Merus N.V.

Dutch statutory board report and financial statements for the fiscal year ended December 31, 2019

TABLE OF CONTENTS

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, 2019 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2019. 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,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this report, including 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 are forward-looking statements.

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, including those described under the section in this report entitled “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.

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 are 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 bispecific and trispecific antibodies that bind to a wide range of targets and display novel and innovative biology. These platforms referred to as Biclonics® and Triclonics™ allows 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 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 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 and/or enrolling patients in a clinical trial regarding the following candidates: MCLA-128 (zenocutuzumab) for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions; MCLA-117 for the potential treatment of acute myeloid leukemia; MCLA-158 for the potential treatment of solid tumors; and MCLA-145, developed in collaboration with Incyte Corporation, for the potential treatment of solid tumors and a hematological malignancy, B-cell lymphoma. We are also developing a late-stage pre-clinical candidate, MCLA-129 in collaboration with Betta Pharmaceuticals, 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 Biclonics® technology platform to identify multiple additional antibody candidates and advance them to clinical development. Further, Merus is developing its next generation Triclonics™ technology, and has pre-clinical trispecific antibody candidates capable of simultaneously binding three targets at once.

2.2 Our Strategy

Our goal is to become a leading oncology company developing innovative bispecific and 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.*** 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 occur infrequently in a wide range of different cancer types. Zenocutuzumab, Merus' most advanced clinical candidate, has been show pre-clinically to potently disrupt binding of NRG1 (and NRG1-fusion proteins) to HER3 and halt NRG1-stimulated tumor cell growth. In October 2019, we reported on the 9 patients with NRG1 gene fusion cancers who had received zenocutuzumab as of that date, either on clinical trial or on an Early Access Program (EAP), including, for several patients, clinical responses and reductions in serum tumor markers. We expect to present data from our Phase 1/2 NRG1 fusion-positive solid tumor trial, *eNRGy*, at a medical conference by the end of 2020. We believe that if zenocutuzumab is successfully developed and obtains regulatory approval, it has the potential to address disease-specific challenges that are not currently being met by existing therapies.

- ***Successfully develop our bispecific antibody candidate MCLA-158.*** We are developing MCLA-158 for the potential treatment of solid tumors. Our Phase 1 clinical trial of MCLA-158 is ongoing, with an amended protocol to allow for the exploration of higher dose cohorts.

- ***Successfully develop our bispecific antibody candidate MCLA-145.*** We are developing MCLA-145, in collaboration with Incyte, in an ongoing Phase 1 trial for the potential treatment of solid tumors and a hematological malignancy, B-cell lymphoma. MCLA-145 is designed to recruit, activate and prevent the exhaustion of tumor-infiltrating T cells, and we believe has the potential to avoid the known side effects of current CD137 agonists in development.

- ***Successfully develop our pre-clinical bispecific antibody candidate MCLA-129.*** We are developing MCLA-129, in collaboration with Betta Pharmaceuticals Co. Ltd. (Betta), currently in IND-enabling studies, for a potential Phase 1 trial as a potential treatment for solid tumors, including non-small cell lung cancer (NSCLC). We presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2019 pre-clinical data demonstrating the ability of MCLA-129 to inhibit tyrosine kinase inhibitor-resistant NSCLC in pre-clinical xenograft models.

- ***Wrap up the Phase 1 trial of our bispecific antibody candidate, MCLA-117, for the treatment of Acute Myeloid Leukemia (AML).*** We are developing MCLA-117 for potential treatment of AML. We announced that as of May 14, 2020, MCLA-117 is being evaluated in a Phase 1 trial in a single-arm, open-label, global study to assess the safety, tolerability and anti-tumor activity of MCLA-117 currently enrolling patients with relapsed/refractory AML. MCLA-117 demonstrated clinical activity in terms of T-cell activation, mild to moderate cytokine release syndrome and blast count reductions in some patients and at some dose cohorts. However, given the limited clinical activity and the evolving treatment landscape in AML, we will not continue enrollment into the planned dose expansion cohorts in the trial.

- ***Accelerate the internal discovery and development of additional bispecific and trispecific antibody candidates.*** We believe we are well positioned to expand our pipeline of Biclonics® and Triclonics™ molecules for the potential treatment of cancer and other forms of disease. We are conducting pre-clinical studies for our internal proprietary pipeline as well with our collaborators including Incyte Corporation (Incyte), Simcere Pharmaceutical Group (Simcere), 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 Biclonics® and Triclonics™ technology platforms and to access unique partner capabilities and capacity. We have entered into collaborations with Incyte, Simcere, and Betta to develop bispecific antibody candidates based on our Biclonics® technology platform. We plan to work with other potential future collaborators to further validate and expand the use of our Biclonics® and Triclonics™ platform in developing bispecific and trispecific antibody candidates. We are also working with ONO Pharmaceutical Co., Ltd., to generate bispecific antibodies for indications outside oncology, which further underscore the breadth of the Merus platform. We believe these collaborations 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

The principal risks and uncertainties which the Company faces include the risks and uncertainties summarized in this section 2.4. See section 3 of this report for additional detail and additional risks and uncertainties which the Company faces.

The Company identified the following principal risks and uncertainties:

1. 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.
2. 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.
3. 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.

4. The Biclonics® technology platform and Triclonics™ technology platform are unproven, novel approaches to the production of molecules for therapeutic intervention.
5. Our employees, agents, independent contractors, principal investigators, contract research organizations, or CROs, consultants, vendors and collaborators may engage in misconduct or other improper activities, including noncompliance with applicable law, regulatory standards and requirements, which could adversely effect on our reputation, business, prospects, operating results, and financial condition.
6. All of our antibody candidates are in pre-clinical or early-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, MCLA-158, or MCLA-145, which we are developing with Incyte, 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.
7. 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.
8. The regulatory approval processes of the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or EMA, 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.
9. 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.
10. 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.
11. 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.
12. 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 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 quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.

13. Our computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches, which could adversely affect our business.
14. Our future growth and ability to compete depends on retaining our key personnel, recruiting additional qualified personnel and managing transitions among these personnel, such as the recent transition of our former President and Chief Executive Officer, and recent resignations of our former Chief Medical Officer and current Chief Scientific Officer.
15. 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.

3 RISK FACTORS

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 €50.4 million, and €24.3 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated loss of €216.7 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 operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing, single agent, Phase 1/2 clinical trial of zenocutuzumab, our most advanced bispecific antibody candidate, for the treatment of solid tumors harboring neuregulin 1 (NRG1) gene fusions and conclude our ongoing Phase 2 clinical trial for the treatment of metastatic breast cancer in combination with other therapies;
- wrap up our ongoing Phase 1 clinical trial of MCLA-117, our bispecific antibody candidate, for the treatment of acute myeloid leukemia (AML), where we have noted, we will not continue enrollment into the planned dose expansion cohorts in the trial;
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors or B-cell lymphomas, which is being co-developed with Incyte Corporation (Incyte);
- continue the research and development of our other pre-clinical antibody candidates, including the development of MCLA-129 in collaboration with Betta Pharmaceuticals Co. Ltd. (Betta);
- expand our clinical programs to explore new potential combination therapies or indications;
- expand and enhance our technology platforms, including our Biclonics® technology platform which generates our pipeline of bispecific product candidates, our Triclonics™ technology platform, which generates pre-clinical trispecific candidates and discover 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 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. We have devoted a significant portion of our financial resources and efforts to developing our full-length human bispecific antibody therapeutics, which we refer to as Biclonics®, our technology platforms, identifying potential antibody candidates, conducting pre-clinical studies of a variety of candidates, and conducting our clinical trials of zenocutuzumab, MCLA-117, MCLA-158, and MCLA-145. We are in the early stages of development of our antibody candidates, and we have not completed development of any Biclonics® 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 bispecific antibody candidates, discovering and developing additional bispecific and trispecific 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 most 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 would 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 our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of zenocutuzumab, MCLA-158, and MCLA-145, wrap up the Phase 1 trial of MCLA-117 where we have noted we will not continue enrollment into the planned dose expansion cohorts in the trial, 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 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 March 31, 2020 will be sufficient to fund our operations into 2022. 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 the Phase 1 clinical trials of MCLA-158, and MCLA-145, and wrap up our Phase 1 clinical trial for MCLA-117 where we will not continue enrollment into the planned dose expansion cohorts in the trial;
- the success of our collaboration with Incyte to develop monospecific and bispecific antibodies candidates, including our ongoing Phase 1 clinical trial for MCLA-145;
- 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 bispecific and multispecific antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of 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 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 Biclonics® technology platform and in development of multispecific antibody candidates using our Triclonics™ technology platform. Our ability to generate royalty and product revenues, which we do not expect will occur for at least the next several years, 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 any future trispecific 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, the EMA 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 Authorisation 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 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 Biclonics® technology platform and Triclonics™ technology platform are unproven, novel approaches to the production of molecules 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 Biclonics® and Triclonics™ 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 Biclonics® and Triclonics™ 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 Biclonics® and Triclonics™ 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 and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper 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 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, we may develop companion diagnostics to 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, the EU legislative bodies, and comparable foreign regulatory authorities as medical devices and typically require separate regulatory approval prior to commercialization. If needed, we intend to develop companion diagnostics in collaboration with or via license agreements with third parties and are dependent on the scientific insights and sustained cooperation and effort of any third-party collaborators in developing and obtaining approval for companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for any companion diagnostics, including issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure by us or our collaborators to develop or obtain regulatory approval of companion diagnostics could delay or prevent approval of our antibody candidates. In addition, our collaborators may encounter production difficulties that could constrain the supply of the companion diagnostics, and both they and we may have difficulties gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it would 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, MCLA-117, MCLA-158, MCLA-145 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, generating and enhancing our Biclonics® technology platform, generating our Triclonics™ technology platform, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for zenocutuzumab, MCLA-117, MCLA-158, and MCLA-145, we have not completed any clinical trials for any antibody candidate. We have not yet demonstrated our ability to successfully complete any Phase 2 clinical trial or any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. 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 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 Brexit, 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, 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, and 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.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU on January 31, 2020 and entered into a transition period during which it will continue its ongoing and complex negotiations with the EU relating to the future relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period.

These developments have created significant uncertainty about the future relationship between the United Kingdom and the EU. Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU-derived laws and regulations to replace or replicate as part of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could further decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict our access to capital. These developments, or the perception that any of them could occur, have had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Any of these factors could have a significant adverse effect on our business, financial condition, results of operations and prospects.

Further, the United Kingdom's withdrawal from the EU has resulted in the relocation of the EMA from the United Kingdom to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the U.K. Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the United Kingdom.

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 December 2019, a strain of novel coronavirus causing the COVID-19 disease was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread to multiple countries, including the Netherlands and the United States. In March 2020, the World Health Organization (WHO) characterized COVID-19 as a pandemic. To date, the COVID-19 pandemic has interfered with the normal function of businesses worldwide, including in the form of travel restrictions, shelter-in-place orders and quarantines, office and school closures, bans on public gatherings and employees being encouraged or required to work from home pursuant to guidance provided by national, state and local officials including the U.S. Center for Disease Control and Prevention (CDC) and European local health agencies, including the Dutch National Institute for Health and Environment or Het Rijksinstituut voor Volksgezondheid en Milieu (RIVM). For example, most of our employees located in the Netherlands are not able to travel to the U.S., where certain of our collaborators and employees are located, which could have an adverse impact on our ability to conduct our business. Additionally, on March 18, 2020, we temporarily suspended our laboratory research activities at our facilities in Utrecht, the Netherlands to help secure the safety of the Company's employees and to adhere to government recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We have since re-opened our laboratory in Utrecht on a limited, and strictly voluntary basis, maintaining social distancing and imposing other requirements consistent with the guidance provided by the CDC and RIVM.

As a result of the COVID-19 pandemic, certain of our CROs and third-party suppliers, as well as collaborators in the U.S. and China that are developing or collaborating with us to develop certain of our pre-clinical 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 and testing of our pre-clinical antibody candidates, including MCLA-129, among other undisclosed pre-clinical candidates associated with our collaborations with Incyte and Simcere, 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, which may delay or prevent our development of our pre-clinical antibody candidates, including MCLA-129. Moreover, although our collaborators based in China have resumed operations, we may experience labor shortages associated with these pre-clinical development activities due to the current restrictions on travel globally, which may force us to reduce related workflows until such travel restrictions are lifted. 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 governmental and private sector restrictions have impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials for zenocutuzumab, MCLA-117, MCLA-158 and

MCLA-145. 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 acquire 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, such as clinical trial site 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, 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 to accept data from clinical trials in affected geographies;
- interruption or delays in our collaborations, including with Incyte, Betta Pharma, Simcere, and our license agreements with Ono and our academic collaborators;
- 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 outbreak continues to rapidly evolve. The extent to which the outbreak further impacts 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 ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat 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-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, MCLA-158, or MCLA-145, which we are developing with Incyte, 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 and effective 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 clinical trials required for the approval of any of our antibody candidates. Although we are conducting ongoing clinical trials for zenocutuzumab, MCLA-117, MCLA-158, and MCLA-145, and are conducting 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 establishing 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 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;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or regulatory authorities, as applicable, to suspend or terminate a trial if we or our collaborators or regulatory authorities, find that the participants are being exposed to unacceptable health risks;
- 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) 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 or completing our planned and ongoing clinical trials. We could encounter delays if a clinical trial is 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 EEA Member States (the 27 EU Member States plus Iceland, Liechtenstein and Norway, and the United Kingdom (until the end of the transition period on December 31, 2020 provided for in the Withdrawal Agreement between the EU 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, the EU and other applicable regulatory authorities' legal requirements, 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) 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 EU 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-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

Interim and preliminary "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 or preliminary "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 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. In addition, we may report interim or preliminary analyses of only certain endpoints rather than all endpoints. 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 and preliminary data and analyses should be viewed with caution. Adverse differences between preliminary 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.

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. To date, patients treated with zenocutuzumab have experienced adverse reactions that may be related to the treatment, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. In May 2016, we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-117. To date, patients treated with MCLA-117 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions including fever, cytokine release syndrome and chills. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors. To date, patients treated with MCLA-158 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions and skin rash associated with mAb EGFR inhibitors. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 developed in collaboration with Incyte. To date, patients treated with MCLA-145 have experienced adverse events irrespective of causality including blood alkaline phosphatase increase, anemia, and hypoalbuminemia, lymphocyte count decrease, and white blood cell count decrease. Febrile neutropenia was the serious treatment emergent adverse event or TEAE that was assessed as related to MCLA-145 by an investigator.

Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, the EMA, 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 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.

Adverse events in the field of oncology could damage public perception of our antibody candidates and negatively affect our business.

The commercial success of our products, if any, will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of our antibody candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of oncology that may occur in the future, could result in a decrease in demand for any products that we may develop.

Future adverse events in oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our antibody candidates. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our antibody candidates.

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 90 patients with tumors harboring NRG1 gene fusions. Solid tumors with NRG1 gene fusions occur infrequently, which could result in slow enrollment of clinical trial participants. In the Phase 1 clinical trial of MCLA-117, we will not continue enrollment into the planned dose expansion cohorts given the limited clinical activitiy planning and the evolving treatment landscape in AML. In the Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors or B-cell lymphoma. 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, the EMA 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, the EMA 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 a 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, the EMA 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, the EMA 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, the EMA 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 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, the EMA 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, the EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with collaborators; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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, the EMA 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, the EMA 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.

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.

If the FDA, the EMA or a comparable foreign regulatory authority approves any of our antibody candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product 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 continued compliance with cGMPs and GCPs for any clinical trials that we conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our antibody candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the antibody candidate.

If there are changes in the application of legislation or regulatory policies, or if problems are discovered with a product or our manufacture of a product, or if we or one of our distributors, licensees or co-marketers fails to comply with regulatory requirements, the regulators could take various actions. These include imposing fines on us, imposing restrictions on the product or its manufacture and requiring us to recall or remove the product from the market. The regulators could also suspend or withdraw our marketing authorizations, requiring us to conduct additional clinical trials, change our product labeling or submit additional applications for marketing authorization. If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations.

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

A key element of our strategy is to use and expand our Biclonics® 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, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

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 intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, the EMA 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; or (iv) laws that require the reporting of true, complete and accurate financial information and data. 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.

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 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 and Congressional challenges to certain aspects of the ACA, as well as efforts by the current presidential administration to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. For example, the Tax Cuts and Jobs Act of 2017 (TCJA), includes a provision repealing, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. It is unclear how these decisions, subsequent appeals, and other efforts to challenge, repeal, or replace the ACA will impact the ACA or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS began paying for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. 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. For example, the 21st Century Cures Act changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain products. 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.

We cannot predict how the policies of changing political administrations could impact, impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. For example, certain policies of the current presidential administration may impact our business and industry. Namely, the current presidential administration has taken several executive actions, including the issuance of a number of Executive Orders. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

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.

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 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 ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new 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, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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 patient data privacy and security regulation by both the U.S. federal government and the states in which we conduct our business. Finally, 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 U.S. federal Food, Drug and Cosmetic Act (FDCA) 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 beginning in 2022, 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 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. 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 disclosure of individually identifiable health 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. For example, California recently enacted legislation, the California Consumer Privacy Act (CCPA) which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right 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, thereby potentially increasing 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 personal information depending on the context.

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 implements 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.

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU 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, the U.S. Privacy Shield is under periodic review by the European Commission. As such, there remains ongoing uncertainty that the Privacy Shield framework and/or model clauses may be invalidated in the future. Further, the United Kingdom's decision to leave the EU has created uncertainty with regard to the status of the UK as an "adequate country" for the purposes of data transfers outside the European Economic Area. In particular, it is unclear how data transfers to and from the UK will be regulated. These changes could require us to make operational changes and could increase costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

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 or obtain or maintain orphan drug exclusivity for our products, 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, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. 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 drug designation entitles a party to 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 drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

We plan to potentially seek orphan drug designation from the FDA and the EMA for our assets in clinical development, including zenocutuzumaband other clinical assets, where supported by data in the appropriate indications that meet the criteria for orphan status. Even if we are able to obtain orphan designation 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 the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA 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.

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.

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, the EMA 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 no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, we will not be successful in commercializing our antibody candidates.

We currently have no marketing, sales and distribution capabilities 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 or delay 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, and we currently have no sales force, marketing or distribution capabilities. 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. We may rely on outside consultants 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, obtaining access to or persuading adequate numbers of physicians 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 2005.

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 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 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, with the exception of MCLA-145 where we retain full U.S. rights, 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 agreements with Simcere, and Betta Pharma, and the research and license agreement with Ono are important to our business. If our Biclonics® 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 agreements with Simcere or 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 these 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 Biclonics® technology platform and our ability to engage in future collaborations or licensing agreements. While we have certain contractual provisions in place in our collaboration agreements with Simcere and Betta Pharma that permit us to supervise development efforts associated with our pre-clinical assets out-licensed to these entities, which have product rights in China, we cannot guarantee that these assets will be developed in China in accordance with our standards as applied to our wholly owned programs. Ono is currently pursuing two antibodies generated by us through use of our proprietary Biclonics® platform in an area outside oncology. To the extent these assets do not successfully advance through clinical development, this may impair our ability to leverage our platform in areas outside oncology or to engage in future license agreements to further expand the use of our platform and generate future revenue. Should any of these collaborations or 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 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 recently developed Triclonics™ technology platform, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical 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, Simcere and Betta, under which we have licensed the development and commercialization 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 Biclonics® 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 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 pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP 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 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 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 Biclonics® technology platform and Triclonics™ 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 Biclonics® technology platform, Triclonics™ technology platform, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those 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 and even if such patents cover our Biclonics® technology platform, Triclonics™ technology platform, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those 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.

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 Biclonics® technology or Triclonics™ 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, or our

Biclonics® technology and Triclonics™ technology platforms 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 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 Biclonics® technology and Triclonics™ 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.

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 plans, or other attributes of our antibody candidates or our Biclonics® technology platform or Triclonics™ technology platform. In such cases, we may not be in a position to develop or commercialize products or bispecific or trispecific 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 may be alleged as covering some of our antibody candidates. 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, 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 by our antibody candidates, 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 antibody candidates. We could also be required to pay substantial damages.

Similarly, the targets of certain of our antibody candidates have also been the subject of research by many companies, which have filed patent applications or have patents related to such targets and their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

It is also possible that 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 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. We might, if possible, also 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 therapeutics 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 also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our products 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.

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 antibody candidates and Biclonics® technology and

Triclonics™ technology platforms. 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. In addition, our antibody candidates may require specific formulations to work effectively and efficiently or companion diagnostics for safely and effective administration of our therapeutic candidates and the rights to these formulations and companion diagnostics may be held by others. 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 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.

Our registered or unregistered trademarks, trade names or service marks may be challenged, 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, 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. 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) at the European Patent Office (EPO) or the USPTO. International applications under the Patent Cooperation Treaty (PCT) are usually filed within 12 months after the priority filing. 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 licensors 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 licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business 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. However, current or former employees, consultants, contractors, collaborators and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements 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. 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 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 other biopharmaceutical 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 try to ensure that our employees do not 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. 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 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 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 computer 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 computer 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, 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 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 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 these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, including in the hiring of IT personnel, and improvements to IT infrastructure and controls, there can be no assurance that our efforts will prevent service interruptions or security breaches.

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 material 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. 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.

Risks Related to Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel, recruiting additional qualified personnel and managing transitions among these personnel, such as the recent transition of our former President and Chief Executive Officer, and recent resignations of our former Chief Medical Officer and current Chief Scientific Officer.

Our success depends upon the contributions of our senior management, 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 therapies and related technologies. The loss of key senior management, managers and senior scientists could delay our research and development activities or impair our ability operate the company effectively. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is 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. Our success also depends on our ability to manage transitions among our senior management and other key personnel. In December 2019, Ton Logtenberg, Ph.D., stepped down as an executive director, a position he held since co-founding our company in 2003, and as President, Chief Executive Officer and Principal Financial Officer, and Sven “Bill” Lundberg, M.D. was appointed as an executive director and as President, Chief Executive Officer and Principal Financial Officer. In April 2020, L. Andres Sirulnik, M.D., Ph.D. resigned as Executive Vice President, Chief Medical Officer effective April 24, 2020, and Mark Throsby, Ph.D., resigned as the Executive Vice President and Chief Scientific Officer of the Company with an effective date of July 31, 2020. These recent changes in our senior management may be disruptive to our business, and if we are unable to manage orderly transitions in these cases or for other key personnel in the future, or if we are unable to recruit suitable replacements for the Chief Medical Officer and Chief Scientific Officer positions, our business may be adversely affected.

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 development, regulatory affairs and 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

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; 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.

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 will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after 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 will need to continue 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 will 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 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. While we remain an emerging growth company, we will not be 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, 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 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.

Members of our senior management, members of our board of directors, and certain shareholders affiliated with members of our board of directors may be able to exercise significant control over us, and the interests of our other shareholders may conflict with the interests of our existing shareholders.

As of December 31, 2019, members of our senior management, our board of directors and shareholders affiliated with members of our board of directors, in the aggregate, beneficially owned approximately 12% of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to significantly affect the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50%

of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and amendments to our articles of association. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of 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.

We have entered into a registration rights agreement pursuant to which we agreed, under certain circumstances, to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. In addition, 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 is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. In addition, in connection with entering into a settlement agreement with Regeneron Pharmaceuticals, we entered into a Share Subscription Agreement with Regeneron, pursuant to which we issued and sold to Regeneron 600,000 of our common shares. Regeneron's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. However, future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price 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 of directors.

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 a friendly party;
- 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.

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 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.

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.

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 in companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board is 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 Dutch Corporate Governance Code (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 entered into force for the Netherlands, but has not entered into force for 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 internationally acceptable 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.

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with the provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules of Nasdaq applicable to U.S. domestic issuers, which will continue to require us to incur significant expenses and expend time and resources.

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We are also no longer exempt from the requirements of Regulation FD promulgated under the Exchange Act related to selective disclosures. We are also no longer permitted to follow our home country’s rules in lieu of the corporate governance obligations imposed by Nasdaq, and are required to comply with the governance practices required by U.S. domestic issuers listed on Nasdaq. We are also required to comply with all other rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. In addition, we are required to report our financial results under U.S. Generally Accepted Accounting Principles, including our historical financial results, which have previously been prepared in accordance with International Financial Reporting Standards. We expect to continue to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources to comply with these requirements. In addition, we may need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

We are an “emerging growth company” and a “smaller reporting company,” and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common shares less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act and a smaller reporting company under the rules promulgated under the Exchange Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved, and reduced executive compensation disclosure. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years following the initial public offering of our common shares, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter, in which case we would no longer be an emerging growth company as of the fiscal year-end.

We are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data or supplemental financial information.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

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 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 2019, 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 2019. 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, and a U.S. Holder does not make an election to treat us as a qualified electing fund (QEF) or a mark-to-market election, excess distributions to a U.S. Holder, and any gain recognized by a U.S. Holder on a disposition of our ordinary shares, would be taxed in an unfavorable way. 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. In addition, gains on the sale of our shares would be treated in the same way as excess distributions. 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. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares. 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 United States Internal Revenue Code of 1986, as amended (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.

Comprehensive tax reform legislation could adversely affect our business and financial condition.

On December 22, 2017, the U.S. government enacted the TCJA, a comprehensive tax legislation that includes significant changes to the taxation of business entities. The TCJA remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which have lessened or increased certain adverse impacts of the TCJA and may do so in the future. We continue to examine the impact the TCJA may have on our business. The effect of the TCJA on our business, whether adverse or favorable, is uncertain, and may not become evident for some period of time. Holders of our common shares should consult their legal and tax advisors regarding the TCJA and the potential tax consequences of investing in our common shares.

4 LEGAL PROCEEDINGS

On April 5, 2018, an unnamed third party and Regeneron Pharmaceuticals Inc. (Regeneron) filed notices of opposition against our EP 2604625 patent, entitled “Generation of Binding Molecules,” in the European Opposition Division of the European Patent Office (the “EPO”). The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron withdrew its opposition pursuant to a global December 20, 2018 settlement with Merus. On August 20, 2018, we timely responded to the submissions with respect to the unnamed third party. An opposition hearing was held in June 2019, wherein the EPO revoked the EP 2604625 patent in its entirety under Art. 123(2) EPC. We timely appealed that decision in December 2019 before the Technical Board of Appeals for the EPO seeking reinstatement of the patent and proposing auxiliary requests for certain amended claims, with further proceedings to be scheduled in the future. As this opposition proceeding continues, we cannot be certain that we will ultimately prevail.

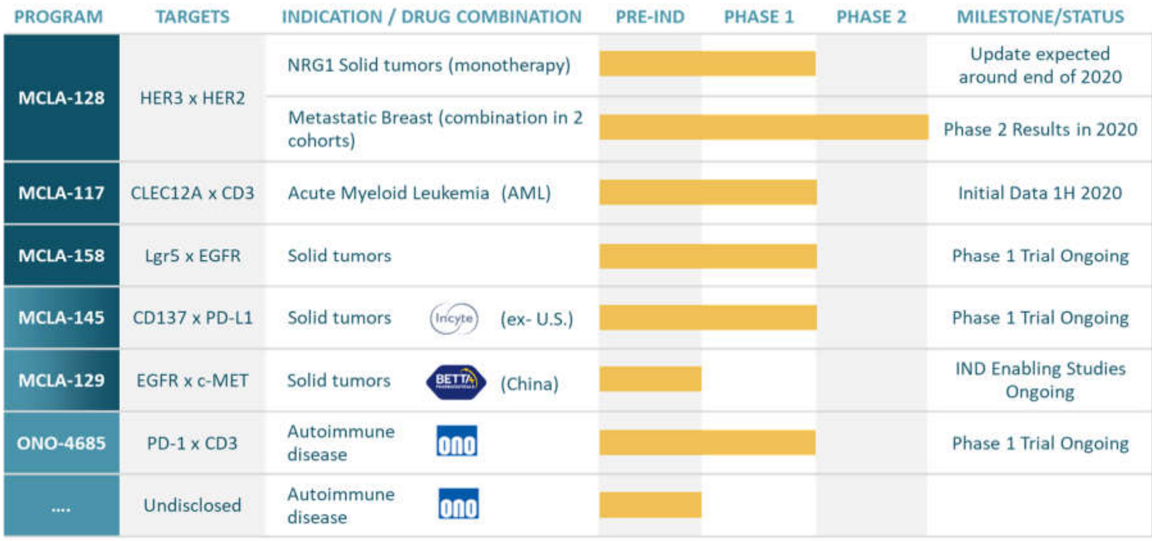
From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any other legal proceedings, which could be deemed to be material.

5 OPERATING AND FINANCIAL REVIEW AND PROSPECTS

5.1 Operating Results

Our Biclonics® and Triclonics™ Candidate Portfolio

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



Collaboration Revenue

The following is a comparison of collaboration revenue for the years ended December 31, 2019 and 2018:

	Year Ended December 31, 2019	Year Ended December 31, 2018	Change	%
	(In euros thousands)			
Incyte	**23,074**	25,376	(2,302)	-9.1%
Ono	**3,788**	5,577	(1,789)	-32.1%
Other	**1,813**	911	902	99.0%
Total collaboration revenue	**28,675**	31,864	(3,189)	
Grant revenue	**(192)**	196	(388)	-198.0%
Total revenue	**28,483**	32,060	(3,577)	-10.0%

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, 2019 decreased €3.6 million as compared to the year ended December 31, 2018, primarily as a result of a decrease in Incyte reimbursement revenue of €2.3 million, €0.8 million lower Ono reimbursement revenue, €0.7 million lower Ono upfront payment revenue and €0.3 million lower Ono milestone revenue, offset by an increase €0.8 million Betta upfront payment revenue.

As of December 31, 2019, we have total deferred revenue of €97.8 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and is expected to be recognized over the next six years.

Operating Expenses

The following is a comparison of operating expenses for the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	**2018**	**Change**	**%**
	(In euros thousands)			
Research and development costs	**49,624**	46,274	3,350	7.2%
General and administrative costs	**32,324**	24,633	7,691	31.2%
Total operating expenses	**81,948**	70,907	11,041	15.6%

Research and Development Expense

Research and development costs consist principally of the costs associated with our research and development activities, conducting preclinical 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 CROs, contract manufacturing organizations, and consultants that conduct and support clinical trials and preclinical studies;
- costs to 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, 2019 increased €3.4 million as compared to the year ended December 31, 2018, primarily as a result of an increase in headcount and higher preclinical research and development-related costs related to our programs, particularly increases in costs for MCLA-117 offset by decreases in zenocutuzumab and MCLA 145.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as 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 bispecific 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, 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, 2019 increased €7.7 million as compared to the year ended December 31, 2018, primarily as a result of an increase in headcount, consulting, accounting and professional fees as well as higher facilities-related expenses.

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 costs.

Other Income

The following is a comparison of other income, net, for the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	**2018**	**Change**	**%**
	(In euros thousands)			
Finance income	**3,130**	7,843	(4,713)	-60.1%
Finance costs	**(237)**	(4)	(233)	5825.0%
Other income	**175**	7,095	(6,920)	-97.5%
Total other income, net	**3,068**	14,934	(11,866)	-79.5%

Other income, net 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. For the year ended December 31, 2018, other income included a gain recognized upon the settlement of litigation with Regeneron of €7.1 million.

Tax Expense

The following is a comparison of income tax expense for the years ended December 31, 2019 and 2018:

	Year Ended December 31,			
	2019	**2018**	**Change**	**%**
	(In euros thousands)			
Current	**253**	353	(100)	-28.3%
Deferred	**(257)**	—	(257)	-100.0%
Tax expense	**(4)**	353	(357)	-101.1%

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.

5.2 Liquidity and Capital Resources

As of December 31, 2019, we had €215.2 million in cash, cash equivalents and investments that are available to fund our current operations. In addition to our existing cash, cash equivalents and investments, 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.

Funding Requirements

Our primary uses of capital are, clinical trial costs, third-party research and development services, personnel related costs, laboratory and related supplies, legal and other regulatory expenses and general overhead costs.

Because our product candidates are in various stages of clinical and preclinical 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. 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 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 stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. 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 in the future, we may have to relinquish valuable rights to our technologies, 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 development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on our research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash, cash equivalents and investments as of December 31, 2019, will be sufficient to fund our planned operating expenses and capital expenditure requirements into 2022, without giving effect to any potential milestone payments we may receive under our collaboration agreements. 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. 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, 2019 and 2018:

	Year Ended December 31,			
	2019	**2018**	**Change**	**%**
	(In euros thousands)			
Net cash used in operating activities	**(56,321)**	(40,499)	(15,822)	39 %
Net cash provided by (used in) investing activities	**22,768**	(19,416)	42,184	-217%
Net cash provided by financing activities	**65,573**	51,589	13,984	27 %

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 increased €15.8 million as compared to the year ended December 31, 2018, primarily as a result of operating cash receipts related to revenue arrangements decreasing €6.5 million, operating cash out flows related to operating expenses increasing €1.9 million and a non-recurring litigation settlement of €7.1 million that was received in 2018.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 increased €42.2 million as compared to the year ended December 31, 2018, primarily as a result of the change in net cash inflows from the maturity of debt securities used to fund current operations of €40.9 million and the increase in purchases of property, equipment and intangibles of €1.4 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 increased €14.0 million as compared to the year ended December 31, 2018, primarily as a result of the increase in receipt of proceeds from our equity issuances of €16.3 million offset by payments of lease liabilities of €1.4 million and decrease of €0.8 million in proceeds received from stock option exercises.

5.3 Off-Balance Sheet Arrangements

We enter into contracts in the normal course of business with CROs for clinical and preclinical research studies, external manufacturers for product 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.

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 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, 2019, 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. (56)*	M	U.S. and Swedish	December 31, 2019**	2023 AGM	100%
Ton Logtenberg, Ph.D. (61)*	M	Dutch	June 16, 2003	31 December 2019**	100%
Mark Iwicki (53)***	M	U.S.	June 4, 2015	2020 AGM	100%

Russell Greig (67)***	M	British	July 20, 2018	2022 AGM	100%
Len Kanavy (58)***	M	U.S.	July 20, 2018	2022 AGM	100%
John de Koning, Ph.D. (51)***	M	Dutch	January 21, 2010	2023 AGM	100%
Anand Mehra, M.D. (44)***	M	U.S.	August 21, 2015	2023 AGM	100%
Gregory Perry (59)***	M	U.S.	May 19, 2016	2020 AGM	100%
Victor Sandor, M.D. (53)***	M	U.S. and Canadian	June 12, 2019	2023 AGM	100%

* Executive director
** Ton Logtenberg resigned as our executive director effective December 31, 2019 and Bill Lundberg was appointed as our executive director effective December 31, 2019. Before December 31, 2019, Bill Lundberg served as non-executive director as from June 12, 2019.
*** Non-executive director

On May 9, 2020, Mr. Greig, and on May 10, 2020, Mr. De Koning resigned from our board of directors, effective upon the conclusion of the 2020 annual general meeting, or AGM. On May 11, 2020, our board of directors nominated Mr. Perry and Mr. Iwicki for re-appointment and Mr. Pucci for appointment at the 2020 AGM as non-executive directors for a term ending immediately after the AGM to be held in 2024. If Mr. Perry and Mr. Iwicki will be re-appointed and Mr. Pucci will be appointed at the 2020 AGM, the board of directors will consist of one executive director and six non-executive directors. Further, on May 11, 2020, our board of directors elected Dr. Mehra as Chairman of our board of directors effective upon the conclusion of the 2020 AGM and re-elected Mr. Perry as Vice Chairman of our board of directors effective upon the conclusion of the 2020 AGM. Due to these changes in the composition of our board of directors, the composition of the committees of our board of directors shall be revised at the occasion of the 2020 AGM.

Bill Lundberg, M.D. has served on our board of directors since June 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 the 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, Dr. Lundberg held roles of increasing responsibility in clinical drug development and medical affairs at Xanthus/Antisoma, Wyeth (now Pfizer), and Genzyme. 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/MIT, and clinical training in Medicine and Medical Oncology from Harvard and the Dana-Farber Cancer Institute.

Ton Logtenberg, Ph.D. served as our President & Chief Executive Officer and an executive board member since co-founding our company in June 2003, and served as our Principal Financial Officer since January 2019, until his resignation effective December 31, 2019. Mr. Logtenberg also served as President of our subsidiary, Merus US, Inc. Prior to joining Merus, Mr. Logtenberg co-founded

Crucell N.V., a biotechnology company specializing in vaccines and biopharmaceutical technology, and served as its executive vice president and chief scientific officer from July 2000 until November 2003. Mr. Logtenberg has served as a member of the board of directors of the Jenner Foundation since 2008 and a member of the board of directors of Utrecht Science Park since November 2014, and a member of the supervisory board of the HUB Foundation since August 2018. Mr. Logtenberg holds a Ph.D. in medical biology from Utrecht University.

Russell G. Greig, Ph.D. has served as the Chairman of our board of directors and been a non-executive member of our board of directors since July 2018. Mr. Greig worked at GlaxoSmithKline, a pharmaceutical company, for three decades, most recently as President of SR One, GlaxoSmithKline's corporate venture group. Prior to joining SR One, he served as President of GlaxoSmithKline's Pharmaceuticals International from 2003 to 2008 as well as on the GlaxoSmithKline corporate executive team. Currently, Mr. Greig serves as Chairman of: BiomX in Israel, MedEye Solutions in the Netherlands, eTheRNA in Belgium and Sanifit in Spain. He was previously Chairman of Ablynx in Belgium (acquired by Sanofi, France), Isconova in Sweden (acquired by Novavax, United States), Novagali in France (acquired by Santen, Japan), Syntaxin in the United Kingdom (acquired by Ipsen, France) and Bionor in Norway, as well as a board member of TiGenix in Belgium (acquired by Takeda, Japan), Oryzon in Spain and Onxeo Pharma (previously BioAlliance Pharma) in France. From 2013 to 2016, he was a venture partner at Kurma Life Sciences (Paris, France), a healthcare investment firm. Mr. Greig received a B.Sc. in Biochemistry from the University of Manchester and a Ph.D. from the University of Manchester.

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 Chairman of our board of directors. Mr. Iwicki is the chief executive officer and chairman of the board of directors of Kala Pharmaceuticals, Inc. and serves as a member of the boards of directors of Aimmune Therapeutics, Inc., Nimbus Therapeutics, Oxeia Biopharmaceuticals and Akero Therapeutics, Inc. In addition, Mr. Iwicki has served on the board of the Wellesley Youth Hockey Association. Mr. Iwicki served as president and chief executive officer and a member of the board of directors of Civitas Therapeutics, Inc. from January 2014 until its acquisition by Acorda Therapeutics, Inc. in October 2014. 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 was president and chief executive officer and director of Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc. Mr. Iwicki holds 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. He currently serves on the board of privately held KMK Consulting. Mr. Kanavy holds a B.S. in Business Administration and an M.B.A. with a specialization in Finance from the University of Scranton.

John de Koning, Ph.D. has served as a non-executive director of our board of directors since January 2010. Mr. De Koning has been a partner at LSP (Life Sciences Partners), a life sciences investment firm, since January 2006. Mr. De Koning currently serves on the boards of the private companies GTX medical, eTheRNA and Aelin Therapeutics. Previously, he served on the supervisory boards of BMEYE (acquired by Edwards Lifesciences), Prosensa (acquired by BioMarin) and Skyline Diagnostics, and as a non-executive director on the boards of argenx, Pronota (acquired by MyCartis) and Innovative Biosensors Inc. Mr. De Koning holds an M.Sc. in medical biology from Utrecht University and a Ph.D. in oncology from the Erasmus University Rotterdam.

Anand Mehra, M.D. has served as a non-executive director of our board of directors since August 2015. Our board of directors has also appointed Dr. Mehra to serve as Chairman of our board of directors effective from the conclusion of the 2020 AGM, succeeding Russell G. Greig, Ph.D. 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 Prothena Corporation PLC. 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 Aclaris, as well as on the boards of several private companies. Within the past five years, he also served on the boards of directors of the publicly held pharmaceutical companies Marinus Pharmaceuticals, Inc., Spark Therapeutics, Inc. and Aerie Pharmaceuticals, Inc. 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 Chairman of our Board since August 2018. Mr. Perry is the Chief Financial Officer at Finch Therapeutics Group, a microbiome therapeutics company since May 2018. Mr. Perry served as 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 the 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 Kala Pharmaceuticals, including as chair of its audit committee. From December 2011 to February 2016, Mr. Perry served on the board of directors of Ocata Therapeutics, including as chair 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.

Prior to joining Array, from September 2014 to June 2019, 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. From February 2010 to September 2014, Dr. Sandor was Vice President and Chief Medical Officer for oncology at Biogen Idec and, from October 2009 to February 2010, held positions of increasing responsibility in oncology product development at AstraZeneca, where he played a lead role in the registration of Arimidex(r) (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.

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 incentivise 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 realisation of the Company's long-term objectives while keeping with the Company's risk profile.

See Note 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 2019 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 2019, 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 2019 are set forth in the table above entitled “Senior Management Remuneration”.

See Note 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, 2019. 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 4 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, 2019, our board of directors was comprised of eight members. Each member of our board of directors is appointed for an initial term of up to four years. 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	2016	2020
Russell G. Greig, Ph.D.	2018	2022
Len Kanavy	2018	2022
John de Koning, Ph.D.	2017	2023
Anand Mehra, M.D.	2016	2023
Gregory Perry	2016	2020
Victor Sandor, M.D.	2019	2023

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, Anand Mehra and John de Koning, 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. It is proposed that, contingent upon Mr. Pucci's appointment at the 2020 AGM, Mr. Pucci shall be appointed as member of the audit committee as per the 2020 AGM, replacing Mr. De Koning. The audit committee shall consist of Gregory Perry, Anand Mehra and Paolo Pucci as per the 2020 AGM, with Mr. Perry serving as the 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 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 Public Company Accounting Oversight Board;
- 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; and
- to conduct or authorize 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 20-F and 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 and Gregory Perry, assists our board of directors in determining management compensation. Mr. Iwicki serves as Chairman of the committee. It is proposed that, contingent upon Mr. Pucci's appointment at the 2020 AGM, Mr. Pucci shall be appointed as member of the compensation committee as per the 2020 AGM. The compensation committee shall consist of Mark Iwicki, Gregory Perry and Paolo Pucci as per the 2020 AGM, with Mr. Iwicki serving as the Chairman of the compensation 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;
- to the extent that the Company is required to include a Compensation Discussion and Analysis ("CD&A") in its US proxy statement, reviewing and discussing with management our CD&A and considering whether it will recommend to the board of directors that the CD&A be included in the proxy statement; and
- if required, 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 20-F and Form 10-K and in this report.

Nomination and Corporate Governance Committee

The nomination and corporate governance committee, which consists of Russell Greig, Mark Iwicki and John de Koning, 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. Mr. Greig serves as Chairman of the nomination and corporate governance committee. It is proposed that Dr. Mehra shall be appointed as member of the nomination and corporate governance committee and shall serve as the Chairman of the nomination and corporate governance committee as per the 2020 AGM, replacing Mr. Greig. The nomination and corporate governance committee shall consist of Anand Mehra and Mark Iwicki as per the 2020 AGM, with Dr. Mehra serving as the 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;
- working 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; and
- to conduct or authorize 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; independence of directors and committee members, and the board of director and committee self-assessment process.

Research and Development Committee

The research and development committee, which consists of Russell Greig, John de Koning, Anand Mehra 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 shall consist of Anand Mehra and Victor Sandor as per the 2020 AGM, with Dr. Sandor serving as the 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 December 31, 2019, we had 130 employees, 58 of whom hold M.D. or Ph.D. degrees. 67 of our employees work in research and development and 63 work in management and administrative areas. All of our employees are located in the Netherlands except for 22 employees located in the United States. None of our employees is 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 DCGC applied to the Company. The text of the DCGC can be accessed at http://www.mccg.nl.

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 and 1.3.2)

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

Self-evaluation non-executive directors and evaluation executive director (best practice provisions 2.2.6, 2.2.7 and 2.4.6)

Whilst the board of directors, its committees and the individual directors are evaluated regularly, without the executive director being present, the board of directors decided to perform such evaluation for the financial year 2019 in the first quarter of 2020.

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.

Presence of non-executive directors at the general meeting of appointment (best practice provision 4.1.8)

During the Company's 2019 AGM, Dr. Sandor, Dr. Lundberg, Dr. Mehra and Mr. De Koning were unable to be present at such meeting as they had other obligations on that date. Dr. Lundberg was present at the Company's extraordinary general meeting held in 2019 at which he was appointed to the position of executive director.

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', 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 decided to perform such evaluation in relation to the fiscal year to which this report relates in the first quarter of 2020.

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". Although the Company has not set specific targets with respect to particular elements of diversity, 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, but also does not set a specific target in this respect. 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 such that at least 30% of the Directors are men and at least 30% of them are women, consistent with applicable Dutch law. 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.

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. 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.

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.

10 FINANCIAL INFORMATION

10.1 Consolidated Financial Statements

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

	Note	As at December 31, 2019	As at December 31, 2018 (restated)*
Non-current assets			
Property and equipment, net	3	**3,307**	2,363
Intangible assets, net	4	**2,560**	2,502
Right-of-use assets	5	**5,339**	—
Deferred tax assets	6	**256**	—
Investments	7	**1,788**	—
Other assets		**1,696**	1,075
		14,946	5,940
Current assets			
Trade receivables	12	**2,361**	2,926
Investments	7	**37,523**	61,800
Other assets	8	**4,404**	4,132
Cash and cash equivalents	16	**175,906**	143,747
		220,194	212,605
Total assets		**235,140**	218,545
Shareholders' equity	9		
Issued and paid-in capital		**2,599**	2,102
Share premium account		**331,029**	264,854
Accumulated loss		**(216,719)**	(175,216)
Translation reserve		**148**	131
Total shareholders' equity		**117,057**	**91,871**
Non-current liabilities			
Lease liabilities	5	**3,979**	—
Deferred revenue	12	**81,115**	97,675
		85,094	97,675
Current liabilities			
Trade payables		**2,696**	2,829
Accrued liabilities	11	**12,050**	9,236
Lease liabilities	5	**1,512**	—
Deferred revenue	12	**16,731**	16,934
		32,989	28,999
Total liabilities		**118,083**	126,674
Total shareholders' equity and liabilities		**235,140**	218,545

* Comparatives were restated. Refer to Note 2 concerning changes in accounting policy for details.

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 COMPREHENSIVE LOSS
(All amounts in euro thousands except per share data)

	Note	Year ended December 31, 2019	2018
			(restated)*
Collaboration revenue	12	**28,675**	31,864
Grant revenue		**(192)**	196
Total revenue		**28,483**	32,060
Research and development costs	13	**(49,624)**	(46,274)
General and administrative costs	13	**(32,324)**	(24,633)
Total operating expenses		**(81,948)**	(70,907)
Operating result		**(53,465)**	(38,847)
Finance income	15	**3,130**	7,843
Finance costs	15	**(237)**	(4)
Other income	15	**175**	7,095
Result before taxation		**(50,397)**	(23,913)
Tax (benefit) expense	6	**(4)**	356
Result after taxation		**(50,393)**	(24,269)
Other comprehensive income			
Items that are or may be reclassified subsequently to profit or loss:			
Foreign currency translation differences - foreign operations		**17**	34
Total comprehensive loss		**(50,376)**	(24,235)
Basic and diluted loss per share	17	**(2.08)**	(1.09)

* Comparatives were restated. Refer to Note 2 concerning changes in accounting policy for details.

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, 2018		19,429,848	1,749	213,618	(158,872)	97	56,592
Transactions with owners of the Company:							
Issuance of shares, net		3,699,997	333	50,380			50,713
Exercise of stock options and vesting of restricted stock units		229,132	20	856			876
Equity settled share-based payments	14				7,925		7,925
Total contributions by and distributions to owners of the Company		3,929,129	353	51,236	7,925		59,514
Result after taxation					(24,269)		(24,269)
Other comprehensive income – foreign currency translation differences						34	34
Balance at December 31, 2018		23,358,977	2,102	264,854	(175,216)	131	91,871
Transactions with owners of the Company:							
Issuance of shares, net		5,462,500	492	66,137			66,629
Exercise of stock options and vesting of restricted stock units		60,740	5	38			43
Equity settled share-based payments	14				8,890		8,890
Total contributions by and distributions to owners of the Company		5,523,240	497	66,175	8,890		75,562
Result after taxation					(50,393)		(50,393)
Other comprehensive income – foreign currency translation differences						17	17
Balance at December 31, 2019		**28,882,217**	**2,599**	**331,029**	**(216,719)**	**148**	**117,057**

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 CASH FLOWS
(All amounts euros in thousands)

	Note	Year Ended December 31, 2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:			
Result after taxation		**(50,393)**	(24,269)
Adjustments for:			
Depreciation and amortization of property and equipment	3,5	**2,180**	546
Amortization of intangible assets	4	**211**	92
Foreign exchange gain		**(1,147)**	(5,553)
Stock-based compensation expense	14	**8,890**	7,925
Deferred income tax benefit	6	**(257)**	—
Net finance income		**(1,449)**	(1,181)
Changes in working capital	16	**(13,833)**	(17,431)
		(55,798)	(39,871)
Interest paid	15	**(237)**	(4)
Taxes paid		**(286)**	(624)
Net cash used in operating activities		**(56,321)**	(40,499)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of investments		**(53,949)**	(75,930)
Proceeds from maturities of investments		**77,841**	58,912
Interest received		**1,196**	1,279
Purchases of intangible assets	4	**(335)**	(2,125)
Purchases of property and equipment	3	**(1,985)**	(1,552)
Net cash provided by (used in) investing activities		**22,768**	(19,416)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of common stock, net of issuance costs	9	**66,972**	50,713
Proceeds from stock options exercised		**43**	876
Payment of lease liabilities	5	**(1,388)**	—
Changes in restricted cash		**(54)**	—
Net cash provided by financing activities		**65,573**	51,589
Foreign exchange impact on cash and cash equivalents		**139**	2,395
Net increase (decrease) in cash and cash equivalents		**32,159**	(5,931)
Cash and cash equivalents, beginning of period		**143,747**	149,678
Cash and cash equivalents, end of period	16	**175,906**	143,747
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 immuno-oncology company developing innovative bispecific 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 €216.7 million as of December 31, 2019. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its bispecific antibody candidates advance through discovery, preclinical development and clinical trials and as it seeks regulatory approval and pursues commercialization of any approved bispecific 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 with third parties and business development opportunities. 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 and cash equivalents and investments of €215.2 million as of December 31, 2019 will be sufficient to fund its operations into 2022.

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.

Certain amounts were reclassified in the prior period financial statements to conform to the current period presentation. These changes in classification do not materially affect the previously reported consolidated financial statements for any period.

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 19, 2020.

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.

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:

Asset Category	Useful Lives
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

Effective January 1, 2019, the Company adopted IFRS 16, *Leases* (“IFRS 16”). This standard applies to all leases, including leases of right-of-use assets in a sublease, except for leases that are within the scope of other standards, such as licenses of intellectual property, service concession arrangements and rights held by a lessee under licensing agreements.

IFRS 16 introduces a single lessee accounting model and requires a lessee to recognize assets and liabilities for all leases with a term of more than 12 months, unless the underlying asset is of low value. A lessee is required to recognize a right-of-use asset representing its right to use the underlying leased asset and a lease liability representing its obligation to make lease payments.

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.

Government Grants

The Company receives certain government and regional grants, which support its research efforts in defined projects, and include contributions towards the R&D cost. When there is reasonable assurance that the Company will comply with the conditions attached to a received grant, and when there is reasonable assurance that the grant will be received, government grants are recognized as revenue on a gross basis in the consolidated statement of profit or loss and comprehensive loss on a systematic basis over the periods in which the Company recognizes expenses for the related costs for which the grants are intended to compensate. In the case of grants related to assets, the received grant will be deducted from the carrying amount of the asset.

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 Expenses

The Company’s finance income and finance expenses 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 bispecific therapeutics.

Changes in Accounting Policy

During the year, the Company changed its accounting policy concerning the classification of investments as current and non-current. In prior years, investments were classified based on their maturity as of the date of purchase being 12 months or more. The policy was changed to classify investments based on their maturity being 12 months or more from the balance sheet date. Classification of investments in this manner is consistent with the classification of other balance sheet items. As a result, €16.9 million was reclassified from non-current investments to current investments for the comparative period ended December 31, 2018, as compared to the Company’s prior financial statements.

During the year, the Company changed its accounting policy concerning payments made to customers. In prior years, amounts paid to customers were recorded net of amounts received from customers. The policy was changed to account for such payments as an expense, to the extent such costs are considered distinct from other amounts received or receivable from a customer. As a result, collaboration revenue and research and development costs were increased €0.6 million for the period ended December 31, 2018, as compared to the Company's prior financial statements.

During the current year, the classification of certain research and development costs, general and administrative costs and other expenses in profit or loss have been modified to reflect more appropriately the nature of the operating expenses and the manner in which economic benefits are derived in the Company. Since the amounts are reclassifications within operating activities in profit or loss, these reclassifications did not have any effect on the consolidated statements of financial position and consolidated statement of cash flows.

Refer to Note 20 concerning a summary of the amounts restated retrospectively in comparative information.

Recently Adopted Accounting Pronouncements

In January 2016, the IASB issued IFRS 16, which supersedes existing lease guidance. Prior to the adoption of IFRS 16, the Company classified leases as operating or finance leases based on its assessment of whether the lease transferred substantially all of the risks and rewards of ownership. A lease asset and lease liability were recognized for those leases classified as finance leases. Operating leases were not recognized in the Company's statement of financial position. IFRS 16 established a right-of-use model that requires all lessees to recognize a lease asset and a lease liability in their statement of financial position that arise from leases with a term that is greater than 12 months. IFRS 16 was effective for annual and interim reporting periods beginning on or after January 1, 2019 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application.

The Company adopted IFRS 16 on January 1, 2019, using a modified retrospective transition approach applied to leases existing as of, or entered into after, January 1, 2019. The Company elected to utilize the package of practical expedients available for expired or existing contracts, which allowed the Company to carryforward historical assessments of whether contracts are or contain leases, lease classification and accounting for initial direct costs. In addition, the Company elected the practical expedients related to the recognition exemption for short-term leases and low-value leases. The adoption of this standard results in leases being recognized in the consolidated statement of financial position, except for short-term leases and low-value leases.

Adoption of the new standard resulted in the recognition of lease assets (right-of-use assets) of €2.8 million and lease liabilities (other current and non-current liabilities) of €3.0 million. To measure the lease liabilities at the date of initial application, the Company discounted the outstanding lease payments using its incremental borrowing rate at January 1, 2019 of 5.25%. See Note 5 for further details.

3. Property and Equipment

Movements in property and equipment, net were as follows:

	For the Year Ended December 31, 2019 (In euro thousands)			
Cost	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
Balance at January 1, 2019	2,759	622	35	3,416
Additions	1,281	434	36	1,751
Effect of movements in exchange	—	(1)	—	(1)
Balance at December 31, 2019	**4,040**	**1,055**	**71**	**5,166**
Accumulated Depreciation	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
Balance at January 1, 2019	802	248	2	1,052
Depreciation	645	151	10	806
Effect of movements in exchange	—	1	—	1
Balance at December 31, 2019	**1,447**	**400**	**12**	**1,859**
Carrying amount at December 31, 2019	**2,593**	**655**	**59**	**3,307**

	For the Year Ended December 31, 2018			

Cost	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
	(In euro thousands)			
Balance at January 1, 2018	1,261	413	—	1,674
Additions	1,498	209	35	1,742
Balance at December 31, 2018	2,759	622	35	3,416

Accumulated Depreciation	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
Balance at January 1, 2018	354	153	—	507
Depreciation	448	96	2	546
Balance at December 31, 2018	802	249	2	1,053
Carrying amount at December 31, 2018	1,957	373	33	2,363

Property and equipment are primarily located in the Netherlands for all periods presented.

4. Intangible Assets

Movements in intangible assets, net were as follows:

	For the Year Ended December 31, 2019		
	(In euro thousands)		
Cost	Patent Licenses	Software Licenses	Total
Balance at January 1, 2019	3,085	57	3,142
Additions	91	178	269
Balance at December 31, 2019	**3,176**	**235**	**3,411**
Accumulated Depreciation	Patent Licenses	Leasehold Improvements	Total
Balance at January 1, 2019	640	—	640
Amortization	188	23	211
Balance at December 31, 2019	**828**	**23**	**851**
Carrying amount at December 31, 2019	**2,348**	**212**	**2,560**

	For the Year Ended December 31, 2018		
	(In euro thousands)		
Cost	Patent Licenses	Software Licenses	Total
Balance at January 1, 2018	860	—	860
Additions	2,225	57	2,282
Balance at December 31, 2018	3,085	57	3,142
Accumulated Depreciation	Patent Licenses	Leasehold Improvements	Total
Balance at January 1, 2018	548	—	548
Amortization	92	—	92
Balance at December 31, 2018	640	—	640
Carrying amount at December 31, 2018	2,445	57	2,502

Amortization of intangible assets are recorded in operating expenses in the consolidated statement of profit or loss and comprehensive loss.

5. Leases

Merus N.V. leases its corporate headquarters under an agreement term of five years, which expires in the fourth quarter of 2021. On May 1, 2018, Merus N.V. leased additional space to expand its corporate headquarters under a separate agreement. Under the terms of the new agreement, the term began on May 1, 2018 and expires in the fourth quarter of 2021. If the leases are not terminated by Merus N.V., they will be automatically renewed for a period of two 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 based on an inflationary measure. Variable payments include amounts due to the lessor for additional services and cost reimbursements and are recognized in profit or loss when incurred.

In March 2019, Merus US, Inc. entered into a 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 and are recognized in profit or loss when incurred.

In July 2019, the Company entered into a lease with Kadans Science Partner XII B.V. ("Kadans"), pursuant to which the Company agreed to lease approximately 5,070 square meters of office and laboratory space in a new multi-tenant office building that is to be constructed in Utrecht, the Netherlands. The initial term of the lease is ten years from the date that the premises are completed in accordance with certain specifications provided in a development agreement (described below), which is expected to occur in mid-2022. The lease will renew for two 5-year terms 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. The lease provides for an estimated initial rent of approximately €1.3 million per annum. The rent amount is subject to adjustment based on the consumer price index (the "CPI") beginning on January 1, 2019 through the completion date and then annually thereafter, subject to certain limitations if the CPI is greater than 3.0%. The final initial rent amount is contingent upon, among other things, the parameters of the final constructed premises, the final floor area, and the CPI adjustment described above, and will be determined upon the completion date and recorded in a first rider, signed by the Company and Kadans, to the lease. The Company is also responsible for certain fit-out costs and service fees related to the premises.

In July 2019, the Company also entered into a development agreement with Kadans and another party, Genmab B.V., which provides for the design, development and construction of the new multi-tenant office building of which the premises is a part.

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

	For the Year Ended December 31, 2019
	(In euro thousands)
Opening balance January 1	—
Initial recognition of right-of-use assets upon adoption of IFRS 16	2,847
Additions to right-of-use assets	3,873
Depreciation	(1,375)
Foreign exchange	(6)
Closing balance December 31	5,339

The schedule of lease payments and balance of lease liabilities as of December 31, 2019 was as follows:

Year	Payments
	(In euro thousands)
2020	1,732
2021	1,607
2022	613
2023	628
2024	644
Thereafter	882
Total lease payments	6,106

Less: amount representing interest	(615)
Total lease liabilities	5,491

Current lease liabilities	1,512
Non-current lease liabilities	3,979
Total lease liabilities	5,491

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

	For the Year Ended December 31, 2019
	(In euro thousands)
Variable lease payments not included in the measurement of lease liabilities	424
Interest on lease liabilities	237
Expense from low-value leases	32
Cash outflow for leases	1,626

6. Taxes

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

	December 31,	
	2019	2018
	(In euro thousands)	
Current year tax expense		
Current year	**323**	423
Changes related to prior years	**(70)**	(67)
	253	356
Deferred tax benefit		
Origination and reversal of temporary differences	**(257)**	—
Tax (benefit) expense	**(4)**	356

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:

	Year Ended December 31,	
	2019	2018
Netherlands statutory income tax rate	**25.0**%	25.0%
U.S. tax rate differential	—	(0.1)
Changes in tax rates	**1.5**	(35.9)
Non-deductible expenses	**(3.7)**	(8.7)
Other	**0.1**	—
Current year losses for which no deferred tax asset was recognised	**(22.9)**	18.2
Effective income tax rate	**0.0**%	(1.5)%

In 2018 and 2019, Dutch tax authorities enacted new tax rates. The effect of the change in the valuation allowance each year reflects the increase or decrease in the valuation allowance against deferred tax assets attributable to the Netherlands.

The movement of deferred tax balances are as follows:

	2019			
	(In euros thousands)			
	Net balance at January 1	Recognized in profit or loss	Foreign exchange	Net balance at December 31

Deferred tax assets				
Lease liability	—	839	(3)	836
Accrued liabilities	—	280	(1)	279
Other	—	5	—	5
Total deferred tax assets	**—**	**1,124**	**(4)**	**1,120**
Deferred tax liabilities				
Operating lease right-of-use assets	**—**	**867**	**(3)**	**864**
Total, net	**—**	**257**	**(1)**	**256**

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

As of December 31, 2019, 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.

Tax loss carryforwards and years of expiry related to Merus N.V. as of December 31, 2019 are as follows:

Expiry Year	**Netherlands Tax Loss Carryforward**
	(In euro thousands)
2024	18,848
2025	89,785
2026	—
2027	30,499
Total	139,132

As of December 31, 2019, the Company had no unrecognized tax benefits. As of December 31, 2019, 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 2016. The statute of limitations for assessment by the Netherlands tax authorities is closed for tax years prior to 2014. 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, 2019 and 2018 consisted of the following:

	December 31,	
	2019	**2018**
		(restated)*
	(in euro thousands)	
Corporate paper and notes	**32,643**	53,338
U.S. treasuries	**1,331**	6,733
U.S. government agency securities	**3,549**	1,729
Current investments	**37,523**	61,800
Corporate paper and notes	**1,788**	—
Non-current investments	**1,788**	—
Total investments	**39,311**	61,800

* Comparative information has been restated, see Note 2.

8. Other Assets

The components of other assets are as follows:

	December 31, 2019	December 31, 2018
	(In euros thousands)	
Prepaid clinical and manufacturing costs	**2,474**	1,839
VAT receivable, net	**641**	891
Interest receivable	**230**	213
Other	**1,059**	1,188
Total	**4,404**	4,131

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, 2019, 45,000,000 shares were authorized for issuance (2018: 45,000,000). 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 February 13, 2018, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with the purchasers named therein (the "Investors"). Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 3,099,997 of its common shares to the Investors at a purchase price equal to $18.00 per share (the "Private Placement"). The Purchase Agreement contains customary representations and warranties from the Company and the Investors and customary closing conditions. On February 15, 2018, the Company completed the sale under the Private Placement and received gross proceeds of approximately $55.8 million, or €44.8 million.

On December 20, 2018, the Company entered into a share subscription agreement (the "Regeneron Subscription Agreement") with Regeneron Pharmaceuticals, Inc. ("Regeneron"). Pursuant to the Regeneron Subscription Agreement, the Company agreed to sell an aggregate of 600,000 of its common shares to Regeneron at a purchase price equal to $25.00 per share. On December 21, 2018, the Company completed the sale under the Regeneron Subscription Agreement and received gross proceeds of $15.0 million. Accordingly, the Company recorded the common shares issued at the fair value of the underlying securities on the date of issuance. The difference between the total proceeds received of $15.0 million, and the aggregate value of common shares issued of $6.9 million, or €6.0 million, was recorded as other income of $8.1 million, or €7.1 million, relating to the litigation settlement during the year ended December 31, 2018.

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.

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, 2020, a total of 1,901,162 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 Incyte collaboration and license agreement, the Company and Incyte have agreed to collaborate with 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 Incyte or that 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, 2019, 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, 2019 and 2018.

Litigation

On March 11, 2014, Regeneron Pharmaceuticals, Inc. ("Regeneron") filed a complaint in the U.S. District Court for the Southern District of New York, alleging that the Company was infringing one or more claims in Regeneron's U.S. Patent No. 8,502,018, entitled "Methods of Modifying Eukaryotic Cells." On December 20, 2018, the Company signed a global settlement and cross-license agreement with Regeneron, where the parties have agreed to end all pending litigation and opposition proceedings pertaining to the Company's and Regeneron's respective antibody generation technologies. Regeneron also purchased 600,000 of the Company's common shares at a price of $25 per share for total aggregate proceeds of $15.0 million. The cross-license and stock purchase were made in conjunction with the agreement to withdraw Regeneron's appeal of the fee award, and agreement to dismissal of all claims to approximately $10.5 million for the reimbursement of attorneys' fees and other expenses, plus interest, awarded to Merus by the trial court. Under the terms of the settlement, Regeneron has withdrawn its appeal of the decision awarding attorneys' fees to the Company as a result of the U.S. District Court litigation described above. In addition, Regeneron has dismissed its stayed case in the Netherlands asserting the EP 1 360 287 B1 patent, and both parties have withdrawn all pending oppositions as of December 20, 2018. As a result of the settlement, the Company recognized a gain of $8.1 million, or €7.1 million, included in other income in the consolidated statement of profit or loss and comprehensive loss for the year ended December 31, 2018.

On April 5, 2018, an unnamed third party and Regeneron Pharmaceuticals Inc. or Regeneron filed notices of opposition against the Company's EP 2604625 patent, entitled "Generation of Binding Molecules," in the European Opposition Division of the European Patent Office (the "EPO"). The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron withdrew its opposition pursuant to a global December 20, 2018 settlement with Merus. On August 20, 2018, the Company timely responded to these submissions with respect to the unnamed third party. An opposition hearing was held in June 2019, wherein the EPO revoked the EP 2604625 patent in its entirety under Art. 123(2) EPC. We timely appealed that decision in December 2019 before the Technical Board of Appeals for the EPO seeking reinstatement of the patent and proposing auxiliary requests for certain amended claims, with further proceedings to be scheduled in the future. As this opposition proceeding continues, the Company cannot be certain that the Company will ultimately prevail.

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 other material legal proceedings.

11. Accrued Liabilities

The components of accrued liabilities are as follows:

	December 31,	
	2019	2018
	(In euro thousands)	
Accrued research and development expenses	**5,891**	4,409
Accrued general and administrative expenses	**2,139**	2,525
Accrued personnel costs	**4,001**	2,083
Other	**19**	219
Total accrued liabilities	**12,050**	9,236

The increase in accrued personnel costs during 2019 is attributable to the increase in the number of employees of the Company.

12. Collaboration Revenue

Incyte

In December 2016, pending regulatory clearance, 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 11 product candidates that result from the Company's application of its proprietary Biclonics® 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 retains the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte has 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 the transaction price allocated to the license and related activities 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 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.

At December 31, 2019, the Company is currently engaged in research and development activities for MCLA-145 and developing candidates for the other programs. No development or commercialization milestones have been achieved to date. Incyte is a shareholder with holdings representing approximately 11.1% of the outstanding shares of the Company as of December 31, 2019, and 13.7% as of December 31, 2018.

ONO

In March 2018, the Company granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on the Company's Biclonics® 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 a combined performance obligation for the provision of a license for the target combination, and research and development services. Revenue was recognized over time as these services are delivered and concluded in 2018. Milestone payments are fully constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

In March 2016, the Company was engaged to perform manufacturing services for Ono in support of their clinical trials that was the subject of a prior arrangement with Ono initiated in 2014. The Company was entitled to compensation to oversee and support a manufacturing process with the use of an outside third-party and to deliver quantities of manufactured product. The Company identified one performance obligation to provide manufacturing supervision services involving the transfer of know-how and the development of a manufacturing process with the third-party and three performance obligations related to the services provided in connection with the delivery of product each having separate and distinct requirements. The Company acts as an agent for Ono with respect to the third-party manufacturing costs incurred for the underlying product and presents the recovery of such costs net in research and development expense in the consolidated statement of profit or loss and comprehensive loss.

The Company received €3.7 million for the year ended December 31, 2019 for development milestones received from Ono based on their progress related to the March 2018 arrangement. The amounts are recognized as revenue in the consolidated statement of profit or loss and comprehensive loss. The Company recognized €4.0 million of the transaction price as revenue in the year ended December 31, 2018 mainly related to the March 2016 arrangement for the three performance obligations for the services provided in connection with the delivery of product completed in the period.

Simcere

In January 2018, the Company granted Simcere an exclusive license to develop and commercialize three bispecific antibodies to be produced by Merus utilizing the Company's Biclonics® technology platform in the area of immuno-oncology in China. 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 product candidates in China. The Company received an upfront, non-refundable payment of $2.8 million, relating to three separate research programs. The Company may be entitled to future development milestone payments.

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.

At December 31, 2019, research and development for two of the three programs is on-going.

Betta

On December 10, 2018, the Company granted Betta an exclusive license to develop and commercialize in China MCLA-129, a proprietary Biclonics® produced by its Biclonics® 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.

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. The technology transfer to deliver the license was completed and the Company recognized the revenue related to this performance obligation of €0.9 million as revenue for the year ended December 31, 2019. 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.

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.

	For the Year Ended December 31, 2019 (In euros thousands)			
	Incyte	Ono	Other	Total
Contract assets				
Trade receivables				
Balance at January 1, 2019	—	61	25	86
Billings	7,575	4,023	848	12,446
Cash receipts	(7,603)	(3,384)	(873)	(11,860)
Foreign exchange	28	—	—	28
Balance at December 31, 2019	**—**	**700**	**—**	**700**
Unbilled receivables				
Balance at January 1, 2019	2,604	236	—	2,840
Accrued receivables	6,494	3,787	985	11,266
Billings	(7,575)	(4,023)	(847)	(12,445)
Foreign exchange	—	—	—	—
Balance at December 31, 2019	**1,523**	**—**	**138**	**1,661**
Contract liabilities				
Deferred revenue				
Balance at January 1, 2019	112,551	—	2,058	114,609
Cash receipts	—	—	848	848
Revenue recognized in the period	(15,935)	—	(1,676)	(17,611)
Foreign exchange	—	—	—	—
Balance at December 31, 2019	**96,616**	**—**	**1,230**	**97,846**
Less: current portion	**(15,935)**	**—**	**(796)**	**(16,731)**
Non-current balance at December 31, 2019	**80,681**	**—**	**434**	**81,115**

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.

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:

	For the Year Ended December 31, 2019 (In euros thousands)			
	Incyte	**Ono**	**Other**	**Total**
Upfront payments	15,935	—	1,423	17,358
Reimbursement revenue	7,139	88	137	7,364
Milestones	—	3,700	253	3,953
Total collaboration revenue	**23,074**	**3,788**	**1,813**	**28,675**
Operating expenses:				
Research and development expense	607	—	—	607
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	**607**	**—**	**—**	**607**
Revenue recognized that was included in deferred revenue at the beginning of the period	**15,935**	**—**	**1,676**	**17,611**

	For the Year Ended December 31, 2018 (In euros thousands)			
	Incyte	**Ono**	**Other**	**Total**
Upfront payments	15,935	700	558	17,193
Reimbursement revenue *	9,441	877	—	10,318
Milestones	—	4,000	353	4,353
Total collaboration revenue	25,376	5,577	911	31,864
Operating expenses:				
Research and development expense *	574	—	—	574
General and administrative expense *	37	—	—	37
Total operating expenses from collaborations *	611	—	—	611
Revenue recognized that was included in deferred revenue at the beginning of the period	15,935	—	—	15,935

* Comparative amounts have been restated, see Note 2.

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, 2019	Year Ended December 31, 2018 (restated)*
		(In euro thousands)	
Research and development costs			
External costs		**23,283**	15,361
Manufacturing		**9,961**	18,914
Employee benefits		**7,349**	3,893
Share-based payments	14	**2,812**	2,710
Depreciation and amortization	3,4,5	**1,511**	448
Other		**4,708**	4,948
Total research and development costs		**49,624**	46,274

General and administrative costs			
Employee benefits		**10,445**	6,467
Consulting		**5,662**	3,441
Share-based payments	14	**6,078**	5,215
Legal fees		**3,093**	4,079
Accounting and professional fees		**2,478**	2,016
Depreciation and amortization	3,4,5	**881**	190
Other		**3,687**	3,225
Total general and administrative costs		**32,324**	24,633

* Comparative amounts have been restated, see Note 2.

Employee benefits included in research and development costs are presented net of WBSO contributions of €4.0 million (2018: €4.3 million).

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 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. 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, 2020 totaled 1,901,162.

Share-Based Compensation Expense

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

	For the Year Ended December 31,	
	2019	2018
	(In thousands)	
Research and development	**2,812**	2,710
General and administrative	**6,078**	5,215
Total	**8,890**	7,925

Stock Option Valuation

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

	For the Year Ended December 31,	
	2019	2018
Risk-free interest rate	**2.5**%	2.9%
Expected life of options (years)	**10.0**	10.0
Expected volatility of underlying stock	**87.0**%	93.7%
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. The Company determines 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. 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.

Stock Option Activity

The following is a summary of stock option activity for the years ended December 31, 2019 and 2018:

	2019			2018		
	Number of Options		Weighted Average Exercise Price per Share	Number of Options		Weighted Average Exercise Price per Share
		€			€	
Outstanding at January 1	**2,633,039**		**14.62**	2,213,985		13.99
Granted	**1,145,221**		**10.78**	625,445		14.96
Exercised	**(12,080)**		**3.53**	(135,888)		6.80
Forfeited or expired	**(451,309)**		**13.96**	(70,503)		12.92
Outstanding at December 31	**3,314,871**		**13.10**	2,633,039		14.62
Exercisable at December 31	**1,795,089**		**13.78**	1,275,669		12.97
Weighted-average remaining contractual life of options outstanding at December 31 (years)			**7.3**			7.0
Range of exercise prices of options outstanding at December 31:						
Minimum		**€**	**1.93**		€	1.93
Maximum		**€**	**27.47**		€	27.47
Weighted-average share price at the date of option exercises		**€**	**11.69**		€	17.03

RSU Activity

The following is a summary of RSU activity for the years ended December 31, 2019 and 2018:

	2019		2018	
	Number of RSUs	Weighted Average Exercise Price per Share	Number of RSUs	Weighted Average Exercise Price per Share
		€		€
Unvested at January 1	**101,302**	**20.03**	194,546	20.03
Granted	**30,000**	**15.44**	—	—
Vested	**(48,660)**	**20.03**	(93,244)	20.03
Unvested at December 31	**82,642**	**18.37**	101,302	20.03

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 €1.1 million and €0.7 million in the years ended December 31, 2019 and 2018, 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 €0.1 million and €0.1 million in the years ended December 31, 2019 and 2018, 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 is to be paid by the Company January 31, 2020. There were no substantive service conditions associated with the benefits awarded other than the passage of time. The Company incrementally recognized €3.4 million in general and administrative expense associated with these benefits in the consolidated statement of profit or loss and comprehensive loss for the year ended December 31, 2019.

15. Other Income

The components of other income are as follows:

	Year Ended December 31, 2019	2018
	(In euro thousands)	
Finance income		
Interest and similar related income	**1,689**	1,809
Net gain from foreign exchange	**1,441**	6,034
Total finance income	**3,130**	7,843
Finance costs		
Interest expense	**(237)**	(4)
Other income		
Litigation settlement gain	**—**	7,095
Miscellaneous income	**175**	—
Total other income	**175**	7,095

Refer to Note 10 concerning the litigation settlement gain.

16. Supplemental Cash Flow Information

	Year Ended December 31, 2019	2018
	(In euro thousands)	
CASH AND CASH EQUIVALENTS		
Bank deposits and similar instruments	**145,594**	123,260
Money market funds and other	**30,312**	20,487
	175,906	143,747
CHANGES IN WORKING CAPITAL:		
Trade receivables	**565**	(2,576)
Prepaid expenses and other current assets	**(580)**	(946)
Trade payables	**18**	618
Accrued expenses	**2,963**	(650)
Deferred revenue	**(16,763)**	(13,877)
Total changes in working capital	**(13,797)**	(17,431)
NON-CASH TRANSACTIONS:		
Lease obligations recognized upon adoption of IFRS 16	**2,847**	—
Lease obligations recognized upon commencement of an operating lease	**3,873**	—
Property, equipment and intangibles included in accounts payable or accruals	**167**	346
Financing costs included in accounts payable or accruals	**148**	—

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:

	Year Ended December 31, 2019	2018
	(In euro thousands except per share data)	
Result after taxation	**(50,393)**	(24,269)
Weighted average shares outstanding	**24,218,083**	22,286,720
Basic and diluted loss per share allocable to common stockholders	**(2.08)**	(1.09)

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:

	For the Year Ended December 31, 2019	2018
	(In euro thousands)	
Short-term employee benefits	**3,316**	3,165
Post-employment benefits	**50**	59
Termination benefits	**846**	—
Share-based compensation	**6,752**	6,386
Total	**10,964**	9,610

	As of December 31, 2019	2018
Outstanding stock options held by key management personnel	**2,204,787**	1,913,312
Weighted average exercise price	**€ 13.41**	€ 14.55
Unvested RSUs	**82,642**	101,302

Amounts attributable to the CEO, who is also a director, included in the above amounts, were as follows:

- salary €0.5 million (2018: €0.4 million) and bonus of €0.2 million (2018: €0.2 million) (collectively short-term employee benefits),
- post-employment benefits of less than €0.1 million (2018: less than €0.1 million),
- termination benefits of €0.6 million (2018: nil) and
- share-based compensation €4.4 million (2018: €2.7 million).

The CEO held 848,863 outstanding stock options as of December 31, 2019 (2018: 758,925) with a weighted-average exercise price of €13.79 (2018: €17.07), and held 63,514 unvested RSUs as of December 31, 2019 (2018: 64,450). As described in Note 14, the former CEO was granted termination benefits, grants of share-based compensation, and modifications to existing awards in December 2019. In addition, termination benefits related to severance granted to the Company's former CFO was recorded in January 2019 of €0.2 million.

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:

	2019		2018	
	Cash Compensation	Stock-based Compensation	Cash Compensation	Stock-based Compensation
	(In euro thousands)		(In euro thousands)	
Russell Greig	**94**	**151**	39	79
Mark Iwicki	**48**	**21**	55	69
Len Kanavy	**40**	**150**	33	153
Wolfgang Berthold (former)	**—**	**51**	19	66
John de Koning	**45**	**95**	41	51
Sven Ante Lundberg (new)	**20**	**108**	—	—
Anand Mehra	**47**	**94**	40	34
Gregory Perry	**52**	**19**	45	55
Victor Sandor (new)	**30**	**134**	—	—
Total	**376**	**823**	272	507

As at December 31, 2019 the following stock options held by directors were outstanding:

	2019		2018	
	Number	Weighted Average Exercise Price	Number	Weighted Average Exercise Price
		€		€
Russell Greig	**18,466**	**16.66**	9,966	19.97
Mark Iwicki	**92,709**	**8.45**	84,209	10.07
Len Kanavy	**30,318**	**15.31**	21,818	16.33
Wolfgang Berthold (former)	**36,540**	**12.28**	36,540	15.22
John de Koning	**36,133**	**12.52**	27,633	14.34
Sven Ante Lundberg (new)	**17,000**	**11.16**	—	—
Anand Mehra	**36,133**	**12.52**	27,633	14.34
Gregory Perry	**36,133**	**12.52**	27,633	14.34
Victor Sandor (new)	**17,000**	**12.81**	—	—
Total and weighted average, respectively	**320,432**	**11.76**	235,432	13.37

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, 2019	December 31, 2018
	(In euros thousands)	
Cash and cash equivalents	**175,906**	143,747
Current investments	**37,523**	61,800
Non-current investments	**1,788**	—
Trade receivables	**2,361**	2,926
Total	**217,578**	208,473

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 AA, while investments are in highly rated vehicles with identical credit ratings.

The aging of trade and unbilled receivables was as follows:

	December 31, 2019	December 31, 2018
	(In euros thousands)	
Neither past due or impaired	**2,361**	2,926
Past due	**—**	—
Total fees	**2,361**	2,926

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, 2019 and 2018. The amounts are gross and undiscounted.

	Year Ended December 31, 2019				
	(In euros thousands)				
	Carrying amount	< 1 year	1 - 2 years	2 - 5 years	> 5 years
Trade payables	**2,696**	**2,696**	**—**	**—**	**—**
Accrued liabilities	**12,050**	**12,050**	**—**	**—**	**—**
Lease liabilities	**5,491**	**1,512**	**1,977**	**2,002**	**—**
	20,237	**16,258**	**1,977**	**2,002**	**—**

	Year Ended December 31, 2018				
	(In euros thousands)				
	Carrying amount	< 1 year	1 - 2 years	2 - 5 years	> 5 years
Trade payables	2,829	2,829	—	—	—
Accrued liabilities	9,236	9,236	—	—	—
	12,065	12,065	—	—	—

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.

1. *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, 2019. The analysis shows the impact that a change in the exchange rate at that date would have on the Company's pre-tax result:

	December 31, 2019 (In euros thousands)		
Financial Statement Line Item Exposure	**Balance**	**Effect on result before taxation if the U.S. dollar strengthens 5%**	**Effect on result before taxation if the U.S. dollar weakens 5%**
Deferred tax assets	256	13	(13)
Other assets	230	12	(12)
Trade receivables	1,523	76	(76)
Investments	39,311	1,966	(1,966)
Cash and cash equivalents	60,291	3,015	(3,015)
Trade payables	(877)	(44)	44
Accrued liabilities	(654)	(33)	33
Balance at December 31, 2019	**100,080**	**5,005**	**(5,005)**

The closing exchange rate per the European Central Bank utilized above for converting the euro to U.S. dollars at December 31, 2019 was 1.1234.

2. *Interest Rate Risk*

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

	December 31,	
	2019	**2018**
	(In euros thousands)	
Variable rate instruments		
Cash and cash equivalents	**175,906**	143,747
Fixed rate instruments		
Current investments	**37,523**	61,800
Non-current investments	**1,788**	—

The weighted average remaining days to maturity for the Company's investment portfolio is 93 days as of December 31, 2019. Due to the short remaining hold period for the Company's investments and resulting limited impact of changes in interest rates on the Company, no sensitivity data is provided.

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. Comparative Information

The changes in comparative information are as follows:

Consolidated Balance Sheet	As at December 31, 2018 (In euro thousands) As previously stated	Reclassification	Restated
Non-current assets:			
Property and equipment, net	2,420	(57)	2,363
Intangible assets, net	2,445	57	2,502
Investments	16,945	(16,945)	—
Current assets:			
Trade and other receivables	7,032	(7,032)	—
Trade receivables	—	2,926	2,926
Other assets	—	4,132	4,132
Investments	44,855	16,945	61,800
Current liabilities:			
Trade payables	3,819	(990)	2,829
Taxes and social security liabilities	256	(256)	—
Accrued liabilities	7,964	1,272	9,236

Consolidated Statement of Profit or Loss and Comprehensive Loss	For the year ended December 31, 2018 (In euro thousands) As previously stated	Reclassification	Restated
Collaboration revenue	31,252	612	31,864
Research and development costs	(46,740)	466	(46,274)
General and administrative costs	(10,395)	(14,238)	(24,633)
Other expenses	(13,160)	13,160	—
	(70,295)	(612)	(70,907)

The above changes are a result of changes in accounting policies adopted in the current year. Refer to Note 2.

21. Subsequent Events

On April 15, 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 has entered into a Settlement Agreement with the Company, pursuant to which Mr. Throsby will be entitled to receive 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 granted to him under the applicable equity-based long-term incentive plan of the Company will continue to vest until October 31, 2020 as if Mr. Throsby had continued in full time service with the Company through such date. The Company is evaluating the accounting for the modification of his unvested equity awards.

There are no other matters occurring subsequent to December 31, 2019 requiring disclosure through the date these consolidated financial statements were authorized for issuance by the board of directors on May 19, 2020.

10.2 Company Financial Statements

MERUS N.V.

SEPARATE STATEMENT OF FINANCIAL POSITION

(All amounts in euro thousands)

	Note	As at December 31, 2019	As at December 31, 2018
Non-current assets			(restated)*
Financial fixed asset	3	**1,815**	947
Property and equipment, net	4	**3,095**	2,360
Intangible assets, net	5	**2,560**	2,502
Right-of-use assets	7	**1,842**	—
Investments	6	**1,788**	—
Other assets	6	**1,516**	953
		12,616	6,762
Current assets			
Trade receivables	6	**2,361**	2,926
Investments	6	**37,523**	57,698
Other assets	6	**9,892**	8,576
Cash and cash equivalents		**167,884**	141,614
		217,660	210,814
Total assets		**230,276**	217,576
Shareholders' equity	10		
Issued and paid-in capital		**2,599**	2,102
Share premium account		**331,029**	264,854
Legal reserves		**148**	133
Accumulated loss		**(216,723)**	(175,220)
Total shareholders' equity		**117,053**	91,869
Non-current liabilities			
Lease liabilities	7	**990**	—
Deferred revenue	9	**81,115**	97,675
		82,105	97,675
Current liabilities			
Trade payables		**2,637**	2,817
Accrued liabilities	8	**10,679**	8,281
Lease liabilities	7	**1,071**	—
Deferred revenue	9	**16,731**	16,934
		31,118	28,032
Total liabilities		**113,223**	125,707
Total shareholders' equity and liabilities		**230,276**	217,576

* Comparatives were restated. Refer to Note 1 concerning changes in accounting policy for details.

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	Year ended December 31, 2019	Year ended December 31, 2018
			(restated)*
Collaboration revenue	11	**28,675**	31,864
Grant revenue		**(192)**	196
Total revenue		**28,483**	32,060
Research and development costs	12	**(46,290)**	(44,795)
General and administrative costs	12	**(34,631)**	(26,824)
Total operating expenses		**(80,921)**	(71,619)
Operating result		**(52,438)**	(39,559)
Finance income	14	**3,113**	7,752
Finance cost	14	**(131)**	(4)
Other income, net	14	**175**	7,095
Result on subsidiary	3	**(1,095)**	481
Result before taxation		**(50,376)**	(24,235)
Tax expense		**—**	—
Result after taxation and comprehensive loss		**(50,376)**	(24,235)

* Comparatives were restated. Refer to Note 1 concerning changes in accounting policy for details.

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. The adoption of new accounting standards only impacted transactions recorded in Merus N.V.

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 translation 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.

Changes in Accounting Policy

During the year, the Company changed its accounting policy concerning the classification of investments as current and non-current. In prior years, investments were classified based on their maturity as of the date of purchase being 12 months or more. The policy was changed to classify investments based on their maturity being 12 months or more from the balance sheet date. Classification of investments in this manner is consistent with the classification of other balance sheet items. As a result, €14.3 million was reclassified from non-current investments to current investments for the comparative period ended December 31, 2018, as compared to the Company's prior financial statements.

During the year, the Company changed its accounting policy concerning payments made to customers. In prior years, amounts paid to customers were recorded net of amounts received from customers. The policy was changed to account for such payments as an expense, to the extent such costs are considered distinct from other amounts received or receivable from a customer. As a result, collaboration revenue and research and development costs were increased €0.6 million for the period ended December 31, 2018, as compared to the Company's prior financial statements.

During the current year, the classification of certain research and development costs, general and administrative costs and other expenses in profit or loss have been modified to reflect more appropriately the nature of the operating expenses and the manner in which economic benefits are derived in the Company. Since the amounts are reclassifications within operating activities in profit or loss, these reclassifications did not have any effect on the consolidated statements of financial position and consolidated statement of cash flows.

Refer to Note 19 concerning a summary of the amounts restated retrospectively in comparative information.

2. Employees

The number of personnel for the year was as follows:

	December 31,	
	2019	2018
Netherlands	**108**	81
United States	**22**	17
Total full-time equivalent employees	**130**	98

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.

	For the year ended December 31,	
	2019	**2018**
	(In euro thousands)	
Balance as at January 1	**947**	433
Result on subsidiary	**(1,095)**	481
Capital contribution for stock-based compensation awarded to employees of the subsidiary	**1,948**	—
Exchange differences	**15**	33
Balance as at December 31	**1,815**	947
Equity of Merus US, Inc. as at December 31	**1,815**	947

4. Property and Equipment

Movements in property and equipment were as follows:

	For the Year Ended December 31, 2019 (In euro thousands)			
Cost	**Laboratory Equipment**	**Office Furniture & Equipment**	**Leasehold Improvements**	**Total**
Balance at January 1, 2019	2,759	616	35	3,410
Additions	1,281	229	—	1,510
Balance at December 31, 2019	**4,040**	**845**	**35**	**4,920**

Accumulated Depreciation	**Laboratory Equipment**	**Office Furniture & Equipment**	**Leasehold Improvements**	**Total**
Balance at January 1, 2019	802	246	2	1,050
Depreciation	645	123	7	775
Balance at December 31, 2019	**1,447**	**369**	**9**	**1,825**
Carrying amount at December 31, 2019	**2,593**	**476**	**26**	**3,095**

Cost	For the Year Ended December 31, 2018 (In euro thousands) Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
Balance at January 1, 2018	1,261	407	—	1,668
Additions	1,498	209	35	1,742
Balance at December 31, 2018	2,759	616	35	3,410

Accumulated Depreciation	Laboratory Equipment	Office Furniture & Equipment	Leasehold Improvements	Total
Balance at January 1, 2018	354	151	—	505
Depreciation	448	95	2	545
Balance at December 31, 2018	802	246	2	1,050
Carrying amount at December 31, 2018	1,957	370	33	2,360

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:

	December 31, 2019	2018
	(In euros thousands)	
Non-current		
Prepaid clinical and manufacturing costs	**1,232**	669
Deposits	**284**	284
Total non-current other assets	**1,516**	953
Current		
Due from subsidiary - Merus US, Inc.	**5,657**	4,562
Prepaid clinical and manufacturing costs	**2,474**	1,839
VAT receivable, net	**641**	891
Interest receivable	**230**	207
Other	**890**	1,077
Total current other assets	**9,892**	8,576

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:

	For the Year Ended December 31, 2019
	(In euro thousands)
Opening balance January 1	—
Initial recognition of right-of-use assets upon adoption of IFRS 16	2,847
Depreciation	(1,005)
Closing balance December 31	1,842

The schedule of lease payments and balance of lease liabilities as of December 31, 2019 was as follows:

Year	Payments
	(In euro thousands)
2020	1,149
2021	1,009
Total lease payments	2,158
Less: amount representing interest	(97)
Total lease liabilities	2,061
Current lease liabilities	1,071
Non-current lease liabilities	990
Total lease liabilities	2,061

Amounts recognized in operating loss and cash flows were as follows:

	For the Year Ended December 31, 2019
	(In euro thousands)
Variable lease payments not included in the measurement of lease liabilities	286
Interest on lease liabilities	131
Expense from low-value leases	32
Cash outflow for leases	1,082

8. Accrued Liabilities

All amounts are short-term and payable within 1 year. The components of accrued liabilities are as follows:

	December 31,	
	2019	2018
	(In euro thousands)	
Accrued research and development expenses	**5,891**	4,409
Accrued general and administrative expenses	**1,891**	2,318
Accrued personnel costs	**2,891**	1,344
Other	**6**	210
Accrued expenses	**10,679**	8,281

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, 2019 relates to accumulated foreign exchange differences on the Company's subsidiary.

It is proposed that the loss for the year ended December 31, 2019, of €50.4 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, 2019	2018 (restated)*
		(In euro thousands)	
Research and development costs			
External costs		**23,283**	15,361
Manufacturing		**9,961**	18,914
Employee benefits		**5,305**	2,556
Share-based payments	13	**1,925**	2,710
Depreciation and amortization	4,5,7	**1,418**	448
Other		**4,398**	4,806
Total research and development costs		**46,290**	44,795
General and administrative costs			
Intercompany charges - Merus US, Inc.		**9,680**	6,910
Share-based payments	13	**5,017**	5,215
Employee benefits		**5,624**	3,095
Consulting		**5,229**	2,992
Legal fees		**3,086**	4,064
Accounting and professional fees		**2,372**	1,947
Depreciation and amortization	4,5,7	**573**	189
Other		**3,050**	2,412
Total general and administrative costs		**34,631**	26,824

* Comparative amounts have been restated. Refer to Note 1.

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. Other Income

The following table presents a breakdown of other income (expense):

	Year Ended December 31,	
	2019	**2018**
	(In euro thousands)	
Finance income		
Interest and similar related income	**1,630**	1,655
Net gain from foreign exchange	**1,483**	6,097
Total finance income	**3,113**	7,752
Finance costs		
Interest expense	**(131)**	(4)
Other income		
Litigation settlement gain	**—**	7,095
Miscellaneous income	**175**	—
Total other income	**175**	7,095

Refer to Note 10 to the consolidated financial statements for a detailed explanation on the litigation settlement gain.

15. Taxation

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

As of December 31, 2019, the tax losses carried forward and expiry were as follows:

Expiry Year	Netherlands Tax Loss Carryforward
	(In euro thousands)
2024	18,848
2025	89,785
2026	—
2027	30,499
Total	139,132

Other deductible temporary difference, which primarily relates to deferred revenue, amounted to €98.3 million at December 31, 2019.

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, 2019	December 31, 2018
	(In euros thousands)	
Cash and cash equivalents	**167,884**	141,614
Current investments	**37,523**	57,698
Non-current investments	**1,788**	—
Trade receivables	**2,361**	2,926
Total	**209,556**	202,238

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:

	Year Ended December 31, 2019 (In euros thousands)				
	Carrying amount	< 1 year	1 - 2 years	2 - 5 years	> 5 years
Trade payables	**2,637**	**2,637**	**—**	**—**	**—**
Accrued liabilities	**10,679**	**10,679**	**—**	**—**	**—**
Lease liabilities	**2,061**	**1,071**	**990**	**—**	**—**
	15,377	**14,387**	**990**	**—**	**—**

	Year Ended December 31, 2018 (In euros thousands)				
	Carrying amount	< 1 year	1 - 2 years	2 - 5 years	> 5 years
Trade payables	3,807	3,807	—	—	—
Accrued liabilities	7,122	7,122	—	—	—
	10,929	10,929	—	—	—

Market Risk

Refer to Note 19 to the consolidated financial statements for further information on market risk.

1. Refer to Note 19 to the consolidated financial statements for further information the Company's exposure to foreign currency risk.
2. Exposure to interest rate risk

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

	December 31,	
	2019	2018
	(In euros thousands)	
Variable rate instruments		
Cash and cash equivalents	**167,884**	141,614
Fixed rate instruments		
Current investments	**37,523**	57,698
Non-current investments	**1,788**	—

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

Refer to Note 18 to the consolidated financial statements for further information on directors and key management personnel compensation, and Note 10 concerning indemnifications of officers and directors.

The cash compensation to directors disclosed in Note 18 to the consolidated financial statements fully consists of mounts of periodically paid remuneration.

In addition, Merus US, Inc. is a related party as the Company's subsidiary. Refer to Note 12 of these financial statements concerning transactions in the periods reported, 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

The following table summarizes the fees of KPMG Accountants N.V., our independent registered public accounting firm, billed to us for each of the last two fiscal years for audit and other services:

	Year Ended December 31,	
	2019	2018
	(In euros thousands)	
Audit fees	**1,566**	1,092
Audit-related fees	**15**	16
Other	**2**	—
Total fees	**1,583**	1,1,08

Audit fees consist of fees billed for the audit of our annual consolidated financial statements and the review of the interim consolidated financial statements, and related services. Audit-related fees relate to assurance services related to a specific research grant. Tax fees consist of fees for professional services, including tax consulting and compliance. We did not incur any tax fees in any of the periods presented in these financial statements. Other fees consist of fees for accounting research tools.

19. Comparative Information

The changes in comparative information are as follows:

Separate Balance Sheet	As at December 31, 2018 (In euro thousands)		
	As previously stated	Reclassification	Restated
Non-current assets:			
Property and equipment, net	2,417	(57)	2,360
Intangible assets, net	2,445	57	2,502
Investments	14,324	(14,324)	—
Current assets:			
Trade and other receivables	11,502	(11,502)	—
Trade receivables	—	2,926	2,926
Other assets	—	8,576	8,576
Investments	43,374	14,324	57,698
Current liabilities:			
Trade payables	3,807	(990)	2,817
Taxes and social security liabilities	169	(169)	—
Accrued liabilities	7,122	1,159	8,281

	For the year ended December 31, 2018 (In euro thousands)		
Separate Statement of Profit or Loss and Comprehensive Loss	As previously stated	Reclassification	Restated
Collaboration revenue	31,252	612	31,864
Research and development costs	(45,197)	402	(44,795)
General and administrative costs	(7,025)	(19,799)	(26,824)
Other expenses	(18,785)	18,785	—
	(71,007)	(612)	(71,619)

The above changes are a result of changes in accounting policies adopted in the current year. Refer to Note 1.

20. 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, 2019 requiring disclosure through the date these separate financial statements were authorized for issuance by the board of directors on May 19, 2020.

Utrecht, May 19, 2020
The Board of Directors:

/s/ S.A. Lundberg

S.A. Lundberg

/s/ R. Greig

R. Greig

/s/ J. de Koning

J. de Koning

/s/ M. Iwicki

M. Iwicki

/s/ L. Kanavy

L. Kanavy

/s/ A. Mehra

A. Mehra

/s/ G. Perry

G. Perry

/s/ V. Sandor

V. Sandor

11 Other Information

11.1 Independent Auditor's Report

KPMG

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 2019 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, 2019 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, 2019 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 2019 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, 2019;

2 the following consolidated statements for 2019: 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 December 31, 2019;

2 the separate statement of profit or loss and comprehensive loss for 2019; 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 believe the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Audit approach

Summary

Materiality
— Materiality of EUR 1,500 thousand — 3% of the result before taxation

Group audit
— Full scope audit of all group entities

Key audit matter
— 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 1,500 thousand (2018: EUR 900 thousand). The increase in materiality is consistent with the increase in research and development activities during the year. The materiality is determined with reference to the result before taxation (3%). We consider the result before taxation as the most appropriate benchmark because this best reflects the nature of the entity being in the 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 for the users of the financial statements for qualitative reasons.

We agreed with the Audit Committee and the Board of Directors that misstatements in excess of EUR 75 thousand, which are identified during the audit, 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 entities. 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. Accounting for the group's activities takes place at the headquarters in Utrecht, the Netherlands. As a consequence, we were able to perform all the audit work 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 scope in relation to fraud

In accordance with the Dutch standards on auditing we are responsible for obtaining a high (but not absolute) level of assurance that the financial statements taken as a whole are free from material misstatement, whether caused by fraud or error.

As part of our risk assessment process we have evaluated events or conditions that indicate an incentive or pressure to commit fraud or provide an opportunity to commit fraud ('fraud risk factors') to determine whether fraud risks are relevant to our audit.

We communicated identified fraud risks throughout our team and remained alert to any indications of fraud throughout the audit.

In accordance with the auditing standard we evaluated the fraud risks that are relevant to our audit:

- management override of controls (a presumed fraud risk)

The presumed fraud risk with regard to revenue recognition is not considered applicable. 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/or non-complex.

Our audit procedures included an evaluation of the design and implementation of internal controls relevant to mitigate these risks and substantive audit procedures, including detailed testing of high risk journal entries in relation to, amongst others, research and development costs and non-routine transactions, and evaluation of management bias. In determining the audit procedures we made use of the company's evaluation in relation to fraud risk management (prevention, detections and response), including the set-up of ethical standards to create a culture of honesty.

As part of our evaluation of any instances of fraud, we inspected the incident register/whistle blowing reports. No incidents of fraud have been brought to our attention.

We communicated our risk assessment and audit response to management and the Audit Committee. Our audit procedures differ from a specific forensic fraud investigation, which investigation often has a more in-depth character.

Our procedures to address fraud risks did not result in the identification of a key audit matter.

We do note that our audit is based on the procedures described in line with applicable auditing standards and are not primarily designed to detect fraud.

Audit scope in relation to non-compliance with laws and regulations

We have evaluated facts and circumstances in order to assess laws and regulation relevant to the company.

We identified laws and regulations that could reasonably be expected to have a material effect on the financial statements based on our general understanding and sector experience, through discussion with relevant management and evaluating the policies and procedures regarding compliance with laws and regulations.

We communicated identified laws and regulations throughout our team and remained alert to any indications of non-compliance throughout the audit. The potential effect of these laws and regulations on the financial statements varies considerably:

- Firstly, the Company is subject to laws and regulations that directly affect the financial statements including taxation and financial reporting (including related company legislation). We assessed the extent of compliance with these laws and regulations as part of our procedures on the related financial statement items.
- Secondly, the Company is subject to many other laws and regulations where the consequences of non-compliance could have an indirect material effect on amounts recognized or disclosures provided in the financial statements, for instance if the Company's products do not meet regulatory standards of approval or fail to maintain patents. We identified the following areas of laws and regulations as those most likely to have such an effect: pharmaceutical and intellectual property laws and regulations.

Auditing standards limit the required audit procedures to identify non-compliance with laws and regulations that have an indirect effect to inquiring of relevant management and inspection of regulatory and legal correspondence, if any. Through these procedures, we did not identify any additional actual or suspected non-compliance other than those previously identified by the company in each of the above areas. We considered the effect of actual or suspected non-compliance as part of our procedures on the related financial statement items.

Our procedures to address compliance with laws and regulations did not result in the identification of a key audit matter.

We do note that our audit is not primarily designed to detect non-compliance with laws and regulations and that management 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 errors or fraud, including compliance with laws and regulations.

The more distant non-compliance with indirect laws and regulations (irregularities) is from the events and transactions reflected in the financial statements, the less likely the inherently limited procedures required by auditing standards would identify it. In addition, as with any audit, there remained a higher risk of non-detection of irregularities, as these may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal controls.

Our key audit matter

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 matters are not a comprehensive reflection of all matters discussed.

These matters were 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 these matters.

Accounting for research and development costs

Description

Research and development (R&D) costs incurred, amounting to EUR 49.6 million (2018: EUR 46.3 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 2019 R&D costs increased in line with the progress of studies and (pre-)clinical trials. As a result of the size of the transactions in combination with the moderate complexity of the related arrangements, 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 expenses originating from vendors that perform clinical and manufacturing services.

Our response

Our audit procedures included 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.

Our observation

Overall, the results of our procedures performed on management's accounting for research and development costs 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.

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 engaged by the Board of Directors as auditor of Merus N.V. for the year 2019 on May 14, 2019, and have operated as auditor since the year 2009 and as statutory auditor as of 2014.

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.

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 the appendix of this auditor's report. This description forms part of our auditor's report.

Amstelveen, May 19, 2020

KPMG Accountants N.V.

B.S. Geerling 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's 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 the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. 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 Shares Carrying Limited Economic Entitlement

The preferred shares in the Company's capital carry a limited entitlement to the Company's profit and reserves. As at December 31, 2019, no preferred shares in the Company's capital were issued.

11.4 Branches

The Company has no branch offices.

11.5 Material Subsequent Events

Refer to Note 21 to the consolidated financial statements for further information on subsequent events.