. The collaboration may encompass up to 10 product candidates that result from the Company's application of its proprietary Biclomics<sup>®</sup> technology platform. During the course of the initial research term, Merus proposes product candidates to Incyte, which evaluates whether to designate proposed product candidates from the Company to make a selection for further research. Proposed product candidates begin at a pre-clinical stage of development. Incyte has certain rights to replace product candidates, including the right to substitute a product candidate after initial selection. The Company would be entitled to future consideration in the form of cost reimbursements for research services, development milestones, commercialization milestones and royalties related to the programs under the arrangement.

At inception of the collaboration, two potential bispecific product candidates were under preliminary evaluation. After further research, a lead candidate was ultimately selected for the first product candidate, designated MCLA-145, and the other potential product candidate was not pursued. For the designated product candidate (MCLA-145), the Company retained the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte obtained the exclusive right to develop and commercialize products and product candidates arising from such program outside the United States. For MCLA-145, the parties will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in each party's respective territories. For all other programs under the arrangement to be selected by Incyte, Incyte will be responsible for all research, development and commercialization costs. The Company may elect to co-fund the development of certain of the other programs in the future, in which case costs and benefits would be shared. The Company has not elected to co-fund any programs to date.

At inception of the arrangement, the Company identified a performance obligation comprised of a combined delivery of a license and related activities, including the activities of the joint steering committee, to which to allocate consideration. The arrangement also allowed for optional future research services to advance selected product candidates through discovery and research. The transaction price was comprised of fixed consideration of an upfront payment of \$120.0 million and proceeds from the sale of shares of \$80.0 million. All other consideration under the arrangement was determined to be variable consideration and fully constrained at inception. \$152.6 million (€143.4 million) of the transaction price was allocated to the license and related activities performance obligation after accounting for the purchase of common shares by Incyte.

On January 23, 2017, the Company completed the sale of shares and exchange of the license. The Company initially deferred \$152.6 million (€143.4 million) of the transaction price allocated to the

license and related performance obligation as deferred revenue, to be recognized as revenue over time as the primary benefit of the license to Incyte is access to the Company's intellectual property covering its Biclomics® technology platform for the generation of potential product candidates. Development milestones, commercialization milestones and royalties are variable consideration, fully constrained, to be recognized in future periods in accordance with the Company's revenue recognition policy. Cost reimbursements for research services are recognized as they are performed over time as these are considered a separate performance obligation.

In January 2022, the Company announced that Incyte elected to opt-out of its ex-U.S. development of MCLA-145, from the parties joint collaboration agreement executed in 2017. At inception of the collaboration, for the designated product candidate (MCLA-145), the Company retained the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte obtained the exclusive right to develop and commercialize products and product candidates arising from such program outside the United States. For MCLA-145, the parties conducted and shared equally the costs of mutually agreed global development activities. Incyte's opt-out of ex-U.S. rights to MCLA-145 provides the Company the exclusive right to develop and commercialize potential MCLA-145 products globally. Under the collaboration, Incyte will continue to support the program for a limited time while ex-U.S. activities are transitioned to the Company, and Incyte will retain a right to a residual royalty of up to 4% on sales of future commercialization of MCLA-145, if approved.

During the year ended December 31, 2022, the Company recognized a €1.0 million development milestone related to a candidate nomination related to one of the programs. There were no additional development or commercialization milestones recognized during the year ended December 31, 2022. During the year ended December 31, 2021, the Company recognized a total of €1.7 million for achieving development milestones and received a €0.9 million payment.

Incyte is a shareholder with holdings representing approximately 7.7% of the outstanding shares of the Company as of December 31, 2022, and 8.2% as of December 31, 2021.

#### *Ono*

In April 2014, the Company granted Ono Pharmaceutical Co., Ltd. ("Ono") an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market a limited number of bispecific antibody candidates based on the Company's Biclomics® technology platform against two undisclosed targets directed to a particular undisclosed target combination.

On March 14, 2018, the Company granted Ono an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market a limited number of bispecific antibody candidates based on the Company's Biclomics® technology platform against two undisclosed targets directed to a particular undisclosed target combination. Ono is responsible for identifying lead candidates and conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. Additionally, Ono controls and has exclusive rights over the worldwide commercialization of any approved products, including worldwide supply, and is solely responsible for all costs and expenses related to commercialization. Ono has also agreed to fund the Company's research and development activities and be responsible for the payment of all costs and expenses for its own research and development activities, which are set out in a mutually agreed upon research plan. The Company retains all rights to use and commercialize any antibodies that are generated under the collaborative research program, excluding the up to five lead and/or selected antibodies against the targets Ono is pursuing, provided that the use and commercialization is not with respect to the particular target combination. Ono agreed to pay the Company an upfront, non-refundable payment of €0.7 million. In addition, the Company was entitled to €0.3 million intended to compensate the Company for research services already completed upon entering into the agreement, and €0.2 million to be paid to the Company over time for full time equivalent funding. The Company is entitled to research and development milestones in addition to royalties on future sales. The Company identified performance obligations for: (1) provision of a license for the target combination, and (2) research and development services. The Company concluded that Ono would be able to develop and benefit from the license, independent of the research and development services. The research and development

services are capable of being performed by third parties with an appropriate sub-license, and are recognized over time as these services are delivered. Milestone payments are fully constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

The Company achieved a €1.0 million development milestone in the year ended December 31, 2022. There were no development milestones achieved in the years ended December 31, 2021.

### *Simcere*

In January 2018, the Company granted Simcere Pharmaceuticals Group ("Simcere") an exclusive license to develop and commercialize up to three bispecific antibodies to be produced by Merus utilizing the Company's Biclomics® technology platform in China (the "Simcere Agreement"). The Company will retain all rights outside of China. The Company has agreed to lead research and discovery activities, while Simcere has agreed to be responsible for the Investigational New Drug ("IND") enabling studies, clinical development, regulatory filings and commercialization of these potential product candidates in China. The Company received an upfront, non-refundable payment of \$2.8 million, relating to three separate research programs.

At inception of the arrangement, the Company identified three performance obligations comprised of the combined delivery of a license and performance of research and development activities with respect to each program. The Company performs research and development activities to achieve candidate nomination. The Company concluded that these activities were not distinct from the underlying license for each program as Simcere would not be able to benefit from the license apart from research and development activities at this phase of development.

The transaction price under the arrangement comprised fixed consideration of \$2.75 million. The transaction price was allocated to each separate performance obligation on a relative standalone fair value basis. The Company deferred the portion of the upfront payment allocated to the three performance obligations as deferred revenue, to be recognized over time. Compensation for research and development services prior to candidate nomination are allocated to each program performance obligation and also recognized over time. Development milestone payments allocated to each of the program performance obligations are constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

During the year ended December 31, 2021, the Company has recognized €0.4 million for milestones achieved under the Simcere Agreement. In January 2022, the Company and Simcere terminated the Simcere Agreement, effective March 30, 2022. There were no milestones achieved during the year ended December 31, 2022.

### *Betta*

On December 10, 2018, the Company granted Betta an exclusive license to develop and commercialize in China MCLA-129, proprietary Biclomics® produced by its Biclomics® technology platform. The Company retains all rights outside of China. Betta has agreed to retain a contract manufacturing organization with experience in filing IND applications with U.S. regulatory authorities and CTAs with European regulatory authorities in order to produce clinical trial materials for the Chinese market and rest of the world. As a key strategic component of the collaboration, Betta will be responsible for IND enabling studies and manufacturing of clinical trial materials in China, which the Company intends to use to assist regulatory filing and early stage clinical development in the rest of the world.

In addition to a non-refundable upfront payment of \$1.0 million, Betta and the Company will share equally the cost of the transfer of the manufacturing technology to a contract manufacturing organization. The Company is also eligible to receive an aggregate of \$12.0 million in milestone payments contingent upon Betta achieving certain specified development and commercial goals as well as tiered royalty payments of net sales of any products resulting from the collaboration in China. In turn, Betta is also entitled to milestone payments based on the Company's progress.

The Company identified a single combined performance obligation, being the delivery of the MCLA-129 license including activities necessary to complete the technology transfer. The Company had no other commitments. The transaction price is comprised of fixed consideration of €0.9 million and fully allocated to the single performance obligation which would be fulfilled at a point in time. The technology transfer to deliver the license was completed in 2018 and the Company recognized the revenue related to this performance obligation of €0.9 million as revenue for the year ended December 31, 2018. Development milestone payments allocated to the performance obligation are constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

No milestones were achieved during the years ended December 31, 2022 and 2021, respectively.

#### *Contract Assets and Liabilities*

The following tables provide amounts by year indicated and by line item included in the Company's accompanying consolidated financial statements attributable to transactions arising from its collaboration arrangements.

	<b>For the Year Ended December 31, 2022</b>			
	<b>(In euros thousands)</b>			
	<b>Incyte</b>	<b>Lilly</b>	<b>Other</b>	<b>Total</b>
<b>Contract assets</b>				
Trade receivables				
Balance at January 1, 2022	1,443	—	38	1,481
Billings	9,185	3,747	1,437	14,369
Cash receipts	(10,595)	(3,747)	(474)	(14,816)
Adjustment			—	—
Foreign exchange	(33)		—	(33)
Balance at December 31, 2022	<u>—</u>	<u>—</u>	<u>1,001</u>	<u>1,001</u>
Unbilled receivables				
Balance at January 1, 2022	2,627	1,062	400	4,089
Accrued receivables	7,458	3,443	1,214	12,115
Billings	(8,222)	(3,747)	(1,437)	(13,406)
Adjustment	—	—	(1)	(1)
Foreign exchange	—	—	—	—
Balance at December 31, 2022	<u>1,863</u>	<u>758</u>	<u>176</u>	<u>2,797</u>
<b>Total</b>	<u><u>1,863</u></u>	<u><u>758</u></u>	<u><u>1,177</u></u>	<u><u>3,798</u></u>
<b>Contract liabilities</b>				
Deferred revenue				
Balance at January 1, 2022	64,747	24,150	194	89,091
Addition to Deferred Revenue	—	514	—	514
Revenue recognized in the period	(15,935)	(9,542)	(194)	(25,671)
Foreign exchange	—	—	—	—
Balance at December 31, 2022	48,812	15,122	—	63,934
Less: current portion	(15,936)	(11,645)	—	(27,581)
Non-current balance at December 31, 2022	<u><u>32,876</u></u>	<u><u>3,477</u></u>	<u><u>—</u></u>	<u><u>36,353</u></u>

The balance of unbilled receivables predominantly represents reimbursement revenue under the Company's collaboration arrangements earned in the period to be billed and collected in the next period, generally quarterly. Note the €0.5 million addition to the transaction price of the arrangement with Lilly was included in other assets as a contract asset based on the current research plan.

### Contract Revenues and Expenses

The following tables provide amounts by year indicated and by line item included in the Company's accompanying consolidated financial statements attributable to transactions arising from its collaboration arrangements:

	<b>For the Year Ended December 31, 2022</b>			
	<b>(In euros thousands)</b>			
	<b>Incyte</b>	<b>Lilly</b>	<b>Other</b>	<b>Total</b>
Upfront payments	15,935	9,542	194	25,671
Reimbursement revenue	8,170	3,443	-	11,613
Milestones	963	-	1,000	1,963
Other	-	-	44	44
<b>Total collaboration revenue</b>	<b>25,068</b>	<b>12,985</b>	<b>1,238</b>	<b>39,291</b>
Operating expenses:				
Research and development expense	700	-	-	700
General and administrative expense	-	-	-	-
<b>Total operating expenses from collaborations</b>	<b>700</b>	<b>-</b>	<b>-</b>	<b>700</b>
Revenue recognized that was included in deferred revenue at the beginning of the period	15,936	9,326	196	25,458
	<b>For the Year Ended December 31, 2021</b>			
	<b>(In euros thousands)</b>			
	<b>Incyte</b>	<b>Lilly</b>	<b>Other</b>	<b>Total</b>
Upfront payments	15,934	11,927	385	28,246
Reimbursement revenue	7,389	2,835	903	11,127
Milestones	1,740	-	425	2,165
<b>Total collaboration revenue</b>	<b>25,063</b>	<b>14,762</b>	<b>1,713</b>	<b>41,538</b>
Operating expenses:				
Research and development expense	1,033	-	128	1,161
General and administrative expense	-	-	-	-
<b>Total operating expenses from collaborations</b>	<b>1,033</b>	<b>-</b>	<b>128</b>	<b>1,161</b>
Revenue recognized that was included in deferred revenue at the beginning of the period	15,934	-	385	16,319

### 13. Operating Expenses

Disaggregated operating expenses as presented in the statement of profit or loss and comprehensive loss by nature are as follows:

	Note	Year Ended December 31,	
		2022	2021
(In euro thousands)			
<b>Research and development costs</b>			
External costs		55,760	35,586
Manufacturing		48,074	27,379
Wages, salaries and other employee benefits		15,776	7,319
Share-based payments	14	10,153	6,100
Depreciation and amortization	3,4,5	2,762	2,064
Other		9,705	4,777
<b>Total research and development costs</b>		<b>142,230</b>	<b>83,225</b>
<b>General and administrative costs</b>			
Wages, salaries and other employee benefits		13,903	10,293
Consulting		7,332	3,349
Share-based payments	14	12,419	8,586
Legal fees		3,513	2,663
Accounting and professional fees		5,901	4,732
Depreciation and amortization	3,4,5	1,121	890
Other		4,819	4,067
<b>Total general and administrative costs</b>		<b>49,008</b>	<b>34,580</b>

Employee benefits included in research and development costs are presented net of WBSO contributions of €5.6 million and €7.8 million for the years ended December 31, 2022 and 2021, respectively. Wages and salaries and social security expenses for research and development costs were €17.1 million and €1.7 million for the year ended December 31, 2022, respectively. Wages and salaries and social security expenses for general and administrative costs were €10.7 million and €0.7 million for the year ended December 31, 2022, respectively.

### 14. Employee Benefits

#### *Equity Settled Share-Based Payments*

##### *2010 Plan*

In 2010, the Company established the Merus B.V. 2010 Employee Option Plan (the “2010 Plan”) that entitled key management personnel, staff and consultants providing similar services to purchase shares in the Company. Under the 2010 Plan, holders of vested options were entitled to purchase depositary receipts for common shares at the exercise price determined at the date of grant. Upon exercise of the option, common shares were issued to a foundation established to facilitate administration of share-based compensation awards and pool the voting interests of the underlying shares, and depositary receipts were issued by the foundation to the individual holders. In connection with the IPO, the 2010 Plan was amended to cancel the depositary receipts and allow individual holders to directly hold the common shares obtained upon exercise of their options.

Options granted under the 2010 Plan generally vest in installments over a four-year period from the grant date: 25% percent 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 thereafter. Options expire after 8 years from the date of grant. The last grant of options pursuant to the 2010 Plan occurred in 2016, with no further grants expected.

### 2016 Plan

In 2016, the Company established the 2016 Incentive Award Plan (the “2016 Plan”). All incentive award grants since 2016 are being made under the 2016 Plan.

Options granted to employees under the 2016 Plan generally vest in installments over a four-year period from the grant date: 25% percent 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 thereafter. Options expire after 10 years from the date of grant.

Options granted to non-executive directors consist of an initial option grant as well as subsequent annual awards. The initial award of options granted vest in installments over a three-year period: 33% of the options vest on the first anniversary of the vesting commencement date, and 67% of the options vest in 24 monthly installments thereafter. Each subsequent award vest over a one-year period in 12 monthly installments thereafter. The Company measures the fair value of an option through the application of an option pricing model, as more fully described below.

The RSUs granted to employees under the 2016 Plan vest in installments over a four-year period from the grant date. Certain RSUs may vest dependent on the attainment of performance criteria. Each RSU represents the right to receive one common share. The fair value of an RSU is determined by reference to the price of the underlying common share.

The number of common shares authorized for issuance for future grants under the plan as of January 1, 2023 totaled 2,810,025.

### Share-Based Compensation Expense

Share-based compensation expense is classified in the consolidated statement of profit or loss and comprehensive loss as follows:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In thousands)</b>	
Research and development	10,153	6,100
General and administrative	12,419	8,586
<b>Total</b>	<b>22,572</b>	<b>14,686</b>

### Stock Option Valuation

The Company uses the Black-Scholes option-pricing model to measure the fair value of stock option awards. Key weighted average assumptions used in the pricing models on the date of grant for options granted to employees are as follows:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Risk-free interest rate	2.0%	0.6%
Contractual life of options (years)	10.0	10.0
Expected term of options (years)	6.3	6.1
Expected volatility of underlying stock	75.5%	85.7%
Expected dividend yield	0.0%	0.0%

The fair value of the shares assumed in the model correspond to the market price on the date of grant. The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option. Prior to April 1, 2022, the Company determined the expected volatility using a blended approach encompassing its historical experience and the historical volatility of a peer group of comparable publicly traded companies with product

candidates in similar stages of development to the Company's product candidates. From April 1, 2022 onward, the expected volatility is based on the annualized daily historical volatility of the Company's stock price for a time period consistent with the expected term of each grant. A simplified method using a weighted-average mid-point between an award's vesting date and expiry is used to estimate the expected life of options in all periods presented as a sufficient history of participant exercise behavior is not readily observable. The Company has applied an expected dividend yield of 0.0% as the Company has not historically declared a dividend and does not anticipate declaring a dividend during the expected life of the options.

#### *RSU Valuation*

The fair value of an RSU is determined by reference to the price of the underlying common share.

#### *Stock Option Activity*

The following is a summary of stock option activity for the years ended December 31, 2022 and 2021:

	2022		2021	
	Number of Options	Weighted Average Exercise Price per Share €	Number of Options	Weighted Average Exercise Price per Share €
Outstanding at January 1	3,984,467	16.23	3,748,911	12.65
Granted	2,002,978	21.90	1,522,210	19.69
Exercised	(102,691)	11.16	(1,104,029)	13.47
Forfeited or expired	(162,408)	19.83	(182,625)	17.29
Outstanding at December 31	<u>5,722,346</u>	19.10	<u>3,984,467</u>	16.23
Exercisable at December 31	2,773,633	16.37	1,841,578	13.78
Weighted-average remaining contractual life of options outstanding at December 31 (years)		7.5		7.4
Range of exercise prices of options outstanding at December 31:				
Minimum		€ 1.93		€ 1.93
Maximum		€ 28.98		€ 25.25
Weighted-average share price at the date of option exercises		€ 23.65		€ 21.70

#### *RSU Activity*

The following is a summary of RSU activity for the years ended December 31, 2022 and 2021:

	2022		2021	
	Number of RSUs	Weighted Average Grant-date Fair value €	Number of RSUs	Weighted Average Grant-date Fair value €
Unvested at January 1	10,000	21.62	59,775	14.77
Granted	35,000	20.76	24,976	19.59
Vested	(20,000)	21.84	(38,882)	15.25
Forfeited	—	0.00	(35,869)	14.89
Unvested at December 31	<u>25,000</u>	20.24	<u>10,000</u>	21.62



### ***Post-Employment Benefit Plan***

The Company has established a post-employment benefit plan for employees of the Netherlands that entitles executive officers and other staff members to retire at the age of 67 and receive annual payments based upon the average salary earned during the service period. The Company has insured the benefit liabilities through purchased non-participating annuities from an insurance company and has no other obligation other than to pay the annual insurance premiums to the insurance company. After purchasing the insurance, the Company has no further obligation (legal or constructive) to pay further amounts if the insurance fund has insufficient assets to pay all employee benefits relating to current and prior service. Contributions to purchase non-participating annuities are expensed as incurred as service costs. Company contributions to the post-employment benefit plan totaled €2.7 million and €2.5 million in the years ended December 31, 2022 and 2021, respectively.

### ***401(k) Savings Plan***

The Company has a defined contribution 401(k) savings plan (the “401(k) Plan”). The 401(k) Plan covers substantially all U.S. employees, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company matches contributions to the 401(k) Plan, matching 50% of an employee’s contribution up to a maximum of 3% of the participant’s compensation. Company contributions to the 401(k) Plan totaled €0.2 million and €0.1 million for the years ended December 31, 2022 and 2021, respectively.

### ***Executive Settlement***

In December 2019, in connection with the departure of the Chief Executive Officer of the Company, the Company awarded benefits, including the following: cash compensation of \$0.9 million, a grant of 30,000 RSUs, extended vesting of his equity incentive awards through June 30, 2021 and extended exercisability of his equity incentive awards through December 31, 2021. The cash compensation was paid by the Company in January 2020. There were no substantive service conditions associated with the benefits awarded other than the passage of time. The Company incrementally recognized \$1.8 million in general and administrative expense associated with these benefits in the consolidated statement of operations for the year ended December 31, 2019.

In April 2020, Mark Throsby, Ph.D. resigned as the Executive Vice President and Chief Scientific Officer of the Company effective July 31, 2020. In connection with his departure, Mr. Throsby entered into a Settlement Agreement with the Company, pursuant to which Mr. Throsby received a severance payment equal to 8 months of his annual salary and amortized bonus aggregating approximately \$0.3 million. Further, subject to Mr. Throsby’s continued compliance with the terms and conditions of the Settlement Agreement, Mr. Throsby’s unvested equity awards continued to vest until October 31, 2020 as if Mr. Throsby had continued in full time service with the Company through such date. The post-termination exercise period of Mr. Throsby’s options was extended to March 31, 2021. The Company incrementally recognized \$0.1 million in respect of the severance payment and a net reversal of \$0.4 million of stock-based compensation expense in respect of share-based payments in research and development expense in the consolidated statement of operations in the prior year.

In March 2021, the Company and Mr. Throsby amended the Settlement Agreement, extending the post-termination expiration period of his outstanding options to extend to October 31, 2021, three months following his performance of certain consulting services through July 31, 2021. As a result, additional compensation cost of \$0.2 million was recognized for the quarter ended March 31, 2021. During the three months ended September 30, 2021, the Company and Mr. Throsby entered into the 2nd Amendment to the Settlement Agreement, extending Mr. Throsby’s consulting services period to November 30, 2021. The 2nd Amendment extends the post-termination expiration period of his outstanding options to February 28, 2022. As the modification occurred in Mr. Throsby’s post-employment period, the options cease to be within the scope of IFRS 2 and are recharacterized as an issuance of a standalone derivative instrument. The Company recognized a \$1.0 million net loss associated with the derivative instrument included as other losses, net in the statement of operations for the year ended December 31, 2021. The Company recognized a \$1.0 million or €0.9 million net

gain associated with the derivative instrument included as other income in the statement of operations during the year ended December 31, 2022.

### 15. Net Finance Income (Costs)

The components of net finance income (costs) are as follows:

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>(In euro thousands)</b>		
<b>Finance income</b>		
Interest and similar related income	3,657	120
Net gain from foreign exchange	24,325	20,991
<b>Total finance income</b>	<b>27,982</b>	<b>21,111</b>
<b>Finance costs</b>		
Interest expense	(567)	(1,366)
Net loss from foreign exchange	—	—
<b>Total finance costs</b>	<b>(567)</b>	<b>(1,366)</b>
<b>Net finance income (costs)</b>	<b>27,415</b>	<b>19,745</b>
<b>Deferred foreign</b>		
<b>Other income</b>		
Litigation settlement gain	—	—
Miscellaneous income	—	—
<b>Total other income</b>	<b>—</b>	<b>—</b>

### 16. Supplemental Cash Flow Information

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>(In euro thousands)</b>		
<b>CASH AND CASH EQUIVALENTS</b>		
Bank deposits and similar instruments	121,268	208,151
Money market funds and other	17,255	5,018
	<b>138,523</b>	<b>213,169</b>
<b>CHANGES IN WORKING CAPITAL:</b>		
Trade receivables	1,772	(4,209)
Prepaid expenses and other current assets	(7,002)	(912)
Trade payables	(3,793)	9,037
Accrued expenses and other liabilities	15,144	2,317
Deferred revenue	(25,158)	7,832
<b>Total changes in working capital</b>	<b>(19,037)</b>	<b>14,065</b>
<b>NON-CASH TRANSACTIONS:</b>		
Lease obligations recognized upon commencement of an operating lease	11,275	1,812
Property, equipment and intangibles included in accounts payable or accruals	2,050	—
Financing costs included in accounts payable or accruals	—	—

## 17. Loss per Share

The calculation of basic and diluted loss per share has been based on the loss attributable to common shareholders and weighted-average number of ordinary shares outstanding.

Basic and diluted loss per share allocable to common shareholders are computed as follows:

	<b>Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands except per share data)</b>	
Result after taxation	(125,461)	(56,723)
Weighted average shares outstanding	44,919,084	38,638,434
Basic and diluted loss per share allocable to common stockholders	<u>(2.79)</u>	<u>(1.47)</u>

## 18. Related Party Transactions

### *Key Management Compensation*

Key management personnel, including those who are also directors, received the following employee benefits included in amounts charged to the consolidated statement of profit or loss and comprehensive loss, and information on stock-based compensation awards:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Short-term employee benefits	5,416	3,661
Post-employment benefits	31	16
Share-based compensation	11,463	8,474
Total	<u>16,910</u>	<u>12,151</u>
	<b>As of December 31,</b>	
	<b>2022</b>	<b>2021</b>
Outstanding stock options held by key management personnel	3,074,819	2,134,524
Weighted average exercise price	€ 18.82	€ 15.87
Unvested RSUs	—	—

Dutch disclosure regulations require the disclosure of compensation of each individual director. The Company's CEO who is a member of key management is also a director. For years ended 2022 and 2021, Sven Ante Lundberg served as a director as well as the CEO.

The following are details of his compensation which is also included in the above disclosure for key management personnel:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Short-term employee benefits	919	982
Post-employment benefits	9	9
Share-based compensation	4,351	4,109
<b>Total</b>	<b>5,279</b>	<b>5,100</b>

	<b>As of December 31,</b>	
	<b>2022</b>	<b>2021</b>
Outstanding stock options held by director	1,005,917	710,917
Weighted average exercise price	€ 19.46€	16.92
Unvested RSUs	—	—

Dutch regulations also require disclosure of amounts relating to a former director's equity compensation. Ton Logtenberg served as a director as well as the CEO through December 31, 2019. As of December 31, 2022, there were no stock options or unvested RSUs held by the former CEO.

#### *Director Compensation*

Directors, excluding those who are also key management personnel, received the following compensation included in amounts charged to the consolidated statement of profit or loss and comprehensive loss:

	<b>2022</b>		<b>2021</b>	
	<b>Cash Compensation (In euro thousands)</b>	<b>Stock-based Compensation (In euro thousands)</b>	<b>Cash Compensation (In euro thousands)</b>	<b>Stock-based Compensation (In euro thousands)</b>
Maxine Gowen	53	443	32	178
Russell Greig (former)	—	4	—	27
Mark Iwicki	58	255	49	147
Len Kanavy	49	428	42	25
John de Koning (former)	—	20	—	45
Anand Mehra	114	172	99	45
Gregory Perry	62	255	52	147
Paolo Pucci	53	283	45	227
Victor Sandor	53	172	45	55
<b>Total</b>	<b>442</b>	<b>2,032</b>	<b>364</b>	<b>896</b>

As at December 31, 2022, the following stock options held by directors who are not key management personnel were outstanding:

	2022		2021	
	Number	Weighted Average Exercise Price €	Number	Weighted Average Exercise Price €
Wolfgang Berthold (former)	18,150	19.22	18,150	18.10
Maxine Gowen	36,801	17.09	20,197	15.86
Mark Iwicki	124,064	10.80	107,460	9.48
Len Kanavy	61,673	16.69	45,069	15.47
Anand Mehra	67,488	15.07	50,884	13.48
Gregory Perry	67,488	15.07	50,884	13.48
Paolo Pucci	39,986	16.77	23,382	15.38
Victor Sandor	48,355	15.92	31,751	14.26
Total and weighted average, respectively	<u>464,005</u>	<u>14.70</u>	<u>347,777</u>	<u>13.08</u>

## 19. Financial Instruments

### *Financial Risk Management*

The Company is exposed to a variety of financial risks: credit risk, liquidity risk and market risk. The Company's overall risk management program seeks to minimize potential adverse effects of these financial risk factors on the Company's financial performance. Management is primarily responsible for the overall risk management approach and for the approval of risk strategies and principles of the Company. The Company's Audit Committee oversees these risk management activities. The Company's management reviews and approves policies for managing each of these risks which are summarized below.

### *Credit Risk*

Credit risk is the risk of financial loss to the Company if a customer or counterparty to a financial instrument fails to meet its contractual obligations and arises principally from the Company's receivables from its collaborators and investments in debt securities and financial institutions. The Company's principal financial assets are held-to-maturity investments, trade receivables, unbilled receivables and cash and cash equivalents that are derived primarily from financing activities and, to a lesser extent, from its operations. The main purpose of these financial assets is to support the Company's operations which consist primarily of research and development, preclinical and clinical development and related manufacturing in support of the Company's preclinical and clinical development programs.

The carrying amount of financial assets represents the maximum credit exposure.

	December 31,	
	2022	2021
	<b>(In euros thousands)</b>	
Cash and cash equivalents	138,523	213,169
Current investments	133,583	149,205
Non-current investments	34,181	17,921
Trade receivables	3,798	5,570
Total	<u>310,085</u>	<u>385,865</u>

Cash and cash equivalents include deposits and investments held with financial institutions with original maturities of less than three months. Investments include commercial paper, securities issued

by several public corporations and the U.S. Treasury with a maturity date of greater than three months at the date of settlement. Cash and cash equivalents are held at banks and financial institutions with credit ratings varying between A and AAA, while investments are in highly rated vehicles with identical credit ratings.

The aging of trade and unbilled receivables was as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euros thousands)</b>	
Neither past due or impaired	3,798	5,570
Past due	—	—
<b>Total fees</b>	<b>3,798</b>	<b>5,570</b>

There is no allowance for impairment relating to trade and unbilled receivables, investments and cash and cash equivalents.

#### *Liquidity Risk*

Liquidity risk is the risk that the Company will not be able to meet its financial obligations as they become due. The Company's core objective is to maintain a balance between continuity of funding and flexibility through the monitoring of cash flows at varying levels to ensure that it has sufficient cash on demand to meet expected operational expenses.

The following are the remaining contractual maturities of financial liabilities as at December 31, 2022 and 2021. The amounts are gross and undiscounted.

	<b>Year Ended December 31, 2022</b>				
	<b>(In euros thousands)</b>				
<b>Carrying amount</b>	<b>&lt; 1 year</b>	<b>1 - 2 years</b>	<b>2 - 5 years</b>	<b>&gt; 5 years</b>	
Trade payables	9,220	9,220	—	—	—
Accrued liabilities	33,368	33,368	—	—	—
Lease liabilities	12,860	1,642	3,298	2,439	5,481
	<u>55,448</u>	<u>44,230</u>	<u>3,298</u>	<u>2,439</u>	<u>5,481</u>

	<b>Year Ended December 31, 2021</b>				
	<b>(In euros thousands)</b>				
<b>Carrying amount</b>	<b>&lt; 1 year</b>	<b>1 - 2 years</b>	<b>2 - 5 years</b>	<b>&gt; 5 years</b>	
Trade payables	11,686	11,686	—	—	—
Accrued liabilities	19,871	19,871	—	—	—
Lease liabilities	4,116	1,801	1,464	851	—
	<u>35,673</u>	<u>33,358</u>	<u>1,464</u>	<u>851</u>	<u>—</u>

#### *Market Risk*

Market risk is the risk that changes in market prices, such as foreign exchange rates and interest rates, will affect the Company's income or the value of its holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return. The Company's market risk relates to foreign exchange and to a lesser extent, interest risks.

#### *Foreign Currency Risk*

Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies. With respect to monetary assets and liabilities denominated in foreign currencies, the Company's primary currency exposure is impacted by monetary assets and liabilities denominated in U.S. dollars. Changes in sensitivity rates reflect various changes in the economy year-over-year. The following table provides a sensitivity analysis for a change in the primary currency exposure for the Company relating to monetary assets and liabilities denominated in U.S. dollars as of December 31, 2022.

The analysis shows the impact that a change in the exchange rate at that date would have on the Company's consolidated pre-tax result and equity:

<b>December 31, 2022</b>			
<b>(In euros thousands)</b>			
<b>Financial Statement Line Item Exposure</b>	<b>Balance</b>	<b>Effect on result before taxation if the U.S. dollar strengthens 5%</b>	<b>Effect on result before taxation if the U.S. dollar weakens 5%</b>
Other assets	181	9	(9)
Trade receivables	2,621	131	(131)
Investments	167,764	8,388	(8,388)
Cash and cash equivalents	44,519	2,226	(2,226)
Trade payables	(2,927)	(146)	146
Accrued liabilities	(16,064)	(803)	803
Balance at December 31, 2022	<u>196,094</u>	<u>9,805</u>	<u>(9,805)</u>

<b>December 31, 2021</b>			
<b>(In euros thousands)</b>			
<b>Financial Statement Line Item Exposure</b>	<b>Balance</b>	<b>Effect on result before taxation if the U.S. dollar strengthens 5%</b>	<b>Effect on result before taxation if the U.S. dollar weakens 5%</b>
Other assets	75	4	(4)
Trade receivables	3,689	184	(184)
Investments	167,126	8,356	(8,356)
Cash and cash equivalents	91,968	4,598	(4,598)
Trade payables	(644)	(32)	32
Accrued liabilities	(10,301)	(515)	515
Balance at December 31, 2021	<u>251,913</u>	<u>12,595</u>	<u>(12,595)</u>

The closing exchange rate per the European Central Bank utilized above for converting the euro to U.S. dollars at December 31, 2022 was 1.0666 and at December 31, 2021 was 1.1326.

#### *Interest Rate Risk*

The interest rate profile of the Company's interest-bearing financial instruments is as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euros thousands)</b>	
Variable rate instruments		
Cash and cash equivalents	138,523	213,169
Fixed rate instruments		
Current investments	133,583	149,205
Non-current investments	34,181	17,921

The company's exposure to interest rate sensitivity is impacted by changes in the underlying U.S. bank interest rates. The Company has not entered into investments for trading or speculative purposes. Due to the conservative nature of the investment portfolio, which is predicated on capital preservation of investments and to provide liquidity to accommodate operational and capital needs and due to the short remaining hold period for the Company's investments, the Company does not believe an immediate one percentage point change in interest rates would have a material effect. Therefore, no sensitivity data is provided. The weighted average remaining days to maturity for the Company's investment portfolio is 201 days as of December 31, 2022.

#### *Accounting Classifications and Fair Values*

The classifications of the Company's financial assets and financial liabilities, all of which are not measure at fair value, are disclosed in the tables above. The fair value of the financial assets and financial liabilities not measured at fair value is not disclosed, as the carrying amount of the financial assets and financial liabilities is a reasonable approximation of the fair value. Accordingly, information on the fair value hierarchy is omitted.

## **20. Employees**

The number of personnel for the year was as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Netherlands	174	141
United States	45	23
Total full-time equivalent employees	<u>219</u>	<u>164</u>

For information on the remuneration of the board and the company's share-based compensation plans, see Notes 14 and 18 to the consolidated financial statements.

## **21. Subsequent Events**

In January 2023, the Company recognized a \$2.5 million or €2.3 million milestone from Incyte related to the initiation of a Phase I study. The milestone payment was received in February 2023.



## **10.2 Company Financial Statements**

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**MERUS N.V.**  
**SEPARATE STATEMENT OF FINANCIAL POSITION**  
(All amounts in euro thousands)

	Note	As at December 31,	
		2022	2021
<b>Non-current assets</b>			
Financial fixed asset	3	5,275	2,994
Property and equipment	4	11,389	3,021
Intangible assets	5	1,829	2,073
Right-of-use assets	7	10,600	1,521
Other assets	6	4,323	1,628
		<u>33,416</u>	<u>11,237</u>
<b>Current assets</b>			
Trade receivables	6	3,798	5,570
Investments	6	78,511	83,682
Other assets	6	184,357	203,173
Cash and cash equivalents		46,595	95,823
		<u>313,261</u>	<u>388,248</u>
<b>Total assets</b>		<u>346,677</u>	<u>399,485</u>
<b>Shareholders' equity</b>			
	10		
Issued and paid-in capital		4,168	3,912
Share premium account		655,849	600,213
Legal reserves		299	174
Accumulated loss		(428,266)	(325,377)
Total shareholders' equity		<u>232,050</u>	<u>278,922</u>
<b>Non-current liabilities</b>			
Lease liabilities	7	9,690	329
Deferred revenue	9	36,353	58,490
		<u>46,043</u>	<u>58,819</u>
<b>Current liabilities</b>			
Trade payables		9,164	11,630
Accrued expenses and other liabilities	8	30,778	18,221
Lease liabilities	7	1,061	1,292
Deferred revenue	9	27,581	30,601
		<u>68,584</u>	<u>61,744</u>
<b>Total liabilities</b>		<u>114,627</u>	<u>120,563</u>
<b>Total shareholders' equity and liabilities</b>		<u>346,677</u>	<u>399,485</u>

*After appropriation of the result for the year.*

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

**MERUS N.V.**

**SEPARATE STATEMENT OF PROFIT OR LOSS AND COMPREHENSIVE LOSS**

(All amounts in euro thousands except per share data)

	Note	<b>Year ended December 31,</b>	
		<b>2022</b>	<b>2021</b>
Collaboration revenue	11	21,749	31,587
Research and development costs	12	(132,599)	(78,674)
General and administrative costs	12	(30,669)	(22,173)
<b>Total operating expenses</b>		<b>(163,268)</b>	<b>(100,847)</b>
<b>Operating result</b>		<b>(141,519)</b>	<b>(69,260)</b>
Finance income	14	26,614	21,481
Finance cost	14	(458)	(1,249)
<b>Net finance income (costs)</b>	14	<b>26,156</b>	<b>20,232</b>
Result on subsidiary	3	(9,973)	(7,489)
<b>Result before taxation</b>		<b>(125,336)</b>	<b>(56,517)</b>
Tax expense		—	—
<b>Result after taxation and comprehensive loss</b>		<b>(125,336)</b>	<b>(56,517)</b>

*The results for the year and the comprehensive loss for the year are fully attributable to the owners of Merus N.V.*

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

**MERUS N.V.**  
**NOTES TO THE SEPARATE FINANCIAL STATEMENTS**

## **1. Significant Accounting Policies**

### ***Basis of Preparation***

Merus N.V.'s separate financial statements have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code on an unconsolidated basis of the entity as a standalone entity. In accordance with subsection 8 of section 362, Book 2 of the Dutch Civil Code, the recognition and measurement principles applied in these separate financial statements are the same as those applied in the consolidated financial statements (see Note 2 to the consolidated financial statements).

For a description of the impact of the adoption of new accounting standards on the separate financial statements, see Note 2 to the consolidated financial statements.

### ***Share-based Compensation***

The share-based compensation awarded to employees of the Company's subsidiary, including the excess, is treated by the parent company as an adjustment of the capital contribution to the subsidiary company.

### ***Investments in Subsidiaries***

Investments in subsidiaries are accounted for in the separate financial statements according to the equity method. The share in the result of investments in subsidiaries consists of the share of the Company in the result of these subsidiaries. Currency translation differences are directly recognized in the legal reserve within equity.

### ***Additional Information***

For 'Additional information' within the meaning of Section 2:392 of the Dutch Civil Code (DCC), refer to the section entitled *Other Information*, of this report.

## **2. Employees**

The number of personnel for the year was as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
Netherlands	174	141
Total full-time equivalent employees	174	141

For information on the remuneration of the board and the company's share-based compensation plans, see Notes 14 and 18 to the consolidated financial statements.

## **3. Financial Fixed Assets**

### ***Subsidiaries***

Merus N.V. has a 100% subsidiary in Merus US, Inc., which was founded on March 1, 2016.

	<b>For the year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>(In euro thousands)</b>		
Balance as at January 1	2,994	2,026
Result on subsidiary	(9,973)	(7,489)
Capital contribution for stock-based compensation awarded to employees of the investee	12,129	8,252
Exchange differences	125	205
Balance as at December 31	<u>5,275</u>	<u>2,994</u>
Equity of Merus US, Inc. as at December 31	5,275	2,994

#### 4. Property and Equipment

Movements in property and equipment were as follows:

<b>For the Year Ended December 31, 2022</b>					
<b>(In euro thousands)</b>					
<b>Cost</b>	<b>Office Furniture</b>				<b>Total</b>
	<b>Laboratory Equipment</b>	<b>&amp; Equipment</b>	<b>Leasehold Improvements</b>	<b>Assets Under Construction</b>	
Balance at January 1, 2022	4,930	871	62	933	6,796
Additions	1,023	664	7,642	—	9,329
Transfers between categories	—	—	863	(863)	—
Disposals	—	—	(62)	—	(62)
Balance at December 31, 2022	<u>5,953</u>	<u>1,535</u>	<u>8,505</u>	<u>70</u>	<u>16,063</u>
<b>Accumulated Depreciation</b>	<b>Office Furniture</b>				<b>Total</b>
	<b>Laboratory Equipment</b>	<b>&amp; Equipment</b>	<b>Leasehold Improvements</b>	<b>Assets Under Construction</b>	
Balance at January 1, 2022	(3,086)	(658)	(31)	—	(3,775)
Depreciation	(829)	(101)	(14)	—	(944)
Disposals	—	—	45	—	45
Balance at December 31, 2022	<u>(3,915)</u>	<u>(759)</u>	<u>—</u>	<u>—</u>	<u>(4,674)</u>
Carrying amount at December 31, 2022	<u>2,038</u>	<u>776</u>	<u>8,505</u>	<u>70</u>	<u>11,389</u>

**For the Year Ended December 31, 2021**

(In euro thousands)

Cost	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Assets Under Construction	Total
Balance at January 1, 2021	4,641	868	62	404	5,975
Additions	298	3	—	529	830
Disposals	(9)	—	—	—	(9)
Balance at December 31, 2021	<u>4,930</u>	<u>871</u>	<u>62</u>	<u>933</u>	<u>6,796</u>

Accumulated Depreciation	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Assets Under Construction	Total
Balance at January 1, 2021	(2,227)	(525)	(19)	—	(2,771)
Depreciation	(868)	(133)	(12)	—	(1,013)
Disposals	9	—	—	—	9
Balance at December 31, 2021	<u>(3,086)</u>	<u>(658)</u>	<u>(31)</u>	<u>—</u>	<u>(3,775)</u>
Carrying amount at December 31, 2021	<u>1,844</u>	<u>213</u>	<u>31</u>	<u>933</u>	<u>3,021</u>

Assets under Construction primarily relates to certain ongoing development and construction costs related to the office lease the Company entered into with Kadans Science Partner XII B.V. that was capitalized during 2022. Property and equipment are primarily located in the Netherlands for all periods presented.

## 5. Intangible Assets

Please refer to Note 4 of the consolidated financial statements for a detailed disclosure on the intangible assets.

## 6. Financial Assets

### *Investments (Non-current and Current)*

Please refer to Note 7 of the consolidated financial statements for a detailed disclosure on investments.

### *Trade Receivables*

All trade and other receivables are short-term and due within 1 year. Please refer to Note 12 of the consolidated financial statements for a detailed disclosure on trade receivables.

## Other Assets

The components of non-current and current other assets are as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euros thousands)</b>	
<b>Non-current</b>		
Prepaid clinical and manufacturing costs	3,329	1,242
Deposits	22	286
Restricted cash	459	100
Other	513	
<b>Total non-current other assets</b>	<b>4,323</b>	<b>1,628</b>
<b>Current</b>		
Prepaid clinical and manufacturing costs	5,974	1,895
Prepaid general and administrative costs	2,528	2,366
VAT receivable, net	1,575	724
Interest receivable	181	75
Due from subsidiary - Merus US, Inc.	173,725	197,104
Other	374	1,009
<b>Total current other assets</b>	<b>184,357</b>	<b>203,173</b>

Other assets that are financial assets include deposits, the amount due from subsidiary, and interest receivable. Amounts due from subsidiary are unsecured and due on demand.

## 7. Leases

Please refer to Note 5 to the consolidated financial statements for further information on leases concerning Merus N.V.

Movements in right-of-use assets were as follows:

	<b>For the Year</b>	
	<b>Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Opening balance January 1	1,521	837
Additions to right-of-use assets	11,275	1,812
Modification	(200)	—
Depreciation	(1,996)	(1,128)
<b>Closing balance December 31</b>	<b>10,600</b>	<b>1,521</b>

The schedule of lease payments and balance of lease liabilities as of December 31, 2022 was as follows:

Year	Payments (In euro thousands)
2023	1,544
2024	1,414
2025	1,414
2026	1,414
2027	1,414
Thereafter	6,030
Total lease payments	13,230
Less: amount representing interest	(2,479)
Total lease liabilities	10,751
Current lease liabilities	1,061
Non-current lease liabilities	9,690
Total lease liabilities	10,751

Amounts recognized in operating loss and cash flows were as follows:

	For the Year Ended December 31,	
	2022	2021
	(In euro thousands)	
Variable lease payments not included in the measurement of lease liabilities	337	361
Interest on lease liabilities	419	49
Expense from low-value leases	54	42
Cash outflow for leases	1,946	1,181

## 8. Accrued Liabilities

All amounts are short-term and payable within 1 year. The components of accrued liabilities are as follows:

	December 31,	
	2022	2021
	(In euro thousands)	
Accrued research and development expenses	24,526	13,398
Accrued personnel costs	3,031	2,748
Due to subsidiary - Merus US, Inc.	—	—
Accrued general and administrative expenses	3,214	1,096
Other	7	979
Accrued expenses and other liabilities	30,778	18,221

## 9. Deferred Revenue

Please refer to Note 12 to the consolidated financial statements for further information on deferred revenue.

## 10. Shareholders' Equity

The legal reserve as of December 31, 2022 relates to accumulated foreign exchange differences on the Company's subsidiary.



It is proposed that the loss for the year ended December 31, 2022, of €125.3 million is charged to the accumulated deficit. In anticipation of the decision to be taken by the general meeting of shareholders, this proposal has already been reflected in the statement of financial position.

Please refer to Note 9 to the consolidated financial statements for further information on equity.

### 11. Collaboration Revenue

Please refer to Note 12 to the consolidated financial statements for further information on collaboration revenue.

### 12. Operating Expenses

Operating expenses presented by nature are outlined below:

	Note	Year Ended December 31,	
		2022	2021
(In euro thousands)			
<b>Research and development costs</b>			
External costs		55,760	35,586
Manufacturing		48,074	27,379
Wages, salaries and other employee benefits		10,178	4,910
Share-based payments	13	6,548	4,174
Depreciation and amortization	4,5,7	2,614	1,934
Other		9,425	4,691
<b>Total research and development costs</b>		<b>132,599</b>	<b>78,674</b>
<b>General and administrative costs</b>			
Share-based payments	13	3,894	2,260
Wages, salaries and other employee benefits		5,693	5,202
Consulting		7,016	3,073
Legal fees		3,478	2,770
Accounting and professional fees		5,837	4,684
Depreciation and amortization	4,5,7	620	451
Other		4,131	3,733
<b>Total general and administrative costs</b>		<b>30,669</b>	<b>22,173</b>

### 13. Employee Benefits

Refer to Note 14 to the consolidated financial statements for a detailed explanation on the share-based compensation expense for the Company.

#### 14. Net Finance Income (Costs)

The following table presents a breakdown of net finance income (costs):

	Year Ended December 31,	
	2022	2021
	(In euro thousands)	
<b>Finance income</b>		
Interest and similar related income	2,314	87
Financial investment exchange differences	125	206
Net gain from foreign exchange	24,175	21,188
<b>Total finance income</b>	<b>26,614</b>	<b>21,481</b>
<b>Finance costs</b>		
Net loss from foreign exchange	—	—
Financial investment exchange differences	—	—
Interest expense	(458)	(1,249)
<b>Total finance costs</b>	<b>(458)</b>	<b>(1,249)</b>
<b>Net finance income (costs)</b>	<b>26,156</b>	<b>20,232</b>

#### 15. Taxation

After consideration of all positive and negative evidence, the Company believes that it is probable that the Netherlands deferred tax assets that are not supported by reversing temporary differences will not be realized. As a result, deferred tax assets and liabilities associated with the Netherlands have not been recognized.

The Company had net operating loss carryforwards for Dutch income tax purposes of €402.3 million and €268.8 million as of December 31, 2022, and 2021, respectively. Tax losses and deductible temporary differences were €34.3 million and €6.6 million for the year ended December 31, 2022 respectively. Under Dutch tax law, net operating loss carryforwards may be used to offset future taxable income in full up to €1.0 million and 50% of taxable income that exceeds €1.0 million. Effective as of January 1, 2022, these losses can be carried forward indefinitely.

Other deductible temporary differences, which primarily relates to deferred revenue, amounted to €69.5 million and €88.2 million at December 31, 2022 and 2021, respectively.

#### 16. Financial Instruments

Refer to Note 19 to the consolidated financial statements for further information on financial risk management.

##### *Credit Risk*

Refer to Note 19 to the consolidated financial statements for further information on credit risk.

The carrying amount of financial assets represents the maximum credit exposure as follows:

	December 31,	
	2022	2021
	(In euros thousands)	
Cash and cash equivalents	46,595	95,823
Current investments	78,511	83,682
Trade receivables	3,798	5,570
<b>Total</b>	<b>128,904</b>	<b>173,445</b>

The table above does not include intercompany receivables as Merus US, Inc operates as service provider for Merus N.V. on a cost-plus basis and as such any receivable balance is only due to timing in cash flows. Since Merus US, Inc. is fully funded by Merus N.V., then Merus N.V. is not exposed to any credit risk as long as it is able to fund Merus US, Inc operations.

Refer to Note 19 to the consolidated financial statements for further information the Company's exposure to credit risk, and the aging of trade receivables. There is no allowance for impairment.

#### *Liquidity Risk*

Refer to Note 19 to the consolidated financial statements for further information on liquidity risk.

The following are the remaining contractual maturities of financial liabilities at the reporting date. The amounts are gross and undiscounted, and include estimated interest payments and excluding the impact of netting agreements:

	<b>Year Ended December 31, 2022</b>				
	<b>(In euros thousands)</b>				
<b>Carrying amount</b>	<b>&lt; 1 year</b>	<b>1 - 2 years</b>	<b>3 - 5 years</b>	<b>&gt; 5 years</b>	
Trade payables	9,164	9,164	—	—	—
Accrued expenses and other liabilities	30,778	30,778	—	—	—
Lease liabilities	10,751	1,061	2,003	2,206	5,481
	<b>50,693</b>	<b>41,003</b>	<b>2,003</b>	<b>2,206</b>	<b>5,481</b>

	<b>Year Ended December 31, 2021</b>				
	<b>(In euros thousands)</b>				
<b>Carrying amount</b>	<b>&lt; 1 year</b>	<b>1 - 2 years</b>	<b>2 - 5 years</b>	<b>&gt; 5 years</b>	
Trade payables	11,630	11,630	—	—	—
Accrued expenses and other liabilities	18,221	18,221	—	—	—
Lease liabilities	1,621	1,292	329	—	—
	<b>31,472</b>	<b>31,143</b>	<b>329</b>	<b>—</b>	<b>—</b>

#### *Market Risk*

Refer to Note 19 to the consolidated financial statements for further information on market risk. Refer to Note 19 to the consolidated financial statements for further information the Company's exposure to foreign currency risk.

Exposure to interest rate risk: The interest rate profile of the Company's interest-bearing financial instruments is as follows:

	<b>December 31,</b>	
	<b>2022</b>	<b>2021</b>
<b>(In euros thousands)</b>		
Variable rate instruments		
Cash and cash equivalents	46,595	95,823
Fixed rate instruments		
Current investments	78,511	83,682

Due to the limited impact of changes in interest rates on the Company no sensitivity data is provided.

#### *Accounting Classifications and Fair Values*

Refer to Note 19 to the consolidated financial statements for further information on classification and measurement of financial instruments.

### 17. Related Party Disclosures

Key management personnel of the subsidiary company, including those who are also directors, received the following employee benefits included in amounts charged to the consolidated statement of profit or loss and comprehensive loss, and information on stock-based compensation awards:

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>(In euro thousands)</b>	
Short-term employee benefits	1,771	1,767
Post-employment benefits	—	14
Share-based compensation	3,262	2,339
<b>Total</b>	<b>5,033</b>	<b>4,120</b>
	<b>As of December 31,</b>	
	<b>2022</b>	<b>2021</b>
Outstanding stock options held by key management personnel	956,861	777,866
Weighted average exercise price	€ 18.79€	15.69
Unvested RSUs	—	—

The cash compensation to directors disclosed fully consists of amounts of periodically paid remuneration.

Refer to Note 18 to the consolidated financial statements for further information on the consolidated directors and key management personnel compensation, and Note 10 concerning indemnifications of officers and directors.

In addition, Merus US, Inc. is a related party as the Company's subsidiary. Refer to Note 6 concerning amounts due from Merus US, Inc. as of the end of each period and Note 3 concerning the investment in the subsidiary. Merus N.V. is a guarantor of the lease for Merus US, Inc. as described in Note 5 of the consolidated financial statements.

### 18. Audit Fees

Audit fees incurred are charges for the services provided by KPMG Accountants N.V., our independent registered public accounting firm. Audit fees consist of fees charged for the audit of our annual consolidated and separate financial statements and the review of the interim consolidated financial statements, and related services, performed related to each reporting period by the external auditor. Audits fees were €1.2 million and €1.2 million for the years ended December 31, 2022 and 2021, respectively. We did not incur any non-audit related fees or tax fees in any of the periods presented in these financial statements.

The fees disclosed for the audit of the financial statements (and other audit engagements) are related to the work performed during the reporting period by the external auditor.

### 19. Subsequent Events

Refer to Note 21 to the consolidated financial statements for further information on subsequent events. There are no other matters occurring subsequent to December 31, 2022 requiring disclosure through the date these separate financial statements were authorized for issuance by the board of directors on May 8, 2023.

## 11 OTHER INFORMATION

### 11.1 Independent Auditor's Report



# Independent auditor's report

To: the General Meeting of Shareholders and the Audit Committee of Merus N.V.

## **Report on the audit of the financial statements 2022 included in the Dutch statutory board report and financial statements**

### *Our opinion*

In our opinion:

- the accompanying consolidated financial statements give a true and fair view of the financial position of Merus N.V. as at December 31, 2022 and of its result and its cash flows for the year then ended, in accordance with International Financial Reporting Standards as adopted by the European Union (EU-IFRS) and with Part 9 of Book 2 of the Dutch Civil Code.
- the accompanying company financial statements give a true and fair view of the financial position of Merus N.V. as at December 31, 2022 and of its result for the year then ended in accordance with Part 9 of Book 2 of the Dutch Civil Code.

### *What we have audited*

We have audited the financial statements 2022 of Merus N.V. (the Company) based in Utrecht, the Netherlands. The financial statements include the consolidated financial statements and the company financial statements.

The consolidated financial statements comprise:

- 1 the consolidated statement of financial position as at December 31, 2022;
- 2 the following consolidated statements for 2022: profit or loss and comprehensive loss, changes in equity and cash flows; and
- 3 the notes comprising a summary of the significant accounting policies and other explanatory information.

The company financial statements comprise:

- 1 the separate statement of financial position as at December 31, 2022;
- 2 the separate statement of profit or loss and comprehensive loss for 2022; and
- 3 the notes comprising a summary of the accounting policies and other explanatory information.

## Basis for our opinion

We conducted our audit in accordance with Dutch law, including the Dutch Standards on Auditing. Our responsibilities under those standards are further described in the ‘Our responsibilities for the audit of the financial statements’ section of our report.

We are independent of Merus N.V. in accordance with the ‘Verordening inzake de onafhankelijkheid van accountants bij assurance-opdrachten’ (ViO, Code of Ethics for Professional Accountants, a regulation with respect to independence) and other relevant independence regulations in the Netherlands. Furthermore, we have complied with the ‘Verordening gedrags- en beroepsregels accountants’ (VGBA, Dutch Code of Ethics).

We designed our audit procedures in the context of our audit of the financial statements as a whole and in forming our opinion thereon. The information in respect of going concern, fraud and non-compliance with laws and regulations, and the key audit matter was addressed in this context, and we do not provide a separate opinion or conclusion on these matters.

## Audit approach

### Summary

#### Materiality

- Materiality of EUR 5.1 million
- 4.1% of the result before taxation

#### Group audit

- Full scope audit of all group entities

#### Going concern and Fraud/Non Compliance with Law and Regulations

- Going concern: no significant going concern risks identified
- Fraud & Non-compliance with laws and regulations (Noclar): the presumed fraud risk of management override of controls was incorporated in our audit and no other risk of fraud & non-compliance with laws and regulations was identified

#### Key audit matters

- Accounting for research and development costs

#### Opinion

Unqualified

## Materiality

Based on our professional judgement we determined the materiality for the financial statements as a whole at EUR 5.1 million (2021: EUR 3.6 million). The increase in materiality is consistent with the increase in research and development activities during the year. The materiality is determined with reference to result before taxation (4.1%). We consider the result before taxation, as the most appropriate benchmark because this best reflects the nature of the entity being in the pre-clinical and clinical development phase, including both operational expenses as well as revenue from collaboration agreements. We have also taken into account misstatements and/or

possible misstatements that in our opinion are material to the users of the financial statements for qualitative reasons.

We agreed with the Audit Committee and the Board of Directors that misstatements identified during our audit in excess of EUR 255 thousand would be reported to them, as well as smaller misstatements that in our view must be reported on qualitative grounds.

### **Scope of the group audit**

Merus N.V. is at the head of a group of components. The group consists of two entities: Merus N.V. and Merus US, Inc. The financial information of this group is included in the consolidated financial statements of Merus N.V.

Our group audit focused on both Merus N.V. and Merus US, Inc. for which we performed a full scope audit. We were able to perform all audit procedures for these entities ourselves.

By performing the procedures mentioned above, we have been able to obtain sufficient and appropriate audit evidence about the group's financial information to provide an opinion about the financial statements.

### **Audit response to going concern – no significant going concern risks identified**

The Board of Directors has performed its going concern assessment and has not identified any significant going concern risks as disclosed in Note 1 (The Company) of the consolidated financial statements. To assess the assessment of the Board of Directors, we have performed, inter alia, the following procedures:

- we considered whether the assessment of the going concern risks included all relevant information of which we are aware as a result of our audit;
- we analysed the Company's financial position as at year-end, and compared it to the previous financial year in terms of indicators that could identify going concern risks;
- we analysed the current financials year's operating loss and the related cash outflows compared to the previous financial year, management's forecasted long range plan and cash runway, and any information of which we are aware as a result of our audit; and
- we evaluated the company's disclosure on cash runway as included in Note 1 of the disclosures of the Company.

The outcome of our risk assessment procedures did not give reason to perform additional audit procedures on management's going concern assessment.

### **Audit response to the risk of fraud and non-compliance with laws and regulations**

In chapters "Risk Management and Control Systems", "Corporate Governance", and "Corporate Values and Code of Business Conduct and Ethics" of the Dutch statutory board report, the Board of Directors describes its responsibilities and conclusions on procedures in respect of the risk of fraud and non-compliance with laws and regulations.

As part of our audit, we have gained insights into the Company and its business environment, and assessed, where considered appropriate, the design and implementation and tested the operating effectiveness of the Company's risk

management in relation to fraud and non-compliance.

Our procedures included, among other things, assessing the Company's code of conduct, whistleblowing procedures and its procedures to investigate indications of possible fraud and non-compliance. Furthermore, we performed relevant inquiries with management, those charged with governance and Legal Counsel. As part of our audit procedures, we:

- obtained an understanding of how the company uses information technology (IT) and the impact of IT on the financial statements, including the potential for cybersecurity incidents to have a material impact on the financial statements;
- assessed other positions held by management and other employees and paid special attention to procedures and governance/compliance in view of possible conflicts of interest;
- evaluated investigation reports, if any, on indications of possible fraud and non-compliance; and
- evaluated correspondence, if any, with supervisory authorities and regulators as well as legal confirmation letters.

In addition, we performed procedures to obtain an understanding of the legal and regulatory frameworks that are applicable to the Company and identified the following areas as those most likely to have a material effect on the financial statements:

- pharmaceutical, intellectual property, and information protection laws and regulations (reflecting the Company's significant number of patents and research and development expenditures); and
- employment law (reflecting the Company's geographically diverse work force, including General Data Protection Regulation).

We evaluated the fraud and non-compliance risk factors to consider whether those factors indicate a risk of material misstatement in the financial statements.

Further, we assessed the presumed fraud risk on revenue recognition as irrelevant, because the revenue transactions are related to collaboration agreements and are not resulting from commercialization of products. As such, the recurring entries related to amortization of deferred upfront payments, milestone payments and reimbursement of expenses are limited and non-complex.

Based on the above and on the auditing standards, we identified the following presumed fraud risk with respect to management override of controls as relevant to our audit and responded as follows:

— **Management override of controls (a presumed risk)**

Risk:

- Management is in a unique position to manipulate accounting records and prepare fraudulent financial statements by overriding controls that otherwise appear to be operating effectively.

Responses:

- We evaluated the design and the implementation and, where considered appropriate, tested the operating effectiveness of internal controls that mitigate fraud risks, such as processes related to journal entries, estimates and the



allocation of costs between research and development costs and other categories of expenses.

- We performed a data analysis of high-risk journal entries, amongst others related to the classification of research and development costs, and evaluated key estimates and judgments for bias by the Company's management, including retrospective reviews of prior years' estimates with respect to share based payments. Where we identified instances of unexpected journal entries or other risks through our data analytics, we performed additional audit procedures to address each identified risk, including testing of transactions back to source information.
- We incorporated elements of unpredictability in our audit, including journal entry testing on specific criteria such as seldom-used accounts and journal entries posted by specific personnel.

As mentioned above, our evaluation of procedures performed related to fraud did not result in an additional key audit matter. We communicated our risk assessment, audit responses and results to the Board of Directors and the Audit Committee.

Our audit procedures did not reveal indications and/or reasonable suspicion of fraud and non-compliance that are considered material for our audit.

### ***Our key audit matters***

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements. We have communicated the key audit matter to the Audit Committee. The key audit matter is not a comprehensive reflection of all matters discussed.

The key audit matter was addressed in the context of our audit of the financial statements as a whole and in forming our opinion thereon, and we do not provide a separate opinion on this matter.

Compared to last year the key audit matter with respect to the identification of distinct performance obligations and determining the over-time revenue recognition for a collaboration and license agreement is not included, as this specifically relates to the financial year 2021 and no new complex collaboration agreement was entered into.

## ***Accounting for research and development costs***

### **Description**

Research and development (R&D) costs incurred, amounting to EUR 142.2 million (2021: EUR 83.2 million), relate to research projects for the development and (pre-)clinical testing of antibody candidates that form the primary business of the Company. None of its candidates generate revenue from drug product sales. In 2022, R&D costs increased in line with the progress of studies and (pre-)clinical trials. The size of the transactions in combination with the diversity of the related arrangements, resulted in significant audit effort. As such, we have considered the accounting for research and development costs as key audit matter, specifically related to the recognition, measurement and classification of accruals related to R&D costs originating from vendors that perform clinical and manufacturing services and the related disclosures as included in Note 13 Operating Expenses to the consolidated financial statements.

### **Our response**

The following are the primary procedures we performed to address this key audit matter:

We evaluated the design and tested the operating effectiveness of internal controls related to the Company's purchase to pay process, including controls over the monthly accrual process. We performed test of details by validating the R&D costs incurred to suppliers' invoices and confirmations in order to verify the completeness, accuracy and existence of the recorded expenses and related accruals. Among others, we have assessed the accounting for significant or more complex contracts for specific vendors and suppliers, and tested the inclusion of the relevant expenses and related accruals for an extended period after the balance sheet date. Furthermore, we have assessed and re-performed management's procedures related to completeness and accuracy of the accruals and related classification of expenses. We have also considered potential management override of controls relating to the classification of research and development costs.

### **Our observation**

Overall, the results of our procedure performed on management's accounting for research and developments costs and the related disclosures as including in Note 13 Operating expense to the consolidated financial statements are satisfactory.

## **Report on the other information included in the Dutch statutory board report and financial statements**

In addition to the financial statements and our auditor's report thereon, the Dutch statutory board report and financial statements contains other information.

Based on the following procedures performed, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements; and
- contains the information as required by Part 9 of Book 2 of the Dutch Civil Code for the management report and other information.

We have read the other information. Based on our knowledge and understanding obtained through our audit of the financial statements or otherwise, we have considered whether the other information contains material misstatements.

By performing these procedures, we comply with the requirements of Part 9 of Book 2 of the Dutch Civil Code and the Dutch Standard 720. The scope of the procedures performed is less than the scope of those performed in our audit of the financial statements.

The Board of Directors is responsible for the preparation of the other information, including the information as required by Part 9 of Book 2 of the Dutch Civil Code.

## **Report on other legal and regulatory requirements**

### ***Engagement***

We were re-engaged by the General Meeting of Shareholders as auditor of Merus N.V. for the year 2022 on April 14, 2022, and have operated as statutory auditor as of 2014 due to legal audit requirement.

## **Description of responsibilities regarding the financial statements**

### ***Responsibilities of the Board of Directors and the Audit Committee for the financial statements***

The Board of Directors is responsible for the preparation and fair presentation of the financial

statements in accordance with EU-IFRS and Part 9 of Book 2 of the Dutch Civil Code. Furthermore, the Board of Directors is responsible for such internal control as management determines is necessary to enable the preparation of the financial statements that are free from material misstatement, whether due to fraud or error. In that respect the Board of Directors, under supervision of the Audit Committee, is responsible for the prevention and detection of fraud and non-compliance with laws and regulations, including determining measures to resolve the consequences of it and to prevent recurrence.

As part of the preparation of the financial statements, the Board of Directors is responsible for assessing the Company's ability to continue as a going concern. Based on the financial reporting frameworks mentioned, the Board of Directors should prepare the financial statements using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so. The Board of Directors should disclose events and circumstances that may cast significant doubt on the company's ability to continue as a going concern in the financial statements.

The Audit Committee is responsible for overseeing the Company's financial reporting process.

### **Our responsibilities for the audit of the financial statements**

Our objective is to plan and perform the audit engagement in a manner that allows us to obtain sufficient and appropriate audit evidence for our opinion.

Our audit has been performed with a high, but not absolute, level of assurance, which means we may not detect all material errors and fraud during our audit.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements. The materiality affects the nature, timing and extent of our audit procedures and the evaluation of the effect of identified misstatements on our opinion.

A further description of our responsibilities for the audit of the financial statements is included in appendix of this auditor's report. This description forms part of our auditor's report.

Rotterdam, May 8, 2023

KPMG Accountants N.V.

J. van Delden RA

Appendix:

Description of our responsibilities for the audit of the financial statements

## Appendix

### Description of our responsibilities for the audit of the financial statements

We have exercised professional judgement and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included among others:

- identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than the risk resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control;
- evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the Board of Directors;
- concluding on the appropriateness of the Board of Directors' use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause a company to cease to continue as a going concern;
- evaluating the overall presentation, structure and content of the financial statements, including the disclosures; and
- evaluating whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

We are solely responsible for the opinion and therefore responsible to obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the group to express an opinion on the financial statements. In this respect we are also responsible for directing, supervising and performing the group audit.

We communicate with the Audit Committee regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant findings in internal control that we identify during our audit.

We provide the Audit Committee with a statement that we have complied with relevant ethical requirements regarding independence, and to communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, related safeguards.

From the matters communicated with the Audit Committee, we determine the key audit matters: those matters that were of most significance in the audit of the financial statements. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter or when, in extremely rare circumstances, not communicating the matter is in the public interest.

## **11.2 Profit Appropriation Provisions**

Pursuant to the Company's articles of association, any profits shown in the adopted statutory financial statements of the Company shall be appropriated as follows, and in the following order of priority:

- a. to the extent that any preferred shares have been cancelled without full repayment as described in the articles of association and without such deficit subsequently having been paid in full, an amount equal to any such (remaining) deficit shall first be distributed to those who held those preferred shares at the moment of such cancellation becoming effective;
- b. if preferred shares are issued and outstanding and to the extent that the mandatory annual distribution on the preferred shares (i.e., an amount equal to the applicable interest rate calculated over the aggregate amount paid up on those preferred shares, calculated in accordance with the relevant provisions of the articles of association), or part thereof, in relation to previous fiscal years has not yet been paid in full, an amount equal to any such (remaining) deficit shall be distributed on the preferred shares;
- c. if preferred shares are issued and outstanding, the mandatory annual distribution (as described above under b.) payable on preferred shares shall then be distributed on the preferred shares;
- d. following those distributions, our board of directors shall determine which part of the remaining profits shall be added to the Company's reserves; and
- e. subject to a proposal by our board of directors to that effect, the remaining profits shall be at the disposal of our general meeting of shareholders for distribution on the common shares.

## **11.3 Special Rights Of Control Under Our Articles**

There are no parties with special rights of control in relation to the Company pursuant to our articles of association.

## **11.4 Non-Voting Shares And Shares Carrying Limited Economic Entitlement**

The Company has not issued non-voting shares. The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As of December 31, 2022, no preferred shares in the Company's capital were issued.

## **11.5 Branches**

The Company has no branch offices.

## **11.6 Material Subsequent Event**

Refer to Note 21 to the consolidated financial statements for further information on subsequent events.



*Signature page to the Dutch statutory board report of Merus N.V. for the fiscal year ended December 31, 2022*

/s/ S. A. Lundberg

Name : S.A. Lundberg  
Capacity : President, CEO & PFO

/s/ A. Mehra

Name : A. Mehra  
Capacity : Chairman

/s/ M.T. Iwicki

Name : M.T. Iwicki  
Capacity : Non-executive director

/s/ P. Pucci

Name : P. Pucci  
Capacity : Non-executive director

/s/ G.D. Perry

Name : G.D. Perry  
Capacity : Non-executive director

/s/ M. Gowen

Name : M. Gowen  
Capacity : Non-executive director

/s/ L.F. Kanavy

Name : L.F. Kanavy  
Capacity : Non-executive director

/s/ V. Sandor

Name : V. Sandor  
Capacity : Non-executive director