

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

**Merus N.V.**

**Dutch statutory board report and financial statements  
for the fiscal year ended December 31, 2018**

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## **1 INTRODUCTION**

### **1.1 Preparation**

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

This report has been prepared by the Company's board of directors pursuant to Section 2:391 of the Dutch Civil Code, or DCC, and also contains (i) the Company's financial statements within the meaning of Section 2:361(1) DCC and (ii) to the extent applicable, the information to be added pursuant to Section 2:392 DCC. This report relates to the fiscal year ended December 31, 2018 and, unless explicitly stated otherwise, information presented in this report is as at December 31, 2018.

The consolidated financial statements included in section 12.1 of this report, or Consolidated Financial Statements, have been prepared in accordance with the International Financial Reporting Standards established by the International Accounting Standards Board and adopted by the European Union. The Company financial statements included in section 12.2, or Company Financial Statements, have been prepared in accordance with Title 9 of Book 2 DCC. For setting the principles for the recognition and measurement of assets and liabilities and determination of the result for its company financial statements, the Company makes use of the option provided in Section 2:362(8) DCC. This means that the principles for the recognition and measurement of assets and liabilities and determination of the result (hereinafter referred to as principles for recognition and measurement) of the Company Financial Statements of the Company are the same as those applied for the Consolidated Financial Statements.

### **1.2 Cautionary statement regarding forward-looking statements**

This report contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated products, are forward-looking statements. We make such forward-looking statements pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the 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," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. The forward-looking statements in this report are only predictions. We have based these forward-looking statements 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 risks,



uncertainties and assumptions described under the sections in this report titled “Risk Factors” and “Operating and Financial Review and Prospects” and elsewhere in this Annual Report. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our operations as a clinical-stage company with a limited operating history and a history of operating losses;
- uncertainty about the initiation, timing, progress and results of clinical trials of our bispecific antibody candidates, including regarding when results of such trials will be made public;
- our expectations related to payments and clinical development under our collaboration agreement, or the Collaboration Agreement, with Incyte Corporation, or Incyte;
- our clinical development plans for MCLA-128, MCLA-117, MCLA-158 , and MCLA-145;
- research and/or development of preclinical programs being co-developed with Incyte, Simcere, Betta Pharmaceuticals Co. Ltd, or Betta, and for other bispecific antibody candidates;
- the timing or likelihood of regulatory filings and approvals for any of our bispecific antibody candidates;
- our ability to establish sales, marketing and distribution capabilities for any of our bispecific antibody candidates for which we may obtain regulatory approval;
- our ability to establish and maintain manufacturing arrangements for our bispecific antibody candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our bispecific antibody candidates and related technology;
- our ability to defend against any claims by third parties that we are infringing upon their intellectual property rights;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- the rate and degree of market acceptance of our bispecific antibody candidates;
- the impact of government laws and regulations on our business;
- our competitive position; and
- other risk factors discussed in this report.

This report contains market data and industry forecasts that were obtained from industry publications. These data involve a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information. While we believe the market position, market opportunity and market size information included in this report is generally reliable, such information is inherently imprecise.

## **2 KEY INFORMATION**

### **2.1 Selected Financial Data**

The following selected consolidated financial data should be read in conjunction with “Operating and Financial Review and Prospects,” our consolidated financial statements and related notes, and other financial information included in this report. We have derived the consolidated statement of profit or loss and comprehensive loss data for the years ended December 31, 2018 and 2017 and the consolidated statement of financial position data as of December 31, 2018 and 2017 from our audited financial statements included elsewhere in this report. Our historical results are not

necessarily indicative of the results that should be expected in the future.

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Restated**</b>	
	<small>(euros in thousands, except share and per share data)</small>	
<b>Statement of Profit or Loss and Comprehensive Loss Data:</b>		
Revenue.....	€ 31,448	€ 21,915
Research and development costs.....	(46,740)	(34,125)
Management and administration costs.....	(10,395)	(13,697)
Other expenses.....	(13,160)	(9,395)
Operating result.....	(38,847)	(35,302)
Other income (expenses).....	14,934	(29,223)
Result before taxation.....	(23,913)	(64,525)
Income tax expense.....	(356)	(249)
Result after taxation.....	(24,269)	(64,774)
Other comprehensive income.....	34	89
Total comprehensive loss for the year.....	€ (24,235)	€ (64,685)
Basic (and diluted) loss per share *.....	€ (1.09)	€ (3.37)
Weighted average shares outstanding, basic and diluted.....	22,286,720	19,196,440

\* For the periods included in these financial statements, share options and restricted stock units were excluded from the diluted loss per share calculation as we were in a loss position in each period presented above. As a result, basic and diluted loss per share is equal.

\*\* Revenue for the year ended December 31, 2017 has been restated due to the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition. Revenue for the year ended December 31, 2017 has been restated to reflect additional revenue of €8.3 million, or €0.43 per share, primarily related to the amortization of the upfront license payment received from Incyte.

	<b>As of December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Restated*</b>	
	<small>(euros in thousands)</small>	
<b>Statement of Financial Position Data:</b>		
Cash and cash equivalents.....	€ 143,747	€ 149,678
Total assets.....	218,519	196,803
Total liabilities.....	126,648	140,211
Accumulated loss.....	(175,085)	(158,775)
Total shareholders' equity.....	91,871	56,592

\* Total liabilities, accumulated loss and total equity have been restated for the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition. The result of the restatement was a decrease to total liabilities and accumulated loss and an increase to total equity of €8.7 million as of December 31, 2017.

## 2.2 Summary of key risk factors

The principal risks and uncertainties which the Company faces include the risks and uncertainties summarized in this section 2.2. See section 2.3 of this report for additional detail and additional risks and uncertainties which the Company faces.

The Company identified the following principal risks and uncertainties:

- 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 will need additional funding in order to complete development of our bispecific antibody candidates and commercialize our products, if approved. Raising additional capital may cause dilution to our holders, restrict our operations or require us to relinquish rights to our technologies or bispecific antibody candidates. 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 have previously identified material weaknesses in our internal control over financial reporting and any future material weaknesses could, if not remediated, result in material misstatements in our financial statements and cause shareholders to lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.
- The Biclomics<sup>®</sup> technology platform is an unproven, novel approach to the production of molecules for therapeutic intervention. We may not be successful in our efforts to use and expand our technology platform to build a pipeline of antibody candidates.
- All of our bispecific 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 bispecific antibody candidates, particularly MCLA-128, MCLA-117, 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 bispecific antibody candidates on a timely basis or at all.
- 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.
- Our employees, 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 have a material adverse effect on our business.
- 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 our collaborators, and directly from individuals.
- We have never commercialized a bispecific 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.
- Our bispecific antibody candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.
- We currently rely on third-party suppliers and other third parties for production of our bispecific antibody candidates and our dependence on these third parties may impair the

advancement of our research and development programs and the development of our bispecific antibody candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved bispecific antibody candidate and our commercialization of any of our bispecific 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, fail to provide us with sufficient quantities of bispecific 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 patents and other intellectual property rights to protect our technology, including bispecific antibody candidates and our Biclomics<sup>®</sup> 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 future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

## 2.3 Risk factors

### 2.3.1 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 immuno-oncology company with a limited operating history. We have incurred net losses of €24.2 million and €64.7 million for the years ended December 31, 2018 and 2017, respectively.

As of December 31, 2018, we had an accumulated loss of €175.1 million. Our losses have resulted principally from expenses incurred in research and development of our bispecific 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 bispecific antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing Phase 2 clinical trial of MCLA-128, our most advanced bispecific antibody candidate, for the treatment of metastatic breast cancer in combination with other therapies and our ongoing, single agent, Phase 1/2 clinical trial for the treatment of gastric and non-small cell lung cancers;
- conduct our ongoing Phase 1 clinical trial of MCLA-117, our second most advanced bispecific antibody candidate, for the treatment of acute myeloid leukemia;
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors with an initial focus on colorectal cancer;
- conduct our ongoing Phase 1 clinical trial of MCLA-145 for the treatment of solid tumors, which is being co-developed with Incyte Corporation, or Incyte;
- continue the research and development of our other bispecific antibody candidates, including the development of MCLA-129 in collaboration with Betta Pharmaceuticals Co. Ltd.;
- expand the clinical programs to explore new potential combination therapies or indications;

- seek to enhance our technology platform, which generates our pipeline of product candidates, and discover and develop additional 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 Biclomics<sup>®</sup>, our technology platform, identifying potential bispecific antibody candidates, conducting pre-clinical studies of a variety of candidates, conducting our clinical trials of MCLA-128, MCLA-117, MCLA-158, and MCLA-145. We are in the early stages of development of our bispecific antibody candidates, and we have not completed development of any Biclomics<sup>®</sup> 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 antibody candidates, obtaining regulatory approval for any bispecific 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 FDA, or the 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 bispecific 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 bispecific 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 MCLA-128, MCLA-117, MCLA-158 and MCLA-145 and continue to research, develop and conduct pre-clinical studies of our other antibody candidates. In addition, if we obtain regulatory approval for any of our bispecific 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.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2018 will be sufficient to fund our operations into the second quarter of 2021. 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 MCLA-128 and the Phase 1 clinical trials of MCLA-117 and MCLA-158;
- the success of our collaboration with Incyte to develop bispecific antibodies candidates,;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our antibody candidates for which we 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 bispecific antibody candidates for which we 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 collaboration with Incyte and any other licensing or collaboration arrangements for any of our bispecific antibody candidates.

***We depend heavily on the success of our bispecific antibody candidates, and we cannot give any assurance that any of our bispecific antibody candidates will receive regulatory approval, which is necessary before they can be commercialized. If we, Incyte, or any other strategic partners we***

*may enter into collaboration agreements with for the development and commercialization of our bispecific antibody candidates, are unable to commercialize our bispecific antibody candidates, or experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.*

We have invested a significant portion of our efforts and financial resources in the development of bispecific antibody candidates using our Biclomics® technology platform. 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 bispecific 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 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 bispecific 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 bispecific antibody candidates. The success of our bispecific antibody candidates will depend on several factors, including the following:

- for bispecific antibody candidates which we may license to others, such as to Incyte, the successful efforts of those parties in completing clinical trials of, receipt of regulatory approval for and commercialization of such bispecific antibody candidates;
- for the bispecific 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 bispecific antibody candidates; and
- for all of our bispecific antibody candidates, if and when approved, acceptance of our bispecific 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 bispecific antibody candidates, which would materially adversely affect our business, financial condition and results of operations.

We have not previously submitted a Biologics License Application, or BLA, to the FDA, a Marketing Authorisation Application, or MAA, to the EMA, or similar regulatory approval filings to comparable foreign authorities, for any bispecific antibody candidate, and we cannot be certain that any of our bispecific antibody candidates will be successful in clinical trials or receive regulatory approval. Further, our bispecific antibody candidates may not receive regulatory approval even if they are successful in clinical trials. If we do not receive regulatory approvals for our bispecific 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 bispecific 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 bispecific 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 bispecific antibody candidates, and we cannot predict success in these jurisdictions.

***The Biclomics<sup>®</sup> technology platform is an unproven, novel approach to the production of molecules for therapeutic intervention.***

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

Our Biclomics<sup>®</sup> technology platform relies 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 product 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 bispecific antibody candidates we are developing. Through collaborations, 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 bispecific antibody candidates. Companion diagnostics are subject to regulation by the FDA, the EU legislative bodies, and comparable foreign regulatory authorities as companion diagnostic medical devices and typically require separate regulatory approval prior to commercialization. If needed, we intend to develop companion diagnostics in collaboration 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 bispecific 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 bispecific 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 bispecific antibody candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our bispecific 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 MCLA-128, MCLA-117, MCLA-158, MCLA-145 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for MCLA-128, MCLA-117 and MCLA-158, and MCLA-145, we have not completed any clinical trials for any bispecific 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 bispecific 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 collaboration with Incyte 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder 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 bispecific 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 bispecific 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. 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 bispecific antibody candidates, 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, or the GDPR, that went into effect in 2018;
- 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 and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

***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, 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, or 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 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.

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

*All of our bispecific 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 bispecific antibody candidates, particularly MCLA-128, MCLA-117, 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 bispecific antibody candidates on a timely basis or at all.*

To obtain the requisite regulatory approvals to market and sell any of our bispecific antibody candidates, we or any collaborator for such candidates must demonstrate through extensive pre-clinical studies and clinical trials that our products 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 bispecific antibody candidates may not be predictive of the results of later-stage clinical trials. Bispecific 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 bispecific antibody candidates. Although we are conducting ongoing clinical trials for MCLA-128, MCLA-117, MCLA-158, and MCLA-145, and are conducting pre-clinical studies for other bispecific 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 establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit suitable patients to participate in a trial;
- the difficulty in certain countries 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;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or Health Authorities, as applicable, to suspend or terminate a trial if we or our collaborators or Health Authorities, find that the participants are being exposed to unacceptable health risks;
- delays in or failure to obtain regulatory approval to commence a trial;
- delays in or failure to obtain institutional review board, or 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 bispecific antibody candidate for use in clinical trials;
- the quality or stability of a bispecific antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our bispecific antibody candidates no longer relevant;
- third party actions claiming infringement by our bispecific 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.

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 28 EU Member States plus Iceland, Liechtenstein and Norway) 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 bispecific antibody candidates, the commercial prospects of our bispecific antibody candidates will be harmed, and our ability to generate product revenues from any of these bispecific antibody candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our bispecific 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 bispecific antibody candidates and impair our ability to commercialize our bispecific antibody candidates 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 bispecific 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 bispecific antibody candidates produced under current good manufacturing practice, or 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, or 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.

***Our bispecific 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 bispecific antibody candidates or following approval, if any, we may need to abandon our development of such bispecific 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 bispecific 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 bispecific antibody candidate, MCLA-128, for the treatment of various solid tumors. Additionally, in January 2018 we commenced a Phase 2 clinical trial in Europe and the United States exploring MCLA-128, in combination with other agents, in patients with metastatic breast cancer. To date, patients treated with MCLA-128 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. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors with an initial focus on colorectal cancer. To date, patients treated with MCLA-158 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions. 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 bispecific 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 bispecific 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, or REMS, 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 product 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 products.

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

The commercial success of our products will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of our bispecific 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 immuno-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 products. Any increased scrutiny could delay or increase the costs of obtaining regulatory approval for our bispecific antibody candidates.

***We depend on enrollment of patients in our clinical trials for our bispecific 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 the MCLA-128 Phase 2 clinical trial, we plan to enroll approximately 120 patients with metastatic breast cancer in the United States and Europe. In the Phase 1 clinical trial of MCLA-117, we plan to enroll approximately 50 adult patients with AML. In the

Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with colorectal cancer and possibly other solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

Our clinical trials will likely compete with other clinical trials for antibody candidates that are in the same therapeutic areas as our bispecific 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 bispecific antibody candidates will increase our costs, slow down our bispecific 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 bispecific antibody candidates.

***We may become exposed to costly and damaging liability claims, either when testing our bispecific 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 bispecific antibody candidates by us and our corporate 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 corporate 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 bispecific antibody candidates or any prospects for commercialization of our bispecific antibody candidates.

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 bispecific antibody candidates were to cause adverse side effects during clinical trials or after approval of the bispecific 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 bispecific antibody candidates.

Although we maintain adequate product liability insurance for our bispecific 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 bispecific 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 bispecific 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 bispecific antibody candidate's clinical development and may vary among jurisdictions. We have not obtained regulatory approval for any bispecific antibody candidate and it is possible that none of our existing bispecific antibody candidates or any bispecific antibody candidates we may seek to develop in the future will ever obtain regulatory approval.

Our bispecific 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 a bispecific antibody candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a bispecific 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 bispecific 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 bispecific 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 bispecific antibody candidates. Even if we believe the data collected from clinical trials of our bispecific 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 bispecific 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 a bispecific antibody candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that bispecific antibody candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our bispecific antibody candidates.

***Even if our bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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 technology platform to build a pipeline of antibody candidates.***

A key element of our strategy is to use and expand our Biclomics<sup>®</sup> 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 bispecific antibody candidates directed at various cancers, we may not be able to develop bispecific antibody candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, 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 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 bispecific 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 bispecific 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 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 bispecific 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, bispecific 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 product 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 bispecific

antibody candidates or misread trends in the biopharmaceutical industry, in particular for our lead bispecific 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 controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

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 bispecific 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.

### **2.3.3 Risks Related to Regulatory Approval of Our Bispecific Antibody Candidates**

***Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our bispecific antibody candidates and may affect the prices we may set. The successful commercialization of our bispecific 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, or collectively the ACA, was enacted, which substantially changes 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, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

We expect that the current presidential administration and U.S. Congress may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. There have also been judicial challenges to certain aspects of the ACA. For example, 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 inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the current presidential administration and the Centers for Medicare & Medicaid Services, or CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision and subsequent appeals, if any, will impact the law. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

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 2027 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 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, or 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 bispecific 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 our 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 our current or 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 bispecific 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, 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 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. For example, in December 2016,

the Cures Act was signed into law and, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation. 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 bispecific 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.

***Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new products and services from being developed or commercialized in a timely manner, which could negatively impact our business.***

The ability of the FDA to review and approve or clear new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. 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, biologics and medical devices to be reviewed and/or approved or cleared 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. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA 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 bispecific 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 the business of 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, or 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;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the U.S. federal Food, Drug and Cosmetic Act, or 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) 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; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, and that requires the tracking and reporting of gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and

- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers and data privacy and security requirements.

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 our collaborators, 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 the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. 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. As such, we may be subject to 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.

Our and our collaborators' clinical trial programs and research collaborations outside the U.S. may implicate international data protection laws, including, in Europe, the General Data Protection Regulation, or 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 Euros 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. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU model clauses. In addition, the U.S. Privacy Shield is under review by the European Commission. As such, it is uncertain whether the Privacy Shield framework and/or model clauses will be invalidated in the near 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. See "Business—Privacy and Data Protection Laws in Europe."

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, 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.

If we or any collaborators fail to comply with applicable federal, state, or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our clinical candidates. 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.

#### **2.3.4 Risks Related to Commercialization of Our Bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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, or COMP, 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 seek orphan drug designation from the FDA and the EMA for our assets in clinical development, including MCLA-128, MCLA-117 and 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our bispecific 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 bispecific 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 bispecific 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 our 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 bispecific antibody candidates. 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 bispecific antibody candidates. 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 bispecific antibody candidates. We expect to experience pricing pressures in connection with the sale of any of our bispecific antibody candidates 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 bispecific 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 bispecific antibody candidates 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.

If our bispecific antibody candidates fail to gain market acceptance, this 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, or if we fail to achieve adequate pricing and/or reimbursement we will not be successful in commercializing our bispecific antibody candidates.***

We currently have no marketing, sales and distribution capabilities because all of our bispecific antibody candidates are still in clinical or pre-clinical development. If any of our bispecific antibody candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our bispecific 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 bispecific 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 our 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 a bispecific 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 a bispecific antibody candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the bispecific antibody candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For bispecific 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.

Factors that may affect our ability to commercialize our bispecific antibody candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our bispecific 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 bispecific antibody candidates. 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 bispecific antibody candidates, we may not generate revenues from them or be able to reach or sustain profitability.

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

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-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 bispecific 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 clinical 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.

### **2.3.5 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 bispecific 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 good clinical practice, or 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 products 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 product 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 bispecific antibody candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our bispecific antibody candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any bispecific antibody candidates that we develop. 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 bispecific antibody candidates. As a result, our results of operations and the commercial prospects for our bispecific 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 Agreement with Incyte is important to our business. If suitable 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 bispecific 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 between 0% and 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 bispecific antibody products arising from the terminated programs.

Termination of the Collaboration Agreement could cause significant delays in our product candidate development and commercialization efforts, which could prevent us from commercializing our bispecific 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 product candidates so that we may continue development activities, or we may be forced to discontinue development of terminated product 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 US rights, we are dependent upon Incyte to successfully develop and commercialize bispecific 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 bispecific antibody 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 bispecific 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.

***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 bispecific antibody candidates will require substantial additional cash to fund expenses. Therefore, for some of our bispecific antibody candidates, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those bispecific antibody candidates. For instance, we have license and collaboration agreements

with ONO, Incyte, Simcere Pharmaceutical Group and Betta Pharmaceuticals Co. Ltd. which we have licensed the development and commercialization of certain of our 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 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 bispecific antibody candidates to market 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 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 bispecific antibody candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our bispecific antibody candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved bispecific antibody candidate and our commercialization of any of our bispecific 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, fail to provide us with sufficient quantities of bispecific 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, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our bispecific antibody candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture bispecific antibody candidates ourselves. The facilities used by our contract manufacturers to manufacture our bispecific 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 bispecific antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval

for their manufacturing facilities. 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific 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 bispecific antibody candidates for future clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs 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 bispecific antibody candidates for our clinical trials, and if approved, ultimately for commercial sale. 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 a bispecific antibody candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of a bispecific 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 bispecific antibody candidates. If our manufacturers, collaborators or we are unable to purchase these raw materials after regulatory approval has been obtained for our bispecific antibody candidates, the commercial launch of our bispecific 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 bispecific antibody candidates.

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 bispecific antibody candidates, if approved.

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

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

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our Biclomics<sup>®</sup> technology platform, our bispecific antibody and antibody candidates, products, their format and methods used to produce, screen, manufacture and purify those antibody and antibody 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 products and bispecific 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 Biclomics<sup>®</sup> technology platform, bispecific antibody candidates, and other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, interpartes 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 a bispecific antibody candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after

March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs.

***Issued patents covering one or more of our products or the Biclomics® technology platform 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. 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 our product candidates or methods, or our Biclomics® technology platform, 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 Biclomics® technology platform, 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 or Patent Office, or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the Patent Office. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our technologies, products, methods or certain aspects of our Biclomics® technology platform. 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 bispecific antibody candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our bispecific 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, methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our bispecific antibody candidates, or other attributes of our bispecific antibody candidates or our Biclomics® technology platform. In such cases, we may not be in a position to develop or commercialize products or bispecific antibody candidates unless we successfully pursue litigation 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 bispecific 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 bispecific 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 products. We could also be required to pay substantial damages. Similarly, the targets of our bispecific 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 technology 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, product candidates or the use of our product 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 bispecific 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 our 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 bispecific antibody candidates that are held to be infringing. We might, if possible, also be forced to redesign bispecific 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 bispecific



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 bispecific antibody candidates through acquisitions and in-licenses.***

We currently have rights to the intellectual property, including patent applications relating to our bispecific antibody candidates. 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 bispecific antibody candidates may require specific formulations to work effectively and efficiently and the rights to these formulations 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 bispecific 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.

For example, we sometimes collaborate with U.S. and non-U.S. academic institutions to accelerate our pre-clinical research or development under written agreements with these institutions. Typically, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to other parties, potentially blocking our ability to pursue elements of the technology at issue in such collaborations.

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 a bispecific antibody candidate or program, we may have to abandon development of that bispecific 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 bispecific antibody candidates, our business may be materially harmed.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our bispecific antibody candidates are obtained, once the patent life has expired for a product, 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 bispecific 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 bispecific 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 EPO or the United States Patent and Trademark Office. International applications under the Patent Cooperation Treaty, or 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 bispecific antibody candidates may be marketed. 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 bispecific 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 bispecific antibody candidates, 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 bispecific 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 products or technologies could use the intellectual property of others without obtaining a proper license.
- 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 products.***

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, or the 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 EP 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 bispecific 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 products 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 products 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 Stock.

***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 information technology 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 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.

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

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

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. These key management individuals include the members of our board of directors. For example, our founder and President, Chief Executive Officer and Principal Financial Officer, Ton Logtenberg, holds a Ph.D. in medical biology, was a professor in the Department of Immunology at Utrecht University and co-founded the Dutch biotechnology company, Crucell N.V.

The loss of key managers and senior scientists could delay our research and development activities. 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 in the future, it may be difficult for us to implement business strategy, which could have a material adverse effect on our business.

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

We expect to 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 anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

### **2.3.8 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 bispecific 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 bispecific 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 securities 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, 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, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on non-U.S. 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 the Sarbanes-Oxley Act of 2002, or 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 20-F. 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 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. 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.

***We have previously identified material weaknesses in our internal control over financial reporting and any future material weaknesses could, if not remediated, result in material misstatements in our financial statements and cause shareholders to lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

As a public reporting company, our management is required to report annually on the effectiveness of our internal control over financial reporting pursuant to Section 404. In connection with this reporting obligation, we evaluate our procedures with respect to our internal control over financial reporting including documenting and testing our controls.

In its review of our internal control over financial reporting in connection with the annual audit for 2017, management identified a material weakness associated with a lack of adequate cut-off procedures to ensure the timely recognition, measurement and classification of operating expenses and recording of certain period-end accruals. Specifically, we did not design and maintain effective internal control over the assessment of the accounting for significant contractual arrangements related to our clinical research and manufacturing agreements and the classification of operating expenses. Management also concluded that two material weaknesses identified for the year ended December 31, 2016 were unremediated as of December 31, 2017. Specifically, we had insufficient accounting resources to fulfill IFRS and SEC reporting requirements and an absence of comprehensive IFRS accounting policies and financial reporting procedures. To remediate these material weaknesses, we (i) redesigned specific processes and controls associated with review of contractual agreements, including to assure proper clinical research and manufacturing expense cut-off, including a quarterly identification and review of significant agreements with our management team to ensure that the relevant accounting implications are identified and considered, (ii) redesigned our controls over proper classification and recognition of operating expenses, including the related balance sheet accounts, (iii) hired several new, experienced personnel in our financial reporting organization and engaged several experienced consultants to further assist our financial reporting organization, (iv) enhanced our documentation of IFRS accounting policies and SEC financial reporting procedures and (v) increased the oversight and review procedures related to our financial close and reporting processes. As of December 31, 2018, our management concluded that these material weaknesses had been remediated and that our internal control over financial reporting was effective as of December 31, 2018.

If other undetected material weaknesses in our internal controls exist, it could result in material misstatements in our financial statements requiring us to restate previously issued financial statements. In addition, material weaknesses, and any resulting restatements, could cause investors to lose confidence in our reported financial information, and could subject us to regulatory scrutiny and to litigation from shareholders, which could have a material adverse effect on our business and the price of our common shares. Furthermore, the correction of any such material weaknesses could require additional remedial measures including additional personnel, which could be costly and time-consuming. If we do not maintain adequate financial and management personnel, processes and controls, we may not be able to manage our business effectively or accurately report our financial performance on a timely basis, which could cause a decline in our common share price and adversely affect our results of operations and financial condition. Failure to comply with the Sarbanes-Oxley Act of 2002 could potentially subject us to sanctions or investigations by the SEC, Nasdaq or other regulatory authorities, which would require additional financial and management resources.

***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, 2018, 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 19% of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to determine 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 DCGC. This may affect the rights of our shareholders.***

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

company with limited liability ( naamloze vennootschap ) listed in the Netherlands that fully complies with the DCGC.

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

We are incorporated under the laws of the Netherlands. Most of our assets are located outside the United States. The United States and the Netherlands currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, we note that the Hague Convention on Choice of Court Agreements 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.

***We are a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.***

We report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above,

our shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers. However, we are subject to Dutch laws and regulations with regard to such matters and voluntarily furnish quarterly unaudited financial information to the SEC on Form 6-K.

***As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.***

We qualify as a foreign private issuer. As a result, in accordance with the listing requirements of Nasdaq, we rely on home country governance requirements and certain exemptions thereunder rather than relying on the corporate governance requirements of Nasdaq. In accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Although we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders, Dutch law does not have a regulatory regime for the solicitation of proxies and the solicitation of proxies is not a generally accepted business practice in the Netherlands, thus our practice will vary from the requirement of Nasdaq Listing Rule 5620(b). In addition, we have opted out of certain Dutch shareholder approval requirements for the issuance of securities 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 of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. Accordingly, our shareholders may not have the same protections afforded to shareholders of companies that are subject to these Nasdaq requirements.

***We may lose our foreign private issuer status which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.***

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. If we no longer qualify as a foreign private issuer as of end of the second quarter of a fiscal year, we would be required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of the start of the following fiscal year. In order to maintain our current status as a foreign private issuer, (a) 50% or more of our common shares must be either directly or indirectly held of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be United States citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance

costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board.

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

We are an “emerging growth company,” as defined in the JOBS 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. As an “emerging growth company,” we are not required to report selected financial data for periods prior to the earliest audited financial statements presented in the registration statement for the initial public offering of our common shares. As a result, we only have to present selected financial data for periods starting with the year ended December 31, 2014. Public companies that are not emerging growth companies must present selected financial data for a five-year period. 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, 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 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 for U.S. federal income tax purposes, which could result in adverse U.S. federal income tax consequences to U.S. investors in the common shares.***

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not believe we were a “passive foreign investment company,” or PFIC, for our taxable year ended December 31, 2018. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (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 disagree with our position that we were not a PFIC in 2018. 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. A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our common shares who is eligible for the benefits of the Treaty and is:

- (1) a citizen or individual resident of the U.S.;
- (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; or
- (3) an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

***If a United States person 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). If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of "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 U.S. corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations from starting 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 any of our 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 of 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.

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

On December 22, 2017, the U.S. government enacted comprehensive tax legislation that includes significant changes to the taxation of business entities, known as the Tax Cuts and Jobs Act, or TCJA. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions and the use of net operating losses, adopting elements of a territorial

tax system and introducing certain anti-base erosion provisions. 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. U.S. Holders should consult their legal and tax advisors regarding the TCJA and the potential tax consequences of investing in our common shares.

### **3 INFORMATION ON THE COMPANY**

#### **3.1 History and Development of the Company**

We were incorporated as Merus B.V. under the laws of the Netherlands on June 16, 2003. Our principal executive offices are located at Yalelaan 62, 3584 CM Utrecht, The Netherlands. Our telephone number at the Utrecht address is +31 30 253 8800. Our website address is [www.merus.nl](http://www.merus.nl). Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report. We have included our website address in this Annual Report solely as an inactive textual reference.

Our agent for service of process in the United States is Merus US, Inc., whose address is 139 Main Street, Cambridge, Massachusetts, United States.

The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC (<http://www.sec.gov>).

Our capital expenditures primarily consist of laboratory equipment and leasehold improvements. For the years ended December 31, 2018 and 2017, the amount of cash paid for our principal capital expenditures was €1.6 million and €0.7 million, respectively. Our current capital expenditures are distributed between the United States and Europe with most of our capital expenditures made in the Netherlands. We expect to finance our current capital expenditures from the cash flows from operating activities, public offerings and private placements and our collaboration and license agreements. We expect our capital expenditures to increase in absolute terms in the near term as we continue to advance our research and development programs and grow our operations. For more information on our capital expenditures, see section 4.2 of this report.

#### **3.2 Business Overview**

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. Our pipeline of full-length human bispecific antibody candidates, which we refer to as Biclomics<sup>®</sup>, are generated from our Biclomics<sup>®</sup> technology platform, which is able to generate a diverse array of antibody-heavy chains against virtually any target, paired with a common light chain. Two heavy chains paired with a common light chain can be combined to produce novel bispecific antibodies that bind a diverse array of targets and display differentiated biology. By binding to two different targets, Biclomics<sup>®</sup> can provide a variety of mechanisms of action. For example, Merus Biclomics<sup>®</sup> can be designed to simultaneously block receptors that drive tumor cell growth and survival and to mobilize the patient's immune response by engaging T-cells and/or activating various killer cells to eradicate tumors. In our pre-clinical studies, our bispecific antibody candidates killed tumor cells, a result that we believe supports their potential development for the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our most advanced bispecific antibody candidate, MCLA-128, for the treatment of HER2-expressing solid tumors. In January 2018, we dosed

the first patient in a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in two metastatic breast cancer, or MBC, populations including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients. MCLA-128 is a full-length IgG bispecific antibody candidate with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 is designed to block the HER3 signaling pathway by employing a DOCK & BLOCK<sup>®</sup> mechanism. MCLA-128 is designed to “dock” onto a specific region of the HER2 receptor to orientate MCLA-128’s HER3 binding arm to “block” HER2:HER3 heterodimerization. Oncogenic signaling through the HER3 pathway, even in the presence of high heregulin concentrations, may thus be blocked. The Phase 2 clinical trial is designed to observe the activity of this HER2/HER3-targeted candidate in combination with current standards of care in areas of unmet need. The trial is ongoing and is enrolling patients at sites in the United States and Europe. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and non-small cell lung cancer, or NSCLC, is ongoing.

We reported interim data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress, or ESMO, in October 2018. As of February 15, 2018, the data showed a clinical benefit rate of 24% (6 of 25 patients), and that MCLA-128 was well tolerated with mainly grade 1/2 adverse events observed in patients treated with MCLA-128 across all indications explored. Single agent antitumor activity was seen in heavily pretreated gastric/gastro-oesophageal junction, or GC/GEJ, cancer patients progressing on anti-HER2 therapy. Notably, the unique mechanism of action of MCLA-128 was published in the May 2018 edition of the scientific journal *Cancer Cell* titled, “Unbiased Combinatorial Screening Identifies a Bispecific IgG1 that Potently Inhibits HER3 Signaling via HER2-Guided Ligand Blockade.” PB4188, the research candidate described in the paper, was identified after screening a panel of hundreds of bispecific antibodies binding to the HER2/HER3 target pair in relevant functional assays. Using a structure function approach, we showed that PB4188 employs a unique mechanism designed to inhibit the growth of tumors by docking to HER2 and blocking ligand interaction with HER3, thereby preventing stabilization of the HER2:HER3 heterodimer and sustained signaling. The activity of PB4188 was unaffected by increasing concentrations of HRG, the ligand for HER3 which mirrors the autocrine or paracrine signaling environment of the tumor, in contrast to monoclonal antibodies against the same targets, tested as single agents or in combination. These *in vitro* findings were also observed in four independent and pathophysiologically relevant xenograft models, which showed dose dependency and correlation with relevant pharmacodynamic factors. This unbiased functional screening led to the identification of development candidate MCLA-128. We believe these results reinforce the potential of our functional screening process that allows for the discovery of unique biology driven by the bispecific antibody format.

In May 2016, we commenced a single-arm, open-label, global Phase 1 clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML, and we announced the filing of the Investigational New Drug application, or IND, in the United States for MCLA-117 in 2018 and the subsequent authorization to proceed with clinical studies by the U.S. Food and Drug Administration, or the FDA.

AML generally has a poor prognosis and limited progress has been made in disease outcomes despite a growing AML patient population. Clinical and pre-clinical studies suggest that treatment-resistant leukemic stem cells are a potential cause of disease relapse. MCLA-117 is designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of AML tumor cells and stem cells in newly diagnosed and relapsed

patients. MCLA-117 is designed to recruit and activate T-cells to kill AML tumor cells and stem cells. In our pre-clinical studies, MCLA-117 killed tumor cells in blood samples of AML patients. If the results of this clinical trial are favorable, we plan to seek orphan drug designation for MCLA-117 for the treatment of AML from the FDA and the European Medicines Agency, or EMA. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. We also intend to evaluate MCLA-117 for the treatment of myelodysplastic syndrome, or MDS.

In addition to MCLA-128 and MCLA-117, we are also developing MCLA-158, a bispecific antibody candidate that is designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5, or Lgr5, and epidermal growth factor receptors, or EGFR, for the potential treatment of solid tumors with an initial focus on metastatic colorectal cancer, and the first Clinical Trials Application, or CTA, to the EMA was approved to initiate a Phase 1 clinical trial in Europe in January 2018. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018. In May 2018, we commenced an open-label, multicenter Phase 1 clinical trial of MCLA-158 and expect emerging data by the end of 2019. MCLA-158 is designed to kill cancer stem cells using two different mechanisms of action. The first mechanism of action involves blocking growth and survival pathways in tumor stem cells. The second mechanism of action involves the recruitment and enhancement of immune effector cells.

We also commenced a clinical trial for MCLA-145, which is being developed in collaboration with Incyte Corporation and is designed to bind to PD-L1 and CD137. MCLA-145, the first drug candidate co-developed under our global research collaboration with Incyte. Developed through an unbiased functional screening of multiple immunomodulatory target combinations, MCLA-145 is a Bionics® T-cell agonist that binds with high affinity and specificity to human PD-L1 and CD137 in preclinical models. The unique immunostimulatory profile of MCLA-145 derives from the ability to potently activate immune effector cells in the context of the tumor microenvironment while simultaneously blocking inhibitory signals in the same immune cell population. In December 2018, we filed an IND for MCLA-145 with the FDA and in January 2019, we received authorization to proceed from the FDA, and the Phase 1 trial initiated in May 2019. We have full rights to develop and commercialize MCLA-145 in the United States and Incyte is responsible for its development and commercialization outside the U.S.

We are also developing MCLA-129, which is being developed pursuant to collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. or Betta Pharmaceuticals. Under the terms of the agreement, Betta Pharmaceuticals has agreed to be responsible for clinical development and commercialization of MCLA-129 in China. As a key strategic component of the collaboration, Betta will retain a contract manufacturing organization with experience in filing Initial New Drug (IND) applications with U.S. and European regulatory authorities in order to produce clinical trial materials for the Chinese market and rest of world. Betta will facilitate regulatory filings and early stage clinical trial materials supply for potential use by us for development of MCLA-129 outside of China. MCLA-129 is a Bionics® binding to EGFR and cMET for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers; the upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. MCLA-129 has two distinct mechanisms of action. First, our DOCK & BLOCK® mechanism of action blocks the signaling of EGFR as well as c-MET, with the potential to inhibit tumor growth and survival. Second, MCLA-129 utilizes ADCC-enhancement technology designed for greater cell-killing potential. Because the DOCK & BLOCK and ADCC

mechanism of action is based on the co-expression of EGFR and c-MET, we expect it to have less toxicity compared to agents targeting EGFR alone.

We also have several other antibody candidates in pre-clinical development that bind to other target combinations. Each of our antibody candidates in our preclinical and clinical pipeline are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA.

Our Biclomics<sup>®</sup> technology platform employs an array of patented technologies and techniques to generate bispecific human antibodies. We utilize our patented MeMo<sup>®</sup> mouse harboring a common light chain in its germline to produce an array of antibodies with diverse heavy chains that are capable of binding virtually any antigen target. Based on the power of the common light chain, and using Merus' patented dimerization technology, Merus can take these diverse panels of heavy chains and efficiently generate large and diverse libraries of bispecific antibodies. We also employ our patented Spleen to Screen<sup>™</sup> technology to efficiently screen panels of common light chain antibodies, designed to allow us to rapidly identify and generate Biclomics<sup>®</sup> therapeutic candidates with differentiated modes of action. The Biclomics<sup>®</sup> technology also includes use of patented host cells to produce these multispecific antibodies efficiently. The Biclomics<sup>®</sup> format retains the IgG format of conventional mAbs and is designed to preserve the format's key features, including stability, long half-life and low immunogenicity, when developing our bispecific antibody candidates. We leverage industry-standard manufacturing processes and infrastructure to efficiently produce Biclomics<sup>®</sup>.

### **Our Strategy**

Our goal is to become a leading immuno-oncology company developing innovative bispecific antibodies to treat and potentially cure various types of cancer. Our business strategy comprises the following components:

- ***Successfully develop our most advanced bispecific antibody candidate, MCLA-128, for the treatment of solid tumors.*** We are developing MCLA-128 for the treatment of patients with HER2-expressing and other solid tumors, including breast, gastric and non-small cell lung cancer. We commenced a Phase 1/2 clinical trial of MCLA-128 in Europe in February 2015. In the dose escalation phase of the trial, the recommended dose of MCLA-128 was established. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies. In January 2018, we commenced a combination Phase 2 clinical trial in the United States for MCLA-128 and we plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and NSCLC is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at ESMO in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients), with MCLA-128 being well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored to date. Promising single agent antitumor activity was seen in heavily pretreated GC/GEJ cancer patients progressing on anti-HER2 therapy. We believe that if MCLA-128 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 second most advanced bispecific antibody candidate, MCLA-117, for the treatment of AML.*** We are developing MCLA-117 for the treatment of patients with AML. We commenced a Phase 1 clinical trial of MCLA-117 in Europe in May 2016 for the

treatment of patients with AML to assess its safety, tolerability and anti-tumor activity and filed an IND in the United States in January 2018, for which we obtained authorization to proceed from the FDA in February 2018. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. If the results of this clinical trial are favorable, we plan to seek orphan drug designation from the FDA and the EMA for MCLA-117 for the treatment of AML. We believe that if MCLA-117 is successfully developed and obtains regulatory approval, it has the potential to transform the treatment of AML. We also intend to evaluate MCLA-117 for the treatment of MDS.

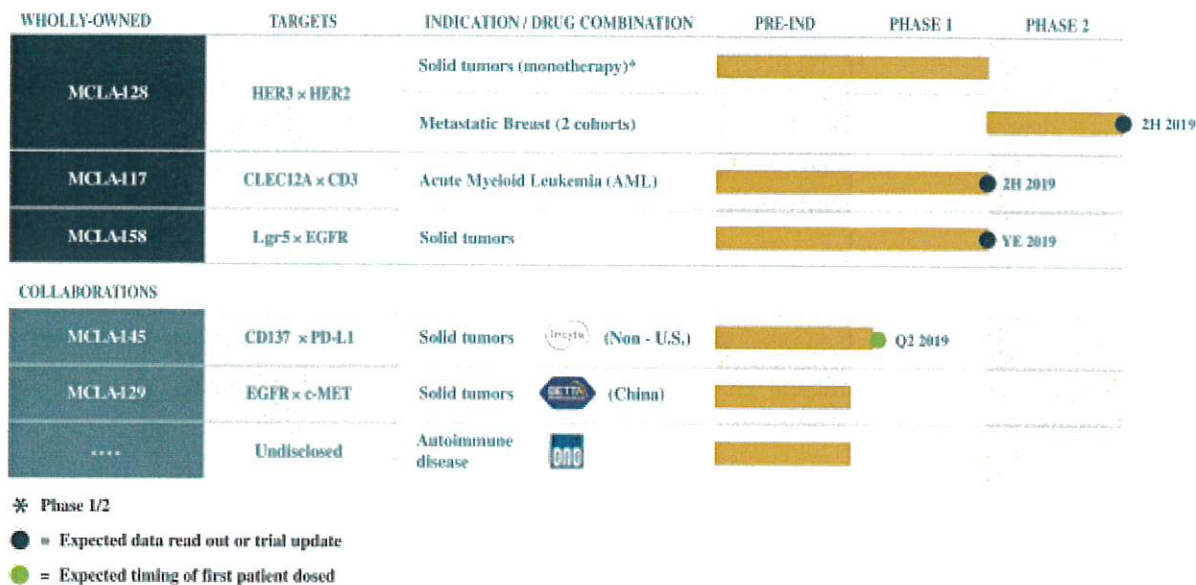
- ***Successfully develop our third bispecific antibody candidate, MCLA-158, for the treatment of metastatic colorectal cancer and other solid tumors .*** We are developing MCLA-158 for the treatment of solid tumors with an initial focus on the treatment of metastatic colorectal cancer. MCLA-158 has received approval of a CTA in several European countries for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018. In May 2018, we commenced an open-label, multicenter Phase 1 clinical trial of MCLA-158. Emerging data for our Phase 1 trial is expected at the end of 2019. MCLA-158 is an investigational, ADCC-enhanced Biclomics<sup>®</sup> designed to bind to cancer stem cells expressing Lgr5 and EGFR. We believe that if MCLA-158 is successfully developed and obtains regulatory approval, it has the potential to address and transform the treatment of metastatic colorectal cancer and other solid tumors.
- ***Successfully develop our fourth bispecific antibody candidate, MCLA-145, for the treatment of solid tumors.*** We commenced a clinical trial for MCLA-145 for the treatment of solid tumors in May 2019. We filed an IND for MCLA-145 with the FDA in December 2018, which received authorization to proceed from the FDA in January 2019. MCLA-145, which is being developed in collaboration with Incyte Corporation and is designed to bind to PD-L1 and CD137, was developed through an unbiased functional screening of multiple immunomodulatory target combinations and is a Biclomics<sup>®</sup> T-cell agonist that has been observed to bind with high affinity and specificity to human PD-L1 and CD137 in preclinical models. We believe that the unique immunostimulatory profile of MCLA-145 derives from its ability to potently activate immune effector cells in the context of the tumor microenvironment while simultaneously blocking inhibitory signals in the same immune cell population.
- ***Accelerate the internal discovery and development of additional immunotherapeutic antibody candidates.*** We believe we are well positioned to expand our pipeline of Biclomics<sup>®</sup> for the treatment of other forms of cancer. Our platform employs our proprietary common light chain transgenic MeMo<sup>®</sup> for the production of diverse human heavy chains that can be paired to generate bispecific antibodies, coupled with our Spleen to Screen<sup>™</sup> technology that is designed to allow us to rapidly identify and generate Biclomics<sup>®</sup> therapeutic candidates with differentiated modes of action that have the potential to kill tumor cells with high potency. We are conducting pre-clinical studies of an array of candidates for our internal proprietary pipeline as well as in collaboration with Incyte.
- ***Seek strategic collaborative relationships.*** We intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Biclomics<sup>®</sup> technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We have entered into collaborations with Incyte, ONO Pharmaceutical Co., Ltd., Simcere Pharmaceutical Group, and Betta Pharmaceuticals to develop bispecific antibody



candidates based on our Bionics® technology platform and plan to work with other collaborators to validate and expand the use of our Bionics® platform and the development of bispecific antibody candidates. We believe these collaborations could potentially provide significant funding to advance our bispecific antibody candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

### Our Product Pipeline

We intend to use our technology platform to develop Bionics® for the treatment of various types of cancer. The following table summarizes our bispecific antibody candidate pipeline:



### Overview of Existing Immunotherapeutics

Despite a number of advances in the past decade, a significant unmet need in cancer still exists. While targeted antibody therapeutics have been successful in treating some cancers, the therapeutic effects of almost all such therapies are transient. Cancer cells are able to adapt to escape recognition and elimination by the immune system, thereby contributing to tumor growth and progression. Acquired resistance to cancer therapies remains a significant clinical problem with patients frequently relapsing and the tumors metastasizing to other organs.

Immunotherapy is a new class of cancer treatment that works to harness the intrinsic powers of the immune system to fight tumor cells. There are a number of immunotherapies that engage various aspects of the immune system, for example: (1) monoclonal antibodies with enhanced ADCC, (2) bispecific T-cell engaging molecules, (3) immunomodulatory monoclonal antibodies and (4) CAR-T and TCR therapies. While these therapies vary in mechanism of action, they rely on specific components of the innate or adaptive immune system to kill tumor cells or counteract signals produced by cancer cells that suppress immune responses. The potential of immunotherapeutic approaches is best demonstrated by the long durable remissions, exceeding 10 years, observed after checkpoint inhibitor treatment in a subset of patients with advanced melanoma. More recent evidence from clinical trials suggests that a growing list of cancers will respond to checkpoint inhibitors.

**Monoclonal Antibodies with Enhanced ADCC.** Monoclonal antibodies bind to a single target expressed by tumor cells and have been modified to more efficiently attract immune effector cells,

such as NK cells and macrophages, to effectively kill tumor cells. Several mAbs with enhanced ADCC for the treatment of solid and leukemic tumors have yielded promising results in clinical trials.

By binding to a single target, mAbs with enhanced ADCC depend on the varying levels of expression of that target on the tumor and normal tissues to leverage the advantage of enhanced tumor cell-killing while minimizing toxicity. Ideal targets for antibodies would be solely expressed by the diseased cell and not by normal cells. Unfortunately, many of these targets are also expressed by healthy tissues. By binding to a single target, mAbs with enhanced ADCC potentially can induce autoimmune toxicity, so-called “on-target, off-tumor” toxicity.

***Bispecific T-Cell Engaging Molecules.*** Bispecific T-cell engaging molecules enhance a patient’s immune response to tumors by re-targeting T-cells to tumor cells. These molecules have been developed for a variety of both hematological and solid tumors and are currently in clinical trials. We are aware of a bispecific T-cell engaging molecule therapeutic that has received regulatory approval for the treatment of acute lymphoblastic leukemia as well as additional bispecific T-cell engaging molecules that are currently in clinical development.

Most T-cell engaging molecules in development are currently based on antibody fragments connected by a flexible linker and, unlike Biclomics<sup>®</sup>, do not utilize the advantages of the full-length IgG format. These molecules may have shorter half-lives than conventional mAbs, which could require continuous infusion of the molecule or could pose manufacturing and immunogenicity challenges.

***Immunomodulatory mAbs.*** Immunotherapeutic strategies have been shown in clinical trials to increase the ability of the immune system to recognize and eradicate tumor cells. Among these treatment strategies, immunomodulatory mAbs that enhance the function of T-cells have achieved noteworthy results for multiple types of cancers. Immunomodulatory mAbs that bind to molecules involved in T-cell inhibition are called checkpoint inhibitors because they block normally negative regulators of T-cell immunity. These checkpoint inhibitors target molecules such as the cytotoxic T-lymphocyte antigen 4, or CTLA-4, and PD-1. Additionally, immunomodulatory mAbs that bind to co-stimulatory molecules involved in T-cell activation, such as the tumor necrosis factor receptors OX40 and CD137, have shown tumor cell-killing activity in pre-clinical animal models of cancer and are currently being evaluated in early-stage clinical trials. Combinations of immunomodulatory mAbs have been observed to enhance the anti-cancer response in pre-clinical studies and in clinical trials of patients with various tumor types, but have also been observed to result in more pronounced toxicities. We believe that Biclomics<sup>®</sup> have the potential to capture the benefits of combinations of immunomodulatory mAbs, combined with more specific targeting to tumor-specific T-cells and tumor cells, thereby potentially diminishing the toxic side effects and providing a cost-effective two-in-one therapeutic for the treatment of cancer patients.

***CAR-T and TCR Therapies.*** T-cells recognize diseased cells by receptors engaging with antigens that are present on cancer cells. CAR-T therapy entails genetically engineering T-cells to express synthetic chimeric antigen receptors, or CARs, that direct T-cells to antigens on the surface of cancer cells. The T-cell receptor, or TCR, modifies T-cells to express high-affinity tumor specific TCRs that recognize intra-cellular antigens present on the surface of target cells. In clinical trials, CAR-T and TCR therapies have been observed to have anti-tumor activity in a narrow spectrum of hematologic cancers.

We believe a key limitation of CAR-T and TCR therapies is the need to retrieve non-compromised immune effector cells from a cancer patient, which requires a complex and costly



individualized process to develop the therapy. These challenges limit their potential and use in a variety of indications, including the treatment of solid tumors.

To address patient populations not responding to single-antibody based drugs, there is an increased focus on synergistically combining immunotherapeutics in the scientific community and from biopharmaceutical companies. Opportunities to create innovative antibody-based therapeutics lie in several technology advances, including bispecific antibodies that bind to multiple targets, Fc-optimization, which enhances the body's immune system to mediate the killing of cancer cells, and antibody drug conjugates, or ADCs.

### **Background on Antibodies**

The conventional antibody is a Y-shaped molecule that consists of two identical heavy chains and two identical light chains, as shown in the figure below. These four chains pair to form two variable regions that bind to antigens, or targets, and a constant region, which includes a region known as the Fc, that binds to receptors present on effector cells in the immune system. In conventional mAbs, the variable regions are identical and bind to the same targets.

In bispecific antibodies, the variable regions can be modified to bind to two different targets. To achieve this in the full-length IgG format, two different heavy chains and two identical light chains, also referred to as the common light chain, are combined.

In both conventional mAbs and IgG bispecific antibodies, the Fc region can bind to Fc receptors present on effector cells. This binding results in the recruitment and activation of immune effector cells and amplifies the immune system's response to antigens bound by the variable region of the antibody. This process is called ADCC. The Fc region can be modified to enhance ADCC so as to generate a more potent immune response against a particular target.

### **Our Biclomics® Platform**

We have a pipeline of Biclomics® generated from our patented technology platform. Our platform enables the rapid identification of immunotherapeutics with the potential to produce tumor cell-killing activity and/or to modulate the tumor microenvironment to promote more effective anti-tumor immune responses, and allows for the flexible and rapid generation of Biclomics® against virtually any particular target pair.

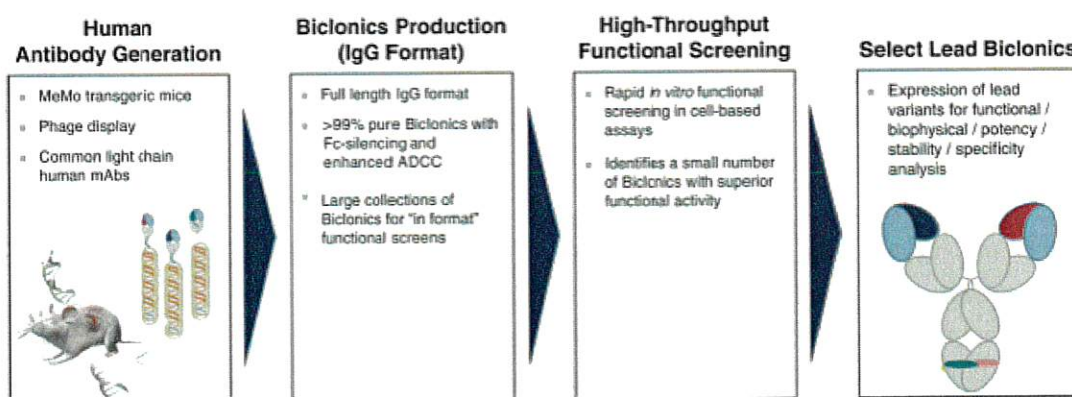
By binding to two different targets, Biclomics® can be designed to block receptors that drive tumor cell growth and survival and to mobilize the patient's immune response by activating various killer cells to eradicate tumors. We believe our Biclomics® platform allows us to approach cancer treatment through multiple modes of action:

- ***Blocking combinations of growth factor receptors that drive tumor cell growth and relapse while simultaneously recruiting immune effector cells through enhanced ADCC.*** Biclomics® may be generated for various combinations of growth factor receptors that play a role in tumors with different molecular profiles, while a modification in the Fc region of the Biclomics® facilitates the enhanced recruitment of immune effector cells, such as NK cells and macrophages, to directly kill tumor cells through ADCC.
- ***Activating T-cells to kill tumor cells by binding to CD3 expressed on T-cells and a tumor-associated target.*** CD3 is a cell-surface molecule present on all T-cells. We create Biclomics® that are designed to simultaneously bind to CD3 and a tumor-associated target, which allows for T-cell recruitment and engagement to selectively kill tumor cells.

- **Blocking two checkpoint inhibitory pathways for more efficient T-cell activation.** Cancer cells are able to block the tumor-killing function of T-cells through the expression of inhibitory molecules. Scientific research has shown that combinations of mAbs are more potent than single mAbs when used against these inhibitory molecules to unblock and revive this mechanism of T-cells which kills tumor cell targets. Biconics<sup>®</sup> can be designed to prevent the blocking of T-cells by cancer cells while retaining the advantages of specific targeting in the tumor environment.
- **Achieving a DOCK & BLOCK<sup>®</sup> mechanism of action to favorably impact hard-to-target receptors that may drive tumor growth or escape.** Biconics<sup>®</sup> are designed to be capable of binding a tumor associated target prevalent on cancer cells, which then permits the other arm of the Biconics<sup>®</sup> to be proximate to bind and block lesser expressed targets that have ligand or enzymatic functions that may tend to drive tumor growth or escape.
- **Blocking a checkpoint inhibitory pathway while simultaneously providing a co-stimulatory signal for more efficient activation of T-cells.** In addition to being blocked by inhibitory molecules, tumor specific T-cells may simultaneously require an activation signal to engage in tumor cell-killing. Biconics can be designed to concurrently alleviate the blocking of T-cells and deliver the signals required to activate the killing potential of T-cells.
- **Simultaneously targeting a growth factor receptor expressed by tumor cells and an immunomodulatory molecule involved in blocking tumor-specific T-cells.** Growth factor receptors like epidermal growth factor receptors, or EGFR, and HER2 are expressed on many tumors. Biconics can be designed to target such growth factor receptors while delivering an activation signal or de-blocking signal to T-cells.

Our process to select lead Biconics<sup>®</sup> for clinical development takes approximately 12 months and is illustrated below. We use our patented MeMo<sup>®</sup> and Spleen to Screen<sup>™</sup> human antibody generation and Biconics<sup>®</sup> production technologies to rapidly build large collections of Biconics<sup>®</sup> directed against particular target pairs. We then test these collections in cell-based functional assays to identify Biconics<sup>®</sup> that have differentiated modes of action. We select the most potent or efficacious Biconics<sup>®</sup> and evaluate them in multiple *in vitro* and *in vivo* assays to identify lead candidates for clinical development.

### Selection of Lead Biconics<sup>®</sup>



Our Biconics<sup>®</sup> technology platform includes the following:

- **Human antibody generation.** Our platform for generating human antibodies employs our patented transgenic mice, which we refer to as MeMo<sup>®</sup>, which harbors a common light chain

in its germline. MeMo<sup>®</sup> harnesses the power of the *in vivo* immune system to yield human antibodies with the potential for high potency, specificity, solubility and low immunogenicity. Upon immunization, MeMo<sup>®</sup> is capable of generating large and diverse panels of heavy chains that all pair with the same common light chain. These heavy chains are then used to generate large and diverse panels of Biclomics<sup>®</sup>, human bispecific, antibodies capable of binding two different targets of virtually any combination. Using this technology, we produce large and diverse panels of high-affinity antibodies against a broad variety of targets. We believe this approach enhances the discovery and development of high-quality human antibodies that, through the common light chain, generates sequences that are ready to be converted into the Biclomics<sup>®</sup> format.

- ***The full-length Immunoglobulin G format.*** The Biclomics<sup>®</sup> format is designed to retain several of the favorable attributes of conventional human IgG mAbs, including their stability and predictability during manufacturing as well as their long half-life and low immunogenicity during treatment of patients. Biclomics<sup>®</sup> consist of two different heavy chains that need to stably form, or heterodimerize, inside a manufacturing cell line. Using our patented dimerization technology, we employ amino acids with opposite charges in each of these heavy chains to efficiently drive this process. The use of a single, or common, light chain in our human Biclomics<sup>®</sup> antibodies is designed to have the heavy chains pair with the correct, common light chain to efficiently form functional antigen binding regions. The combination of these approaches prevents the need for additional, more artificial techniques, such as the use of linkers or chemical reactions, to force the pairing of different parts of the bispecific antibody. The resulting Biclomics<sup>®</sup> are bispecific heterodimeric IgG antibodies that closely mimic IgG antibodies that are produced naturally by the immune system.

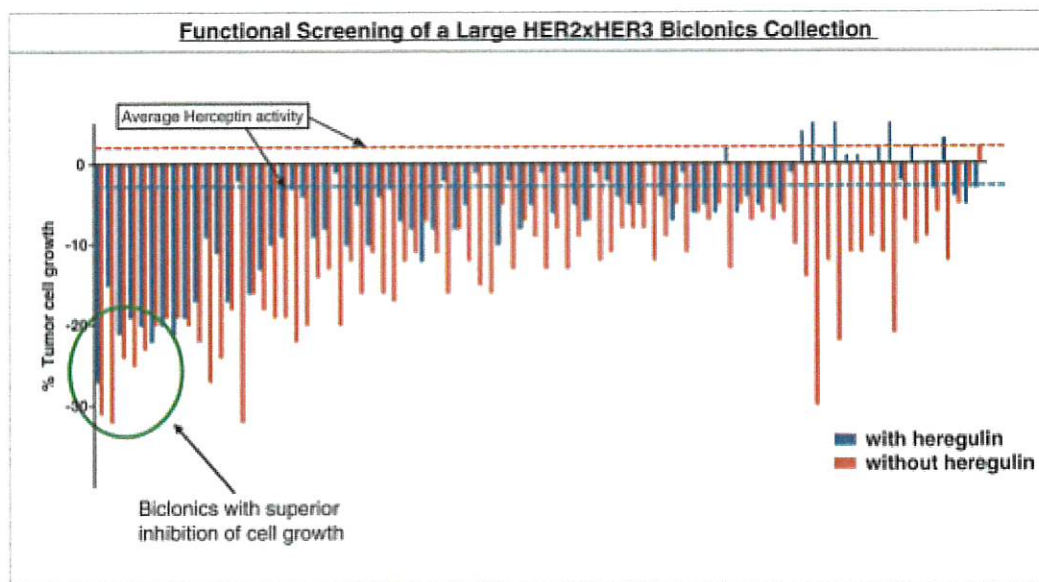
The Biclomics<sup>®</sup> format also permits us to make modifications to the Fc region of the IgG antibody in order to enhance or limit effector functions associated with this part of the molecule. This strategy has been successfully executed with conventional therapeutic mAbs. In order to enhance efficacy and promote immunotherapeutic activity, we can use genetically altered cell lines used in production to generate Biclomics<sup>®</sup> that are enhanced for ADCC, resulting in the improved ability to recruit NK cells and macrophages. This ADCC enhancement has been made to our most advanced bispecific antibody candidate, MCLA-128, and other of our antibody candidates, MCLA-158 and MCLA-129. In order to improve safety and tolerability, we can modify our Biclomics<sup>®</sup> to prevent the excessive release of signaling proteins called cytokines, which can overstimulate the immune system. This process is called Fc-silencing as it blocks the ability of our Biclomics<sup>®</sup> to bind to certain protein receptors on cells, known as Fc receptors, which are associated with cytokine release. We utilize Fc silencing in the design of our bispecific antibody candidate, MCLA-117.

- ***High-throughput functional screening.*** We employ our Spleen to Screen<sup>™</sup> technology to rapidly screen panels of target-specific common light chain antibodies. Subsequently, DNA constructs are generated and introduced into mammalian cells that encode panels of target-specific human antibodies. The common light chain format and modified Fc region of the IgG antibody ensure the secretion of virtually pure Biclomics<sup>®</sup> into the cell culture medium. The medium of thousands of cell cultures is harvested and individually used in cell- and tissue-based functional assays to permit the identification of Biclomics<sup>®</sup> with differentiated modes of action.

For example, the chart below shows the results of a pre-clinical study in which hundreds of different Biclomics targeting HER2 and HER3 were functionally screened against tumor cell samples, with and without heregulin present. Of the antibody candidates depicted in the chart, 40 exhibited



superior inhibition of cell growth compared to trastuzumab, a drug commonly prescribed for the treatment of breast cancer, and were selected in the process leading to identification of MCLA-128.



### Benefits of Biclomics®

We believe our Biclomics® technology platform provides the following benefits:

- **Rapid generation of human IgG antibodies having diversity at the heavy chain targeting an array of antigens, that are ready to be paired to produce our Biclomics®, bispecific antibodies.** Use of our patented MeMo®, Spleen to Screen™, heterodimerization and Fc modification technologies, permits us to rapidly generate a large amount of diverse bispecific antibodies capable of targeting an array of antigen combinations.
- **Biclomics® are stable, bispecific, full-length human IgG antibodies with no linkers or fusion proteins.** Biclomics® retain the IgG format of antibodies that are produced naturally by the immune system. Additionally, in contrast to many other bispecific antibody formats, Biclomics® do not require linkers to force the correct pairing of heavy and light chains or exploit fusion proteins to add functionality to the molecule. These qualities minimize time-consuming engineering efforts and allow us to create Biclomics® with predictable behavior during pre-clinical development.
- **Biclomics® preserve the stability, behavior and adaptability of normal IgG antibodies.** Biclomics® are based on the robust and commonly used IgG format to yield the favorable *in vivo* qualities associated with conventional mAbs, such as stability, long half-life and low immunogenicity. As a result, our Biclomics® format provides attractive options for dosage schedules and methods of administration, rendering them compatible with multiple modes of action for the efficient killing of tumor cells. Further, the IgG format allows us to apply previously established technologies to further optimize our Biclomics® for therapeutic use.
- **Biclomics® can be reliably manufactured with high yields.** Because our Biclomics® retain the IgG format of antibodies, our Biclomics® are manufactured using the large-scale industry-standard processes that are also used for the production of conventional mAbs, and the yields of Biclomics® we obtain are comparable to those of normal IgG antibodies. In stable cell lines, we are able to obtain over 90% of bispecific antibody formation using these processes and the IgG-based purification process results in up to greater than 98% purity for our Biclomics®.

- ***Our Biclomics® technology platform allows for functional evaluation of Biclomics® in the relevant therapeutic format leading to the discovery of therapeutic candidates with differentiated properties.*** Our Biclomics® technology platform enables rapid functional screening of large collections of bispecific antibodies which allows us to identify lead candidates with multiple mechanisms of action that have the potential to effectively kill tumor cells with high potency. This is an important step in the identification of lead bispecific antibody candidates with functionalities that compare favorably against other forms of immunotherapeutics, such as conventional mAbs as well as their combinations.

### **Our Bispecific Antibody Candidate Portfolio**

We commenced a Phase 2, open-label, multi-center, international clinical trial of our most advanced bispecific antibody candidate, MCLA-128 for the treatment of patients with MBC in January 2018 and plan to provide an update in the second half of 2019. Concurrently, our Phase 1/2 study of MCLA-128 in gastric and non-small cell lung cancers is ongoing. Additionally, we commenced a Phase 1, single-arm, open-label clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of patients with AML in May 2016, and announced the filing of an IND in the United States for MCLA-117 in January 2018, which subsequently received authorization from the FDA. Dose escalation in the Phase 1 trial is ongoing. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. In May 2018, we commenced a Phase 1, open-label, multicenter clinical trial of MCLA-158, for the treatment of solid tumors with an initial focus on metastatic colorectal cancer, for which we have received CTA approvals in several European countries. We filed an IND with FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018, and have expanded the trial to the United States. Emerging data for our Phase 1 trial is expected at the end of 2019. In addition, we commenced a Phase I clinical trial for MCLA-145, which is designed to bind to PD-L1 and CD137 and is part of our collaboration with Incyte, in May 2019, for the treatment of solid tumors. In addition, we have several other antibody candidates in preclinical development as part of our collaboration with Incyte, among other preclinical candidates in various stages of development, which we are developing with Sincere and Betta for which we have full ex-China rights, and that are part of Merus' wholly-owned internal proprietary pipeline.

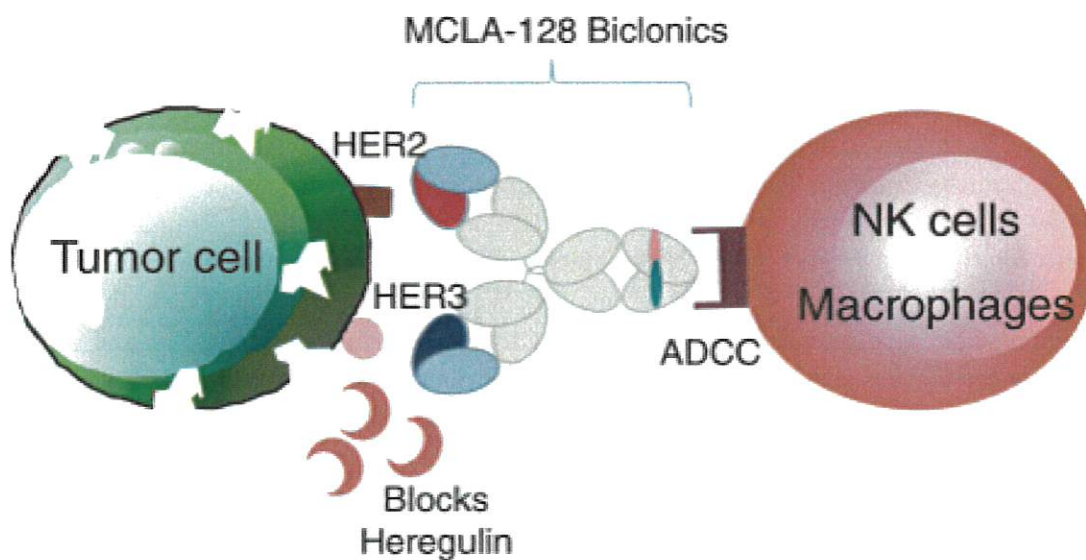
#### ***MCLA-128***

MCLA-128 is an ADCC-enhanced Biclomics® that is designed to bind HER2 to block the HER3 signaling pathway. HER3-mediated inherent and acquired resistance to HER2-targeted therapies has been implicated in various solid tumors, including breast, gastric and non-small cell lung cancer tumor cells. The scientific rationale for targeting HER2, or human epidermal growth factor receptor 2, and HER3, or human epidermal growth factor receptor 3, is that HER2 is amplified in many solid tumors and is associated with poor prognosis and the activation of HER3 causes cancer cells to be or to become resistant to treatment. On the surface of tumor cells, HER2 preferably pairs, or dimerizes, with HER3, and the resulting pair drives malignant progression of HER2-expressing cancer cells. Heregulin, which is the ligand for HER3, causes cancer cells to grow and become resistant to treatment with HER2-targeted therapies.

We have designed MCLA-128 to overcome the inherent and acquired resistance of tumor cells using two different mechanisms. The first mechanism blocks growth and survival pathways to stop tumor expansion, while preventing tumor cells from escaping through activation of the

HER3/hereregulin pathway. The second mechanism, enhanced ADCC, involves the recruitment and enhancement of immune effector cells, such as NK cells and macrophages, to directly kill the tumor through a modification of the Fc region. This dual mechanism of action is illustrated in the graphic below. MCLA-128 is designed to block the HER3 signaling pathway by employing a DOCK & BLOCK<sup>®</sup> mechanism. MCLA-128 is designed to “dock” onto a specific region of the HER2 receptor to orientate MCLA-128’s HER3 binding arm to “block” HER2:HER3 heterodimerization. Oncogenic signaling through the HER3 pathway, even in the presence of high heregulin concentrations, may thus be blocked.

### MCLA-128 Mechanism of Action

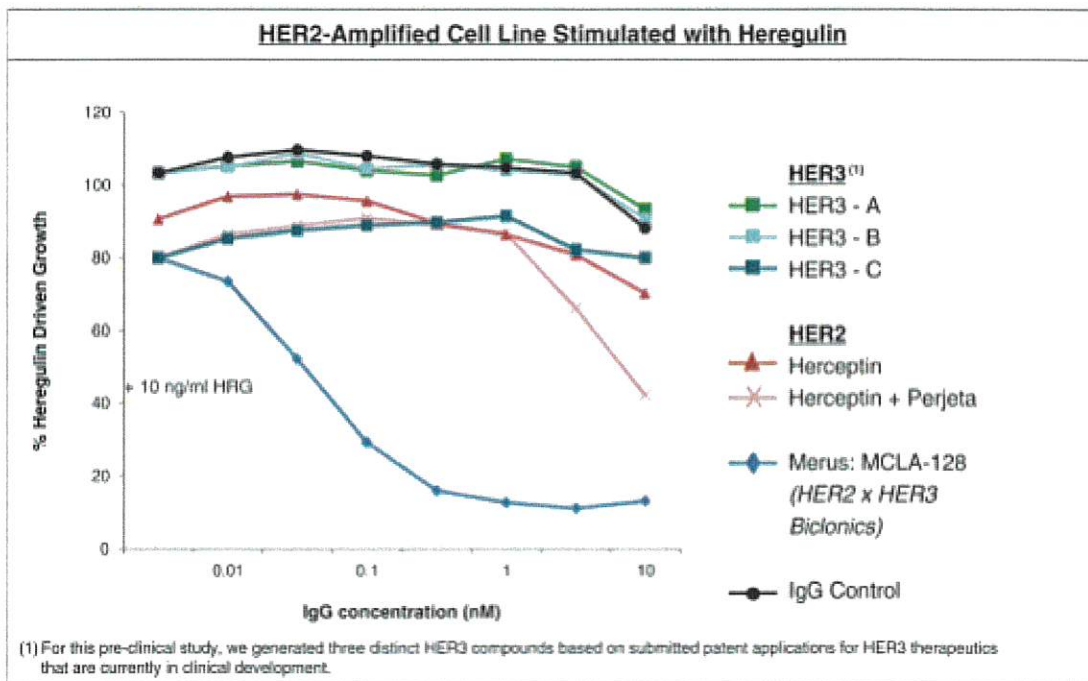


### *Pre-Clinical Studies*

In our pre-clinical studies of HER2-expressing tumor cell lines, we measured the impact of MCLA-128 on heregulin-driven growth and cellular changes, characterized by a metastatic phenotype. In these studies, we observed that both growth and metastatic characteristics were poorly blocked by therapeutic mAbs targeting HER2 and HER3, while the application of MCLA-128 resulted in the inhibition of heregulin induced changes in cultures of cancer cells. MCLA-128 also blocked activation of two key signaling pathways for the growth and survival of tumor cells more effectively than the combination of the currently approved therapeutic HER2 mAbs, Herceptin (trastuzumab) and Perjeta (pertuzumab).

As shown in the chart below, the administration of MCLA-128 reduced heregulin-driven tumor growth at significantly lower concentrations than mAbs targeting HER2 or HER3 and the combination of Herceptin and Perjeta.



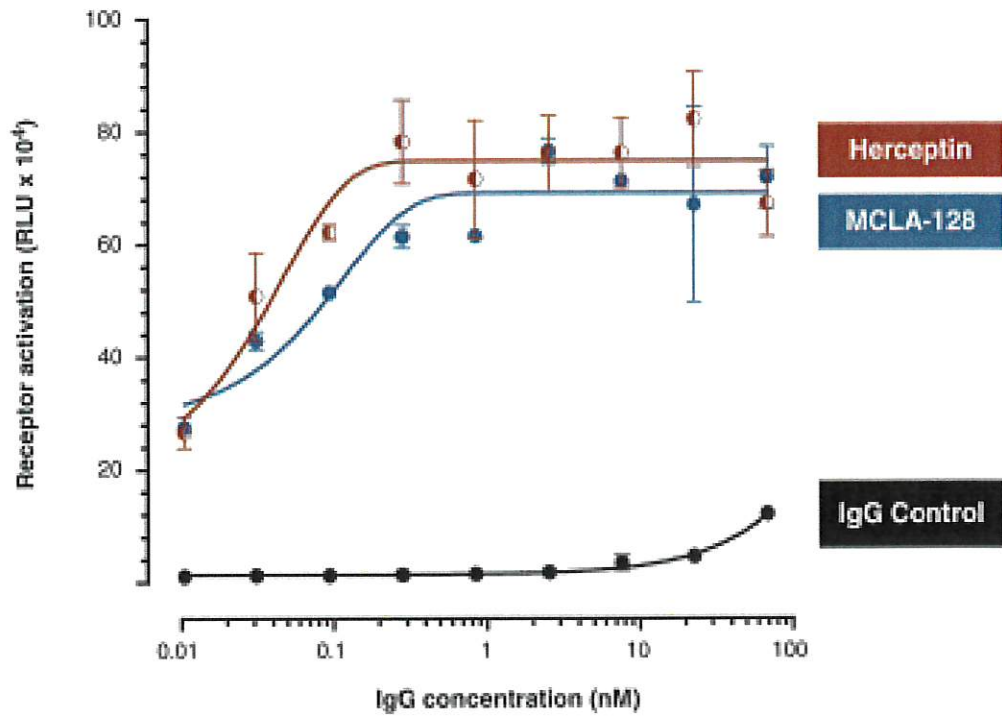


MCLA-128 also blocked phosphorylation and activation of key proteins in the signaling pathways for the cell growth and survival of cancer cell lines, a result that was not observed with the combination of HER2 mAbs, Herceptin and Perjeta.

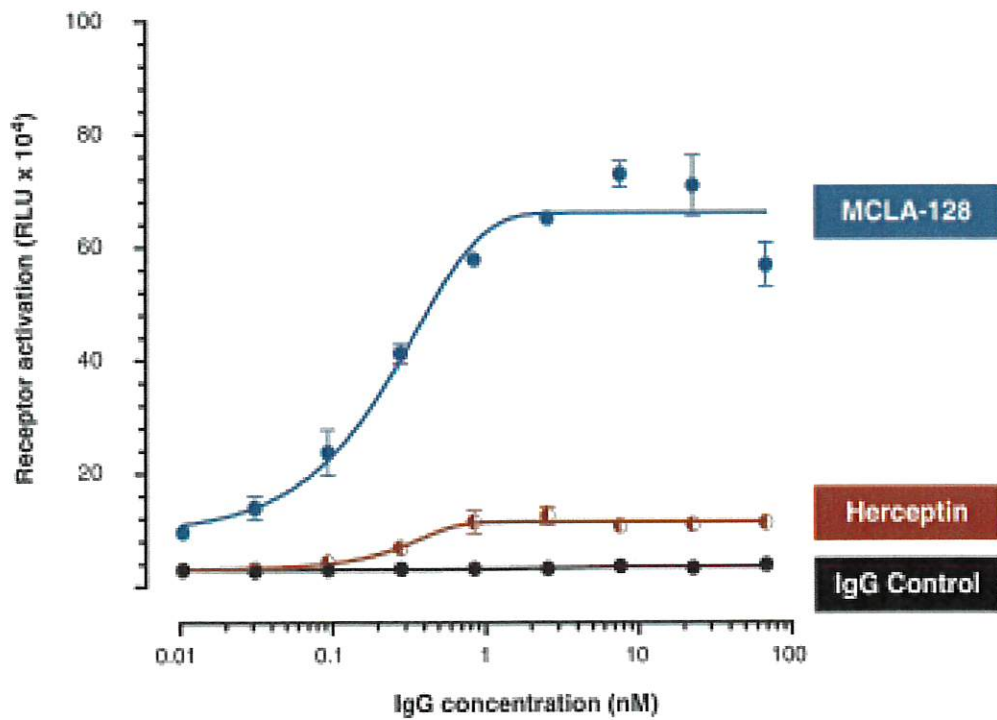
We also studied the ADCC activity of MCLA-128 in cell lines expressing different types of Fc receptors. As shown in the two charts below, because MCLA-128 is ADCC enhanced, it was able to bind and activate Fc receptors required for the recruitment of immune killer cells regardless of the receptor affinity of the patient. Studies have estimated that more than 50% of the patient population carry Fc receptors that are of low affinity and are poorly activated by therapeutic antibodies such as Herceptin. We have observed in our pre-clinical studies that MCLA-128 was also more potent than Herceptin in activating immune killer cells carrying low affinity Fc receptors.

### Fc Receptor Activation by MCLA-128 (FcγR Subtype)

### High affinity FcγR expressing cells (Herceptin responders)

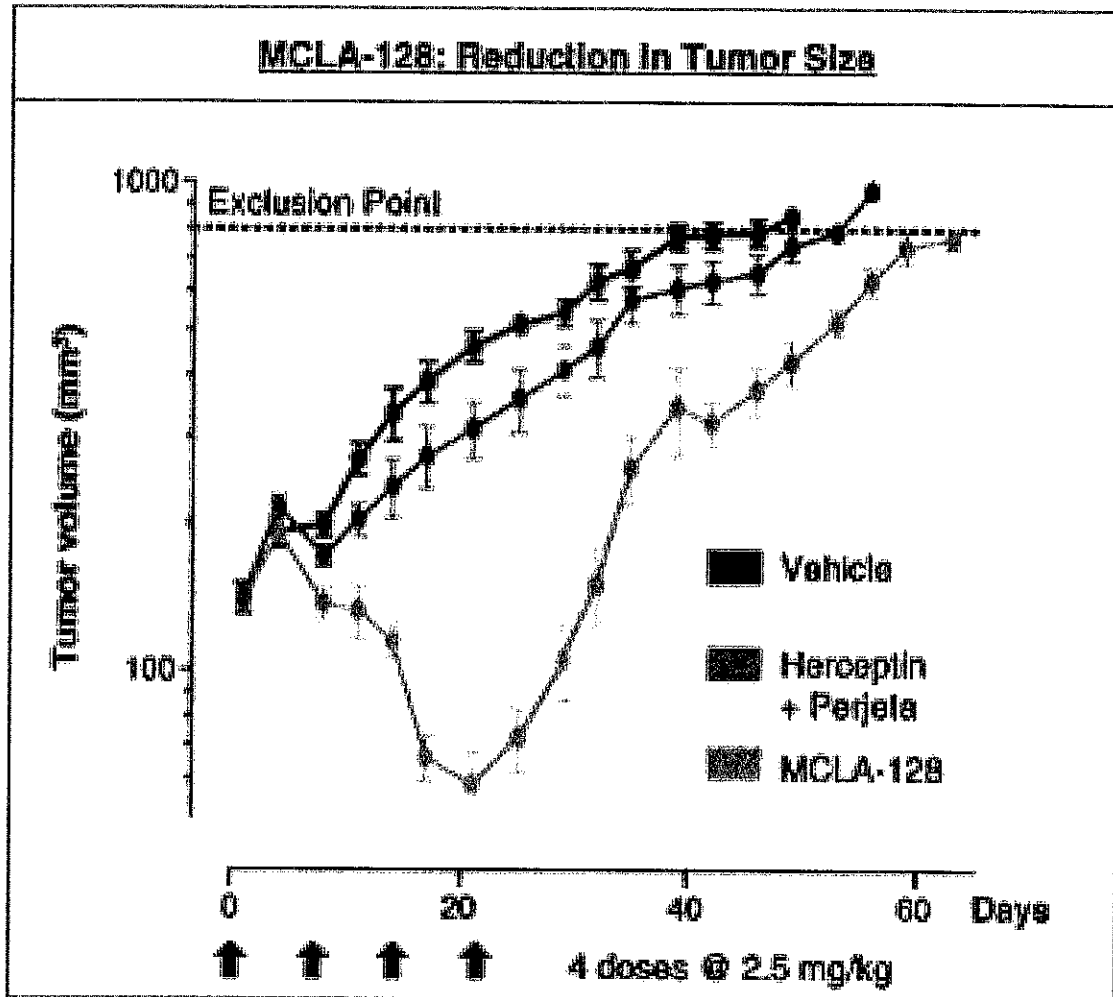


### Low affinity FcγR expressing cells (Herceptin non-responders)

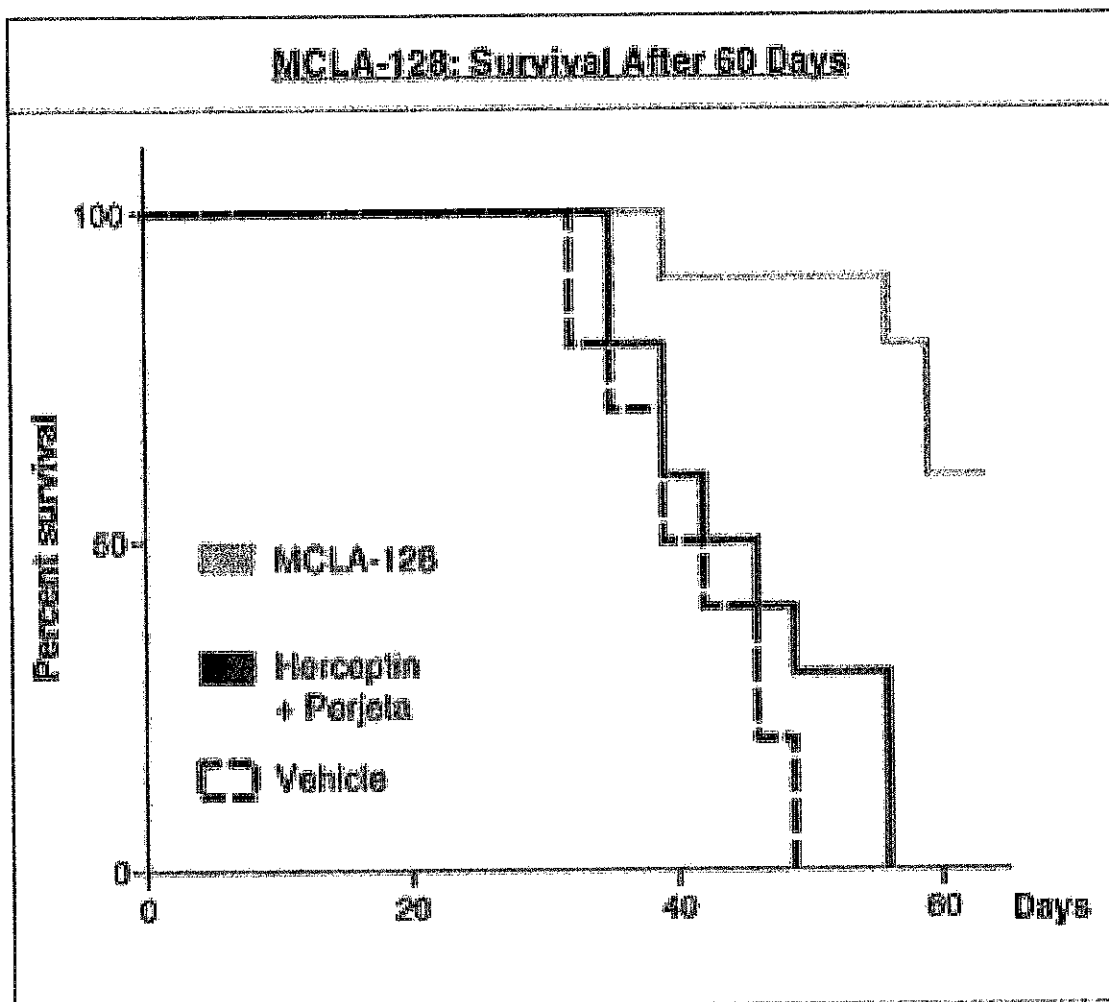




In the pre-clinical studies, we also compared the ability of MCLA-128 to inhibit the *in vivo* growth of cell lines such as JIMT-1, which is an aggressive breast cancer line resistant to HER2-targeted therapies. In these studies, we administered four doses of MCLA-128 at 2.5 mg/kg. The MCLA-128-treated mice experienced as high as a 58% reduction of their tumor size during the 21-day treatment period, compared to a less than 11% reduction after administration of a combination of Herceptin and Perjeta. Regrowth of the tumor was observed after treatment was halted on day 21. This result is illustrated in the chart below.



Analysis of tumors taken from mice at day 21 showed that HER3 signaling was effectively blocked when treated with MCLA-128 whereas no effect was observed with the combination of Herceptin and Perjeta. Pre-clinical studies have been conducted to evaluate whether tumor suppression can be sustained by continuing treatment over the 60-day observation period. The result was that tumor suppression was not sustained. However, a higher percentage (60%) of mice treated with MCLA-128 survived beyond 60 days than mice receiving either the vehicle or the combination of Herceptin and Perjeta. This result is illustrated in the chart below.



#### *Clinical Development of MCLA-128*

In February 2015, we commenced an open-label Phase 1/2 clinical trial of MCLA-128 in Europe for the treatment of HER2-expressing solid tumors. The first part of the trial, the dose escalation phase, is complete. In Part 1 of this trial, MCLA-128 was well-tolerated up to the highest tested dose of 900 mg and we observed early positive efficacy results. No dose limiting toxicities were observed. The cumulative safety and available pharmacokinetic, or PK, data, along with the aid of a PK simulation study, were used to support a recommended dose for a Phase 2 clinical trial of 750 mg, administered over 120 minutes, which we are using in Part 2 of this trial. The Part 2 is ongoing, and is designed to further study the safety, tolerability and clinical efficacy of MCLA-128 in patients with solid tumors that are relapsed or refractory to available standard treatment or for whom no curative therapy is available.

For this Phase 1/2 trial, we have implemented an exploratory biomarker investigation using tumor tissue and blood samples from patients. The biomarkers we are evaluating include heregulin expression, HER2 and HER3 receptor expression and PI3K/AKT pathway activation status, which refers to an intracellular pathway regulating processes such as cell survival, cell proliferation and cell growth. We believe this approach, in conjunction with genetic profiling, will allow for the validation of biomarker assays and will provide guidance for enrolling additional patients based on relevant biomarkers.

Adverse events observed have included infusion related reactions, which were mild or moderate in severity and well managed with premedication or symptomatic medication. No severe GI events or symptomatic cardiac events have been reported.

The Phase 2 portion of the study is ongoing and designed to explore selected metastatic indications including breast, gastric and non-small cell lung cancers. In May 2017, we announced the results of our first-in-human Phase 1/2 study of MCLA-128 in solid tumors, including final Phase 1 data and preliminary activity in patients with HER2-positive MBC from the Phase 2 portion of the trial.

As part of the ongoing study, a cohort of 11 HER2-positive MBC patients has been treated with single agent MCLA-128 (9 patients at RP2D and two patients at 480 mg q3 weeks from part 1). These MBC patients were all heavily pretreated, having received a median of 6 prior lines of metastatic therapy, all having 2-5 prior HER2 inhibitor therapies, and some of the patients with outright disease progression to the last line of therapy. One MBC patient achieved a confirmed partial response (>8+ months) and 7 had stable disease (including 4 sustained stabilizations lasting greater than 5 months). The clinical benefit rate (complete and partial responses plus stable disease lasting at least 12 weeks) among the cohort of MBC patients was 64% or 7 of 11 patients. We believe the antitumor activity reported as single agent and extensive preclinical evidence support further development of MCLA-128 in combination in MBC.

In January 2018, we commenced a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in two MBC populations including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients. The MCLA-128 Phase 2 clinical trial is ongoing and expected to enroll approximately 120 patients in total across the United States and Europe. The first cohort, HER2-positive MBC patients who are progressing on anti-HER2 therapies including trastuzumab, pertuzumab and TDM-1, will receive MCLA-128 in combination with trastuzumab and chemotherapy. The second cohort, MBC patients with confirmed hormone receptor positive status and HER2-low (immuno-histo-chemistry (IHC) HER2 1+ or 2+ and fluorescent in-situ hybridization (FISH) negative for HER2 amplification) who are progressing on hormone therapies and CDK4/6 inhibitors, will receive MCLA-128 in combination with endocrine therapy. The primary endpoint for both cohorts is the clinical benefit rate at 24 weeks. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019.

We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at ESMO in October 2018. As of February 15, 2018, a clinical benefit rate of 24% (6 of 25 patients) was observed, and MCLA-128 was well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored. Single agent antitumor activity, including one patient with a durable complete response of 5.8 months, was seen in heavily pretreated GC/GEJ cancer patients progressing on one to three anti-HER2 therapy.

### ***MCLA-117***

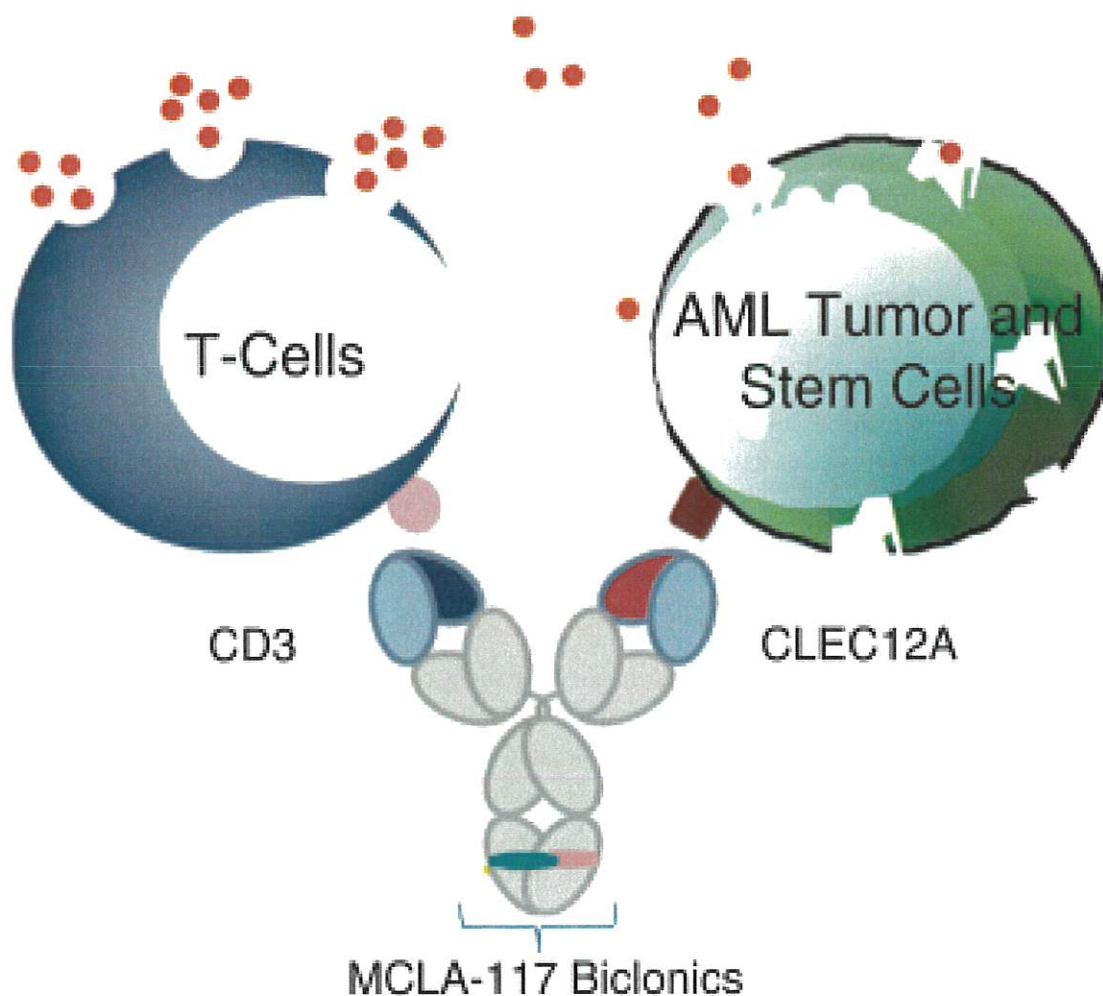
#### ***MCLA-117 for AML***

MCLA-117 is a Biclomics<sup>®</sup> that is designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on AML tumor cells and stem cells. CLEC12A is not found on normal blood stem cells nor on cells that give rise to red blood cells and platelets nor is it present on other non-hematopoietic cells in the body. This is in contrast to the expression patterns of CD123 and CD33, which are present on normal blood stem cells, and in the case

of CD33, also the cells that give rise to red blood cells and platelets. Both CD123 and CD33 are being explored by others as targets for AML therapy. We believe that the expression pattern of CLEC12A makes it an attractive and differentiated molecule for targeted therapy in cancer patients. Moreover, CLEC12A is expressed on approximately 90 to 95% of newly diagnosed and relapsed cases of AML, and we believe that many patients with AML could potentially benefit from treatment with MCLA-117.

By binding to CD3 and CLEC12A, MCLA-117 is designed to recruit and activate T-cells to kill CLEC12A-expressing AML tumor cells and stem cells. AML tumor stem cells are thought to be resistant to current chemotherapeutic treatment regimens, and the inability to eliminate these cells with conventional therapies is thought to significantly contribute to disease relapse in AML patients. We believe that elimination of this leukemic stem cell population by treatment with MCLA-117 may prevent recurrence of the tumor. The mechanism of action of MCLA-117 is illustrated in the graphic below.

### MCLA-117 Mechanism of Action



Unlike some other bispecific antibody formats, the full-length IgG format of MCLA-117 and its associated longer half-life is designed to keep it from having to be administered through continuous infusion using infusion pumps. In addition, through Fc-silencing, MCLA-117 is designed to avoid binding to Fc receptors present on macrophages and other blood cells that could result in toxicity.

We believe that MCLA-117 could be developed as induction therapy, as consolidation therapy to treat minimal residual disease and as rescue therapy for patients with relapsed or refractory AML. We intend to explore its use both as a single agent and in combination with commonly used chemotherapy agents and other treatment regimens of AML. We expect the safety profile of MCLA-117 to be favorable based on the restricted expression of CLEC12A in human tissues which is anticipated to result in manageable neutropenia. We also expect infusion related reactions based on the observed level of cytokine release upon co-culture with blood cells, which can be mitigated by gradual dose increments and by providing co-medication when required. As CLEC12A is not expressed on megakaryocyte and erythroid progenitor cells, we expect the application of MCLA-117 would not result in a decrease of platelet counts or red blood cells.

In our pre-clinical studies, MCLA-117 specifically targeted and killed AML tumor cells mediated by a high affinity of the Biclonics for CLEC12A and a relatively low affinity for CD3. In these studies, MCLA-117 recruited T-cells to selectively kill tumor cells in blood samples of AML patients containing an unfavorable ratio of T-cells to AML tumor cells. We observed that 1,000 ng/ml of MCLA-117 was sufficient to induce the elimination of tumor cells.

As shown in the figure below, treatment of an AML patient's blood samples with MCLA-117 resulted in the efficient killing of AML tumor cells in our pre-clinical studies. An unmanipulated primary blood sample containing both CLEC12A positive patient tumor cells and T-cells was cultured for 10 days with either a dosage of 1,000 ng/ml of MCLA-117 or a dosage of a control Biclonics® that did not bind to CLEC12A but retained CD3 binding activity. On day 10, the percentage of AML tumor cells in the culture dish dosed with MCLA-117 had decreased from 93% to 1% while the proportion of T-cells had increased from 5% to 95%, indicating that CD3 positive T-cells had been activated to proliferate, engage and kill the AML tumor cells by MCLA-117. In contrast, the percentage of AML tumor cells in the culture dish dosed with a control Biclonics had slightly decreased from 93% to 81% while the proportion of T-cells had only increased from 5% to 16%, indicating that binding to CLEC12A by MCLA-117 was required to result in the efficient killing of AML tumor cells.

We commenced a Phase 1, single-arm, open-label clinical trial in Europe of MCLA-117 in May 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity. The first phase of the trial is designed as a dose escalation study, followed by a second safety dose expansion phase. The study is designed to enroll adult patients with all AML subtypes. Patients with relapsed or refractory disease and newly diagnosed, untreated AML patients who are older than 65 years and are usually not eligible as candidates for intensive or conventional approved treatments would all be eligible for enrollment in the trial. The trial is ongoing and we expect to enroll approximately 50 patients in this trial.

The primary endpoint of the Phase 1 trial is the assessment of the safety and tolerability of MCLA-117 in order to determine the maximum tolerated dose and frequency of administration. Secondary endpoints include pharmacokinetic measures, anti-tumor response and clinical benefit. To date, patients treated with MCLA-117 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions.

In January of 2018, we submitted an IND to the FDA for MCLA-117 for the potential treatment of AML, which was authorized to proceed by the FDA in February 2018, and have expanded the trial to the United States. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117.

If the results of the clinical trial are favorable, we plan to seek orphan drug designation from the FDA and the EMA for MCLA-117 in the United States and in Europe, respectively, for the treatment of AML.

#### *MCLA-117 for MDS*

We also intend to evaluate MCLA-117 for the treatment of MDS. MDS is a disease that occurs when the blood-forming cells in the bone marrow lose the ability to develop normally. Patients with MDS have lower numbers of one or more types of cells in the blood such as red blood cells and platelets and are at higher risk to develop AML. Similar to AML, we believe that the expression pattern of CLEC12A makes it an attractive and differentiated molecule for targeted therapy in patients with MDS. CLEC12A is expressed in approximately 89% of patients with MDS, and we believe that many patients with MDS could potentially benefit from treatment with MCLA-117.

#### *MCLA-158*

MCLA-158 is an investigational ADCC-enhanced Biclomics that is designed to bind to Lgr5 and EGFR-expressing cancer stem cells for the treatment of solid tumors, including colorectal cancer. Cancer stem cells are a subpopulation of long-lived and chemo-resistant cells that contribute to the growth and metastatic potential of a tumor. Cancer stem cells have the capacity to divide and give rise to new cancer stem cells via a process called self-renewal, the capacity to differentiate or change into the other cells that form the bulk of the tumor and an ability to withstand chemotherapy and radiation exposure. We believe these features make cancer stem cells an attractive therapeutic target to overcome the inherent and acquired resistance of tumors to conventional therapies.

In 2012, colorectal cancer was the third most common cancer worldwide. Patients with metastatic disease have a mean survival time of less than two years. Approximately 90% of all colorectal cancers display mutational activation of the Wnt pathway. The Wnt pathway is critical for the maintenance of stem cells and has been linked to cancer. Lgr5 is an amplifying receptor of the Wnt pathway, is over-expressed in approximately 70% of advanced colorectal cancers and is correlated with lymph node metastases. Lgr5 expression is higher in metastatic tumors and associated with tumor-initiating cells or cancer stem cells. Lgr5 positive cells are highly mitotically active and are expected to be particularly dependent on growth and survival factors that activate EGFR.

We have designed MCLA-158 to target cancer stem cells expressing Lgr5 and EGFR using two different mechanisms of action. The first mechanism of action blocks growth and survival pathways in cancer stem cells. The second mechanism of action, enhanced ADCC, involves the recruitment and enhancement of immune effector cells to directly kill cancer stem cells that persist in solid tumors, such as colorectal cancer, and cause relapse and metastasis.

In our pre-clinical studies, we used our proprietary technology combined with high content imaging to identify MCLA-158 after screening hundreds of bispecific antibodies for activity in more than 20 patient-derived colorectal cancer organoids. Organoids are cell cultures based on cancer cells from patients that mimic the physiology of tumor growth and depend on the presence of cancer stem cells for their maintenance. In our pre-clinical studies, MCLA-158 was significantly more potent than an EGFR-targeting mAb, cetuximab, in inhibiting the growth of patient-derived colorectal cancer organoids. In our ex-vivo organoid studies, MCLA-158 selectively blocked the ability of colorectal cancer organoids to regrow after serial passaging, suggesting that MCLA-158 has the potential to eliminate stem cells *in vitro*.

In our pre-clinical studies MCLA-158 has been observed to be selectively more active in human tumor-derived organoids than in organoids derived from normal human colon. The activity of MCLA-158 on the tumor organoid size was more than 100 times greater than on the normal colon organoids. In contrast, the activity of cetuximab was similar to the activity of MCLA-158 on normal colon organoids and 20 to 100 times less than the activity of MCLA-158 on tumor organoids. We observed this result on three additional normal colon organoids and four tumor organoids, three of which were derived from metastatic lesions.

Based on our pre-clinical studies to date and the expression pattern of Lgr5 and EGFR and their known roles in tumor progression, we believe that MCLA-158 has the potential to improve the survival outcome of patients with metastatic colorectal cancer, non-small cell lung cancer, ovarian cancer and potentially other solid tumors.

We have received approval of CTAs in several European countries for MCLA-158 for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. The first CTA was approved to initiate a Phase 1 clinical trial in Europe in January 2018. We filed an IND for MCLA-158 with the FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018. In May 2018, we commenced an open-label, multicenter Phase 1 clinical trial of MCLA-158 in patients with solid tumors with an initial focus on metastatic colorectal cancer and expect emerging data by the end of 2019. The Phase 1 trial consists of two parts: dose escalation and dose expansion. The dose escalation part is intended to determine the appropriate dose of MCLA-158. The dose expansion part is intended to evaluate the safety and tolerability of the defined dose of MCLA-158 in patients with solid tumors. The trial is also designed to evaluate preliminary antitumor activity of single-agent MCLA-158. We expect to enroll approximately 120 adult patients with colorectal cancer and possibly other solid tumors in this trial. Recruitment in the trial is ongoing.

### ***Other Bispecific Antibody Candidates***

#### ***MCLA-145***

MCLA-145 is an investigational Biclomics<sup>®</sup> that is designed to bind to PD-L1 and CD137. We received authorization to proceed under the IND for MCLA-145 from the FDA in January 2019 and initiated a Phase 1 clinical trial in May 2019. MCLA-145 is designed to enhance the activation of tumor specific tumor infiltrating lymphocytes. MCLA-145 is the first drug candidate co-developed under our global research and collaboration with Incyte Corporation. We have full rights to develop and commercialize MCLA-145 in the United States and Incyte is responsible for its development and commercialization outside the United States.

#### ***MCLA-129***

MCLA-129 is a Biclomics<sup>®</sup>, designed to bind EGFR and cMET, for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers. The upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. MCLA-129 has two distinct mechanisms of action. First, our DOCK & BLOCK<sup>®</sup> mechanism of action blocks the signaling of EGFR as well as c-MET, with the potential to inhibit tumor growth and survival. Second, MCLA-129 utilizes ADCC-enhancement technology designed for greater cell-killing potential. Because the DOCK & BLOCK and ADCC mechanism of action is based on the co-expression of EGFR and c-MET, we expect it to have less toxicity compared to agents targeting EGFR alone. MCLA-129 is being developed pursuant to collaboration and license agreement with Betta Pharmaceuticals. Under

the terms of the agreement, Betta Pharmaceuticals has agreed to be responsible for clinical development and commercialization of MCLA-129 in China. As a key strategic component of the collaboration, Betta will 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 world. Betta will facilitate regulatory filings and early stage clinical trial materials supply for potential use by us for development of MCLA-129 outside of China.

#### *Pre-Clinical Discovery Programs*

We intend to further leverage our Biclomics<sup>®</sup> technology platform to identify multiple additional antibody candidates and advance them to clinical development. Each of these antibody candidates are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA. Our current focus is on a number of immunotherapeutic targets and pathways that have demonstrated promising tumor killing ability in early-stage clinical trials and scientific literature. Using our platform, we will continue to evaluate new targets and combinations to identify potential candidates with the highest immunotherapeutic potential and select those candidates to be advanced into clinical trials.

#### **Collaboration Agreements**

As part of our business strategy, we intend to continue to seek research collaborations in order to derive further value from our Biclomics<sup>®</sup> platform and more fully exploit its potential.

#### *Incyte Corporation*

We have entered into a collaboration and license agreement, or the Collaboration Agreement, with Incyte Corporation, or Incyte. Under the terms of the Collaboration Agreement, we and Incyte have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing our proprietary bispecific technology platform. The collaboration encompasses up to 11 independent programs, including some of our current preclinical immuno-oncology discovery programs. For one of the current clinical programs, concerning MCLA-145, we retain 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, we and Incyte will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in our respective territories. We have the option to co-fund development of products arising from one specified program, and subject to certain conditions, to a second specified program, in each case exchange for a share of profits in the United States, as well as the right to participate in a specified proportion of detailing activities in the United States for one of such programs. If we exercise our co-funding option for a program, we would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing Incyte for certain development costs incurred prior to the option exercise. All products as to which we have exercised our option to co-fund development would be subject to joint development plans and overseen by a joint development committee, with Incyte having final determination as to such plans in cases of dispute.

For each program other than MCLA-145, where we have not elected to co-fund development or where we do not have such a co-funding option, Incyte is solely responsible for all costs of global development and commercialization activities. We retain the rights to our bispecific technology



platform as well as clinical and pre-clinical candidates and future programs emerging from our platform that are outside the scope of the Collaboration Agreement.

In January 2017, upon the Collaboration Agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120 million for the rights granted under the Collaboration Agreement. For each program as to which we do not have commercialization or co-development rights, we are eligible to receive up to \$100 million in future contingent development and regulatory milestones and up to \$250 million in commercialization milestones, as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which we have exercised our option to co-fund development, we are eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If we opt to cease co-funding a program as to which we exercised our co-development option, then we will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which we choose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the United States. For MCLA-145, for which we retain all commercial rights in the United States, we and Incyte are each eligible to receive tiered royalties on net sales in the other's territory at rates ranging from 6% to 10%.

The Collaboration Agreement will continue on a program-by-program basis until neither party has any royalty payment obligations with respect to such program or, if earlier, the termination of the Collaboration Agreement or any program in accordance with the terms of the Collaboration Agreement. The Collaboration Agreement may be terminated in its entirety, or on a program-by-program basis, by Incyte for convenience. The Collaboration Agreement may also be terminated by either party under certain other circumstances, including material breach, or on a program-by-program basis for patent challenge of patents under the applicable program, in each case as set forth in the Collaboration Agreement. If the Collaboration Agreement is terminated in its entirety or 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, if we elect to pursue development and commercialization of products arising from the terminated programs.

In connection with the Collaboration Agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which, in January 2017, we issued and sold to Incyte 3,200,000 common shares for an aggregate purchase price of \$80.0 million.

### ***ONO Pharmaceutical***

In April 2014, we entered into a strategic research and license agreement with ONO, under which we granted ONO an exclusive, worldwide, royalty-bearing license to research, test, make, use and market a limited set of bispecific antibody candidates, if approved, based on our Biclomics<sup>®</sup> technology platform, directed to two undisclosed targets.

ONO paid us a non-refundable upfront fee of €1.0 million, and we are eligible to receive up to an aggregate of €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved four of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €2.7 million in milestone payments. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we and our affiliates are

prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combination that are the subject of this agreement. ONO also provides funding for our research and development activities under an agreed-upon plan. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

On March 14, 2018, we entered into a second contract research and license agreement with ONO. Pursuant to an exclusive option granted to ONO in the prior agreement executed in April 2014, ONO exercised its option to enter into the March 2018 agreement. We granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on our Biclomics<sup>®</sup> technology platform against two undisclosed targets directed to a particular undisclosed target combination. ONO identifies and selects the licensed bispecific antibodies for which it is responsible for conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. 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 agreed to fund our 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. We retain 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 has agreed to pay an upfront non-refundable payment of €700,000 for the rights granted and we are also eligible to receive an aggregate of €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under the License Agreement, if any, the Company is eligible to receive a mid-single digit royalty on net sales.

For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combination that are the subject of this agreement. ONO also provides funding for our research and development activities under an agreed-upon plan. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

#### ***Simcere Pharmaceutical Group***

On January 8, 2018, we entered into an agreement with Simcere Pharmaceutical Group, or Simcere, granting Simcere an exclusive license to develop and commercialize in China three bispecific antibodies to be produced by Merus utilizing our proprietary Biclomics<sup>®</sup> technology platform in the area of immuno-oncology. We retain all rights outside of China.

We have agreed to lead research and discovery activities while Simcere has agreed to be responsible for the IND-enabling studies, clinical development, regulatory filings and commercialization of these product candidates in China. We received an upfront payment, and are eligible to receive milestone payments contingent upon Simcere achieving certain specified development and commercial goals. To date, we have achieved one undisclosed milestone payment under this agreement. We are eligible to receive tiered royalty payments on sales of any products resulting from the collaboration in China from Simcere. Simcere is eligible to receive tiered royalty payments on sales outside of China from us.

#### ***Betta Pharmaceuticals Co. Ltd.***

On December 10, 2018, we entered into a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd., or Betta, where we granted Betta an exclusive license to develop and commercialize in China MCLA-129, a Merus proprietary Biclronics<sup>®</sup> produced by our Biclronics<sup>®</sup> technology platform. We retain all rights outside of China. Under the terms of the agreement, Betta will retain a contract manufacturing organization with experience in filing IND applications with U.S. authorities and CTAs with European regulatory authorities in order to produce clinical trial materials for the Chinese market and the 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 we intend 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, we and Betta will share equally the cost of the transfer of the manufacturing technology to a contract manufacturing organization. We are also eligible to receive 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. Betta is eligible to receive milestone payments contingent upon us achieving certain specified development and commercial goals, and is eligible to receive tiered royalty payments of net sales outside of China.

#### **Manufacturing**

Our Biclronics<sup>®</sup> technology platform relies on third parties for biological materials. We rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our bispecific antibody candidates and products, if approved. We currently do not have any agreements for the commercial production of bispecific product candidates, but we have contracted several biopharmaceutical CMOs for the clinical manufacturing of MCLA-128, MCLA-117, MCLA-158 and MCLA-145. We believe that the standardized Biclronics<sup>®</sup> manufacturing process can be transferred to additional CMOs and potential future co-development or co-commercialization collaborations or partnerships for the production of clinical and commercial supplies of our Biclronics<sup>®</sup> in the ordinary course of business.

#### **Sales and Marketing**

We have not yet defined our sales, marketing or product distribution strategy for MCLA-128, MCLA-117, MCLA-158 or any of our other bispecific antibody candidates because our bispecific antibody candidates are still in pre-clinical or early-stage clinical development. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force, or the

establishment of our own commercial and specialty sales force. We plan to further evaluate these alternatives as we approach approval for one of our bispecific antibody candidates.

### **Competition**

We compete directly with companies that focus on immuno-oncology and companies dedicating their resources to cancer therapies. We also face competition from academic research institutions, governmental agencies and other various public and private research institutions. With the proliferation of new drugs and therapies into oncology, we expect to face increasingly intense competition as new technologies become available. Any bispecific antibody candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

Many of our competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Mergers and acquisitions in the pharmaceutical, biotechnology and diagnostic industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining top qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, manufacturer's production capacity, as well as in acquiring technologies complementary to, or necessary for, our programs.

The key competitive factors affecting the success of all of our therapeutic bispecific antibody candidates, if approved, are likely to be their efficacy, safety, dosing convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, less expensive, more convenient or easier to administer, or have fewer or less severe effects than any products that we may develop. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if our bispecific antibody candidates achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then.

In addition to currently marketed therapies, there are also a number of products in late-stage clinical development to treat cancer, including other bispecific antibodies or similar molecules. Our closest competitors in this area include Affimed N.V., Zymeworks Inc., Genmab A/S, MacroGenics, Inc., Merrimack Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc. and Xencor, Inc. The bispecific antibody candidates in development by competitors may provide efficacy, safety, dosing convenience and other benefits that are not provided by currently marketed therapies. As a result, they may provide significant competition for any of our bispecific antibody candidates for which we obtain marketing approval.

### **Intellectual Property**

We strive to protect and enhance the proprietary technologies, inventions, and improvements that we believe are important to our business, including seeking, maintaining, and defending patent

rights, whether developed internally or licensed from third parties. Our policy is to seek to protect our proprietary position by, among other methods, pursuing and obtaining patent protection in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, platforms and antibody candidates that are important to the development and implementation of our business.

As of March 7, 2018:

- Our patent portfolio related to our bispecific antibody candidate MCLA-128 consists of one PCT application, filed on February 27, 2015 which entered national phases in the United States, Europe and 17 other foreign countries with an expected expiry not earlier than February 27, 2035. Claims are directed to the MCLA-128 composition of matter and methods of using MCLA-128 to treat subjects having or at risk of having an ErbB-2 and/or ErbB3 positive tumor. In addition, our portfolio includes four PCT patent application covering further methods of using MCLA-128, including in combination therapies, to treat patients, three of which were filed on April 3, 2018, and one filed on May 17, 2018.
- Our patent portfolio related to our bispecific antibody candidate MCLA-117 consists of a first PCT application, filed on September 27, 2013, which entered national phases in the United States, Europe and 14 foreign countries with an expected expiry not earlier than September 27, 2033. There is currently one pending US application, one issued EP patent and a pending EP divisional application, 14 pending foreign applications, and five issued patents in several foreign jurisdictions. In addition, we filed a second PCT application related to MCLA-117 on July 8, 2016, which has entered national phases in the United States, Europe and 13 foreign countries with an expected expiry not earlier than July, 2036. There is currently one issued U.S. patent and two pending U.S. applications, one issued and one pending EP applications, and 13 pending foreign applications. Claims are related to the MCLA-117 composition of matter and methods of using MCLA-117 in the treatment or prevention of MDS, chronic myelogenous leukemia, or CML, or AML. In addition, our portfolio includes one PCT patent application covering methods of using MCLA-117, including in combination therapies.
- Our patent portfolio related to our bispecific antibody candidate MCLA-158 consists of one PCT filed on October 21, 2016, which entered or will enter national/regional phases in the United States, Europe and 14 other foreign countries with an expiry no earlier than October 21, 2036. Claims are directed to the MCLA-158 composition of matter and methods of using MCLA-158 in the treatment or prevention of various solid tumors.
- Our patent portfolio related our bispecific antibody candidate MCLA-145 consists of one PCT filed on September 22, 2017, which entered or will enter national/regional phases in the United States, Europe and 18 other foreign countries with an expiry no earlier than September 2037. Claims are directed to the MCLA-145 composition of matter and methods of using MCLA-145 in the treatment or prevention of various solid tumors.
- Our patent portfolio related our bispecific antibody candidate MCLA-129 consists of one PCT filed on August 9, 2018, with an expiry no earlier than August 2038. Claims are directed to the MCLA-129 composition of matter and methods of using MCLA-129 in the treatment or prevention of various solid tumors.
- Our patent portfolio related to our MeMo<sup>®</sup> mouse consists of three issued U.S. patents, eight pending U.S. applications, one issued European patent that has been validated in many countries, and five pending European applications, 12 issued foreign patents and 10 pending foreign applications, all with an expected expiry not earlier than June 29, 2029. Claims are

directed to a common light chain animal and methods of producing antibodies by exposing the animal to an antigen.

- Our patent portfolio related to our Spleen to Screen™ technology consists of two issued U.S. patents, one pending U.S. application, one issued European Patent, one pending European application and two issued foreign patents, with three foreign pending applications, all with an expected expiry not earlier than September 26, 2032. For a discussion concerning opposition proceedings against this patent family see section 7 “Legal Proceedings” and Note 21 to our Consolidated Financial Statements included in section 12.1 in this report.
- Our patent portfolio related to recombinant production of mixtures of antibodies, and includes claims directed to host cells generating multi-specific antibodies consists of five issued U.S. patents, and four pending U.S. applications, two issued European patents, 15 issued foreign patents, and four pending foreign applications, all with an expected expiry not earlier than July, 2023.

We plan to continue to expand our intellectual property estate by filing patent applications directed to dosage forms, methods of treatment and additional compositions created or identified from our Biclomics® technology platform, improvements to our Biclomics® technology platform and ongoing development of our antibody candidates. Specifically, we seek patent protection in the United States and internationally for novel compositions of matter directed to aspects of the molecules, basic structures and processes for manufacturing these molecules and the use of these molecules in a variety of therapies.

Our patent portfolio is intended to cover, but is not limited to, the composition of matter of our bispecific antibody candidates, their methods of use, the Biclomics® technology platform used to generate them, related technologies and/or other aspects of the inventions that are important to our business, including our MeMo® mouse, Spleen to Screen™ technology, and recombinant host cells capable of producing our antibody candidates, methods of purification, and heterodimerization, among other proprietary technology. We also rely on trademarks, trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

We also rely on know-how, continuing technological innovation and in-licensing opportunities to develop, strengthen, and maintain our proprietary positions.

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and other proprietary rights of third parties. For important factors related to our proprietary technology, inventions, improvements, platforms and bispecific antibody candidates, please see the section entitled “Risk Factors—Risks Related to Intellectual Property and Information Technology.”

### **Government Regulation**

We are subject to extensive regulation. We expect our bispecific antibody candidates to be regulated as biologics. Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy,

labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products.

### ***U.S. Biological Products Development Process***

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

- completion of extensive nonclinical, sometimes referred to as pre-clinical laboratory tests, and pre-clinical animal trials and applicable requirements for the humane use of laboratory animals and formulation studies in accordance with applicable regulations, including good laboratory practices, or GLPs;
- submission to the FDA of an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations, commonly referred to as good clinical practice, or GCP, regulations and any additional requirements for the protection of human research subjects and their health information, to establish the safety and efficacy of the proposed biological product for its intended use;
- submission to the FDA of a BLA for marketing approval that includes substantive evidence of safety, purity, and potency from results of nonclinical testing and clinical trials;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the biological product is produced to assess compliance with current Good Manufacturing Practice, or cGMP, requirements to assure that the facilities, methods and controls are adequate to preserve the biological product's identity, strength, quality and purity;
- potential FDA audit of the nonclinical and clinical trial sites that generated the data in support of the BLA; and
- FDA review and approval, or licensure, of the BLA.

Before testing any biological bispecific antibody candidate in humans, the bispecific antibody candidate enters the pre-clinical testing stage. Pre-clinical tests, also referred to as nonclinical trials, generally include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the bispecific antibody candidate. The conduct of the pre-clinical tests must comply with federal regulations and requirements including GLPs.

The clinical trial sponsor must submit the results of the pre-clinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol, to the FDA as part of the IND. Some pre-clinical testing may continue even after the IND is submitted. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a biological bispecific antibody candidate at any time before or during clinical trials due to safety concerns or non-compliance. If the FDA imposes a clinical hold, trials may not recommence without FDA authorization and then only under terms authorized by the FDA.

Clinical trials involve the administration of the biological bispecific antibody candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not

employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety, including stopping rules that assure a clinical trial will be stopped if certain adverse events should occur. Each protocol and any amendments to the protocol must be submitted to the FDA as part of the IND. Clinical trials must be conducted and monitored in accordance with the FDA's regulations comprising the GCP requirements, including the requirement that all research subjects provide informed consent. Further, each clinical trial must be reviewed and approved by an independent institutional review board, or IRB, at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The biological bispecific antibody candidate is initially introduced into healthy human subjects and tested for safety. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The biological bispecific antibody candidate is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy, potency, and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

Post-approval clinical trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication, particularly for long-term safety follow-up.

During all phases of clinical development, regulatory agencies require extensive monitoring and auditing of all clinical activities, clinical data, and clinical trial investigators. Annual progress reports detailing the results of the clinical trials must be submitted to the FDA. Written IND safety reports must be promptly submitted to the FDA and the investigators for serious and unexpected adverse events, any findings from other trials, tests in laboratory animals or *in vitro* testing that suggest a significant risk for human subjects, or any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must submit an IND safety report within 15 calendar days after the sponsor determines that the information qualifies for reporting. The sponsor also must notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction within seven calendar days after the sponsor's initial receipt of the information. The FDA or the sponsor or its data safety monitoring board may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the



IRB's requirements or if the biological bispecific antibody candidate has been associated with unexpected serious harm to patients.

There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries. Sponsors of clinical trials of FDA-regulated products, including biologics, are required to register and disclose certain clinical trial information, which is publicly available at [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to discuss the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed until the new product or new indication being studied has been approved.

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological bispecific antibody candidate as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. To help reduce the risk of the introduction of adventitious agents with use of biological products, the PHS Act emphasizes the importance of manufacturing control for products whose attributes cannot be precisely defined. The manufacturing process must be capable of consistently producing quality batches of the bispecific antibody candidate and, among other things, the sponsor must develop methods for testing the identity, strength, quality, potency and purity of the final biological product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the biological bispecific antibody candidate does not undergo unacceptable deterioration over its shelf life.

#### ***U.S. Review and Approval Processes***

After the completion of clinical trials of a biological bispecific antibody candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological bispecific antibody candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan, or PSP, within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. Unless otherwise required by regulation, PREA does not apply to any biological product for an indication for which orphan designation has been granted.

Under the Prescription Drug User Fee Act, or PDUFA, as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may

request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological bispecific antibody candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

Notwithstanding the submission of relevant data and information, the FDA may ultimately decide that the BLA does not satisfy its regulatory criteria for approval and deny approval. Data obtained from clinical trials are not always conclusive and the FDA may interpret data differently than the applicant interprets the same data. If the FDA decides not to approve the BLA in its present form, the FDA will issue a complete response letter that usually describes all of the specific deficiencies in the BLA identified by the FDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. Additionally, the complete response letter may include recommended actions that the applicant might take to place the application in a condition for approval. If a complete response letter is issued, the applicant may either resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application.

If a product receives regulatory approval, the approval may be significantly limited to specific diseases and dosages or the indications for use may otherwise be limited, which could restrict the commercial value of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling. The FDA may impose restrictions and conditions on product distribution, prescribing, or dispensing in the form of a REMS, or otherwise limit the scope of any approval. In addition, the FDA may require post marketing clinical trials, sometimes referred to as Phase IV clinical trials, designed to further assess a biological product's safety and effectiveness, and testing and surveillance programs to monitor the safety of approved products that have been commercialized.

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or

the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

### ***Orphan Drug Designation***

The FDA may grant orphan drug designation to drugs intended to treat a rare disease or condition that affects fewer than 200,000 individuals in the United States, or if it affects more than 200,000 individuals in the United States, there is no reasonable expectation that the cost of developing and marketing the drug for this type of disease or condition will be recovered from sales in the United States. Orphan product designation must be requested before submitting a BLA. After the FDA grants orphan product designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan product designation does not convey any advantage in or shorten the duration of the regulatory review and approval process.

In the United States, orphan drug designation entitles a party to 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 with orphan exclusivity is unable to assure sufficient quantities of the approved orphan designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our bispecific antibody candidate is determined to be contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

### ***Expedited Development and Review Programs***

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new biological products that meet certain criteria. Specifically, new biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new biologic may request that the FDA designate the biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it is intended to treat a serious disease or condition and has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or

prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product subject to accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act, or FDASIA, enacted in 2012, the FDA established a Breakthrough Therapy Designation which is intended to expedite the development and review of products that treat serious or life-threatening diseases or conditions. A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the features of Fast Track designation, as well as more intensive FDA interaction and guidance. The Breakthrough Therapy Designation is a distinct status from both accelerated approval and priority review, but these can also be granted to the same bispecific antibody candidate if the relevant criteria are met. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. All requests for breakthrough therapy designation will be reviewed within 60 days of receipt, and FDA will either grant or deny the request.

Fast Track designation, priority review, accelerated approval and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process. Even if we receive one of these designations for our bispecific antibody candidates, the FDA may later decide that our bispecific antibody candidates no longer meet the conditions for qualification. In addition, these designations may not provide us with a material commercial advantage.

#### ***Post-Approval Requirements***

Maintaining substantial compliance with applicable federal, state, and local statutes and regulations requires the expenditure of substantial time and financial resources. Rigorous and extensive FDA regulation of biological products continues after approval, particularly with respect to cGMP requirements. We will rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of any products that we may commercialize. Manufacturers of our products are required to comply with applicable requirements in the cGMP regulations, including quality control and quality assurance and maintenance of records and documentation. Other post-

approval requirements applicable to biological products include record-keeping requirements, reporting of adverse effects, and reporting updated safety and efficacy information.

We also must comply with the FDA's advertising and promotion requirements, such as those related to direct-to-consumer advertising, the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"), industry-sponsored scientific and educational activities, and promotional activities involving the internet. Discovery of previously unknown problems or the failure to comply with the applicable regulatory requirements may result in restrictions on the marketing of a product or withdrawal of the product from the market as well as possible civil or criminal sanctions. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant or manufacturer to administrative or judicial civil or criminal sanctions and adverse publicity. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, mandated corrective advertising or communications with doctors, debarment, restitution, disgorgement of profits, or civil or criminal penalties.

Biological product manufacturers and other entities involved in the manufacture and distribution of approved biological products are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP requirements and other laws. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval.

#### ***U.S. Patent Term Restoration and Marketing Exclusivity***

Depending upon the timing, duration and specifics of the FDA approval of the use of our bispecific antibody candidates, some 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, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biological product is eligible for the extension and the application for the extension must be submitted prior to the expiration of the patent and within a 60-day period from the date the product is first approved for commercial marketing. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA; however, there can be no assurance that any such extension will be granted to us.

### ***Biosimilars and Exclusivity***

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approve biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical trial or studies. Interchangeability requires that a product is biosimilar to the reference product and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic. However, complexities associated with the larger, and often more complex, structures of biological products, as well as the processes by which such products are manufactured, pose significant hurdles to implementation of the abbreviated approval pathway that are still being worked out by the FDA. For example, in January 2017 the FDA issued draft guidance outlining considerations for sponsors seeking to demonstrate interchangeability with a reference biologic. However, to date the FDA has not approved a BLA for an interchangeable biological product.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing 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 BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. Certain aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation, and meaning of the BPCIA remain subject to significant uncertainty.

### ***FDA Regulation of Companion Diagnostics***

We expect that our bispecific antibody candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations for our products. These diagnostics, often referred to as companion diagnostics, are regulated as medical devices. In the United States, the FD&C Act and its implementing regulations, and other federal and state statutes and regulations govern, among other

things, medical device design and development, pre-clinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for our bispecific antibody candidates will utilize the PMA pathway.

If use of a companion diagnostic is essential to safe and effective use of a drug or biologic product, then the FDA generally will require approval or clearance of the diagnostic contemporaneously with the approval of the therapeutic product. On August 6, 2014, the FDA issued a final guidance document addressing the development and approval process for “*In Vitro* Companion Diagnostic Devices.” According to the guidance, for novel candidates such as our bispecific antibody candidates, a companion diagnostic device and its corresponding drug or biologic candidate should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling. The guidance also explains that a companion diagnostic device used to make treatment decisions in clinical trials of a drug generally will be considered an investigational device, unless it is employed for an intended use for which the device is already approved or cleared. If used to make critical treatment decisions, such as patient selection, the diagnostic device generally will be considered a significant risk device under the FDA’s Investigational Device Exemption, or IDE, regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of *in vitro* companion diagnostic devices on issues related to co-development of these products, and in December 2018, the FDA issued a draft guidance describing considerations for the development and labeling of *in vitro* companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these *in vitro* companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA’s Center for Biologics Evaluation and Research and by the FDA’s Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device’s safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive pre-clinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically

inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

If the FDA evaluations of both the PMA application and the manufacturing facilities are favorable, the FDA will either issue an approval letter or an approvable letter, which usually contains a number of conditions that must be met in order to secure the final approval of the PMA, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards is not maintained or problems are identified following initial marketing. PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the United States.

### ***Government Regulation Outside of the United States***

In addition to regulations in the United States, we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products. Because biologically sourced raw materials are subject to unique contamination risks, their use may be restricted in some countries.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application much like the IND prior to the commencement of human clinical trials. In the European Union, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed.



The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity; during this period, no marketing authorization application may be accepted and no marketing authorization may be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

The criteria for designating an "orphan medicinal product" in the European Union are similar in principle to those in the United States. Under Article 3 of Regulation (EC) 141/2000, a medicinal product may be designated as orphan if (1) it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition; (2) either (a) such condition affects no more than five in 10,000 persons in the European Union when the application is made, or (b) the product, without the benefits derived from orphan status, would not generate sufficient return in the European Union to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the European Union, or if such a method exists, the product will be of significant benefit to those affected by the condition, as defined in Regulation (EC) 847/2000. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers and are, upon grant of a marketing authorization, entitled to ten years of market exclusivity for the approved therapeutic indication. The application for orphan drug designation must be submitted before the application for marketing authorization. The applicant will receive a fee reduction for the marketing authorization application if the orphan drug designation has been granted, but not if the designation is still pending at the time the marketing authorization is submitted. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The 10-year market exclusivity may be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria for orphan designation, for example, if the product is sufficiently profitable not to justify maintenance of market exclusivity. Additionally, marketing authorization may be granted to a similar product for the same indication at any time if:

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;

- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

#### ***Other Healthcare Laws***

In addition to FDA restrictions on marketing of pharmaceutical and biological products, other U.S. federal and state healthcare regulatory laws restrict business practices in the biopharmaceutical industry, which include, but are not limited to, state and federal anti-kickback, false claims, data privacy and security, and physician payment and drug pricing transparency laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for or recommending the purchase, lease, or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases, or recommendations may be subject to scrutiny if they do not meet the requirements of a statutory or regulatory exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the statute has been violated.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA to a stricter standard such that 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. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal false claims and civil monetary penalties laws, including the civil False Claims Act, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false, fictitious or fraudulent claim for payment to, or approval by, the federal

government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. A claim includes "any request or demand" for money or property presented to the U.S. government. Actions under the civil False Claims Act may be brought by the Attorney General or as a qui tam action by a private individual in the name of the government. Violations of the civil False Claims Act can result in very significant monetary penalties and treble damages. Several pharmaceutical and other healthcare companies have been prosecuted under these laws for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of products for unapproved ( e.g. , off-label) uses. In addition, the civil monetary penalties statute imposes penalties against any person who is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Given the significant size of actual and potential settlements, it is expected that the government authorities will continue to devote substantial resources to investigating healthcare providers' and manufacturers' compliance with applicable fraud and abuse laws.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the U.S. federal Anti-Kickback Statute, the ACA broadened the reach of certain criminal healthcare fraud statutes created under HIPAA by amending the intent requirement such that 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.

In addition, there has been a recent trend of increased federal and state regulation of payments made to physicians and certain other healthcare providers. The ACA imposed, among other things, new annual reporting requirements through the Physician Payments Sunshine Act for covered manufacturers for certain payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of \$150,000 per year and up to an aggregate of \$1 million per year for "knowing failures." Covered manufacturers must submit reports by the 90th day of each subsequent calendar year. In addition, certain states require implementation of compliance programs and compliance with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and/or tracking and reporting of pricing and marketing information as well as gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities.

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, administrative, civil and criminal penalties, damages, fines, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, the curtailment or restructuring of our operations, exclusion from participation in federal and state healthcare programs, reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement, and individual imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

To the extent that any of our bispecific antibody candidates, once approved, are sold in a foreign country, we may be subject to similar foreign laws and regulations, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, and implementation of corporate compliance programs and reporting of payments or other transfers of value to healthcare professionals.

#### ***Privacy and Data Protection Laws in Europe***

We are subject to European laws relating to our and our suppliers', collaborators' and subcontractors' (where they act as processors) collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, and where we process personal data in the context of the activities of that establishment (e.g., undertaking clinical trials). We and our suppliers, collaborators and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation, or GDPR, and national laws and regulations implementing or supplementing it.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner compatible with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the European Economic Area, or EEA unless certain steps are

taken to ensure an adequate level of protection, and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure, and to be able to demonstrate, protection. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, requires the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with certain service providers.

In addition, to the extent a company processes, controls or otherwise uses “special category” personal data (including patients’ health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. The GDPR provides a broad right for EU member states to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition.

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. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU model clauses. In addition, the U.S. Privacy Shield is under review by the European Commission. As such, it is uncertain whether the Privacy Shield framework and/or model clauses will be invalidated in the near 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, including finding alternative bases for the compliant transfer of personal data from the EEA to the United States, and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

There are costs and administrative burdens associated with compliance with the GDPR and the resultant changes in the EU and EEA member states’ national laws. Any failure or perceived failure to comply with global privacy laws carries with it the risk of significant penalties and sanctions of up to €20 million or 4% of global turnover. These laws or new interpretations, enactments or supplementary forms of these laws, could create liability for us, could impose additional operational requirements on our business, could affect the manner in which we use and transmit patient information and could increase our cost of doing business. Claims of violations of privacy rights or contractual breaches, 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.

### **Coverage and Reimbursement**

Significant uncertainty exists as to the coverage and reimbursement status of any pharmaceutical or biological products for which we obtain regulatory approval. In the United States and markets in other countries, patients who are prescribed treatments for their conditions and

providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of any products for which we receive regulatory approval for commercial sale will therefore depend, in part, on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care plans, private health insurers and other organizations.

In the United States, the process for determining whether a third-party payor will provide coverage for a pharmaceutical or biological product typically is separate from the process for setting the price of such product or for establishing the reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the FDA-approved products for a particular indication. A decision by a third-party payor not to cover our bispecific antibody candidates could reduce physician utilization of our products once approved and have a material adverse effect on our sales, results of operations and financial condition. Moreover, a third-party payor's decision to provide coverage for a pharmaceutical or biological product does not imply that an adequate reimbursement rate will be approved. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. Additionally, coverage and reimbursement for new products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will be a time-consuming process.

In the European Union, governments influence the price of products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product candidate to currently available therapies. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on health care costs in general, particularly prescription products, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. In addition, in some countries, cross border imports from low-priced markets exert a commercial pressure on pricing within a country.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of pharmaceutical or biological products have been a focus in this effort. Third-party payors are increasingly challenging the prices charged for medical products and services, examining the medical necessity and reviewing the cost-effectiveness of pharmaceutical or biological products, medical devices and medical services, in addition to questioning safety and efficacy. If these third-party payors do not consider our products to be cost-effective compared to other available therapies, they may not cover our products after FDA approval or, if they do, the level of payment may not be sufficient to allow us to sell our products at a profit.

### **Healthcare Reform**

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced 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; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; and created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. There have also been judicial challenges to certain aspects of the ACA. For example, 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 inseparable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the Trump Administration and the Centers for Medicare & Medicaid Services, or CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision, subsequent appeals, if any, will impact the law. The ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

We expect that other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and lower reimbursement, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent 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 pharmaceutical and biological products. 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Additionally, on August 2, 2011, the Budget Control Act of 2011 was enacted, which, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several 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.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products once approved or additional pricing pressures.

### **3.3 Organizational Structure**

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

### **3.4 Property, Plant and Equipment**

We lease approximately 12,320 square meters of office and laboratory space in Utrecht, the Netherlands. This facility serves as our corporate headquarters and central laboratory facility. The leases for this space expire on October 31, 2021. We have also entered into a lease for 7,583 square feet of additional office space in Cambridge, Massachusetts, which we have occupied since May 6, 2019 and has a term of seven years.

#### **Environmental Issues**

For information on environmental issues that may affect our utilization of our Dutch facility, please see the section 2.3.2 of this report titled “Risk Factors—Risks Related to the Development and Clinical Testing of Our Bispecific Antibody Candidates— *“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 .”*

## **4 OPERATING AND FINANCIAL REVIEW AND PROSPECTS**

### **4.1 Operating Results**

#### **Overview**

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. Our pipeline of full-length human bispecific antibody candidates, which we refer to as Biclomics<sup>®</sup>, are generated from our Biclomics<sup>®</sup> technology platform, which is able to generate a diverse array of antibody-heavy chains against virtually any target, paired with a common light chain. Two heavy chains paired with a common light chain can be combined to produce novel bispecific antibodies that bind a diverse array of targets and display differentiated biology. By binding to two different targets, Biclomics<sup>®</sup> can provide a variety of mechanisms of action. For example, Merus Biclomics<sup>®</sup> can be designed to simultaneously block receptors that drive tumor cell growth and survival and to mobilize the patient’s immune response by engaging T-cells and/or activating various killer cells to eradicate tumors. In our pre-clinical studies, our bispecific antibody candidates killed tumor cells, a result that we believe supports their potential development for the treatment of cancer.



In February 2015, we commenced a Phase 1/2 clinical trial of our most advanced bispecific antibody candidate, MCLA-128, for the treatment of HER2-expressing solid tumors. In January 2018, we dosed the first patient in a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in two metastatic breast cancer, or MBC, populations including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients. MCLA-128 is a full-length IgG bispecific antibody candidate with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 is designed to block the HER3 signaling pathway by employing a DOCK & BLOCK<sup>®</sup> mechanism. MCLA-128 is designed to “dock” onto a specific region of the HER2 receptor to orientate MCLA-128’s HER3 binding arm to “block” HER2:HER3 heterodimerization. Oncogenic signaling through the HER3 pathway, even in the presence of high heregulin concentrations, may thus be blocked. The Phase 2 clinical trial is designed to observe the activity of this HER2/HER3-targeted candidate in combination with current standards of care in areas of unmet need. The trial is ongoing and is enrolling patients at sites in the United States and Europe. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and non-small cell lung cancer, or NSCLC, is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress in October 2018. As of February 15, 2018, the data showed a clinical benefit rate of 24% (6 of 25 patients), and that MCLA-128 was well tolerated with mainly grade 1/2 adverse events observed in patients treated with MCLA-128 across all indications explored. Single agent antitumor activity was seen in heavily pretreated gastric/gastro-oesophageal junction, or GC/GEJ, cancer patients progressing on anti-HER2 therapy.

In May 2016, we commenced a Phase 1, single-arm, open-label, global clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML, and we announced the filing of the Investigational New Drug application, or IND, in the United States, or the U.S., for MCLA-117 in 2018 and the subsequent authorization to proceed with clinical studies by the Food and Drug Administration, or the FDA. AML generally has a poor prognosis and limited progress has been made in disease outcomes despite a growing AML patient population. Clinical and pre-clinical studies suggest that treatment-resistant leukemic stem cells are a potential cause of disease relapse. MCLA-117 designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of AML tumor cells and stem cells in newly diagnosed and relapsed patients. MCLA-117 is designed to recruit and activate T-cells to kill AML tumor cells and stem cells. In our pre-clinical studies, MCLA-117 killed tumor cells in blood samples of AML patients. We plan to seek orphan drug designation for MCLA-117 for the treatment of AML from the FDA and the European Medicines Agency, or the EMA. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. We also intend to evaluate MCLA-117 for the treatment of myelodysplastic syndrome.

In addition to MCLA-128 and MCLA-117, we are also developing MCLA-158, a bispecific antibody candidate that is designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5, or Lgr5, and epidermal growth factor receptors, or EGFR, for the potential treatment of solid tumors with an initial focus on metastatic colorectal cancer, and the first Clinical Trials Application to the EMA was approved to initiate a Phase 1 clinical trial in Europe in January 2018. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018,

which received authorization to proceed from the FDA in April 2018. In May 2018, we commenced a Phase 1, open-label, multicenter clinical trial of MCLA-158 and expect emerging data by the end of 2019. MCLA-158 is designed to kill cancer stem cells using two different mechanisms of action. The first mechanism of action involves blocking growth and survival pathways in tumor stem cells. The second mechanism of action involves the recruitment and enhancement of immune effector cells.

We also commenced a clinical trial for MCLA-145, which is being developed in collaboration with Incyte Corporation, or Incyte, and is designed to bind to PD-L1 and CD137. In December 2018, we filed an IND for MCLA-145 with the FDA and in January 2019, we received authorization to proceed from the FDA.

We also have several other antibody candidates in preclinical development that bind to other target combinations. Each of our antibody candidates in our preclinical and clinical pipeline are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA.

Since our inception in June 2003, our initial operations were focused on organizing and staffing our company, business planning, raising capital, and establishing our proprietary Bionics<sup>®</sup> platform technology, bispecific antibody candidates, and our intellectual property portfolio. In more recent periods, we have devoted a significant portion of our financial resources and efforts to continued development of our Bionics<sup>®</sup> technology platform, identifying potential bispecific antibody candidates and conducting pre-clinical studies and initiating and conducting our clinical trials of MCLA-128, MCLA-117, MCLA-158, and MCLA-145. We do not currently have any approved products and have never generated any revenue from product sales.

We have financed our operations primarily through (i) the initial public offering of our common shares, (ii) a public placement of equity securities with Incyte (iii) upfront and milestone payments received from Incyte, ONO Pharmaceutical Co., Ltd., or Ono, and Simcere Pharmaceutical Group, or Simcere, (iv) a private placement of common shares on February 15, 2018, and (v) a public placement of equity securities with Regeneron Pharmaceuticals Inc. or Regeneron.

On May 6, 2016, the general meeting of our shareholders resolved to approve and effect a capital reorganization, based on a reverse share split. The effect of the reverse share split was a 1-for-1.8 reverse share split of the outstanding common and preferred shares held by our shareholders. This reverse share split became effective on May 6, 2016. All share, per-share and related information presented in the financial statements and corresponding disclosure notes have been retrospectively adjusted, where applicable, to reflect the impact of the reverse share split.

In May 2016, we completed the initial public offering of our common shares, or the IPO, and issued 6,139,926 common shares, including 639,926 common shares issued upon the partial exercise of the underwriters of their option to purchase additional shares, for net proceeds to us, after deducting underwriting discounts and commissions and offering expenses, of \$53.3 million.

In February 2018, we issued and sold an aggregate of 3,099,997 of our common shares to certain new and existing investors for aggregate gross proceeds of approximately \$55.8 million, or €44.8 million, at a purchase price of \$18.0 per share.

In December 2016, we entered into a collaboration and license agreement with Incyte, or the Incyte collaboration and license agreement. Under the terms of the Incyte collaboration and license

agreement, we and Incyte agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing our proprietary bispecific technology platform. The collaboration encompasses up to 11 independent programs, including two of our current preclinical immuno-oncology discovery programs. In January 2017, upon the Incyte collaboration and license agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120.0 million, or €112.0 million. For more on the Incyte collaboration and license agreement, see “Collaboration Agreements” below. In connection with the Incyte collaboration and license agreement, we entered into a Share Subscription Agreement, pursuant to which, in January 2017, we issued and sold to Incyte 3,200,000 common shares for an aggregate purchase price of \$80.0 million, or €74.7 million.

In December 2018, we issued and sold an aggregate of 600,000 shares to Regeneron Pharmaceuticals, Inc., or Regeneron, in connection with our settlement of certain litigation and administrative opposition proceedings with Regeneron for aggregate gross proceeds of \$15.0 million, or €13.1 million. Accordingly, we 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, or €13.1 million, and the aggregate value of common shares issued of \$6.9 million, or €6.0 million, was recorded as a gain on litigation settlement of \$8.1 million, or €7.1 million, during the year-ended December 31, 2018.

As of December 31, 2018, we held cash and cash equivalents of €143.7 million and investments of €61.8 million.

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

We anticipate that we will require additional financing to support our continuing operations. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity or debt financings or other sources, which may include collaborations and business development opportunities with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2018 will be sufficient to fund our operations into the second quarter of 2021. For this assessment we have taken into consideration our existing cash and cash equivalents of €143.7 million and investments of €61.8 million as of December 31, 2018. See section 4.2 in this report.

#### **Collaboration and Other Revenue Generating Agreements**

As part of our business strategy, we intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Bionics<sup>®</sup> technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We believe that these collaborations could potentially provide significant funding to advance our antibody candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

### ***Incyte Corporation***

We have entered into the Incyte collaboration and license agreement with Incyte. Under the terms of the Incyte collaboration and license agreement, we and Incyte have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing our proprietary bispecific technology platform. The collaboration encompasses up to 11 independent programs, including some of our current preclinical immuno-oncology discovery programs. For one of the current clinical programs concerning MCLA-145, we retain the exclusive right to develop and commercialize products and product candidates in the U.S., while Incyte has the exclusive right to develop and commercialize products and product candidates arising from such program outside the U.S. For MCLA-145, we and Incyte will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in our respective territories. We have the option to co-fund development of products arising from one specified program, and subject to certain conditions, to a second specified program, in each case exchange for a share of profits in the U.S., as well as the right to participate in a specified proportion of detailing activities in the U.S. for one of such programs. If we exercise our co-funding option for a program, we would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing Incyte for certain development costs incurred prior to the option exercise. All products as to which we have exercised our option to co-fund development would be subject to joint development plans and overseen by a joint development committee, with Incyte having final determination as to such plans in cases of dispute.

For each program other than MCLA-145, where we have not elected to co-fund development or where we do not have such a co-funding option, Incyte is solely responsible for all costs of global development and commercialization activities. We retain the rights to our technology platform as well as clinical and pre-clinical candidates and future programs emerging from our platform that are outside the scope of the Incyte collaboration and license agreement.

In January 2017, upon the Collaboration Agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120.0 million, or €112.0 million, for the rights granted under the Collaboration Agreement. For each program as to which we do not have commercialization or co-development rights, we are eligible to receive up to \$100.0 million in future contingent development and regulatory milestones and up to \$250.0 million in commercialization milestones, as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which we have exercised our option to co-fund development, we are eligible to receive a 50% share of profits (or sustain 50% of any losses) in the U.S. and tiered royalties ranging from 6% to 10% of net sales of products outside of the U.S. If we opt to cease co-funding a program as to which we exercised our co-development option, then we will no longer receive a share of profits in the U.S. but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which we choose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the

U.S.. For MCLA-145, for which we retain all commercial rights in the U.S., we and Incyte are each eligible to receive tiered royalties on net sales in the other's territory at rates ranging from 6% to 10%.

The Incyte collaboration and license agreement will continue on a program-by-program basis until neither party has any royalty payment obligations with respect to such program or, if earlier, the termination of the Incyte collaboration and license agreement or any program in accordance with the terms of the Incyte collaboration and license agreement. The Incyte collaboration and license agreement may be terminated in its entirety, or on a program-by-program basis, by Incyte for convenience. The Incyte collaboration and license agreement may also be terminated by either party under certain other circumstances, including material breach, or on a program-by-program basis for patent challenge of patents under the applicable program, in each case as set forth in the Incyte collaboration and license agreement. If the Incyte collaboration and license agreement is terminated in its entirety or 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, if we elect to pursue development and commercialization of products arising from the terminated programs.

In connection with the Incyte collaboration and license agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which, in January 2017, we issued and sold to Incyte 3,200,000 common shares for an aggregate purchase price of \$80.0 million, or €74.7 million.

In accordance with International Financial Reporting Standards, or IFRS, 15, Revenue from Contracts with Customers, or IFRS 15, and the prior revenue guidance, we combined the Incyte collaboration and license agreement and Share Subscription Agreement and accounted for them as a single contract based on the following criteria: (i) they were entered into at the same time with the same customer; (ii) the arrangements' mutual existence is acknowledged in the separate agreements; and (iii) they were negotiated as a package with a single commercial objective. As a result, our fixed consideration pursuant to the arrangement with Incyte is \$152.6 million, consisting of the \$120.0 million, or €112.0 million, non-refundable upfront fee from the Incyte collaboration and license agreement and \$32.6 million, or €31.4 million, in consideration from the issuance and sale of common shares pursuant to the Share Subscription Agreement.

#### ***ONO Pharmaceutical***

In April 2014, we entered into a strategic research and license agreement with ONO, under which we granted ONO an exclusive, worldwide, royalty-bearing license to research, test, make, use and market bispecific antibody candidates based on our Biclomics® technology platform with undisclosed targets.

ONO paid us a non-refundable upfront fee of €1.0 million. We are eligible to receive up to an aggregate of €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved four of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €2.7 million in milestone payments. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we and our affiliates are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combinations that are the subject of this agreement. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless

terminated earlier. ONO also provides funding for our research and development activities under an agreed-upon plan. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

In March 2016, we entered into a separate agreement to provide chemistry, manufacturing and controls, or CMC, services to ONO. In consideration of the performance of the CMC services, ONO agreed to pay fees of €1.4 million for full-time equivalent reimbursement and an aggregate of €3.0 million of milestone payments for the delivery of a master cell bank, delivery of toxicology drug product, and delivery of GMP drug product. During 2018, we achieved all three of the milestones and received an aggregate of €3.0 million in milestone payments.

On March 14, 2018, we entered into a second contract research and license agreement with ONO. Pursuant to an exclusive option granted to ONO in a prior agreement executed in April 2014, ONO exercised its option to enter into the March 2018 agreement. We granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on our Biclomics<sup>®</sup> technology platform against two undisclosed targets directed to a particular undisclosed target combination. ONO identifies and selects the licensed bispecific antibodies for which it is responsible for conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. 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 agreed to fund our 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. We retain 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 has agreed to pay an upfront non-refundable payment of €700,000 for the rights granted and we are also eligible to receive an aggregate of €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under the License Agreement, if any, the Company is eligible to receive a mid-single digit royalty on net sales.

For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combination that are the subject of this agreement. ONO also provides funding for our research and development activities under an agreed-upon plan. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

***Sincere Pharmaceutical Group***

On January 8, 2018, we entered into an agreement with Simcere granting Simcere an exclusive license to develop and commercialize in China three bispecific antibodies to be produced by us utilizing our proprietary Bionics<sup>®</sup> technology platform in the area of immuno-oncology. We will retain all rights outside of China. Under the terms of the agreement, we have agreed to lead research and discovery activities, while Simcere has agreed to be responsible for the IND-enabling studies, clinical development, regulatory filings and commercialization of these product candidates in China. As a key strategic component of the collaboration, Simcere will be responsible for IND-enabling studies and manufacturing of clinical trial materials in China, which we intend to use to assist regulatory filing and early stage clinical development in the rest of the world.

We received an upfront, non-refundable payment of \$2.75 million, or €2.3 million, relating to three separate research programs. We are eligible to receive up to an aggregate of \$52.2 million, or €45.6 million, in milestone payments contingent upon Simcere achieving certain specified development and commercial goals. To date, we have achieved one milestone under this agreement and have received an aggregate of \$0.8 million, or €0.6 million, in milestone payments. We will be eligible to receive tiered royalty payments on sales of any products resulting from the collaboration in China from Simcere. Simcere will be eligible to receive tiered royalty payments on sales outside of China from us.

#### ***Betta Pharmaceuticals Co. Ltd.***

On December 10, 2018, we entered into a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd., or Betta, where we granted Betta an exclusive license to develop and commercialize in China MCLA-129, a proprietary Bionics<sup>®</sup> produced by our Bionics<sup>®</sup> technology platform. We retain all rights outside of China. Under the terms of the agreement, 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 we intend 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, or €0.9 million, we and Betta will share equally the cost of the transfer of the manufacturing technology to a contract manufacturing organization. We are also eligible to receive an aggregate of \$12.0 million, or €10.5 million in milestone payments contingent upon Betta achieving certain specified development and commercial goals. We are also eligible to receive from Betta tiered royalty payments of net sales of any products resulting from the collaboration in China. Betta is eligible to receive from us an aggregate of \$12.0 million, or €10.5 million, in milestone payments contingent upon us achieving certain specified development and commercial goals, and is eligible to receive tiered royalty payments of net sales outside of China.

### **Financial Operations Overview**

#### ***Revenue***

To date, our revenue has consisted principally of the amortization of up-front payments and milestones as well as cost reimbursements in support of our license and collaboration agreements and revenue from several government grants, primarily with respect to research and development activities

related to the use of our Bionics<sup>®</sup> technology in various indication areas. We have no products approved for sale. We do not expect to receive any revenue from any bispecific antibody candidates that we develop, including MCLA-128, MCLA-117, MCLA-158 and MCLA-145, and our preclinical bispecific antibody candidates until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates. Our ability to generate revenue for each product candidate for which we receive regulatory approval will depend on numerous factors, including competition, commercial manufacturing capability and market acceptance of our products.

We have derived the majority of our revenue to date from research, collaboration and license agreements with Incyte, ONO, Simcere and Betta. These agreements contain multiple promised goods and services, including license rights to certain of our product candidates and research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products, if any.

Effective January 1, 2018, we adopted IFRS 15 using the retrospective method, with the effect of initially applying this standard recognized at the beginning of the earliest period presented.

We had two open contracts on the adoption date and have assessed these contracts under the new revenue standard. In addition, we elected to apply the practical expedient to not apply this guidance to contracts that were completed before the beginning of the earliest period presented, or January 1, 2016, and the practical expedients for contract modifications (assessing the contracts in combination with any modifications before January 1, 2016).

The adoption of IFRS 15 impacted the amortization of our upfront license payments under the collaboration and license agreement entered into with Incyte on December 20, 2016 and under the research and license agreement entered into with ONO on April 8, 2014. We previously recognized revenue from upfront license payments on a straight-line basis over the contractual term or the period of continuing managerial involvement, which was previously estimated to be 21 years for the Incyte collaboration and license agreement and 4.5 years for the ONO research and license agreement. Upon adoption of IFRS 15, we assessed the goods and services promised under the Incyte collaboration and license agreement and identified only one performance obligation to which the transaction price was allocated – a license to our proprietary technology combined with the joint steering committee, or JSC, services during the research term. The transfer of the license and the JSC participation represented one combined performance obligation since they were not deemed distinct. As a result, under IFRS 15, revenue from upfront license payments under the Incyte collaboration and license agreement will be recognized as we satisfy the combined performance obligation, or over the nine-year research term, which is a period during which we have a present enforceable obligation to provide JSC services.

As a result of the adoption of IFRS 15, our prior years' consolidated financial statements have been restated. We adopted the new standard using the retrospective method. The impact of adopting IFRS 15 resulted in a decrease of approximately €8.7 million to deferred revenue with an offset to accumulated deficit, effective January 1, 2018.

Under IFRS 15, revenue from contracts with customers, including contracts from Incyte, Simcere, Ono and Betta, is recognized when our customer obtains control of the promised goods or



services, in an amount that reflects the consideration that we had determined to expect to receive in exchange for those goods or services.

#### *Up-front License Payments*

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Revenue attributable to the amortization of upfront license payments relates to the contracts with Incyte, Ono, Simcere and Betta.

#### *Milestones*

At the inception of each arrangement that includes pre-commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate 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 our 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 we recognize revenue as or when the performance obligations under the contract are satisfied. Any such adjustments affect revenue in the period of adjustment. At the end of each subsequent reporting period, we reevaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust our estimate of the overall transaction price. Revenue attributable to milestones or the amortization of milestones relates to the contracts with Ono and Simcere.

#### *Research and Development Cost Reimbursement*

Research and development cost reimbursement revenue, which is typically related to reimbursements from collaborators for our performance of research and development services under the respective agreements, is recognized on the basis of labor hours valued at a contractually agreed rate. Research and development cost reimbursement revenue also includes reimbursements for related out-of-pocket expenses and third-party costs. Research and development cost reimbursement revenue is recognized in the same period as the costs for which they are intended to compensate. We typically act as the principal under such arrangements and, therefore, record these reimbursements on a gross basis. Revenue attributable to research and development cost reimbursement relates to the contracts with Incyte and Ono.

#### *Government Grants*

We also receive certain government and regional grants, which support our research efforts in defined projects, and include contributions towards the research and development 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 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.

### ***Research and Development Costs***

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 contract research organizations, or 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;
- costs associated with obtaining and maintaining patents and other intellectual property; and
- amortization and depreciation of tangible and intangible fixed assets used to develop our product candidates.

We expense research and development costs when we incur them. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. We expense the manufacturing costs of our internally-developed product candidates that are used in clinical trials as they are incurred, as research and development expense. 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 expenses are expected to increase as we advance the clinical development of MCLA-128, MCLA-117 and MCLA-158 and, in collaboration with Incyte, MCLA-145, and further advance the research and development of our preclinical bispecific antibody candidates and other earlier stage products. The successful development of our bispecific antibody candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our bispecific antibody candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

- the scope, rate of progress and expense of our research and development activities;
- clinical trials and early-stage results;
- the terms and timing of regulatory approvals;
- the expense of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; and
- the ability to market, commercialize and achieve market acceptance for MCLA-128, MCLA-117, MCLA-158 and MCLA-145 or any other bispecific antibody candidate that we may develop in the future.

A change in the outcome of any of these variables with respect to the development of any of our antibody candidates would significantly change the costs, timing and viability associated with the development of that antibody candidate. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct preclinical and clinical studies beyond those which we currently anticipate will be required for the completion of clinical development or if we experience significant delays in enrollment in any clinical trials, we could be required to expend significant additional financial resources and time on the completion of our clinical development programs.

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 bispecific 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.

#### ***Management and Administration Costs***

Our management and administration costs consist principally of salaries and related expenses for employees other than research and development staff, including employees in finance, legal, human resources, investor relations and business development functions. These costs include all salary, salary-related expenses and share-based compensation expenses. We expect that our management and administration costs will increase in the future as our business expands and we increase our headcount to support the expected growth in our operating activities and public company requirements.

#### ***Other Expenses***

Other expenses consist principally of:

- professional fees for auditing and tax services and consulting expenses not related to research and development activities;
- professional fees for legal services, including litigation costs, not related to the protection and maintenance of our intellectual property;
- cost of facilities, communication and office expenses;
- board of director fees and corresponding share-based compensation expenses;
- information technology services and cybersecurity enhancements, investigations or remediations; and
- amortization and depreciation of tangible and intangible fixed assets not related to research and development activities.

We expect our other expenses will increase in the future as we expand our operating activities and we continue to incur additional costs associated with operating as a public company. We expect other expenses to increase in future periods to support our research and development efforts, including the continuation of the clinical trials of our bispecific antibody candidates as treatments for various cancers and the initiation of clinical trials for potential new antibody candidates. These cost increases will likely be due to increased headcount, expanded infrastructure and increased costs for insurance.

Public company-related expense increases will include costs of additional legal fees, accounting, tax and audit fees, consulting fees, director and officer liability insurance premiums and costs related to investor relations.

### *Other Income (Expense)*

Other income consists of a gain recorded in connection with our settlement of certain litigation with Regeneron. On December 20, 2018, we signed a global settlement and cross-license agreement with Regeneron, where the parties have agreed to end all pending litigation and administrative, opposition proceedings pertaining to our and Regeneron's respective antibody generation technologies. Regeneron also purchased 600,000 of our common shares at a price of \$25.0 per share for total aggregate proceeds of \$15.0 million, or €13.1 million. Accordingly, we 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, or €13.1 million, and the aggregate value of common shares issued of \$6.9 million, or €6.0 million, was recorded as a gain on litigation settlement of \$8.1 million, or €7.1 million, during the year-ended December 31, 2018.

Finance income consists of interest earned on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains on our U.S. dollar denominated cash, cash equivalents and investments.

Finance expenses consist of net foreign exchange losses on our U.S. dollar denominated cash, cash equivalents and investments, interest and related expenses for the settlement of our forward contract for the Share Subscription Agreement with Incyte and interest accrued on our formerly outstanding indebtedness and financing costs associated with our registration statements.

## **Results of Operations**

### *Comparison of Years Ended December 31, 2018 and 2017*

The below table summarizes our results of operations for the years ended December 31, 2018 and 2017.

	Year Ended December 31,		Change	
	2018	2017 Restated*	Amount	%
	<b>(euros in thousands)</b>			
Revenue .....	€ 31,448	€ 21,915	€ 9,533	43%
Research and development costs.....	(46,740)	(34,125)	12,615	37%
Management and administration costs	(10,395)	(13,697)	(3,302)	-24%
Other expenses.....	(13,160)	(9,395)	3,765	40%
Operating result.....	(38,847)	(35,302)	3,545	10%
Other income (expenses).....	14,934	(29,223)	(44,157)	-151%
Income tax expense.....	(356)	(249)	107	43%
Result after taxation .....	(24,269)	(64,774)	(40,505)	-63%
Other comprehensive income.....	34	89	(55)	-62%
Total comprehensive loss for the year .....	€ (24,235)	€ (64,685)	(€ 40,450)	-63%

\* See Note 4 to our consolidated financial statements included in section 12.1 of this report for details regarding the restatement as a result of a change in accounting policy.

### **Revenue**

Total revenue increased by €9.5 million to €31.4 million for the year ended December 31, 2018, from €21.9 million for the year ended December 31, 2017. The increase in total revenue is primarily attributable to the amortization of upfront license payments and milestone payments and an increase in R&D cost reimbursement revenue.

Our revenues are generated entirely in the Netherlands. In the following table, revenue is disaggregated by primary source of revenue as follows:

	Year Ended December 31,		Change	
	2018	2017 Restated	Amount	%
	(euros in thousands)			
Upfront payment amortization .....	€ 17,686	€ 14,933	€ 2,753	18%
R&D cost reimbursement and milestone .....	13,566	5,787	7,779	134%
Revenue from contracts with customers .....	31,252	20,720	10,532	51%
Income from grants on research projects .....	196	1,195	(999)	-84%
	€ 31,448	€ 21,915	€ 9,533	44%

\* See Note 4 to our consolidated financial statements included in section 12.1 of this report for details regarding the restatement as a result of a change in accounting policy.

Upfront payment amortization increased by €2.8 million to €17.7 million for the year ended December 31, 2018, from €14.9 million for the year ended December 31, 2017. For the year ended December 31, 2018, we recognized amortization of €15.9 million on upfront payments related to the Incyte collaboration and license agreement, amortization of €1.2 million on upfront payments related to the second ONO research and license agreement, €0.5 million on upfront payments related to the Simcere collaboration and license agreement and less than €0.1 million on the upfront payment related to the Betta collaboration and license agreement. For the year ended December 31, 2017, we recognized €14.9 million of amortization of the upfront payment related to the Incyte collaboration and license agreement.

R&D cost reimbursement and milestone revenue for the year ended December 31, 2018, was €13.6 million and consisted of cost reimbursements, milestone payment amortization and research milestones achieved in support of our research and license agreements with Incyte, ONO and Simcere. During the year ended December, 2018, we recognized €8.8 million of cost reimbursements in support of our research and license agreements with Incyte and €0.4 million of cost reimbursements in support of our research and license agreements with ONO. We recognized an aggregate of €4.0 million in research milestones under our ONO agreements for the year ended December 31, 2018 and €0.4 million in research milestone payment amortization under our Simcere agreements for the year ended December 31, 2018.

R&D cost reimbursement and milestone revenue for the year ended December 31, 2017 was €5.8 million and consisted of cost reimbursements in support of our research and license agreements with Incyte and ONO. We did not recognize any research milestones during 2017.

During 2018, we recognized €0.2 million in grant income compared to €1.2 million in grant income for the year ended December 31, 2017. On June 12, 2017, the European Commission approved for reimbursement the final installment of the FP-7 grant for €0.7 million. Revenue for this final installment was recorded in income from grants on research projects during the year ended December 31, 2017.

### **Research and Development Costs**

	Year Ended December 31,		Change	
	2018	2017	Amount	%
Research and development costs.....	€ 46,740	€ 34,125	€ 12,615	37%

Research and development costs increased €12.6 million, or 37%, to €46.7 million for the year ended December 31, 2018, from €34.1 million for the year ended December 31, 2017. The increase was primarily due to the following:

- €10.1 million increase in spending for our MCLA-128 program in support of our ongoing clinical trials as well as higher costs in our preclinical and discovery programs associated with development, manufacturing and production design activities;
- €4.1 million increase in for our MCLA-145 program associated with manufacturing and production activities to support the initiation of our Phase I clinical trial;
- €4.4 million decrease in expenses associated with manufacturing activities for MCLA-158 and MCLA-117, partially offset by an increase in ongoing clinical costs;
- Increase of €1.1 million for conducting research and development, preclinical, manufacturing and production design in connection with various preclinical and discovery programs;
- €1.6 million increase in employee salary and related benefits attributable to the hiring of more development personnel and an increase of €0.7 million of subsidies under the Wet Bevordering Speur- & Ontwikkelingswerk Act, or WBSO Act, partially offset by a €0.5 million decrease in share-based compensation expenses; and
- €1.3 million increase in costs related to other research and development expenses not allocated to projects, including depreciation of lab equipment and increased lab supplies.

€1.3 million increase in costs related to other research and development expenses not allocated to projects, including depreciation of lab equipment and increased lab supplies.

### **Management and Administration Costs**

	Year Ended December 31,		Change	
	2018	2017	Amount	%
Management and administration costs .....	€ 10,395	€ 13,697	€ (3,302)	-24%

Management and administration costs decreased €3.3 million, or 24%, during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The decrease was primarily attributable to lower share-based compensation expenses of €4.2 million, partially offset by an increase in headcount in finance, legal and business development functions to support the expansion of our operations, which resulted in an increase in salary and related expenses of €0.9 million.

### **Other Expenses**

	Year Ended December 31,		Change	
	2018	2017	Amount	%
Other expenses.....	€ 13,160	€ 9,395	€ 3,765	40%

Other expenses increased €3.8 million, or 40%, during the year ended December 31, 2018 as compared to the year ended December 31, 2017. The increase was due to an increase in consulting, accounting and professional fees of €2.3 million in support of maintaining a public company status, an increase in facilities expenses of €1.3 million in support of higher headcount, an increase in legal expenses of €0.4 million related to the litigation and opposition costs related to certain litigation with Regeneron, which was settled in December 2018, partially offset by a decrease in travel expenses of €0.2 million.

***Other Income (Expense)***

	Year Ended December 31,		Change	
	2018	2017	Amount	%
	(euros in thousands)			
Finance income				
Interest income and similar related income.....	€ 1,809	€ 1,112	€ 697	63%
Net gain on foreign exchange .....	6,034	—	6,034	100%
	7,843	1,112	6,731	605%
Other income.....	7,095	—	7,095	100%
Finance costs				
Interest and other expenses .....	(4)	(190)	(186)	-98%
Net loss on foreign exchange .....	—	(19,449)	(19,449)	-100%
Derivative financial instrument expense .....	—	(10,696)	(10,696)	-100%
	(4)	(30,335)	(30,331)	-100%
Total other income (expense).....	€ 14,934	€ (29,223)	€ (44,157)	-151%

Finance income increased €6.7 million, or 605%, during the year ended December 31, 2018 as compared to the year ended December 31, 2017. This increase was due to foreign exchange gains on our U.S. dollar denominated cash, cash equivalents and investments of approximately €6.0 million due to a weakening U.S. dollar relative to the euro during 2018. As of December 31, 2018, we held approximately \$49.3 million and \$70.8 million in U.S. dollar denominated cash and cash equivalent accounts and investment accounts, respectively, subject to the fluctuation in foreign currency between the euro and U.S. dollar. Interest income primarily results from interest earned on cash held on account and accretion of investment earnings. Our current year increase in cash, cash equivalents and investments was due primarily to \$55.8 million of funds received as part of the private placement of common shares during the first quarter of 2018 as well as \$15.0 million of funds received as part of the Regeneron Share Subscription Agreement during the fourth quarter of 2018.

Other income for the year ended December 31, 2018 included a gain of €7.1 million related to our settlement of certain litigation with Regeneron. On December 20, 2018, we 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 our and Regeneron's respective antibody generation technologies. Regeneron also purchased 600,000 of our common shares at a price of \$25.0 per share. Accordingly, we 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, or €13.1 million, and the aggregate value of common shares issued of \$6.9 million, or €6.0 million, was recorded as a gain on litigation settlement of \$8.1 million, or €7.1 million, during the year-ended December 31, 2018.

Finance costs for the year ended December 31, 2017 included an amount of €10.7 million related to the effective settlement, on January 23, 2017, of the forward contract related to the Share Subscription Agreement with Incyte. During the year ended December 31, 2017, we also expensed €0.2 million of prepaid share issuance costs related to a potential future issuance of shares under the Company's F-3 Registration Statement when the future issuance was no longer considered probable.

We experienced increased losses on our U.S. dollar denominated cash, cash equivalents and investments of approximately €19.1 million during 2017. As of December 31, 2017, we held approximately \$98.0 million and \$49.4 million in U.S. dollar denominated cash and cash equivalent accounts and investment accounts, respectively, subject to the fluctuation in foreign currency between the euro and U.S. dollar.

### ***Income Tax Expense***

Income tax expenses were €0.4 million and €0.2 million for the years ended December 31, 2018 and 2017, respectively. Current-year income tax expense was attributable to our U.S. operating subsidiary, which was established in February 2016 to provide general management services and strategic advisory services to us.

### **Critical Accounting Policies and Significant Judgments and Estimates**

Our operating and financial review is based on our consolidated financial statements, which we have prepared in accordance with IFRS as issued by the International Accounting Standards Board, or the IASB. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on our historical experience, trends in the industry and various other factors that are believed to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. There have been no material adjustments to prior period estimates for any of the periods included in this Annual Report on Form 20-F.

Our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Annual Report on Form 20-F. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

### ***Revenue Recognition***

Effective January 1, 2018, we adopted IFRS 15. This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

We have derived the majority of our revenue to date from research, collaboration and license agreements with Incyte, ONO, Simcere and Betta. These agreements contain multiple promised goods and services, including license rights to certain of our product candidates and research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable upfront fees; reimbursement of research and development costs;



development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products, if any.

Under the new revenue standard, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration that we expect to receive in exchange for those goods or services.

We recognize revenue following the five-step model prescribed under IFRS 15:

- Identification of the contract with the customer;
- Identification of the performance obligations;
- Determination of the transaction price, including the constraint on variable consideration;
- Allocation of the transaction price to the performance obligations in the contract; and
- Recognition of revenue when (or as) the Company satisfies each performance obligation.

In order to account for contracts with customers, such as agreements with Incyte, ONO, Sincere and Betta, we identify the promised goods or services in the contract and evaluate whether such promised goods or services represent performance obligations. We account for those components as separate performance obligations when the following criteria are met:

- 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
- our 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 us 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, we evaluate 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, we determine 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, we utilize 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.

If the license to the intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize revenue when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises, we utilize 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. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. When we recognize revenue allocated to the license at a point in time, we may experience significant fluctuations in our revenue from quarter to quarter and year to year depending on the timing of transactions.

At the inception of each arrangement that includes pre-commercial milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate 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 our 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 we recognize revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, we reevaluate the probability of achievement of such development milestones and any related constraint, and if necessary, adjust its estimate of the overall transaction price. Any such adjustments may significantly affect our revenue in the period of adjustment.

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, we recognize 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, we have not recognized any royalty revenue.

We also receive certain government and regional grants, which support our research efforts in defined projects, and include contributions towards the cost of research and development. When there is reasonable assurance that we 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 profit or loss account on a systematic basis over the periods in which the entity 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***

We incur research and development expenses related to our clinical and preclinical drug development programs, which include: (i) payroll and related costs (including share-based payment expenses) associated with research and development personnel; (ii) costs related to clinical trials and preclinical testing of our technologies under development; (iii) costs to develop product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses; (iv) expenses for research services provided by universities and contract laboratories; and (v) other research and development expenses. Research and development expenses are recognized in our consolidated statement of profit or loss and comprehensive loss as incurred and have typically no alternative future uses.

Research and development expenses are capitalized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure attributable to the intangible asset during its development.

As part of the process of preparing its consolidated financial statements, we are required to estimate certain of our research and development expenses, including estimates of third-party contract costs relating to preclinical studies and clinical trial activities and related contract manufacturing expenses. This process involves reviewing open contracts and purchase orders, communicating with research and development personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The most significant estimates relate to expenses incurred under agreements with contract research organizations and contract manufacturing organizations that conduct research and development, preclinical and clinical activities on our behalf.

The majority of our service providers invoice monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers to gauge the reasonableness of our estimates.

Differences between actual and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

### ***Share-Based Compensation***

We maintain stock ownership programs that entitle key management personnel, staff, directors and consultants providing similar services to purchase or receive our common shares. Under these programs, holders of vested options are entitled to purchase our common shares at the exercise price determined at the date of grant while holders of vested restricted stock units, or RSUs, are entitled to the right to receive our common shares.

Share-based compensation is recognized as an expense in our consolidated financial statements based on the grant date fair value over the vesting period in accordance with each separate vesting tranche of the award granted, taking into consideration actual and expected forfeitures at each reporting date and at the respective vesting dates.

The options vest in installments over a four-year period from the grant date: 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the

options vest in 36 monthly installments. The RSUs vest in installments over a four-year period from the grant date.

The fair value of the RSUs is based on the market value of our common shares on the date of grant.

The fair value of share options is calculated using the Hull & White option pricing model, which considers the terms and conditions attached to the grants made and is reflective of expected exercise behavior. Prior to our IPO, the estimated fair value of each share option granted was determined utilizing the Black-Scholes option pricing model. Both models use of subjective assumptions, including expected volatility.

Due to the lack of a public market for the trading of our common stock prior to our IPO and a lack of historical and implied volatility data, we have based our estimate of expected volatility on the historical volatility of a group of similar companies that are publicly traded. We selected companies with comparable characteristics to us, including enterprise value, risk profiles, position within the industry and with historical share price information sufficient to meet the expected term of the share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available.

#### *Valuation of Our Common Shares*

Since we were not listed on a national securities exchange until May 19, 2016, there was no published share price information available until May 19, 2016.

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

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

- the progress of our research and development programs;
- achievement of enterprise milestones, including entering into collaboration and licensing agreements, as well as funding milestones;
- contemporaneous third-party valuations of our common shares for our most recent share issuances;
- our need for future financing to fund operations;
- the prices at which we sold our preferred shares and the rights and preferences of our preferred shares and our preferred shares relative to our common shares;
- the likelihood of achieving a discrete liquidity event, such as a sale of our company or an initial public offering given prevailing market conditions;
- external market and economic conditions impacting our industry sector; and
- the lack of an active public market for our common shares and our preferred shares.

In determining the fair values of our common shares as of each grant date, three generally accepted approaches were considered: income approach, market approach and cost approach. In addition, the guidance prescribed by the American Institute of Certified Public Accounts, or AICPA, *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* has been considered.

### ***Income Taxes***

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

Federal and state income taxes were paid in the U.S. because of our U.S. subsidiary; however, no tax charge or income was recognized in our Dutch entity during the reporting period since we are in a loss-making position and have a history of losses. We have tax loss carry-forwards of €75.9 million and €149.2 million as of December 31, 2018 and 2017, respectively. As a result of Dutch income tax law, tax loss carry-forwards are subject to a time limitation of nine years from the year these tax losses were incurred. Legislation has been enacted that decreases the carry-forwards time limitation of tax losses incurred after December 31, 2018 from 9 years to 6 years.

Deferred income tax assets are recognized for tax losses and other temporary differences to the extent that the realization of the related tax benefit through future taxable profits is probable. We recognize deferred tax assets arising from unused tax losses, unused tax credits and temporary differences only to the extent that there are sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses, unused tax credits and temporary differences can be utilized. Our judgement is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized. We agreed with the Dutch tax authorities in November 2018 that the \$120.0 million upfront license fee received from Incyte Corporation will be fully recognized in 2017 for Dutch corporate income tax purposes. As a result, \$120.0 million of our tax losses were fully recognized in 2017. This results in a temporary difference of €114.6 million between the book carrying amount and the Dutch tax basis of zero of the deferred revenue as of December 31, 2018. This temporary difference also includes other similar license fees.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the "Innovation Box." Based on the Innovations Box ruling, we would owe on the first 75% of qualifying profits under the Dutch jurisdiction effectively 7% for Dutch income taxes. The remaining profit would be taxed at the headline Dutch statutory tax rate. The headline Dutch statutory tax rate is 25% for fiscal years 2018 and 2019. Legislation has been enacted amending the headline Dutch statutory tax rate to 22.55% for fiscal year 2020 and 20.5% for fiscal year 2021 and onwards. Taxable profits will only qualify for the Innovations Box once the tax losses carried forward are completely utilized. The agreement with the Dutch tax authorities was originally signed for the fiscal years beginning in 2011 through 2015 and was subsequently extended up to and including fiscal year 2019. Since we are loss-making, no Dutch income tax is recognized in profit or loss.

## ***Investments***

Since the adoption of IFRS 9, Financial Instruments on January 1, 2018, we classify and account for our investments at amortized cost using the effective interest rate method.

Prior to the adoption of the new guidance, our investments were classified and accounted for as held-to-maturity under IAS 39 and were initially measured at fair value. Subsequent to initial recognition, they were measured at amortized cost using the effective interest rate method. Investments were classified as held-to-maturity and carried at amortized cost as we had the positive intent and ability to hold them until maturity.

The initial adoption of IFRS 9 had no impact on previously reported amounts.

Interest income from these securities is included in finance income.

### **Recent Accounting Pronouncements**

For a discussion of recently adopted or issued accounting pronouncements please refer to section 12.1, Consolidated Financial Statements, within this report.

## **4.2 Liquidity and Capital Resources**

### ***Sources of Funds***

Since our inception in 2003, we have devoted substantially all of our resources to developing our platform technology, bispecific antibody candidates, building our intellectual property portfolio, developing our supply chain, business planning, raising capital and providing for general and administrative support for these operations. We do not currently have any approved products and have never generated any revenue from product sales. We have principally financed our operations through (i) the initial public offering of our common shares, (ii) a public placement of equity securities with Incyte, (iii) an upfront and milestone payments received from Incyte, Ono and Sincere (iv) a private placement of common shares on February 15, 2018, and (v) a placement of equity securities with Regeneron in December 2018.

On May 24, 2016, we closed an initial public offering of 5,500,000 of our common shares and, on May 26, 2016, of an additional 639,926 of our common shares, at a price to the public of \$10.0 per share. We received net proceeds, after deducting underwriting discounts and commissions and offering expenses, of \$53.3 million. On May 19, 2016, our common shares were listed on the Nasdaq and all of our preferred shares converted into common shares.

In December 2016, we entered into the Incyte collaboration and license agreement, and the Share Subscription Agreement, with Incyte. In January 2017, we received an upfront payment of \$120.0 million (€110.2 million) from Incyte pursuant to the Incyte collaboration and license agreement and \$80.0 million (€74.7 million) upon the issuance and sale by us of 3.2 million common shares to Incyte pursuant to the Share Subscription Agreement, for total cash proceeds to us of \$200.0 million (€184.4 million).

On February 13, 2018, we entered into a purchase agreement with the purchasers named therein (the "Investors"). Pursuant to the purchase agreement, we agreed to sell an aggregate of 3,099,997 of our common shares, nominal value €0.09 per share, to the Investors for aggregate gross

proceeds of approximately \$55.8 million (€44.8 million), at a purchase price equal to \$18.00 per share. The closing of the private placement occurred on February 15, 2018.

On December 20, 2018, we issued and sold an aggregate of 600,000 shares to Regeneron in connection with our settlement of certain litigations and administrative, opposition proceedings with Regeneron for aggregate gross proceeds of \$15.0 million (€13.1 million).

As of December 31, 2018, we had cash and cash equivalents of €143.7 million and investments of €61.8 million.

### ***Cash Flows***

The table below summarizes our cash flows for each of the periods presented.

	<b>Year Ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Net cash used in operating activities .....	€ (40,499)	€ (37,413)
Net cash used in investing activities .....	(19,416)	(41,625)
Net cash from financing activities .....	51,589	186,222
Net increase/(decrease) in cash and cash equivalents .....	<u>€ (8,326)</u>	<u>€ 107,184</u>

During 2018, we used €40.5 million of cash in operating activities, as compared to the use of €37.4 million in cash during 2017, an increase in the use of cash of €3.1 million. This increase in net cash used in operating activities was primarily the result of changes in working capital of €6.3 million, an increase in taxes paid of €0.6 million, partially offset by the decrease in net loss adjusted for non-cash items of €3.8 million. Our non-operating and non-cash charges during the year ended December 31, 2018 primarily consisted of unrealized foreign exchange results of €5.6 million and share option expenses of €7.9 million.

Our non-operating and non-cash charges during the year ended December 31, 2017 primarily consisted of unrealized foreign exchange results of €15.8 million, share option expenses of €12.8 million and the change in fair value of the derivative financial instrument of €10.7 million.

Net cash used in investing activities for the years ended December 31, 2018 and 2017 was €19.4 million and €41.6 million, respectively. The decrease in net cash used in investing activities of €22.2 million for the year ended December 31, 2018 related primarily to the maturity of our short-term investments of €58.9 million and higher interest received of €0.3 million, partially offset by a €34.1 million increase in investments purchased, a €2.1 million increase in purchases of intellectual property and a €0.8 million increase in purchases of property, plant and equipment.

The increase in net cash used in investing activities of €41.2 million for the year ended December 31, 2017 primarily related to a €41.8 million increase in investments purchased and a €0.2 million increase in purchases of property, plant and equipment, partially offset by higher interest received of €0.8 million.

Net cash provided by financing activities in 2018 was €51.6 million, which was primarily related to proceeds received from our private placement offering that closed in February 2018 and proceeds received from Regeneron Pharmaceuticals in the fourth quarter of 2018. Net cash provided by financing activities in 2017 was €186.2 million, which was primarily related to the receipt of

€186.7 million from the Incyte Agreements, partially offset by the full repayment of the loan from Rabobank of €0.5 million.

### ***Operating and Capital Expenditure Requirements***

We have not achieved profitability since our inception and, as of December 31, 2018, we had an accumulated loss of €175.1 million. 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 bispecific antibody candidates.

We expect our expenses to increase substantially in connection with our ongoing development activities related to MCLA-128, MCLA-117, MCLA-158, and MCLA-145, and continued research and development of our pre-clinical programs. In addition, we expect to continue to incur additional costs associated with operating as a public company. We anticipate that our expenses will increase substantially if and as we:

- conduct the clinical trials for MCLA-128, our most advanced bispecific antibody candidate in Phase 2 for metastatic breast cancer populations and Phase 1/2 in other solid tumors;
- conduct the Phase 1 clinical trial of MCLA-117, our second most advanced bispecific antibody candidate;
- conduct the Phase 1 clinical trial of MCLA-158, our third most advanced bispecific antibody candidate;
- conduct the Phase 1 clinical trial of MCLA-145, our fourth most advanced bispecific antibody candidate;
- continue the research and development of our other antibody candidates in preclinical development;
- seek to enhance our technology platform, which generates our pipeline of Biclomics<sup>®</sup>, and discover and develop additional antibody candidates;
- seek regulatory approvals for any bispecific antibody candidates that successfully completes 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 approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims or enforcing our intellectual property rights;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims or enforcing our intellectual property rights;
- experience any delays or encounter any issues any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2018 will be sufficient to fund our operations into the second quarter of 2021. For this assessment, we have taken into consideration our existing cash and cash equivalents of €143.7 million, which include the \$55.8 million, or €44.8 million, in proceeds received from our private placement offering that closed in February 2018, \$15.0 million, or €13.1 million, in proceeds received from Regeneron's purchase of 600,000 of our common shares in connection with our



settlement of certain litigations and administrative, opposition proceedings and investments of €61.8 million as of December 31, 2018.

In our opinion, our working capital is sufficient for our present requirements. However, we have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with the development of MCLA-128, MCLA-117, MCLA-158, MCLA-145 and our preclinical programs and because the extent to which we may enter into collaborations with third parties for development of these bispecific antibody candidates is unknown, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our bispecific antibody candidates. Our future capital requirements for MCLA-128, MCLA-117, MCLA-158, MCLA-145 or our pre-clinical programs will depend on many factors, including:

- the progress, timing and completion of pre-clinical testing and clinical trials for our current or any future bispecific antibody candidates;
- the number of potential new antibody candidates we identify and decide to develop;
- the costs involved in growing our organization to the size needed to allow for the research, development and potential commercialization of our current or any future bispecific antibody candidates;
- the costs involved in filing patent applications and maintaining and enforcing patents or defending against claims or infringements raised by third parties;
- the time and costs involved in obtaining regulatory approval for our bispecific antibody candidates and any delays we may encounter as a result of evolving regulatory requirements or adverse results with respect to any of these bispecific antibody candidates;
- any licensing or milestone fees we might have to pay during future development of our current or any future bispecific antibody candidates;
- selling and marketing activities undertaken in connection with the anticipated commercialization of our current or any future bispecific antibody candidates and costs involved in the creation of an effective sales and marketing organization; and
- the amount of revenues, if any, we may derive either directly or in the form of royalty payments from future sales of our bispecific antibody candidates, if approved.

Identifying potential bispecific antibody candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our bispecific antibody candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Additional 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 and may require the issuance of warrants, which could potentially dilute your ownership interest.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or bispecific antibody candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development programs or any future commercialization efforts or grant rights to develop and market bispecific antibody candidates that we would otherwise prefer to develop and market ourselves.

#### 4.3 Research and Development, Patent and Licenses, etc

For a discussion of our research and development activities, see section 3.2 and section 4.1 of this report.

#### 4.4 Trend Information

Other than as disclosed elsewhere in this Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events that are reasonably likely to have a material adverse effect on our net revenues, income from continuing operations, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial conditions. For more information, see section 3.2, section 4.1 and section 4.2 of this report.

#### 4.5 Off-Balance Sheet Arrangements

During the periods presented, we did not and do not currently have any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

#### 4.6 Tabular Disclosure of Contractual Obligations

##### Contractual Obligations and Commitments

Minimum future payments of our contractual obligations as of December 31, 2018 are as follows:

	Total	Payments Due by Period			More than 5 years
		Less than 1 year	1-3 years	3-5 years	
		(euros in thousands)			
Operating lease obligations* .....	€4,685	€1,579	€3,106	€—	€—
Total.....	€4,685	€1,579	€3,106	€—	€—

\* Amounts in the table reflect payments due for our office and laboratory facilities in Utrecht, Netherlands

In March 2019, we entered into a lease agreement for approximately 7,583 square feet of office space in Cambridge, Massachusetts. The lease has a term of seven years and expires on April 1,

2026. The lease provides for escalating rent each year, with total cash payments of approximately \$4.9 million, or €4.2 million, payable over the lease term.

As of December 31, 2018, we had several ongoing clinical and nonclinical contracts for our various pipeline programs. We enter 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 not included in the table above as generally they are cancellable, with notice, at our option and do not have significant cancellation penalties.

## 5 DIRECTORS AND EMPLOYEES

### 5.1 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 3.2 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, 2018, 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
Ton Logtenberg, Ph.D. (60)*	M	Dutch	16 June 2003	N/A***	100% attendance
Mark Iwicki (52)**	M	U.S.	4 June 2015	2020 AGM	88.9% attendance
Russell Greig (66)**	M	British	20 July 2018	2022 AGM	100% attendance
Len Kanavy (57)**	M	U.S.	20 July 2018	2022 AGM	100% attendance
John de Koning, Ph.D. (50)**	M	Dutch	21 January 2010	2019 AGM	100% attendance
Anand Mehra, M.D. (43)**	M	U.S.	21 August 2015	2019 AGM	100% attendance
Gregory Perry (58)**	M	U.S.	19 May 2016	2020 AGM	100% attendance

\* Executive director

\*\* Non-executive director

\*\*\* Ton Logtenberg does not have a fixed expiration date for his current term of office.

On May 21, 2019, our board of directors also nominated Mr. Victor Sandor and Mr. Sven Ante Lundberg for appointment at the 2019 AGM as non-executive directors for a term ending immediately after the annual general meeting to be held in 2023 and to nominate Dr. Mehra and Mr. De Koning for re-appointment as non-executive directors for a term ending immediately after the annual general meeting to be held in 2023. If each nominated director is appointed at the 2019 AGM, the board of directors will consist of nine directors.

**Ton Logtenberg, Ph.D.** has served as our President & Chief Executive Officer and an executive board member since co-founding our company in June 2003, and has served as our Principal Financial Officer since January 2019. Dr. Logtenberg also serves as President of our subsidiary, Merus US, Inc. Prior to joining Merus, Dr. 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. Dr. 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. Dr. 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. Dr. Greig worked at GlaxoSmithKline 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, Dr. Greig serves as Chairman of: AM Pharma and 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 board member of TiGenix in Belgium (acquired by Takeda, Japan), Oryzon in Spain and Onxeo Pharma (previously BioAlliance Pharma) in France, and a venture partner at Kurma Life Sciences (Paris, France).

**Mark Iwicki** has been a non-executive member 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 been a non-executive member of our board of directors since July 2018. Mr. Kanavy most recently served as Senior Vice President, Commercial Business Operations at Genentech where he was responsible for strategic decisions of the U.S. commercial business including product launches, valuation of business development opportunities, clinical development plan options

and pricing. 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 MBA with a specialization in Finance from the University of Scranton.

**John de Koning, Ph.D.** was nominated to serve on our board of directors by Coöperatief LSP IV U.A., one of our shareholders, and has been a non-executive member of our board of directors since January 2010. Dr. De Koning has been a partner at LSP (Life Sciences Partners) since January 2006. Dr. 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. Dr. 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.** was nominated to serve on our board of directors by Sofinnova Venture Partners IX, L.P., one of our shareholders, and has been a non-executive member of our board of directors since August 2015. Dr. Mehra has been with Sofinnova Investments (f.k.a. Sofinnova Ventures) since 2007, most recently holding the position of a general partner where he focuses on working with entrepreneurs to build drug development companies. He has led the firm's investments in Vcept Therapeutics (acquired by Allergan), Aerie Pharmaceuticals, Inc., Aclaris Therapeutics, Inc., and Prothena Corporation PLC. He currently serves as a member of the boards of directors of Spark Therapeutics, Inc. and Aclaris Therapeutics, Inc., as well as on the boards of several private companies. Dr. Mehra holds his M.D. from Columbia University's College of Physicians and Surgeons.

**Gregory D. Perry** has been a non-executive member of our board of directors since May 2016 and Vice Chairman of our board of directors since August 2018. Mr. Perry is the Chief Financial Officer at Finch Therapeutics Group and serves as a member of the Board of Directors of Kala Pharmaceuticals. Mr. Perry served as Chief Financial and Administrative Officer of Novelion Therapeutics Inc. or Novelion, a public company, from November 2016 to December 2017. Prior to this, Mr. Perry was Chief Financial Officer of Aegerion Pharmaceuticals Inc., a public 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., a public company, from January 2014 to June 2015. Before joining Eleven Biotherapeutics, Mr. Perry served as the Interim Chief Financial Officer of InVivo Therapeutics, a public 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 public 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. Mr. Perry previously was 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 (a public biotechnology company), 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.

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

## 5.2 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.

Name	Fees earned or paid in Cash	Option Awards(2)	Total
	(in euros)		
Ton Logtenberg, Ph.D.....	€ 633,449	€ 1,218,935	€ 1,852,384
Russell Greig, Ph.D.....	€ 38,603	€ 122,283	€ 160,886
Wolfgang Berthold, Ph.D.(3).....	€ 19,315	€ 129,625	€ 148,940
Lionel Carnot(4).....	€ 20,401	€ —	€ 20,401
John de Koning, Ph.D.....	€ 40,768	€ 59,453	€ 100,221
Mark Iwicki.....	€ 55,066	€ 59,453	€ 114,519
Len Kanavy.....	€ 32,859	€ 52,303	€ 85,162
Anand Mehra, M.D.....	€ 39,863	€ 59,453	€ 99,316
Gregory Perry.....	€ 45,356	€ 59,453	€ 104,809

(2) Amount shown represents the grant date fair value of option awards granted in 2018 measured using the Hull & White option pricing model. For a description of the assumptions used in valuing these awards, see note 12 to our consolidated financial statements included in section 12.1 of this report.

(3) Dr. Berthold resigned from our board of directors on June 28, 2018.

(4) Mr. Carnot resigned from our board of directors on July 20, 2018.

### 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 2018 pursuant to our short-term incentive plan accounted for 70% of the 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 2018, accounted for 30% of the senior management's bonus opportunity. The board of directors determined that the Company achieved the corporate objectives at the 75% level. The actual bonus amounts paid to our senior management for 2018 are set forth in the table above entitled "Senior Management Remuneration".

See note 19 to the Consolidated Financial Statements (included in section 12.1 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.

### **5.3 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, 2018. 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 5 to 1 (rounded to the nearest integer).

### **5.4 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. Our board of directors is comprised of seven members. Each board member is elected for a term of up to four years. Board members may be re-appointed for subsequent terms. Board members must retire periodically in accordance with a rotation plan. Our board members do not have a retirement age requirement under our Articles of Association. Our board members are elected, or re-appointed as the case may be, by our general meeting of shareholders in accordance with the Articles of Association to serve until their successors are duly elected and qualified.

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
Ton Logtenberg, Ph.D.....	2016	N/A *
Mark Iwicki.....	2016	2020
Russell G. Greig .....	2018	2022
Len Kanavy .....	2018	2022
John de Koning, Ph.D. ....	2017	2019
Anand Mehra, M.D. ....	2016	2019
Gregory Perry.....	2016	2020

\* Ton Logtenberg does not have a fixed expiration date for his current term of office.

There are no arrangements or understanding between us and any of our non-executive directors providing for benefits upon termination of their service.

### **Committees of the Board of Directors**

Our board of directors has established an Audit Committee, Compensation Committee, Nomination and Corporate Governance Committee, which operate pursuant to written charters adopted by our board of directors. With effect from January 1, 2019, our board of directors has also established a Research and Development Committee

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 committee.

The audit committee's responsibilities include:

- recommending the appointment of the independent auditor to the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the board on at least an annual basis;
- reviewing and discussing with the board and the independent auditor our financial statements and our financial reporting process; and
- approving or ratifying any related person transaction (as defined in our related person transaction policy) in accordance with our related person transaction policy.

The audit committee is also charged with overseeing the responsibilities of the Board of Directors with respect to:



- the Company's funding;
- the application of information and communication technology by the Company, including risks relating to cybersecurity;
- the operation of the Company's Code of Business Conduct and Ethics and its other internal policies;
- the Company's tax policy;
- reviewing and discussing the effectiveness of the design and operation of the internal controls with the Board of Directors, including any identified material failings in the internal controls; and ii. any material changes made to, and any material improvements planned for, the internal controls.

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 management 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; this report; Merus' accounting, legal, and tax matters; certain accounting highlights; risks associated with its business and our internal risk management and control systems.

#### *Compensation Committee*

The compensation committee, which consists of Mark Iwicki, Len Kanavy and Gregory Perry, assists our board of directors in determining management compensation. Mr. Iwicki serves as Chairman of the committee. The compensation committee prepares a proposal for the board concerning the compensation of each member of our management to be proposed for adoption by the general meeting of shareholders.

The compensation committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to management compensation;
- evaluating each member of management's performance in light of such policies and reporting to the board;
- analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of management;
- recommending any equity long-term incentive component of each member of management's compensation in line with the remuneration policy and reviewing our management compensation and benefits policies generally; and
- reviewing and assessing risks arising from our compensation policies and practices.

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; 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 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.

The nomination and corporate governance committee's responsibilities include:

- drawing up selection criteria and appointment procedures for board members and management;
- reviewing and evaluating the size and composition of our board and management and making a proposal for a composition profile of the board at least annually;
- recommending nominees for election to our board and its corresponding committees;
- assessing the functioning of individual members of the board and management and reporting the results of such assessment to the board; and
- developing and recommending to the board our rules governing the board, reviewing and reassessing the adequacy of such rules governing the board and recommending any proposed changes to the board.

We are a foreign private issuer. As a result, in accordance with the rules of the Nasdaq Stock Market LLC, we comply with Dutch governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards.

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; independence of directors and committee members, and the board of director and committee self-assessment process.

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

With effect from January 1, 2019, the board of directors established a research and development committee, which consists of Anand Mehra, Russell Greig and John de Koning. Dr. Mehra serves as Chairman of the research and development committee.

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

Because the research and development committee was only formed with effect from January 1, 2019, the committee did not meet during the fiscal year to which this report relates.

## **5.5 Employees**

As of December 31, 2018, we had 98 employees, 50 of whom hold M.D. or Ph.D. degrees. Seventy-seven of our employees work in research and development and 21 work in management and administrative areas. All of our employees are located in the Netherlands except for 17 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.

## 6 MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

### 6.1 Major Shareholders

The following table sets forth information relating to the beneficial ownership of our common shares as of December 31, 2018 by:

- each person known to us who beneficially owns 5% or more of our outstanding common shares;
- each member of our board of directors; and
- each member of our senior management.

The number of common shares beneficially owned by each entity, person, director or senior manager is determined in accordance with the rules of the U.S. Securities and Exchange Commission, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the entity or individual has sole or shared voting power or investment power as well as any shares that the entity or individual has the right to acquire within 60 days following December 31, 2018 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person, as applicable.

Common shares that a person has the right to acquire within 60 days following December 31, 2018 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. As of December 31, 2018, we had 23,358,977 common shares outstanding. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Merus N.V., at Yalelaan 62, 3584 CM Utrecht, The Netherlands.

Name of beneficial owner	Shares beneficially owned	
	Number	Percent
<b>5% or greater shareholders:</b>		
BVF <sup>(1)</sup> .....	4,514,913	19.3%
Incyte Corporation <sup>(2)</sup> .....	3,200,000	13.7%
Bay City Capital Coöperatief U.A. <sup>(3)</sup> .....	2,113,574	9.1%
Sofinnova Venture Partners IX, L.P. <sup>(4)</sup> .....	1,961,039	8.4%
Aquilo Capital Management, LLC <sup>(5)</sup> .....	1,480,855	6.3%
Coöperatief LSP IV UA <sup>(6)</sup> .....	1,225,661	5.3%
Baker Brothers Life Sciences L.P. <sup>(7)</sup> .....	1,160,014	5.0%
<b>Senior management and Board of Directors:</b>		
Ton Logtenberg, Ph.D. <sup>(8)</sup> .....	762,263	3.2%
Hui Liu, Ph.D. <sup>(9)</sup> .....	178,553	*
L. Andres Sirulnik <sup>(10)</sup> .....	141,394	*
Mark Throsby, Ph.D. <sup>(11)</sup> .....	165,751	*
Lex B.H. Bakker, Ph.D. <sup>(12)</sup> .....	49,110	*
Peter B. Silverman <sup>(13)</sup> .....	31,414	*

John de Kruijff <sup>(14)</sup> .....	37,444	*
Russell G. Greig, Ph.D. ....	—	—
Mark Iwicki <sup>(15)</sup> .....	74,475	*
Len Kanavy <sup>(16)</sup> .....	8,166	*
John de Koning, Ph.D. <sup>(17)</sup> .....	24,132	*
Anand Mehra <sup>(4)</sup> <sup>(18)</sup> .....	1,985,171	8.5%
Gregory Perry <sup>(19)</sup> .....	24,132	*

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

- (1) Consists of (a) 2,179,666 shares held directly by Biotechnology Value Fund, L.P. (“BVF”), (b) 1,659,586 shares held directly by Biotechnology Value Fund II, L.P. (“BVF2”), (c) 315,275 shares held by Biotechnology Value Trading Fund OS LP (“Trading Fund OS”) (d) 100,751 shares held directly by Investment 10, L.L.C. (“Investment 10”), and (e) 259,635 shares held directly by MSI BVF SPV LLC (“MSI”). BVF Partners OS Ltd. (“Partners OS”), as the general partner of Trading Fund OS, may be deemed to beneficially own the shares held by Trading Fund OS. BVF Partners L.P. (“Partners”), as the general partner of BVF and BVF2, the investment manager of Trading Fund OS, Investment 10, and MSI and the sole member of Partners OS, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, Investment 10, and MSI. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by Partners Investment 10, and MSI. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares beneficially owned by BVF Inc. The beneficial ownership information is based on a Schedule 13G/A filed with the SEC on February 14, 2019 and information known to us. The address for each of these entities is 44 Montgomery Street, 40th Floor, San Francisco, CA 94104.
- (2) Consists of 3,200,000 common shares held directly by Incyte Corporation (“Incyte”).
- (3) Consists of (a) 2,062,025 common shares held directly by Bay City Capital Fund V, L.P. (“Fund V”), (b) 39,295 common shares held by Bay City Capital Fund V Co-Investment Fund, L.P. (“Fund V-SBS”) are the two sole investors of COOP. Bay City Capital Management V LLC (“BCCM V”) is the general partner of Fund V and Fund V-SBS, and (c) 12,254 common shares held directly by Bay City Capital LLC (“BCC”). BCC is the adviser and manager of BCCM V. BCCM V and BCC represent Fund V and Fund V-SBS, respectively. Thus, BCCM V and BCC share voting and investment power over the shares held by each of Fund V and Fund V-SBS. Lionel Carnot is a member of BCCM V and is employed as a managing director of BCC together with Fred Craves, Carl Goldfischer, Dayton Misfeldt and Rob Hopfner. As such, each of these individuals may be deemed to share voting and investment power over these entities, and they disclaim beneficial ownership of all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on a Schedule 13D filed with the SEC on November 28, 2018. The mailing address for BCC, Fund V, Fund V-SBS and BCCM V is De Boelelaan 7, 1083 HJ Amsterdam, Netherlands.
- (4) Consists of 1,961,039 common shares held directly by Sofinnova Venture Partners IX, L.P. (“Sofinnova VP”). Sofinnova Management IX, L.L.C. (“Sofinnova Management”) is the general partner of Sofinnova VP and Anand Mehra, Michael Powell and James Healy are the managing members of Sofinnova Management. Sofinnova Management, Anand Mehra (a member of our board), Michael Powell and James Healy may be deemed to have shared voting and dispositive power over the shares owned by Sofinnova VP. Such entities and individuals disclaim beneficial ownership over all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on information known to us and a Schedule 13D filed with the SEC on September 27, 2017. The address for Sofinnova VP and Sofinnova Management is 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, California 94025.
- (5) Consists of (a) 1,194,112 common shares held directly by Aquilo Capital, L.P. (“Aquilo”) and (b) 286,743 common shares held directly by Aquilo Capital II, L.P. (“Aquilo II”). Aquilo Capital Management LLC (“Aquilo Management”) is the general partner of Aquilo and Aquilo II and Marc

Schneidman is the managing member of Aquilo Management. Aquilo Management and Mr. Schneidman may be deemed to be beneficial owners of the shares held by Aquilo and Aquilo II, and Aquilo and Aquilo II may be deemed to beneficially own the shares held by the other entity. The beneficial ownership information presented is based on a Schedule 13G/A filed with the SEC on February 14, 2019 and information known to us. The address for Aquilo and Aquilo II is One Letterman Drive, Suite D4900, San Francisco, California, 94129.

- (6) Consists of 1,225,661 common shares held directly by Coöperatief LSP IV U.A. (“LSP”). LSP IV Management BV (“LSP Management”) is the sole director of LSP. The managing directors of LSP Management are Martijn Kleijwegt, Rene Kuijten and Joachim Rothe. As such, LSP Management, Martijn Kleijwegt, Rene Kuijten and Joachim Rothe may be deemed to beneficially own and share voting power over these shares. LSP Management, Martijn Kleijwegt, Rene Kuijten and Joachim Rothe disclaim beneficial ownership of the shares. John de Koning, a member of our board, is employed as a partner at LSP. Mr. de Koning has no beneficial ownership of these shares, but he has a pecuniary interest in these shares pursuant to his employment at LSP. Beneficial ownership information is based on a Schedule 13D/A filed with the SEC on June 3, 2016. LSP’s mailing address is c/o LSP, Johannes Vermeerplein 9, 1071 DV Amsterdam, Netherlands.
- (7) Consists of (a) 1,054,257 common shares held directly by Baker Brothers Life Sciences, L.P. (“Life Sciences”) and (b) 105,757 common shares held directly by 667, L.P. (“667”, and together with Life Sciences, the “Baker Funds”). Baker Bros. Advisors LP (“Advisors”) is the Investment Adviser for the Baker Funds and has sole voting and investment power with respect to the shares held by the Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Advisors. Baker Bros. Advisors (GP) LLC, Julian C. Baker and Felix J. Baker as principals of the Baker Bros. Advisors (GP) LLC, and Advisors disclaim beneficial ownership of all shares. Beneficial ownership information is based on a Schedule 13G filed with the SEC on February 14, 2017. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.
- (8) Consists of (a) 160,814 common shares held by BioPhrase, B.V. (“BioPhrase”), Dr. Logtenberg’s personal holding company, (b) 129,647 common shares held by Dr. Logtenberg, (c) 464,068 options to purchase common shares held by Dr. Logtenberg, including options that vest within 60 days following December 31, 2018 and (d) 7,734 restricted stock units (“RSUs”) held by Dr. Logtenberg, including RSUs that vest within 60 days following December 31, 2018.
- (9) Consists of (a) 40,490 common shares, (b) 136,317 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 1,746 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (10) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (11) Consists of (a) 11,038 common shares, (b) 152,589 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 2,124 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (12) Consists of (a) 9,010 common shares, (b) 39,776 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 324 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (13) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (14) Consists of (a) 1,811 common shares, (b) 35,396 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 237 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (15) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (16) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (17) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.

- (18) Consists of (a) 1,961,039 shares held by Sofinnova Venture Partners IX LP prior to this offering and (b) 24,132 options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (19) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.

To our knowledge, other than as provided in the table above, our other filings with the SEC and this Annual Report on Form 20-F, there has been no significant change in the percentage ownership held by any major shareholder since January 1, 2016.

## **6.2 Related Party Transactions**

The following is a description of related party transactions we have entered into since January 1, 2016 or currently in effect with any member of our board of directors or our executive officers and the holders of 5% or more of our common shares.

### **Registration Rights**

#### ***Registration Rights Agreement with Incyte***

In connection with the Incyte collaboration and license agreement, we entered into a Share Subscription Agreement, or the Subscription Agreement, with Incyte pursuant to which we agreed to register the common shares held by Incyte by June 1, 2017. We also agreed to use our reasonable best efforts to keep the registration statement effective until the earlier of (a) all of the common shares held by Incyte having been sold pursuant to an effective registration statement or in compliance with Rule 144 promulgated under the Securities Act of 1933, as amended, or the Securities Act, (b) at such time when the common shares held by Incyte could, in the opinion of counsel satisfactory to us, be sold by Incyte in a single transaction under the terms of the Subscription Agreement and the volume and manner of sale limitations under Rule 144 of the Securities Act, and (c) at such time as the registration statement registering the common shares has been effective for 42 months following the lock-up period of the common shares as specified in the Subscription Agreement. On June 1, 2017, we filed a registration statement on Form F-3 (File No. 333-218432) with the U.S. Securities and Exchange Commission registering the common shares held by Incyte, which was amended on June 14, 2017.

#### ***Registration Rights Agreement with Certain Investors***

We have entered into a registration rights agreement, or the Registration Rights Agreement, with certain of our shareholders, pursuant to which such shareholders are entitled to the following rights with respect to the registration of their common shares for public resale under the Securities Act. The registration of common shares as a result of the following rights being exercised would enable their holders to trade these shares without restriction under the Securities Act when the applicable registration statement is declared effective.

#### ***Demand Registration Rights***

If the holders of, at least, 30% of the registrable securities then outstanding request that we effect a registration with respect to all or part of their registrable securities, we may be required to register all or part of the registrable securities then outstanding. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration

intend to distribute their shares by means of an underwriting, the managing underwriter of such offering has the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

#### *Piggyback Registration Rights*

If we propose to register any of our common shares under the Securities Act, subject to certain exceptions, the holders of registrable securities are entitled to notice of the registration and to include their registrable securities in the registration. If our proposed registration involves an underwriting, the managing underwriter of such offering has the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

#### *Form S-3 Registration Rights*

If the holders of our registrable securities then outstanding request that we effect a registration of some or all of their registrable securities and we are entitled under the Securities Act to register our common shares on a registration statement on Form F-3, we are obligated to effect such registration. We are not obligated to effect a registration pursuant to these F-3 registration rights if (i) the expected aggregate net proceeds from the sale of the registrable securities for which registration is requested is equal to or less than \$1.0 million or (ii) if, within a given 12-month period, we have already effected two registrations on Form F-3 for the holders of registrable securities.

#### *Expenses*

Ordinarily, other than underwriting discounts and commissions, we are required to pay all expenses incurred by us related to any registration effected pursuant to the exercise of these registration rights. These expenses may include all registration and filing fees, printing expenses, fees and disbursements of our counsel, reasonable fees and disbursements of a counsel for the selling security holders and blue sky fees and expenses.

#### *Termination of Registration Rights*

The registration rights terminate upon the earlier of May 24, 2020, or, with respect to the registration rights of an individual holder, when the holder can sell all of such holder's registrable securities in a three-month period without restriction under Rule 144 under the Securities Act.

#### **Indemnification Agreements**

We have entered into agreements with our board of directors and our senior management to indemnify them against expenses and liabilities to the fullest extent permitted by law. These agreements provide, subject to certain exceptions, for indemnification for related expenses including, among other expenses, attorneys' fees, judgments, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, we provide our board of directors and senior management with directors' and officers' liability insurance.

For further information on related party transactions, see Note 20 to the Consolidated Financial Statements (included in section 12.1 of this report).

Where applicable, best practice provisions 2.7.3, 2.7.4 and 2.7.5 of the DCGC have been observed with respect to the transactions referenced above in this section 6.2.

## 7 LEGAL PROCEEDINGS

On March 11, 2014, Regeneron Pharmaceuticals, Inc., or Regeneron, filed a complaint in the United States District Court for the Southern District of New York alleging that we were infringing one or more claims in Regeneron's U.S. Patent No. 8,502,018, entitled "Methods of Modifying Eukaryotic Cells", or the '018 patent. In 2015, the trial court entered judgments finding that we do not infringe the claims of the '018 patent, that the patent is invalid, and that the patent was procured through inequitable conduct and is unenforceable. On July 27, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the trial court's conclusion that Regeneron engaged in inequitable conduct before the United States Patent and Trademark Office while prosecuting the '018 patent and affirmed that the '018 patent is unenforceable. On December 26, 2017, the Federal Circuit denied Regeneron's petition for rehearing and rehearing en banc seeking a review of that decision and on October 1, 2018, the Supreme Court of the United States denied Regeneron's petition for certiorari, rendering the case finally resolved in our favor.

On March 26, 2018, the trial court granted our motion for attorneys' fees, expert fees, and costs associated with our defense of the above litigation, and ordered the parties to address the amount of the award. We provided a detailed explanation of our attorneys' fees, expert fees, and costs of such award, which Regeneron responded to seeking a reduction of the amount. The matter was fully briefed as of May 18, 2018, and the court issued an Order on June 25, 2018, which published on July 10, 2018, granting our motion for \$8,332,453.46 in attorneys' fees, \$465,390.34 in expert fees, and \$1,717,100.69 in litigation expenses and costs, along with pre- and post-judgment interest. Regeneron appealed the decision awarding attorneys' fees to us to the Federal Circuit, filing its opening brief on November 7, 2018.

On March 11, 2014, Regeneron served a writ in the Netherlands alleging that we were infringing one or more claims in their European patent EP 1 360 287 B1. We had opposed that patent in June 2014. On September 17, 2014, Regeneron's patent EP 1 360 287 B1 was revoked in its entirety by the European Opposition Division of the European Patent Office, or the EPO. In Europe, an appeal hearing occurred in October and November 2015 at the Technical Board of Appeal for the EPO at which time the patent was reinstated to Regeneron with amended claims. On October 2, 2017, we filed an appeal with the Technical Board of Appeal for the EPO to address whether the patent having claims amended during the course of opposition complies with Art. 84 EPC, Art. 123(2) EPC and Rule 80 EPC. On May 25, 2018, at Regeneron's request, a hearing before the Technical Board of Appeals for the EPO was scheduled for September 13, 2018, to address whether the description of EP 1 360 287 B1 patent having claims amended during the course of opposition complies with Art. 84 EPC, Art. 123(2) EPC and Rule 80 EPC. The Technical Board of Appeals provided preliminary views on the matter on August 23, 2018, after which our appeal filed on October 2, 2017 was withdrawn on September 5, 2018.

Regeneron also previously raised opposition proceedings against certain of our patents in jurisdictions including Europe, Japan and Australia.

On December 20, 2018, we 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 certain of our and Regeneron's respective antibody generation technologies. Regeneron also purchased 600,000 of our common shares at a price of \$25 per share for total aggregate proceeds



to us 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 us 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 against one another pending as December 20, 2018.

On April 5, 2018, Regeneron and an unnamed third party filed notices of opposition against our EP 2604625 patent entitled "Generation of Binding Molecules," in the EPO. The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron has withdrawn its opposition pursuant to the December 20, 2018 settlement. On August 20, 2018, we timely responded to these submissions, with proceedings to be ongoing pursuant to the filing of the unnamed third party. An opposition hearing is currently scheduled for June 2019. As this opposition proceeding continues, we cannot assure you 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 material legal proceedings.

## **8 QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

We refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on our exposure to market risk, our policy and objectives in hedging market risks and the use of financial instruments.

## **9 CONTROLS AND PROCEDURES**

### **9.1 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.

#### **Evaluation of Disclosure Controls and Procedures**

Our management, under the supervision and with the participation of our President, Chief Executive and Principal Financial Officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act, as amended) as of December 31, 2018. Based on that evaluation, our chief executive and principal financial officer concluded that, as of December 31, 2018, our disclosure controls and procedures were effective at the reasonable assurance level.

### **Management's Annual Report on Internal Control over Financial Reporting**

Our management, including our chief executive and principal financial officer, is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. This assessment was performed under the direction and supervision of our chief executive and principal financial officer, and based on criteria set forth in “Internal Control—Integrated Framework (2013)” issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

Based on this assessment, our management concluded that, as of December 31, 2018, our internal control over financial reporting was effective.

### **Remediation of Material Weaknesses**

A material weakness is a control deficiency or a combination of control deficiencies in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

As reported in our Annual Report on Form 20-F for the year ended December 31, 2017, we identified three material weaknesses as of December 31, 2017, two of which were unremediated material weaknesses identified for the year ended December 31, 2016. In our review of our internal control over financial reporting for the year ended December 31, 2017, management identified a material weakness associated with a lack of adequate cut-off procedures to ensure the timely recognition, measurement and classification of operating expenses and recording of certain period-end accruals. Specifically, we did not design and maintain effective internal control over the assessment of the accounting for significant contractual arrangements related to our clinical research and manufacturing agreements and the classification of operating expenses. In our review of our internal control over financial reporting in connection with the annual audit for the year ended December 31, 2016, management identified two material weaknesses related to insufficient accounting resources required to fulfill IFRS and SEC reporting requirements and the absence of comprehensive IFRS accounting policies and financial reporting procedures.

During the year ended December 31, 2018, we implemented a remediation plan for the material weaknesses identified above and, among other things, (i) redesigned specific processes and controls associated with review of contractual agreements, including to assure proper clinical research and manufacturing agreements expense cut-off, including a quarterly identification and review of significant agreements with the management team to ensure that the relevant accounting implications are identified and considered, (ii) redesigned our controls over proper classification and recognition of operating expenses, including the related balance sheet accounts, (iii) hired several new, experienced personnel in our financial reporting organization and engaged several experienced consultants to further assist our financial reporting organization, (iv) enhanced our IFRS accounting policies and procedures and (v) increased the oversight and review procedures related to our financial close and reporting processes. Management has completed the testing and evaluation of the design and operating effectiveness of these controls and concluded that, as of December 31, 2018, we had remediated the previously reported material weaknesses in internal control over financial reporting.

### **Changes in Internal Control over Financial Reporting**

Other than as described in this section, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control over financial reporting during the year ended December 31, 2018 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

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.

## **10 CORPORATE GOVERNANCE**

### **10.1 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.

#### *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 annual general meeting held in 2018 both Mr. Kanavy and Mr. Greig were unable to be present at such meeting as they had other obligations on that date.

*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.

## **10.2 General Meeting of Shareholders**

### **10.2.1 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.

### **10.2.2 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.

### **10.2.3 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 10.2.1). 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.

### **10.3 Evaluation**

During the fiscal year to which this report relates, our board of directors has evaluated 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 has considered (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. On the basis of these evaluations, our board of directors has concluded that our board of directors are functioning properly.

## **10.4 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 recognises 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.

## **10.5 Corporate values and Code of Business Conduct and Ethics**

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, management, including our principal executive officer, principal financial officer and principal accounting officer, board of directors, consultants, and others temporarily assigned to perform work or services for us. The Code of Conduct is available on our website at <https://ir.merus.nl/static-files/4dfe52fa-e01e-4a32-8ffe-99a55877a236>. We intend to satisfy the disclosure requirement under Item 16B(e) of Form 20-F regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above. Our board of directors is responsible for administering the Code of Conduct. The board of directors is allowed to amend, alter or terminate the Code of Conduct.

## **11 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.



## 12 FINANCIAL INFORMATION

### 12.1 Consolidated Financial Statements

#### Consolidated Statement of Financial Position

*After appropriation of the result for the year*

	Note	December 31, 2018	December 31, 2017 Restated*
(euros in thousands)			
<b>Non-current assets</b>			
Property, plant and equipment, net .....	5	2,420	1,168
Intangible assets, net .....	6	2,445	312
Non-current investments.....	8	16,945	7,060
Other assets .....		1,075	129
		<u>22,885</u>	<u>8,669</u>
<b>Current assets</b>			
Trade and other receivables .....	9	7,032	4,413
Current investments .....	8	44,855	34,043
Cash and cash equivalents .....		143,747	149,678
		<u>195,634</u>	<u>188,134</u>
<b>Total assets</b> .....		<u>218,519</u>	<u>196,803</u>
<b>Shareholders' equity</b>			
Issued and paid-in capital .....	12	2,102	1,749
Share premium account .....		264,854	213,618
Accumulated loss.....		(175,085)	(158,775)
Total shareholders' equity .....		<u>91,871</u>	<u>56,592</u>
<b>Non-current liabilities</b>			
Deferred revenue.....	11	97,675	112,551
<b>Current liabilities</b>			
Trade payables .....		3,819	2,855
Taxes and social security liabilities .....		256	243
Deferred revenue.....	11	16,934	15,935
Other liabilities and accruals.....	10	7,964	8,627
		<u>28,973</u>	<u>27,660</u>
<b>Total liabilities</b> .....		<u>126,648</u>	<u>140,211</u>
<b>Total shareholders' equity and liabilities</b> .....		<u>218,519</u>	<u>196,803</u>

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

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

## Consolidated Statement of Profit or Loss and Comprehensive Loss

	Note	2018	2017 Restated*
(euros in thousands, except per share data)			
<b>Revenue</b> .....	13	<b>31,448</b>	21,915
		<b>31,448</b>	21,915
Research and development costs .....		<b>(46,740)</b>	(34,125)
Management and administration costs.....		<b>(10,395)</b>	(13,697)
Other expenses .....		<b>(13,160)</b>	(9,395)
<b>Total operating expenses</b> .....	14	<b>(70,295)</b>	(57,217)
<b>Operating result</b> .....		<b>(38,847)</b>	(35,302)
Finance income .....	16	<b>7,843</b>	1,112
Finance cost .....	16	<b>(4)</b>	(30,335)
Other income .....	16	<b>7,095</b>	—
<b>Other income (expense)</b> .....		<b>14,934</b>	(29,223)
<b>Result before taxation</b> .....		<b>(23,913)</b>	(64,525)
Income tax expense.....	7	<b>(356)</b>	(249)
<b>Result after taxation</b> .....		<b>(24,269)</b>	(64,774)
Exchange differences from translation of foreign operations...		<b>34</b>	89
<b>Total other comprehensive income for the period</b> .....		<b>34</b>	89
<b>Total comprehensive loss for the period</b> .....		<b>(24,235)</b>	(64,685)
Basic (and diluted) loss per share** .....	17	<b>(1.09)</b>	(3.37)

The results and comprehensive losses for the years presented are fully attributable to the owners of the Company.

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

\*\* For the periods included in these financial statements, share options and restricted stock units were excluded from the diluted loss per share calculation as the Company was in a loss position in each period presented above. As a result, basic and diluted loss per share are equal.

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

### Consolidated Statement of Changes in Equity

	Note	Common share capital	Common share premium	Accumulated loss	Total equity
<b>Balance at January 1, 2017</b> .....		1,448	139,878	(107,295)	34,031
Impact of adoption of accounting standard* .....		—	—	390	390
<b>Restated balance at January 1, 2017*</b> .....		<u>1,448</u>	<u>139,878</u>	<u>(106,905)</u>	<u>34,421</u>
Restated result after taxation for the period* .....		—	—	(64,774)	(64,774)
Other comprehensive income .....		—	—	89	89
Total comprehensive loss.....		—	—	<u>(64,685)</u>	<u>(64,685)</u>
Transactions with owners of the Company:					
Issuance of shares (net).....	12	301	73,740	—	74,041
Equity settled shared-based payments .....	15	—	—	12,815	12,815
<b>Total contributions by and distributions to owners of the Company</b> .....		<u>301</u>	<u>73,740</u>	<u>12,815</u>	<u>86,856</u>
<b>Restated balance at December 31, 2017*</b> .....		<u>1,749</u>	<u>213,618</u>	<u>(158,775)</u>	<u>56,592</u>
<b>Restated balance at January 1, 2018*</b> .....		1,749	213,618	(158,775)	56,592
Result .....		—	—	(24,269)	(24,269)
Other comprehensive loss .....		—	—	34	34
Total comprehensive loss.....		—	—	<u>(24,235)</u>	<u>(24,235)</u>
Transactions with owners of the Company:					
Issuance of shares (net).....	12	353	51,236	—	51,589
Equity settled shared-based payments .....	15	—	—	7,925	7,925
<b>Total contributions by and distributions to owners of the Company</b> .....		<u>353</u>	<u>51,236</u>	<u>7,925</u>	<u>59,514</u>
<b>Balance at December 31, 2018</b> .....		<u>2,102</u>	<u>264,854</u>	<u>(175,085)</u>	<u>91,871</u>

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

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

## Consolidated Statement of Cash Flows

	Note	2018	2017
		(euros in thousands)	Restated*
<b>Cash flows from operating activities</b>			
Result after taxation .....		(24,269)	(64,774)
Adjustments for:			
Change in fair value derivative .....	8, 16	—	10,667
Unrealized foreign exchange results .....	16	(5,553)	15,767
Depreciation and amortization .....	5, 6	638	318
Share-based payment expenses .....	15	7,925	12,815
Net finance (income) expenses .....		(1,181)	(1,040)
		(22,440)	(26,247)
Changes in working capital:			
Trade and other receivables .....	9	(2,576)	(1,837)
Other assets .....		(946)	(20)
Trade payables .....		618	505
Other liabilities and accruals .....	10	(663)	4,977
Deferred revenue .....	11	(13,877)	(14,933)
Tax and social security liabilities .....		13	214
<b>Cash used in operating activities</b> .....		<b>(39,871)</b>	<b>(37,341)</b>
Interest paid .....	16	(4)	(29)
Taxes paid .....	7	(624)	(43)
<b>Net cash used in operating activities</b> .....		<b>(40,499)</b>	<b>(37,413)</b>
<b>Cash flows from investing activities</b>			
Purchases of investments .....	8	(75,930)	(41,830)
Proceeds from investment maturities .....	8	58,912	—
Purchase of intellectual property .....	6	(2,125)	—
Acquisition of property, plant and equipment .....	5	(1,552)	(724)
Interest received .....	9, 16	1,279	929
<b>Net cash used in investing activities</b> .....		<b>(19,416)</b>	<b>(41,625)</b>
<b>Cash flows from financing activities</b>			
Proceeds from issuing shares, net of issuance costs .....	12	50,713	74,738
Financing costs .....	16	—	(190)
Proceeds from stock option exercises .....	12	876	—
Proceeds from collaboration and license agreement .....	12	—	111,993
Repayment of borrowings .....		—	(486)
Changes in restricted cash .....		—	167
<b>Net cash provided by financing activities</b> .....		<b>51,589</b>	<b>186,222</b>
<b>Net increase (decrease) in cash and cash equivalents</b> .....			
		<b>(8,326)</b>	107,184
Effects of exchange rate changes on cash and cash equivalents .....		2,395	(14,423)
Cash and cash equivalents, beginning of period .....		149,678	56,917
<b>Cash and cash equivalents, end of period</b> .....		<b>143,747</b>	<b>149,678</b>
<b>Supplemental disclosure of non-cash activities:</b>			
Changes in accrued capital expenditures .....		346	52

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

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

## Notes to the Consolidated Financial Statements

### 1. General Information

#### Nature of Business

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 One Broadway, Cambridge, Massachusetts, United States (“U.S.”). These consolidated financial statements as at and for year ended December 31, 2018 comprise Merus N.V. and Merus US, Inc. (collectively, the “Company”).

Merus N.V. was incorporated in the Netherlands, with its statutory seat in Utrecht. In connection with becoming a listed company on the Nasdaq Global Market (“Nasdaq”), on May 19, 2016, Merus N.V.’s legal structure under Dutch law was changed from a private company with limited liability (in Dutch: *besloten vennootschap met beperkte aansprakelijkheid*) to a public company with limited liability (in Dutch: *naamloze vennootschap*) and Merus N.V.’s name changed from “Merus B.V.” to “Merus N.V.” The address of the Company’s registered office is Yalelaan 62, 3584 CM Utrecht, The Netherlands. The Company 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 €175.1 million as of December 31, 2018. 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, Merus expects that its existing cash and cash equivalents of €143.7 million and investments of €61.8 million as of December 31, 2018 will be sufficient to fund its operations into the second quarter of 2021. Therefore the financial statements of the Company have been prepared on the basis of the going concern assumption.

#### Reverse Share Split

On May 6, 2016, the general meeting of the Company’s shareholders resolved to approve and effect a capital reorganization, based on a reverse share split. The effect of the reverse share split was a 1-for-1.8 reverse share split of the outstanding common and preferred shares held by the Company’s shareholders. This reverse share split became effective on May 6, 2016.

#### Initial Public Offering

On May 24, 2016, the Company closed the initial public offering of 5,500,000 of its common shares and, on May 26, 2016, of an additional 639,926 of its common shares, at a price to the public of \$10.0 per share (the "IPO"). Net proceeds to the Company after deducting underwriting discounts and commissions and offering expenses were \$53.3 million. On May 19, 2016, the Company's common shares were listed on the Nasdaq and all of the Company's preferred shares converted into common shares.

### **Follow-on Public Offering**

On June 1, 2017, the Company filed with the U.S. Securities and Exchange Commission a registration statement on Form F-3 (Registration Number 333-218432) (the "F-3 Registration Statement"), under which it registered up to \$250.0 million of its securities and 3,200,000 shares sold to Incyte Corporation ("Incyte"). The F-3 Registration Statement became effective on June 16, 2017. On June 1, 2017, the Company also entered into a sales agreement with Cowen and Company, LLC ("Cowen"), under which the Company may issue and sell from time to time up to \$50.0 million of its common shares registered under the F-3 Registration Statement through Cowen as its sales agent. Sales of common shares, if any, will be made at market prices by any method that is deemed to be an "at the market" offering. The aggregate compensation payable to Cowen as sales agent equals 3.0% of the gross sales price of the shares sold through it pursuant to the sales agreement. No sales have been made by the Company under the sales agreement.

### **Private Placement of Common Shares**

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, nominal value €0.09 per share, to the Investors at a purchase price equal to \$18.0 per share (the "Private Placement"). The Purchase Agreement contained 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 aggregate gross proceeds of approximately \$55.8 million, or €44.8 million.

## **2. Basis of Presentation**

These consolidated financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as adopted by the EU and the relevant articles of Part 9 of Book 2 of the Dutch Civil Code. 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 have been prepared under the historical cost convention unless otherwise stated in the below accounting policies.

These consolidated financial statements have been authorized for issuance on May 22, 2019.

### **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"). The consolidated financial statements are presented in euros, which is Merus N.V.'s functional currency.

The functional currency of Merus US, Inc. is the U.S. dollar. All amounts are rounded to the nearest thousand euros, except where otherwise indicated.

### **Segment Reporting**

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

### **Use of Estimates, Judgements and Assumptions**

In the application of the Company's accounting policies, management is required to make judgments, estimates and assumptions that affect the reported amounts of assets, liabilities, income and expenses that are not readily apparent from other sources. The estimates and associated assumptions are based on historical experience and other factors that are considered to be relevant. Actual results may differ from these estimates.

Estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized prospectively.

The following are the critical judgments and assumptions that management has made in the process of applying the Company's accounting policies and that have the most significant effect on the amounts recognized in the consolidated financial statements.

#### *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.

Prior to the Company's IPO, the estimated fair value of each share option granted was determined utilizing the Black-Scholes option pricing model. Subsequent to the IPO, the Company's judgment was that the Hull & White option pricing model is the most appropriate method for determining the fair value of its share options since it considers the terms and conditions attached to the grants made and is reflective of expected exercise behavior.

Since the Company was not listed on a national securities exchange until May 19, 2016, there was no published share price information available until May 19, 2016. Consequently, the Company estimated the fair value of its common shares and the expected volatility for the period up to May 19, 2016.

As the Company's shares have not been publicly traded for a sufficient amount of time, the expected volatility is set by considering the historic share price volatility of a set of peer companies.

For pre-IPO valuations, the continuous yield on euro government bonds with a term to maturity comparable to the expected life of the share options, as published by the European Central



Bank, was applied. For post-IPO valuations, the continuous yield on U.S. Treasury Bills with a term to maturity comparable to the expected life of the share options, as published by the U.S. Department of Treasury, is applied.

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 12 to the consolidated financial statements.

#### *Capitalization of Development Costs*

The criteria for capitalization of development costs have been considered by management and determined not to have been met through December 31, 2018. Therefore, all development expenditures relating to internally generated intangible assets in the year ended December 31, 2018 were expensed as incurred.

#### *Income Taxes*

The criteria for the recognition of unused tax losses and deductible temporary differences are disclosed in Note 3. As of December 31, 2018, deferred tax assets have not been recognized in respect of tax losses and deductible temporary differences as the Company has no history of generating taxable profits. Therefore, at the balance sheet date, there is no convincing evidence that sufficient taxable profit will be available against which the tax losses and deductible temporary differences can be utilized. The amount of the unrecognized tax losses and deductible temporary differences is disclosed in Note 7.

Merus US, Inc., which is incorporated in the U.S. in the State of Delaware, is subject to statutory U.S. Federal corporate income taxes and state income taxes for Massachusetts. Current year income tax expense was attributable entirely to Merus US, Inc. which provides general management services and strategic advisory services to the Company. Corporate income tax expenses were €0.4 million and €0.2 million for the years ended December 31, 2018 and 2017, respectively.

#### *Revenue Recognition*

Pursuant to the Company's research, collaboration and license agreements with ONO Pharmaceutical Co., Ltd. ("ONO"), Incyte, Jiangsu Simcere Pharmaceutical Co. Ltd. ("Simcere") and Betta Pharmaceuticals Co. Ltd. ("Betta"), 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 and was impacted by the adoption of IFRS 15. See Note 4 and Note 11.

#### *Accrual of R&D expenses*

Research and Development ("R&D") expenses are recognized in the consolidated statement of profit or loss and comprehensive loss as incurred and have no alternative future uses.

As part of the process of preparing its consolidated financial statements, the Company is required to estimate certain of its R&D expenses, including estimates of third-party contract costs relating to preclinical studies and clinical trial activities and related contract manufacturing expenses.

This process involves reviewing open contracts and purchase orders, communicating with R&D personnel to identify services that have been performed for the Company and estimating the level of service performed and the associated cost incurred for the service when the Company has not yet been invoiced or otherwise notified of the actual cost. See Note 14.

The majority of the Company's service providers invoice monthly in arrears for services performed or when contractual milestones are met. The Company makes estimates of its R&D expenses as of each reporting date in its consolidated financial statements based on facts and circumstances known to it at that time. The Company periodically confirms the accuracy of its estimates with the service providers to gauge the reasonableness of its estimates. Differences between actual and estimated expenses recorded have not been material and are adjusted for in the period in which they become known.

### **3. Significant Accounting Policies**

The accounting policies set out below have been consistently applied to all periods presented in the consolidated financial statements.

Income and expenses are accounted for on an accrual basis. Profit is only included when realized at the statement of financial position date. Losses originating before the end of the financial year are taken into account if they have become known before preparation of the financial statements.

#### **Basis of consolidation**

##### *(i) Subsidiaries*

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.

##### *(ii) Loss of control*

When the Company loses control over a subsidiary, it derecognizes the assets and liabilities of the subsidiary, and any non-controlling interests and other components of equity. Any resulting gain or loss is recognized in profit or loss. Any interest retained in the former subsidiary is measured at fair value when control is lost.

##### *(iii) Transactions eliminated on consolidation*

Intercompany balances and transactions, and any unrealized income and expenses arising from intercompany transactions, are eliminated in consolidation. Unrealized gains arising from transactions with equity-accounted investees are eliminated against the investment to the extent of the Company's interest in the investee. Unrealized losses are eliminated in the same way as unrealized gains, but only to the extent that there is no evidence of impairment.

#### **Foreign Currency Transactions**

Foreign currency transactions are translated using the exchange rates at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation of monetary assets and liabilities denominated in foreign currencies at the

exchange rate at the reporting date are generally recognized in the statement of profit or loss and comprehensive loss as a component of finance costs.

The results and financial position of foreign operations that have a functional currency different from the presentation currency are translated into the presentation currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each statement of profit or loss and comprehensive income or loss are translated at average exchange rates (unless this is not a reasonable approximation of the cumulative effect of the rates prevailing on the transaction dates, in which case income and expenses are translated at the exchange rates at the dates of the transactions); and
- all resulting exchange differences are recognized in other comprehensive income.

### **Property, Plant and Equipment**

Property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses (if any). Cost includes expenditures that are directly attributable to the acquisition of the items. Depreciation of property, plant and equipment is recognized in the consolidated statement of profit and loss and comprehensive loss on a straight-line basis over estimated useful lives of generally five years, taking residual value into account. If significant parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Subsequent expenditures are capitalized only when the expenditure will increase the future economic benefit of the asset. All other expenditures are expensed in the consolidated statement of profit or loss and comprehensive loss.

Depreciation rates are based on the following estimated economic useful lives of the tangible fixed assets concerned:

- Plant and equipment: 5 years
- Leasehold improvements: Shorter of useful life or term of lease
- Other fixed assets: 5 years

### **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 finite and amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. Amortization begins when the asset is available for use.

#### *Patents*

Patents acquired separately by the Company are reported at cost less accumulated amortization and accumulated impairment losses. Amortization is recognized in the consolidated statement of profit and loss and comprehensive loss on a straight-line basis over the shorter of the estimated economic or

legal lives. The estimated useful life and amortization method are reviewed at the end of each reporting period, with the effect of any changes in estimates being accounted for on a prospective basis.

### *R&D*

The Company incurs R&D expenses related to its clinical trials and preclinical drug development programs. Development expenses are defined as expenses incurred to achieve technical and commercial feasibility. Expenditures on research activities are recognized as an expense in the period in which it is incurred.

Development is capitalized if, and only if, all of the following have been demonstrated:

- the technical feasibility of completing the intangible asset so that it will be available for use or sale;
- the intention to complete the intangible asset and use or sell it;
- the ability to use or sell the intangible asset;
- how the intangible asset will generate probable future economic benefits;
- the availability of adequate technical, financial and other resources to complete the development and to use or sell the intangible asset; and
- the ability to measure reliably the expenditure.

### **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.

#### *Receivables*

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

#### *Derivative Financial Assets and Liabilities*

Derivative financial instruments are initially recognized at fair value on the date on which a derivative contract is entered into and are subsequently remeasured at fair value with net changes in fair value presented as finance expenses (negative net changes in fair value) or finance income (positive net changes in fair value) in the consolidated statement of profit or loss and comprehensive loss. Derivatives are carried as financial assets when the fair value is positive and as financial liabilities when the fair value is negative. Derivatives embedded in host contracts are accounted for as separate derivatives and recorded at fair value if their economic characteristics and risks are not closely related to those of the host contracts and the host contracts are not held for trading or designated at fair value through profit or loss. These embedded derivatives are measured at fair value with changes in fair value recognized in profit or loss. Reassessment only occurs if there is either a change in the terms of the contract that significantly modifies the cash flows that would otherwise be required or a reclassification of a financial asset out of the fair value through profit or loss category.

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

For the purpose of presentation in the statement of cash flows as well as the statement of financial position, cash and cash equivalents include deposits held with financial institutions with original maturities of less than three months from the date of acquisition. Cash and cash equivalents include €49.1 million of investments with a three month or less maturity, callable on demand. The carrying values of cash equivalents approximate fair value due to their short-term maturities.

#### **Treatment of equity issuance costs**

Costs related to the issuance of new shares have been accounted for as follows:

- Incremental costs, if any, that are directly attributable to issuing new shares are included as prepaid expenses and are deducted from equity on the date the Company closes its new share transactions (net of any income tax benefit). Such as, for example, the date of the closing of its IPO, follow-on public offerings or the share subscription agreements with Incyte or Regeneron Pharmaceuticals Inc. (“Regeneron”);

- Incremental costs directly associated with a probable, successful future offering of equity instruments are also deferred and deducted from equity when the new shares are issued;
- Costs that relate to listing on Nasdaq, or other new share transaction costs that are otherwise not incremental and directly attributable to issuing new shares, are recorded as an expense in the consolidated statement of profit or loss and comprehensive loss; and
- Costs that relate to both share issuance and listing are allocated between those functions on a rational and consistent basis.

### **Provisions**

A provision is recognized if the following applies:

- the company has a legal or constructive obligation, arising from a past event;
- the amount can be estimated reliably; and
- it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation.

If all or part of the payments that are necessary to settle a provision are virtually certain to be fully or partially compensated by a third party upon settlement of the provision, then the compensation amount is presented separately as an asset. Provisions are determined by discounting the expected future cash flows at a pre-tax rate that reflects current market assessments of the time value of money and the risks specific to the liability. The unwinding of the discount is recognized as finance cost.

### **Impairment**

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

At each reporting date, the Company considers evidence of impairment for these assets at both an individual asset and a collective level. All individually significant assets are individually assessed for impairment. Those found not to be impaired are then collectively assessed for any impairment that has been incurred but not yet individually identified. Assets that are not individually significant are collectively assessed for impairment. Collective assessment is carried out by grouping together assets with similar risk characteristics.

To assess impairment for its financial assets, the Company uses the general expected credit loss model over the next twelve months of the expected life of its financial assets. Under this model, the Company calculates the allowance for credit losses by considering on a discounted basis, the cash shortfalls it would incur in various default scenarios for prescribed future periods and multiplying the shortfalls by the probability of each scenario occurring. The allowance on the financial asset is the sum of these probability-weighted outcomes.

For the Company's investments, the Company applies the low credit risk simplification as it does not believe there to be any credit risk related to these assets given the credit quality ratings required by the Company's investment policy. At every reporting date, the Company evaluates whether a particular debt instrument is considered to have low credit risk using all supportable information.

Impairment losses are recognized in the consolidated statement of profit or loss and comprehensive loss and is the amount required to adjust the loss allowance at the reporting date to the amount that is required to be recognized based on the aforementioned policy. If the amount of impairment loss subsequently decreases and the decrease can be related objectively to an event

occurring after the impairment was recognized, then the previously recognized impairment loss is reversed through profit or loss.

### *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.

### **Revenue Recognition**

Effective January 1, 2018, the Company adopted IFRS 15, Revenue from Contracts with Customers ("IFRS 15"). This standard applies to all contracts with customers, except for contracts that are within the scope of other standards, such as leases, insurance, collaboration arrangements and financial instruments.

The terms of the contracts within the scope of 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. The impact of the new revenue standard IFRS 15 was also assessed for the instances under the ONO research and license agreement (defined below) where the Company acts as an agent. The Company concluded that no control was obtained for these pass-through arrangements to reimburse costs under the ONO research and license agreement and as such the costs were netted in R&D instead of being recognised as expense.

#### *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.

#### **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 15).

## **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.

### *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.

## **Leases**

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

At inception of an arrangement, the Company determines whether such an arrangement is or contains a lease.

At inception or on reassessment of the arrangement, the Company separates payments and other consideration required by such an arrangement into those for the lease and those for other elements on the basis of their relative fair values. If the Company concludes for a finance lease that it is impracticable to separate the payments reliably, then an asset and a liability are recognized at an amount equal to the fair value of the underlying asset. Subsequently, the liability is reduced as payments are made and an imputed finance cost on the liability is recognized using the Company's incremental borrowing rate.

#### *Leased Assets*

Assets held by the Company under leases that transfer to the Company substantially all of the risks and rewards of ownership are classified as finance leases. The leased assets are measured initially at an amount equal to the lower of their fair value and the present value of the minimum lease payments. Subsequent to initial recognition, the assets are accounted for in accordance with the accounting policy applicable to that asset.

Assets held under other leases are classified as operating leases and are not recognized in the Company's statement of financial position.

#### *Lease Payments*

Payments made under operating leases are recognized in the consolidated statement of profit or loss and comprehensive loss on a straight-line basis over the term of the lease. Lease incentives received are recognized as an integral part of the total lease expense, over the term of the lease.

Minimum lease payments made under finance leases are apportioned between the finance expense and the reduction of the outstanding liability. The finance expense is allocated to each period during the lease term so as to produce a constant periodic rate of interest on the remaining balance of the liability.

### **Finance Income and Finance Expenses**

The Company's finance income and finance expenses include:

- interest and related income;
- interest expense and changes in fair value of the forward contract (derivative);
- 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.

### **Income Tax**

Income 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.

#### **4. Recently Issued or Adopted International Financial Reporting Standards**

##### **Newly Adopted International Financial Reporting Standards**

###### ***IFRS 15, Revenue from Contracts with Customers***

In May 2014, the IASB issued IFRS 15, which supersedes existing revenue recognition guidance. Prior to the adoption of IFRS 15, revenue was recognized to the extent that it was probable that the economic benefits would flow to the Company and the revenue could be reliably measured. The standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. IFRS 15 was effective for annual and interim reporting periods beginning on or after January 1, 2018 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 the new standard effective January 1, 2018, using the retrospective method, with the effect of initially applying this standard recognized at the beginning of the earliest period presented. The Company had two open contracts on the adoption date and has assessed these contracts under the new revenue standard. In addition, the Company elected to apply the practical expedient to not apply this guidance to contracts that were completed before the beginning of the earliest period presented, or January 1, 2016, and the practical expedients for contract modifications (assessing the contracts in combination with any modifications before January 1, 2016). Under the practical expedient, the Company excluded certain option and exclusivity agreements that expired in 2015 and 2014, respectively.

The adoption of IFRS 15 impacted the amortization of the Company's upfront license payments under the collaboration and license agreement entered into with Incyte on December 20, 2016 (the "Incyte collaboration and license agreement") and under the research and license agreement entered into with ONO on April 8, 2014 (the "ONO research and license agreement"). The Company previously recognized revenue from upfront license payments on a straight-line basis over the contractual term or the period of continuing managerial involvement, which was previously estimated to be 21 years for the Incyte collaboration and license agreement and 4.5 years for the ONO research and license agreement. Upon adoption of IFRS 15, the Company assessed the goods and services promised under the Incyte collaboration and license agreement and identified only one performance obligation to which the transaction price was allocated—a license to the Company's proprietary technology combined with the joint steering committee ("JSC") services during the research term. The transfer of the license and the JSC participation represented one combined performance obligation since they were not deemed distinct. As a result, under IFRS 15, revenue from upfront license payments under the Incyte collaboration and license agreement will be recognized as the Company satisfies the combined performance obligation, or over the nine-year research term, which is a period during which the Company has a present enforceable obligation to provide JSC services.

As a result of the adoption of IFRS 15, prior year financial statements have been restated. The impact of adopting IFRS 15 resulted in a decrease of approximately €8.7 million to deferred revenue with an offset to accumulated deficit, effective January 1, 2018.

The following financial statement line items have been shown to reflect the adjustments recognized for each individual line item in the Company's respective consolidated financial statements for the period noted:

*Consolidated Statement of Profit or Loss and Comprehensive Loss*

	<b>Year ended December 31, 2017 (As originally presented)</b>	<b>IFRS 15 adoption</b>	<b>Year ended December 31, 2017 Restated</b>
	<b>(euros in thousands)</b>		
Revenue .....	13,600	8,315	21,915
Operating result .....	(43,617)	8,315	(35,302)
Total comprehensive loss for the period .....	(73,000)	8,315	(64,685)
Loss per share – basic and diluted .....	(3.80)	0.43	(3.37)

*Consolidated Statement of Financial Position*

	<b>December 31, 2017</b> <b>(As originally presented)</b>	<b>IFRS 15 adoption</b>	<b>December 31, 2017 Restated</b>
	<b>(euros in thousands)</b>		
Accumulated loss.....	(167,480)	8,705	(158,775)
Deferred revenue, non-current.....	130,195	(17,644)	112,551
Deferred revenue .....	6,996	8,939	15,935

*Consolidated Statement of Cash Flows*

	<b>Year ended December 31, 2017</b> <b>(As originally presented)</b>	<b>IFRS 15 adoption</b>	<b>Year ended December 31, 2017 Restated</b>
	<b>(euros in thousands)</b>		
Result after taxation.....	(73,089)	8,315	(64,774)
Changes in working capital .....			
Deferred revenue .....	(6,618)	(8,315)	(14,933)

***IFRS 9 Financial Instruments***

IFRS 9, Financial Instruments (“IFRS 9”) replaces the provisions of IAS 39 that relate to the recognition, classification and measurement of financial assets and financial liabilities; derecognition of financial instruments; impairment of financial assets and hedge accounting. IFRS 9 also significantly amends other standards dealing with financial instruments such as IFRS 7, Financial Instruments: Disclosures. The Company assessed the classification and measurement of the financial instruments it held at the date of initial application of IFRS 9, or January 1, 2018, and has classified its financial instruments into the appropriate IFRS 9 categories. There were no changes to the carrying value of the Company’s financial instruments resulting from this reclassification and, accordingly, there was no impact to the Company’s opening accumulated deficit at January 1, 2018, as a result of the adoption of IFRS 9.

IFRS 9 replaces the ‘incurred loss’ model in IAS 39 with an ‘expected credit loss’ (“ECL”) model. The new impairment model applies to financial assets measured at amortized cost, contract assets and debt investments at fair value recorded through other comprehensive loss, but not to investments in equity instruments. Under IFRS 9, credit losses are recognized earlier than under IAS 39. Under IFRS 9, loss allowances are measured on either 12-month ECLs, which result from possible default events within the 12 months after the reporting date, or lifetime ECLs, which result from all possible default events over the expected life of a financial instrument.

The Company’s financial assets recorded at amortized cost consist of cash and cash equivalents, investments and trade and other receivables. These financial assets are considered to have a low credit risk and, as such, there was no impact to the Company’s opening accumulated deficit as a result of the change in impairment methodology.

**Newly Issued International Financial Reporting Standards**

### ***IFRS 16 Leases***

In January 2016, the IASB issued IFRS 16, Leases. IFRS 16 established a right-of-use model that requires all lessees to recognize a right-of-use asset and a lease liability in their statement of financial position that arise from leases with a term that is greater than twelve months. The standard is effective for periods beginning on or after January 1, 2019.

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 the practical expedients available under the transition guidance including, but not limited to, the recognition exemption for short-term and low-value leases.

The Company has reviewed its existing lease contracts and the impact of the new leasing standard on its consolidated statement of profit or loss and comprehensive loss, financial position and related disclosures. Although the Company is in the process of evaluating the full impact of IFRS 16 on its consolidated financial statements, it expects to recognize a lease liability and related right-of-use asset of approximately €3.0 million in its consolidated statement of financial position for its real estate leases existing as of January 1, 2019. This amount does not include the Cambridge, Massachusetts office lease, which was executed in March 2019 (see Note 22). The Company is still evaluating the impact of its non-real estate leases, but it is not expected to be material to the Company's financial statements. The Company's consolidated statement of profit or loss and comprehensive loss will reflect additional depreciation expense due to the right-of-use assets, an increase in finance costs for effective interest expense on its lease liabilities and a decrease in rent expense. The Company also expects to expand its disclosures regarding the amounts, timing and uncertainties of cash flows related to its lease portfolio.

### ***IFRIC 23 Uncertainty over Income Tax Treatments***

IFRIC 23 Uncertainty over Income Tax Treatments ("IFRIC 23") clarifies how the recognition and measurement requirements of IAS 12, Income taxes, are applied where there is uncertainty over income tax treatments. An uncertain tax treatment is any tax treatment applied by an entity where there is uncertainty over whether that treatment will be accepted by the tax authority. Under IFRIC 23, the key test is whether it's probable that the tax authority will accept the company's chosen tax treatment allowing for the assumption that the tax authorities will have full knowledge of all relevant information in assessing a proposed tax treatment. IFRIC 23 applies for annual periods beginning on or after January 1, 2019, with early adoption permitted. The Company does not expect IFRIC 23 will have a material impact on the Company's financial statements.

## 5. Property, Plant and Equipment

Movements in property, plant and equipment, net were as follows:

	<b>Plant and equipment</b>	<b>Other fixed assets</b>	<b>Total</b>
	(euros in thousands)		
<b>Balance as at January 1, 2017</b>			
Costs .....	649	1,386	2,035
Accumulated depreciation .....	(221)	(1,166)	(1,387)
Book value .....	<u>428</u>	<u>220</u>	<u>648</u>
<b>Changes in book value</b>			
Additions .....	663	113	776
Depreciation.....	(186)	(70)	(256)
Disposals (Cost) .....	(51)	(1,086)	(1,137)
Disposals (Accumulated depreciation) .....	51	1,086	1,137
Balance .....	<u>477</u>	<u>43</u>	<u>520</u>
<b>Balance as at December 31, 2017</b>			
Costs .....	1,261	413	1,674
Accumulated depreciation .....	(356)	(150)	(506)
Book value .....	<u>905</u>	<u>263</u>	<u>1,168</u>
<b>Changes in book value</b>			
Additions .....	1,498	300	1,798
Depreciation.....	(448)	(98)	(546)
Disposals (Cost) .....	—	—	—
Disposals (Accumulated depreciation) .....	—	—	—
Balance .....	<u>1,050</u>	<u>202</u>	<u>1,252</u>
<b>Balance as at December 31, 2018</b>			
Costs .....	2,759	713	3,472
Accumulated depreciation .....	(804)	(248)	(1,052)
Book value .....	<u>1,955</u>	<u>465</u>	<u>2,420</u>



## 6. Intangible Assets

The intangible assets, net are related to acquired intellectual property rights were as follows:

	2018	2017
	<i>(euros in thousands)</i>	
<b>Balance as at January 1</b>		
Historical cost .....	860	860
Accumulated amortization .....	(548)	(486)
Book value .....	312	374
Additions.....	2,225	—
Amortization for the year .....	(92)	(62)
Book value as at December 31 .....	2,445	312
<b>Balance as at December 31</b>		
Historical cost .....	3,085	860
Accumulated amortization .....	(640)	(548)
Book value .....	2,445	312

During the year ended December 31, 2018, the Company acquired or licensed certain intellectual property and, under the terms of the related agreements, paid €2.2 million in fees. The transactions were accounted for as an asset acquisition. As a result, the Company capitalized €2.2 million as intangible assets in its consolidated statements of financial position. The Company amortizes the cost of the acquired or licensed intellectual property over its estimated economic life based on the remaining legal life of the related patents from the date of acquisition or license.

## 7. 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, 2018, the tax losses carried forward amounted to €75.9 million as compared to €140.5 million at December 31, 2017 (as restated for the adoption of IFRS 15. See Note 4 for details). The deductible temporary difference, which completely relates to deferred revenue, amounted to €114.6 million at December 31, 2018.

In November 2018, the Dutch tax authorities confirmed that the \$120.0 million upfront license fee received from Incyte can be fully recognized in 2017 for Dutch corporate income tax purposes, which resulted in a significant reduction of the Company's tax loss carry-forwards. The treatment of upfront license fees received is consistently applied by the Company for Dutch corporate income tax purposes. There will be no impact on the Company's consolidated statements of financial position or consolidated statement of profit or loss and comprehensive loss as no deferred tax asset was recognized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the Innovations Box. Based on the Innovations Box ruling, the Company would owe on the first 75% of qualifying profits under the Dutch jurisdiction effectively 7% for Dutch income taxes. The remaining profit would be taxed at the headline Dutch statutory tax rate of 25%. The headline Dutch statutory tax rate is 25% for fiscal years 2018 and 2019. Legislation has been enacted amending the headline Dutch statutory tax rate to 22.55% for fiscal year 2020 and 20.5% for fiscal year 2021. Taxable profits will

only qualify for the Innovations Box once the tax losses carried forward are completely utilized. The agreement with the tax authorities was originally signed for the tax years beginning in 2011 through 2015 and was subsequently extended up to and including year 2019. Since the Company is loss-making, no Dutch income tax is recognized in the consolidated statement of profit or loss and comprehensive loss.

Merus US, Inc., which is incorporated in the U.S. in the State of Delaware, is subject to statutory U.S. Federal corporate income taxes and state income taxes for Massachusetts at a blended rate of 28% and 40% for the years ended December 31, 2018 and 2017, respectively. Current year income tax expense was attributable entirely to Merus US, Inc. which was established on February 17, 2016 and provided general management services and strategic advisory services to the Company. Corporate income tax expenses were €0.4 million and €0.2 million for the years ended December 31, 2018 and 2017, respectively.

## 8. Investments

On January 1, 2018, the Company adopted IFRS 9 and classifies and accounts for its investments at amortized cost. The Company's investments as of December 31, 2017 were classified and accounted for as held-to-maturity under IAS 39. The initial adoption of IFRS 9 had no impact on previously reported amounts (See Note 4).

The Company's investments include investments in commercial paper, debt securities issued by several public corporations and the U.S. Treasury. 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 original investment date are classified as non-current.

Investments as of December 31, 2018 and 2017 consisted of the following:

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Commercial paper.....	€ 22,208	€ 15,527
U.S. Treasury securities.....	6,733	9,177
Corporate fixed income bonds.....	14,185	7,886
Agency bonds.....	1,729	1,453
<i>Current investments</i> .....	<b>44,855</b>	<b>34,043</b>
Corporate fixed income bonds.....	16,945	7,060
<i>Non-current investments</i> .....	<b>16,945</b>	<b>7,060</b>
Total investments.....	<b>€ 61,800</b>	<b>€ 41,103</b>

The Company first began its investment program during the fourth quarter of 2017. During the years ended December 31, 2018 and 2017, the Company purchased investments totaling €75.9 million and €41.8 million, respectively, which are held and denominated in U.S. dollars. During the years ended December 31, 2018 and 2017, the Company received proceeds of €58.9 million and €0, respectively, relating to investment maturities. As a result of the fluctuation in foreign currency between the euro and U.S. dollar, the Company recorded foreign currency exchange net gains of €3.2 million as a component of finance income for the year ended December 31, 2018. For the year

ended December 31, 2017, the Company recorded foreign currency exchange net losses of €0.8 million as a component of finance expense.

## 9. Trade and Other Receivables

All trade and other receivables are short-term and due within 1 year.

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	(euros in thousands)	
Trade receivables .....	€ 2,690	€ 1,594
Unbilled receivables .....	236	710
VAT receivable.....	891	582
Prepaid expenses.....	2,783	427
Prepaid pension costs.....	—	838
Interest receivable.....	213	170
Other receivables .....	219	92
	<b>€ 7,032</b>	<b>€ 4,413</b>

Trade and unbilled receivables relate primarily to invoicing for cost reimbursements relating to the Incyte collaboration and license agreement, ONO research and license agreement and Sincere research and license agreement. VAT receivable relates to a value added tax receivable from the Dutch tax authorities based on the tax application for the fourth quarter of 2018. The Company is evaluating if the benefits of claiming foreign VAT are favorable compared to the related costs and expects to finalize the assessment and conclude in the course of 2019.

Prepaid expenses consist of expenses that were paid but are related to activities taking place in subsequent periods and prepaid taxes. The increase in prepaid expenses at December 31, 2018 relates primarily to advance payments made to contract research and contract manufacturing organizations in support of the Company's preclinical, clinical trial, and contract manufacturing activities.

## 10. Other Liabilities and Accruals

All amounts are short-term and payable within 1 year.

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	(euros in thousands)	
Audit fees.....	€ 167	€ 96
Personnel related.....	560	446
Accrued bonus .....	1,523	1,545
R&D costs.....	4,409	5,272
IP legal fees.....	212	509
Subsidy advance received.....	42	224
Other accruals .....	1,051	535
	<b>€ 7,964</b>	<b>€ 8,627</b>

Accrued R&D costs relate to third-party contract costs for preclinical studies and clinical trial activities and related contract manufacturing expenses. The decrease in R&D costs is due to the timing of invoices received.

Accrued bonuses relate to employee bonuses for the financial year 2018, which were paid out in February 2019.

Subsidy advances received relate to active grants where the Company has received cash in excess of allowances, which is required to be repaid or recognized as grant revenue when the relevant reimbursable costs are incurred as services are performed.

## 11. Deferred Revenue

Deferred revenue consisted of the following:

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Restated*</b>	
	<b>(euros in thousands)</b>	
Deferred revenue – current portion.....	€ 16,934	€ 15,935
Deferred revenue.....	<b>97,675</b>	<b>112,551</b>
	<b>€ 114,609</b>	<b>€ 128,486</b>

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

Of the total deferred revenue balance at December 31, 2018, €112.6 million related to the Incyte collaboration and license agreement and a share subscription agreement (the “Incyte share subscription agreement”) entered into by the Company with Incyte on December 20, 2016 (together, the “Incyte Agreements”) and €2.1 million related to the collaboration and license agreement entered into by the Company with Simcere on January 8, 2018 (the “Simcere collaboration and license agreement”). The total deferred revenue balance at December 31, 2017, related solely to the Incyte Agreements.

Under the Incyte collaboration and license agreement, Incyte agreed to pay the Company a \$120.0 million, or €112.0 million, non-refundable upfront payment, and under the Incyte share subscription agreement, Incyte agreed to purchase 3.2 million common shares at a price per share of \$25.0, for an aggregate purchase price of \$80.0 million. In January 2017, the Company completed the sale of its common shares under the Incyte share subscription agreement and received the \$80.0 million in aggregate purchase price. In February 2017, the Company received the \$120.0 million, or €112.0 million, non-refundable upfront payment and recorded it as deferred revenue.

The Company combined the Incyte collaboration and license agreement and Incyte share subscription agreement and accounted for them as a single contract based on the following criteria: (i) they were entered into at the same time with the same customer; (ii) the arrangements’ mutual existence is acknowledged in the separate agreements; and (iii) they were negotiated as a package with a single commercial objective.

As the Incyte share subscription agreement was denominated in a foreign currency (U.S. dollars) other than the Company’s functional currency (euro), the Company determined that the freestanding forward contract to sell its own shares at a future date, to which the Company became committed on December 20, 2016, did not qualify as equity and thus a freestanding forward contract (derivative asset) was recognized in the Company’s consolidated statement of financial position. The difference between the purchase price of \$25.0 per common share in the Incyte share subscription agreement and the market price of the Company’s common shares on December 20, 2016 was considered to be part of the consideration received under the Incyte Agreements. As a result, on December 20, 2016, the Company recorded a liability (deferred revenue) of \$32.6 million, or

€31.4 million, in its consolidated statement of financial position for the same amount as the fair value of the freestanding forward contract (derivative asset). The deferred revenue liability is not remeasured subsequent to the initial recognition and is accounted for in the same manner as the non-refundable upfront payment.

The Company's fixed consideration under the Incyte Agreements is \$152.6 million, consisting of the \$120.0 million, or €112.0 million, non-refundable upfront payment from the Incyte collaboration and license agreement and \$32.6 million, or €31.4 million, in consideration from the issuance and sale of common shares pursuant to the Incyte share subscription agreement. The transaction price was allocated to a single combined performance obligation that includes a license to the Company's technology combined with the JSC services during the research term. Revenue from upfront license payments under the Incyte collaboration and license agreement will be recognized as the Company satisfies the combined performance obligation, or over the nine-year research term, which is a period during which the Company has present enforceable obligation to provide JSC services.

Under the Simcere collaboration and license agreement, the Company agreed to grant Simcere an exclusive license to develop and commercialize in China three bispecific antibodies to be produced by Merus utilizing the Company's Biclomics<sup>®</sup> technology platform in the area of immuno-oncology. The Company will retain all rights outside of China. As part of the agreement, 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 \$2.75 million, or €2.3 million, relating to three separate research programs. Each research program was determined to be a separate performance obligation and consideration was allocated to each separate obligation. In addition, the Company received a payment of \$0.8 million, or €0.6 million, relating to one of the programs, which was also recorded as deferred revenue.

The Company amortizes the upfront and milestone payment to revenue over time based on the estimated duration of each research program. As of December 31, 2018, the first and second research programs had commenced. For the year ended December 31, 2018, the Company recognized revenue of €0.9 million, relating to these two programs for the amortization of upfront and milestone payments. The remaining research program had not commenced as of December 31, 2018. Accordingly, no revenue has been recognized related to the remaining research program.

On March 14, 2018, the Company entered into a second contract research and license agreement with ONO (the "second ONO research and license agreement"). Pursuant to an exclusive option granted to ONO in the ONO research and license agreement, ONO exercised its option to enter into the second ONO research and license agreement. 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 Biclomics<sup>®</sup> technology platform against two undisclosed targets directed to a particular undisclosed target combination.

Under the terms of the agreement, ONO identifies and selects the licensed bispecific antibodies for which it is responsible for 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 R&D activities and be responsible for the payment of all costs and expenses for its own R&D 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, €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 identified a single performance obligation of providing research services to ONO, which were fully completed in 2018, and recognized all deferred payments received of approximately €1.2 million as revenue during the year ended December 31, 2018.

On December 10, 2018, the Company entered into a collaboration and license agreement with Betta (the "Betta collaboration and license agreement"), where the Company granted Betta an exclusive license to develop and commercialize in China MCLA-129, a proprietary Biclomics<sup>®</sup> produced by its Biclomics<sup>®</sup> technology platform.

The Company retains all rights outside of China. Under the terms of the Betta collaboration and license agreement, 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, or €0.9 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, or €10.5 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, which includes a license to MCLA-129 and other promised goods and services, and will recognize revenue over time based on the estimated duration of the IND-enabling studies. For the year ended December 31, 2018, the Company recognized revenue of less than €0.1 million.

Betta is eligible to receive from the Company an aggregate of \$12.0 million, or €10.5 million, in milestone payments contingent upon the Company achieving certain specified development and commercial goals, and is eligible to receive tiered royalty payments of net sales outside of China.

## **12. Shareholders' Equity**

### **Reverse Share Split**

On May 6, 2016, the general meeting of the Company's shareholders resolved to approve and effect a capital reorganization, based on a reverse share split. The effect of the reverse share split was a 1-for-1.8 reverse share split of the outstanding common and preferred shares held by the Company's shareholders. This reverse share split became effective on May 6, 2016.

### **Initial Public Offering**

On May 24, 2016, the Company closed the initial public offering of 5,500,000 of its common shares and, on May 26, 2016, of an additional 639,926 of its common shares, at a price to the public of \$10.0 per share. Net proceeds to the Company after deducting underwriting discounts and commissions and offering expenses were \$53.3 million. On May 19, 2016, the Company's common shares were listed on the Nasdaq and all of the Company's preferred shares converted into common shares.

### **Share Subscription Agreement with Incyte**

Concurrent with the Incyte collaboration and license agreement discussed above under Note 11, the Company entered into the Incyte share subscription agreement on December 20, 2016. On January 23, 2017, under the terms of the Incyte share subscription agreement, the Company issued 3,200,000 of its common shares to Incyte at the agreed price per share of \$25.0, for an aggregate purchase price of \$80.0 million, or €74.7 million. The Company received proceeds of €74.4 million, net of issuance costs of €0.2 million. A €1.1 million discount on the subscription share price, combined with a €0.4 million foreign currency translation accompanying the issuance of these shares, increased share capital by €0.3 million and share premium by €73.4 million.

### **Private Placement of Common Shares**

On February 13, 2018, the Company entered into the Purchase Agreement. 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 \$18.0 per share. 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.

### **Share Subscription Agreement with Regeneron**

On December 20, 2018, the Company entered into a share subscription agreement with Regeneron (the "Regeneron Subscription Agreement"). See Note 21 for details. 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 \$25.0 per share. The Regeneron Subscription Agreement contains customary representations and warranties from the Company and Regeneron and customary closing conditions. On December 21, 2018, the Company completed the sale under the Regeneron Subscription Agreement and received gross proceeds of \$15.0 million, or €13.1 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, or €13.1 million, and the aggregate value of common shares issued of \$6.9 million, or €6.0 million, was recorded as a gain on litigation settlement of \$8.1 million, or €7.1 million, during the year-ended December 31, 2018.

### **Issued and Paid-in Share Capital**

All issued shares have been fully paid in cash.

### ***Common Shares***

At December 31, 2018 and 2017, a total of 23,358,977 and 19,429,848 common shares, respectively, were issued and fully paid in cash. The following is a tabular reconciliation of common shares outstanding for the years ended December 31, 2018 and 2017, respectively.

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
Common Shares outstanding at January 1, .....	<b>19,429,848</b>	16,085,851
Issued for cash .....	<b>3,699,997</b>	3,200,000
Exercise of common share options .....	<b>135,888</b>	136,666
Vesting of RSUs .....	<b>93,244</b>	7,331
Common Shares outstanding at December 31, .....	<b><u>23,358,977</u></b>	<u>19,429,848</u>

### ***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.

### **Share-Based Payment Arrangements**

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 are exercisable once vested. The options granted under the 2010 Plan vest in installments 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 seventy-five percent of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options become vested on the fourth anniversary of the vesting commencement date. Options lapse on the eighth anniversary of the date of grant.

Prior to the IPO, participants that voluntarily left the Company, except for members of the former Supervisory Board, were required to offer to the foundation the depositary receipts acquired from exercising options against payment of the exercise price or the lower fair market value of the underlying shares. This obligation for a participant to offer depositary receipts to the foundation upon resignation within four years from exercising the options was treated as a non-market vesting condition. In connection with the IPO, the foundation was dissolved and the common shares underlying depositary receipts distributed. In addition, the 2010 Option Plan was amended such that a participant is no longer required to offer depositary receipts to the foundation upon resignation.



The reduction of the vesting period has been accounted for, taking into consideration the modified vesting conditions, to reflect the best estimate available of the options that are expected to vest. At the modification date in 2016, the cumulative expense for the options has been trued-up to reflect the reduced vesting period. This amendment of a non-market vesting (service) condition did not impact the fair value of the options granted.

In connection with the IPO, the Company established the 2016 Incentive Award Plan (the "2016 Plan"). Following the IPO, the Company is no longer making grants under the 2010 Plan; however, the terms of the 2010 Plan will continue to govern grants made under the 2010 Plan. All new incentive award grants since the IPO are being made under the 2016 Plan.

Options granted under the 2016 Plan are exercisable once vested. The options granted under the 2016 Plan vest in installments 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 seventy-five percent of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. Options will lapse on the tenth anniversary of the date of grant.

The RSUs granted under the 2016 Plan also vest in installments over a four-year period from the grant date. Each RSU represents the right to receive one common share.

The Company also established the Supervisory Board Compensation Program, which was subsequently replaced by the Non-Executive Director Compensation Program to reflect the change in governance structure of the Company (see Note 1). As part of this program, non-executive directors are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as annual awards.

The initial awards granted under the Non-Executive Compensation Program vest in installments over a three-year period. Thirty-three percent of the options vest on the first anniversary of the vesting commencement date, and the remaining sixty seven percent of the options in 24 substantially equal monthly installments thereafter, such that the award shall be fully vested on the third anniversary of the vesting commencement date. Each subsequent award shall vest and become exercisable in 12 substantially equal monthly installments following the vesting commencement date, such that the subsequent award shall be fully vested on the first anniversary of the date of grant.

Share-based payment expenses are recognized as from the IPO date for each subsequent award that a non-executive director is entitled to over their remaining term. Since subsequent awards are not subject to shareholder approval, the grant date is established and expenses are based on grant date fair value. The grant date fair value is not updated in each future reporting period and therefore the estimated fair value is not revised and expense recognized is based on the actual grant date fair value of the awards granted.

Pursuant to the "evergreen" provisions of the 2016 Plan, the number of common shares authorized for issuance under the plan automatically increased by 934,359 common shares to 1,469,785 common shares effective January 1, 2019.

#### **Measurement of Fair Value of the Equity-Settled Share-Based Payment Arrangements**

The fair value of the share options granted to the employee and the Board of Directors has been measured using a binomial option pricing model. Service and non-market performance conditions attached to the transactions were not taken into account in measuring fair value. Key management personnel include the Company's executive management and the Board of Directors.

The inputs used in the measurement of the fair values and the related fair values at the grant dates for the options granted during the respective years were as follows:

	<b>Year ended December 31,</b>			
	<b>2018</b>		<b>2017</b>	
	<b>Key Management Personnel</b>	<b>All Other Employees</b>	<b>Key Management Personnel</b>	<b>All Other Employees</b>
	€	€	€	€
Fair value .....	<b>6.82-12.27</b>	<b>7.74-13.32</b>	9.04-16.10	8.94-18.02
Share price .....	<b>13.01-19.90</b>	<b>12.29-21.02</b>	17.08-24.54	13.71-27.47
Exercise price.....	<b>13.01-19.90</b>	<b>12.29-21.02</b>	17.08-24.54	13.71-27.47
Expected volatility (weighted-average) .....	<b>94.71%</b>	<b>92.16%</b>	95.05%	94.88%
Expected life .....	<b>10 years</b>	<b>10 years</b>	10 years	10 years
Expected dividends .....	<b>0%</b>	<b>0%</b>	0%	0%
Risk-free interest rate .....	<b>2.79%-3.20%</b>	<b>2.83%-3.10%</b>	2.29%-2.51%	2.24%-2.62%

#### **Reconciliation of outstanding share options**

The number of share options and the weighted average exercise prices of share options granted were as follows for the respective years:

	<b>Year ended December 31,</b>			
	<b>2018</b>		<b>2017</b>	
	<b>Weighted average exercise price</b>	<b>Number of options</b>	<b>Weighted average exercise price</b>	<b>Number of options</b>
	(€)		(€)	
Outstanding at January 1.....	<b>13.99</b>	<b>2,213,985</b>	8.69	1,394,844
Forfeited during the year.....	<b>14.48</b>	<b>(38,874)</b>	17.27	(58,164)
Expired during the year.....	<b>11.00</b>	<b>(31,629)</b>	8.67	(762)
Exercised during the year.....	<b>6.80</b>	<b>(135,888)</b>	2.24	(136,666)
Granted during the year .....	<b>14.96</b>	<b>625,445</b>	19.88	1,014,733
Outstanding at December 31.....	<b>14.62</b>	<b>2,633,039</b>	13.99	2,213,985
Exercisable at December 31.....		<b>1,275,669</b>		687,070

The options outstanding at December 31, 2018 had an exercise price in the range of €1.93 to €27.47 (2017: €1.93 to €27.47) and a weighted-average remaining contractual life of 7.0 years (2017: 8.25 years).

The weighted-average share price at the date of exercise for share options exercised in 2018 was €17.03.

The number of share options outstanding, by group of employees, was as follows:

<b>Group of employees entitled</b>	<b>December 31,</b>	
	<b>2018</b>	<b>2017</b>
Key management personnel .....	<b>2,148,744</b>	1,777,437
All other employees .....	<b>484,295</b>	436,548
	<b>2,633,039</b>	<b>2,213,985</b>

During 2017, the Company granted RSUs to Key Management Personnel. The following table summarizes the Company's RSU's activity:

	<b>Year ended December 31,</b>			
	<b>2018</b>		<b>2017</b>	
	<b>Weighted average grant date fair value</b>	<b>Number</b>	<b>Weighted average grant date fair value</b>	<b>Number</b>
	<b>(€)</b>		<b>(€)</b>	
Unvested at January 1 .....	<b>20.03</b>	<b>194,546</b>	—	—
Forfeited during the year.....	—	—	20.03	(12,219)
Expired during the year.....	—	—	—	—
Vested during the year .....	<b>20.03</b>	<b>(93,244)</b>	20.03	(7,331)
Granted during the year .....	—	—	20.03	214,096
Unvested at December 31 .....	<b>20.03</b>	<b>101,302</b>	20.03	<b>194,546</b>

### 13. Revenue

Revenue is recognized at the amount to which the Company expects to be entitled for the transfer of promised goods or services to customers.

#### *Disaggregation of Revenue*

The Company's revenues are generated entirely in the Netherlands. In the following table, revenue is disaggregated by primary source of revenue as follows:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017 Restated*</b>
	<b>(euros in thousands)</b>	
Upfront payment amortization.....	€ 17,686	€ 14,933
R&D cost reimbursement and milestone .....	<b>13,566</b>	5,787
Revenue from contracts with customers .....	<b>31,252</b>	20,720
Income from grants on research projects .....	<b>196</b>	1,195
	<b>€ 31,448</b>	<b>€ 21,915</b>

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

For the year ended December 31, 2018, the Company recognized amortization of €15.9 million on upfront payments related to the Incyte collaboration and license agreement, amortization of €1.2 million on upfront payments related to the second ONO research and license agreement, €0.5 million on upfront payments related to the Simcere collaboration and license agreement and less than €0.1 million on the upfront payment related to the Betta collaboration and license agreement. For the year ended December 31, 2017, the Company recognized €14.9 million of amortization of the upfront payment related to the Incyte collaboration and license agreement.

R&D cost reimbursement and milestone revenue for the year ended December 31, 2018, was €13.6 million and consisted of cost reimbursements, milestone payment amortization and research milestones achieved in support of the Company's research and license agreements with Incyte, ONO and Simcere. During the year ended December, 2018, the Company recognized €8.8 million of cost reimbursements in support of the Company's research and license agreements with Incyte and €0.4 million of cost reimbursements in support of the Company's research and license agreements with ONO. The Company recognized an aggregate of €4.0 million in research milestones under its ONO agreements and €0.4 million in research milestone payment amortization under its Simcere agreements for the year ended December 31, 2018. The Company did not recognize any revenue relating to research milestones under its Betta collaboration and license agreement for the year ended December 31, 2018.

R&D cost reimbursement and milestone revenue for the year ended December 31, 2017 was €5.8 million and consisted of cost reimbursements in support of the Company's agreements with Incyte and ONO. The Company did not recognize any research milestones during 2017.

The Company has been awarded grants consisting of cash allowances for specific R&D projects. The unconditional receipt of the grant allowances is dependent on the final review of the reporting provided by the Company at the end of the contract term. For the years ended December 31, 2018 and 2017, the Company recognized €0.2 million, and €1.2 million in grant income, respectively. As of August 2018, all grants awarded were completed. On June 12, 2017, the European Commission approved for reimbursement the final installment of the FP-7 grant and the Company subsequently recognized the remaining €0.7 million to grant revenue. On October 16, 2017, the Company received notification from the European Commission requesting the Company to revise its final report and indicated that the remaining €0.4 million of funds were to remain with the Company and distributed to the other beneficiaries to the program. In November 2017, the Company remitted €0.2 million to the other beneficiaries and recognized an additional €0.2 million of grant revenue.

### ***Contract Balances***

A trade receivable is recorded when the Company satisfies a performance obligation by transferring a promised good or service and has earned the unconditional right to consideration from its customer. Trade receivables relate to invoicing for cost reimbursements, upfront payments and research milestones achieved in support of the Company's research and license agreements with Incyte, ONO, Simcere and Betta. Payment terms relating to receivables with Incyte, ONO and Simcere are 30 days and payment terms relating to receivables with Betta are 60 days.

A contract asset is recorded when the Company satisfies a performance obligation by transferring a promised good or service and has earned the right to consideration from its customer. These assets represent a conditional right to consideration. Contract assets relate to unbilled amounts for cost reimbursements and research milestones achieved in support of the Company's research and license agreements with Incyte and ONO.

A contract liability is recorded when consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services under the terms of the contract. Contract liabilities are recognized as revenue as control of the products or services is transferred to the customer and all revenue recognition criteria have been met. Contract liabilities relate to upfront payments received related to the Incyte collaboration and license agreement, ONO research and license agreement and the Simcere research and license agreement.

The following table presents changes in the Company's trade receivables, contract assets and contract liabilities during the year ended December 31, 2018:

	December 31, 2017 Restated	Additions	Deductions	December 31, 2018
(euros in thousands)				
<b>Trade receivables</b>				
Trade receivables .....	1,594	19,951	(18,855)	2,690
<b>Total trade receivables .....</b>	<b>1,594</b>	<b>19,951</b>	<b>(18,855)</b>	<b>2,690</b>
<b>Contract assets</b>				
Unbilled receivables .....	710	1,045	(1,519)	236
<b>Total contract assets .....</b>	<b>710</b>	<b>1,045</b>	<b>(1,519)</b>	<b>236</b>
<b>Contract liabilities</b>				
Deferred revenue.....	128,486	4,137	(18,014)	114,609
<b>Total contract liabilities.....</b>	<b>128,486</b>	<b>4,137</b>	<b>(18,014)</b>	<b>114,609</b>

The following table presents changes in the Company's trade receivables, contract assets and contract liabilities during the year ended December 31, 2017:

	December 31, 2016 Restated	Additions	Deductions	December 31, 2017 Restated
(euros in thousands)				
<b>Trade receivables</b>				
Trade receivables .....	205	122,781	(121,392)	1,594
<b>Total trade receivables .....</b>	<b>205</b>	<b>122,781</b>	<b>(121,392)</b>	<b>1,594</b>
<b>Contract assets</b>				
Unbilled receivables .....	—	121,240	(120,530)	710
<b>Total contract assets .....</b>	<b>—</b>	<b>121,240</b>	<b>(120,530)</b>	<b>710</b>
<b>Contract liabilities</b>				
Deferred revenue.....	31,426	111,993	(14,933)	128,486
<b>Total contract liabilities.....</b>	<b>31,426</b>	<b>111,993</b>	<b>(14,933)</b>	<b>128,486</b>

As a result of the adoption of IFRS 15, total deferred revenue was reduced by €8.7 million as of December 31, 2017. See Note 4 for details.

For the year ended December 31, 2018, deductions from deferred revenue are comprised of revenue recognized that was included in deferred revenue at the beginning of the period totaling €15.9 million and revenue recognized that was not included in deferred revenue at the beginning of the period totaling €2.1 million. For the year ended December 31, 2017, deductions from deferred revenue

are comprised of revenue recognized that was included in deferred revenue at the beginning of the period totaling €3.2 million and revenue recognized that was not included in deferred revenue at the beginning of the period totaling €11.7 million.

#### 14. Total Operating Expenses

The following table presents a breakdown of operating expenses:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Manufacturing costs.....	<b>€ 18,914</b>	€ 13,567
IP and license costs.....	<b>1,852</b>	1,858
Personnel related R&D.....	<b>7,036</b>	6,673
Other R&D costs.....	<b>18,938</b>	12,027
<i>Total R&amp;D costs</i> .....	<b>46,740</b>	34,125
<i>Management and administration costs</i> .....	<b>10,395</b>	13,697
Litigation costs.....	<b>1,425</b>	1,039
Other operating expenses.....	<b>11,735</b>	8,356
<i>Total other expenses</i> .....	<b>13,160</b>	9,395
<b>Total operating expenses</b> .....	<b>€ 70,295</b>	<b>€57,217</b>

R&D costs primarily include: (i) payroll and related costs (including share-based payment expenses) associated with R&D personnel; (ii) costs related to clinical trials and preclinical testing of the Company's technologies under development; (iii) costs to develop product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses; (iv) expenses for research services provided by universities and contract laboratories; (v) costs associated with obtaining and maintaining patents and other intellectual property; and (vi) other R&D expenses.

Other R&D costs consist mainly of laboratory supplies and depreciation expense related to R&D activities, which cannot be specifically allocated to a research project.

The following table presents a breakdown of other R&D costs:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Discovery and preclinical costs.....	<b>€ 5,506</b>	€ 2,473
Clinical costs.....	<b>9,169</b>	5,919
Other R&D costs.....	<b>4,263</b>	3,635
<i>Total other R&amp;D costs</i> .....	<b>€ 18,938</b>	€ 12,027

Management and administrative costs consist of salaries and related expenses for employees in finance, legal, human resources, investor relations and business development functions. These costs include all salary, salary related expenses and share-based compensation expenses.

Other operating expenses consist primarily of expenses related to professional fees for consulting, audit, and tax services of €6.3 million (2017: €4.0 million), which support the finance

function in maintaining and establishing public company status and general legal, insurance and facility related expenses amounting to €4.2 million (2017: €3.2 million).

Operating expenses presented by nature are outlined below:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Contract manufacturing .....	<b>€ 18,914</b>	€ 13,567
Other external and outsourced costs .....	<b>32,459</b>	22,333
Employee costs and related benefits .....	<b>18,284</b>	20,999
Depreciation and amortization.....	<b>638</b>	318
Total operating expenses .....	<b>€ 70,295</b>	<b>€ 57,217</b>

The other external and outsourced costs consist mainly of preclinical costs of €5.5 million (2017: €2.5 million), clinical costs of €9.2 million (2017: €5.9 million) and IP costs of €3.3 million (2017: €2.9 million).

#### 15. Employee Benefits

Details of the employee benefits are as follows:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Salaries and wages .....	<b>€ 10,783</b>	€ 9,556
WBSO subsidy.....	<b>(4,257)</b>	(3,523)
Social security premiums.....	<b>919</b>	621
Health insurance .....	<b>330</b>	222
Pension costs.....	<b>749</b>	652
Share-based compensation.....	<b>7,925</b>	12,815
Other personnel expense.....	<b>1,835</b>	656
	<b>€ 18,284</b>	<b>€ 20,999</b>

Share-based compensation expense recognized as employee benefit expenses during the years ended December 31, 2018 and 2017 was as follows:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
R&D costs.....	<b>€ 2,710</b>	€ 3,245
Management and administration costs.....	<b>4,742</b>	8,942
Other expenses.....	<b>473</b>	628
	<b>€ 7,925</b>	<b>€ 12,815</b>

Subsidies earned under the WBSO relating to eligible R&D costs are deferred and recognized in the Company's income statement as a reduction to labor costs over the period labor costs are expected to be incurred.

The Company's headcount at December 31, 2018 was approximately 98 full-time equivalents and consisted of 81 employees in the Netherlands and 17 employees in the U.S. A total of 21 employees who are devoted to activities other than R&D and overall management of the Company were included under management and administration costs for the year ended December 31, 2018.

The Company's headcount at December 31, 2017 was approximately 83 full-time equivalents and consisted of 70 employees in the Netherlands and 13 employees in the U.S. A total of 21 employees who are devoted to activities other than R&D and overall management of the Company were included under management and administration costs for the year ended December 31, 2017.

#### 16. Other Income (Expense)

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

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Finance income		
Interest income and similar related income .....	<b>1,809</b>	1,112
Net gain on foreign exchange .....	<b>6,034</b>	—
	<b>7,843</b>	1,112
Other income .....	<b>7,095</b>	—
Finance costs		
Interest and other expenses .....	<b>(4)</b>	(190)
Net loss on foreign exchange .....	—	(19,449)
Derivative financial instrument expense .....	—	(10,696)
	<b>(4)</b>	(30,335)
<b>Total other income (expense) .....</b>	<b>€ 14,934</b>	<b>€ (29,223)</b>

Interest income primarily results from interest earned on cash held on account and accretion of investment earnings.

The Company presents foreign currency gains and losses on a net basis as either finance income or finance expense depending on whether foreign currency movements are in a net gain or net loss position.

Other income consists of a gain recorded in connection with the Regeneron Subscription Agreement. See Note 12 and Note 21 for details. 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 \$25.0 per share. On December 21, 2018, the Company completed the sale under the Regeneron Subscription Agreement and received gross proceeds of \$15.0 million, or €13.1 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, or €13.1 million, and the aggregate value of common shares issued of \$6.9 million, or €6.0 million, was recorded as a gain on litigation settlement of \$8.1 million, or €7.1 million, during the year-ended December 31, 2018.

On December 20, 2016, the Company entered into the share subscription agreement with Incyte and recognized a freestanding forward contract (derivative asset) of \$32.6 million, or €31.4 million, in its statement of financial position. In accordance with IAS 39, the finance costs for the year ended December 31, 2017 and 2016, include an amount of €10.7 million and €19.2 million, respectively, related to a fair value remeasurement of the forward contract through December 31, 2016 and through January 23, 2017, the date the shares were issued to Incyte.

#### 17. Loss per share



The Company calculates basic net income (loss) per share attributable to equity holders of the Company and diluted net loss per share attributable to equity holders of the Company by dividing the net income (loss) attributable to equity holders of the Company by the weighted average number of common shares outstanding during the period. Diluted net income per share attributable to common stockholders is computed by dividing net income attributable to equity holders of the Company by the diluted number of shares outstanding during the period.

Except where the result would be antidilutive to net income, diluted net income per share attributable to equity holders of the Company is computed assuming the exercise of share options and the vesting of RSUs (using the treasury stock method), as well as their related income tax effects.

Basic and diluted net loss per share attributable to equity holders of the Company was calculated as follows:

	<b>Year ended December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>Restated*</b>	
	<b>(euros in thousands, except per share data)</b>	
<b>Numerator:</b>		
Net loss attributable to equity holders of the Company.....	<b>€ (24,235)</b>	€ (64,685)
<b>Denominator:</b>		
Weighted average shares outstanding – basic and diluted.....	<b>22,286,720</b>	19,196,440
Loss per share – basic and diluted .....	<b>€ (1.09)</b>	€ (3.37)

\* See Note 4 for details regarding the restatement as a result of a change in accounting policy.

During the years ended December 31, 2018 and 2017, share options and unvested RSUs were excluded from the calculation of net loss per attributable to equity holders of the Company due to their antidilutive effect.

The Company did not declare dividends for any of the years presented in these financial statements.

## 18. Financial Instruments

As discussed in Note 4, the Company’s initial adoption of IFRS 9 had no impact on previously reported amounts.

### 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 for MCLA-128, MCLA-117, MCLA-158 and MCLA-145.

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

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Trade and unbilled receivables .....	€ 2,296	2,283
Investments .....	61,800	41,103
Cash and cash equivalents .....	143,747	149,678
	<b>€ 208,473</b>	<b>€ 193,064</b>

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:

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Neither past due nor impaired.....	€ 2,926	€ 2,283
Past due.....	—	—
	<b>€ 2,926</b>	<b>€ 2,283</b>

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

### Liquidity Risk

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

The following are the remaining contractual maturities of financial liabilities as at December 31, 2018 and 2017. The amounts are gross and undiscounted.

<b>December 31, 2018</b>	<b>Carrying amount</b>	<b>Total</b>	<b>&lt; 12</b>	<b>1 - 2</b>	<b>2 - 5</b>	<b>More</b>
			<b>months</b>	<b>years</b>	<b>years</b>	<b>than 5</b>
			<b>(euros in thousands)</b>			

Trade payables .....	3,819	3,819	3,819	—	—	—
Other liabilities and accruals.....	7,964	7,964	7,964	—	—	—
	<u>11,783</u>	<u>11,783</u>	<u>11,783</u>	<u>—</u>	<u>—</u>	<u>—</u>

**December 31, 2017**

	<u>Carrying amount</u>	<u>Total</u>	<u>&lt; 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
			(euros in thousands)			
Trade payables .....	2,855	2,855	2,855	—	—	—
Other liabilities and accruals.....	6,176	6,176	6,176	—	—	—
	<u>9,031</u>	<u>9,031</u>	<u>9,031</u>	<u>—</u>	<u>—</u>	<u>—</u>

**Market Risk**

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

*Foreign currency risk*

Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies. With respect to monetary assets and liabilities denominated in foreign currencies, the Company’s primary currency exposure is impacted by monetary assets and liabilities denominated in U.S. dollars. Changes in sensitivity rates reflect various changes in the economy year-over-year.

The following table provides a sensitivity analysis for a change in the primary currency exposure for the Company relating to monetary assets and liabilities denominated in U.S. dollars as of December 31, 2018. The analysis shows the impact that a change in the exchange rate at that date would have on the Company’s total comprehensive loss:

<u>Financial Statement Line Item Exposure</u>	<u>Balance</u>	<u>Effect on profit before tax if USD strengthens 5%</u>	<u>Effect on profit before tax if USD weakens 5%</u>
		(euros in thousands)	
Cash and cash equivalents .....	43,074	2,154	(2,154)
Total investments.....	61,800	3,090	(3,090)
Trade and other receivables .....	2,886	144	(144)
Other assets .....	123	6	(6)
Taxes and social security liabilities .....	(88)	(4)	4
Trade payables, other liabilities and accruals ..	(4,795)	(240)	240
	<u>103,000</u>	<u>5,150</u>	<u>(5,150)</u>

The closing exchange rate per the European Central Bank utilized above for converting the U.S. dollar to euro at December 31, 2018 was 0.8734.

*Exposure to interest rate risk*

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

As per December 31,

	2018	2017
	(euros in thousands)	
<b>Fixed-rate instruments</b>		
Investments .....	61,800	41,103
<b>Variable rate instruments</b>		
Cash and cash equivalents .....	143,747	149,678

The weighted average remaining days to maturity for the Company's investment portfolio is 135 days as of December 31, 2018. 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.

### 19. Board Compensation and Key Management Personnel

On May 29, 2017, the Company changed its governance structure from a two-tier model consisting of a Management Board acting under the supervision of a separate Supervisory Board to a one-tier board model with a unitary Board of Directors consisting of an executive director and non-executive directors. In the one-tier board model, the Board of Directors as a collective (i.e., the executive director and the non-executive directors) are charged with both the management and monitoring functions of the Company's general course of affairs inclusive of the Company's overall business strategy and financial policies. The executive director manages the day to-day business and operations of the Company and implements the Company's strategy. The non-executive directors focus on the supervision of policy and the performance of the duties of all directors, as well as the Company's general state of affairs.

Prior to May 29, 2017, the Company's Management Board was in charge of managing the Company and consisted of Ton Logtenberg, Chief Executive Officer ("CEO") and Shelley Margetson, the former Chief Operating Officer ("COO"). Ms. Margetson resigned as a statutory director of the Company effective as of May 24, 2017 and ended her employment with the Company effective as of August 1, 2017. The Supervisory Board was responsible for the supervision of the Management Board and the general course of affairs of the Company. Subsequent to May 29, 2017, the members of the Supervisory Board are now non-executive directors, while Mr. Logtenberg remains as the lone executive director on the unitary Board of Directors.

In addition to Board of Directors, the Company employs certain key management personnel responsible for executing the day-to-day business and operations of the Company. Key management personnel are those persons having authority and responsibility for planning, directing and controlling the activities of the Company. The Company includes the following employees in this classification: Alexander Berthold Hendrik Bakker, Ph.D., Chief Development Officer, John de Kruif, Chief Technology Officer, Hui Liu, Ph.D., Chief Business Officer and Head of Merus U.S., Peter Silverman, General Counsel and Chief Intellectual Property Officer, L. Andres Sirulnik, M.D., Ph.D., Chief

Medical Officer (“CMO”), and Mark Throsby, Ph.D., Chief Scientific Officer. On January 2, 2019, Mr. Crowley resigned as the Executive Vice President and CFO to pursue other opportunities.

### Executive Directors

In 2018 and 2017, the following amounts were charged to the consolidated statement of profit or loss and comprehensive loss for the remuneration of the statutory directors:

	December 31,				Total
	Gross Salary	Bonus	Pension	Option cost	
	(in euros)				
Ton Logtenberg, CEO and Principal Financial Officer					
2018 .....	445,606	155,962	31,881	2,696,918	3,330,367
2017 .....	432,782	337,945	51,528	4,675,590	5,497,845
Shelley Margetson(*), Former COO					
2018 .....	—	—	—	—	—
2017 .....	(**) 420,782	—	19,595	451,752	892,129

(\*) Resigned as a statutory director of the Company effective as of May 24, 2017.

(\*\*) Gross salary includes severance payments totaling €257,260.

During the year ended December 31, 2018, Mr. Logtenberg was granted 129,000 share options. As of December 31, 2018 and 2017, Mr. Logtenberg held 758,925 and 661,629 share options, respectively, with a weighted average exercise price of €17.07 and €14.20, respectively. As of December 31, 2018 and 2017, Mr. Logtenberg held 64,450 and 123,745 unvested RSUs, respectively.

Upon Ms. Margetson’s separation date, she was entitled to an accelerated vesting of any unvested share options and RSUs held that would have vested during the 12-month period following her separation date.

### Key Management Personnel

The remainder of the key management personnel has received the following remuneration:

Remuneration	2018	2017
	(in euros)	
Short-term employment benefits .....	2,705,438	2,808,998
Post-employment benefits.....	40,882	108,416
Other long-term benefits.....	—	—
Termination benefits.....	—	—
Share-based compensation.....	3,688,978	5,171,233
Total.....	<u>6,435,298</u>	<u>8,088,647</u>

Some of the key management personnel have long-term benefits in the form of life and long-term disability insurance policies, which have been affected in their name as well as severance conditions in case of termination without cause or leave for a good reason.

A number of key management personnel, or their related parties, hold positions in other companies that result in them having control or significant influence over these companies. These companies did not enter into transactions with the Company during the year.

On February 15, 2017, the Company appointed Peter Silverman as its Senior Vice President, Legal. A total 50,000 share options were granted to Mr. Silverman with an exercise price of €24.54 per share.

On November 1, 2016, the Company appointed John Crowley as its CFO. A total of 183,241 share options were granted to Mr. Crowley with an exercise price of €15.24 per share. On January 2, 2019, Mr. Crowley resigned as the Executive Vice President and CFO. In connection with his departure, Mr. Crowley entered into a separation and release agreement with the Company, pursuant to which Mr. Crowley will be entitled to receive a severance payment equal to 6 months of his annual salary.

### Non-Executive Directors

In May 2016, the Company established the Supervisory Board Remuneration Program, which was subsequently replaced by the Non-Executive Compensation Program to reflect the change in governance structure of the Company. As part of this program, non-executive directors are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as subsequent annual share-based awards.

The following amounts were charged to the consolidated statement of profit or loss and comprehensive loss for the remuneration of the members of the Board:

Name	Year ended December 31, 2018			Year ended December 31, 2017		
	Cash compensation	Option cost	Total	Cash compensation	Option cost	Total
	(in euros)			(in euros)		
Russell Greig .....	38,603	79,333	117,936	—	—	—
Mark Iwicki .....	55,066	68,666	123,732	59,840	120,596	180,436
Len Kanavy .....	32,859	152,485	185,344	—	—	—
Wolfgang Berthold ...	19,315	65,776	85,091	37,530	90,944	128,474
Lionel Carnot* .....	20,401	—	20,401	35,445	61,870	97,315
John de Koning .....	40,768	51,044	91,812	38,573	113,613	152,186
Anand Mehra .....	39,863	34,449	74,312	39,615	83,683	123,298
Gregory Perry .....	45,356	54,797	100,153	41,700	103,169	144,869
<b>Total .....</b>	<b>292,231</b>	<b>506,550</b>	<b>798,781</b>	<b>252,703</b>	<b>573,875</b>	<b>826,578</b>

(\*) former board member

As at December 31, members of the Board held the following number of options:

Name	December 31, 2018		December 31, 2017	
	Number	Weighted average exercise price	Number	Weighted average exercise price
Russell Greig .....	9,966	€ 19.97	—	—
Mark Iwicki .....	84,209	€ 10.07	79,226	€ 7.32
Len Kanavy .....	21,818	€ 16.33	—	—
Wolfgang Berthold .....	36,540	€ 15.22	24,040	€ 8.90
Lionel Carnot* .....	—	—	22,650	€ 11.80
John de Koning .....	27,633	€ 14.34	22,650	€ 11.80
Anand Mehra .....	27,633	€ 14.34	22,650	€ 11.80
Gregory Perry .....	27,633	€ 14.34	22,650	€ 11.80
Total .....	<u>235,432</u>	<u>€ 11.52</u>	<u>193,866</u>	<u>€ 9.61</u>

(\* ) former board member

## 20. Related party disclosures

For the years ended December 31, 2018 and 2017, certain Key Management Personnel and other senior management received regular salaries, bonuses and contributions to post-employment schemes as well as non-cash compensation as disclosed in Note 19. Additionally, members of the Board of Directors received compensation for their services in the form of cash compensation as well as non-cash compensation, as disclosed in Note 19.

On May 24, 2017, the Company entered into a settlement agreement with Shelley Margetson, the Company's former Chief Operating Officer pursuant to which Ms. Margetson resigned as a statutory director of the Company effective as of May 24, 2017 and ended her employment with the Company effective as of August 1, 2017. As part of the terms of the settlement agreement, Ms. Margetson is entitled to a severance payment equal to 12 months of her annual base salary, 50% of which was paid in a lump sum in August 2017 and the remaining 50% is being paid in the form of salary continuation over the six-month period following August 1, 2017. In addition, Ms. Margetson was entitled to an accelerated vesting of any unvested Company options and restricted stock units held by Ms. Margetson that would have vested during the 12-month period following her separation date. As of December 31, 2018 and 2017, the Company had an accrual of €0 and less than €0.1 million, respectively, related to this agreement included in accrued personnel.

On January 2, 2019, John Crowley resigned as the Executive Vice President and Chief Financial Officer of the "Company. In connection with his departure, Mr. Crowley entered into a Separation and Release Agreement with the Company, pursuant to which Mr. Crowley is entitled to receive a severance payment equal to 6 months of his annual salary. The transaction will be recorded in the Company's consolidated financial statements during the three months ending March 31, 2019.

As disclosed in Note 11 and Note 13, the Company entered into the Incyte collaboration and license agreement and the Incyte share subscription agreement in which the terms and transactional amounts incurred between Incyte and the Company are more fully described.

As of March 31, 2019, the following shareholders currently hold a position in the Board of Directors and have filed a form 13-D to reflect ownership in the Company of greater than 5%:

- Coöperatief LSP IV U.A.
- Sofinnova Venture Partners IX, L.P.

Additionally, Ton Logtenberg, the Company's President, CEO and Principal Financial Officer and Executive Director, is the sole the Director and owner of Biophrase BV ("Biophrase"). As of March 31, 2019, Biophrase is a less than 1% shareholder. There were no transactions between the Company and Biophrase BV in 2018.

## 21. Commitments and contingencies

### *Lease Commitments*

The Company leases its corporate headquarters under an agreement, which expires in the fourth quarter of 2021. If the lease is not terminated by Merus N.V., it will be automatically renewed for a period of two years. The agreed rental price is €0.4 million per year. On May 1, 2018, the Company 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. The agreed upon rental price is €0.6 million per year.

For leases that contain fixed increases in the minimum annual lease payment during the original term of the lease, the Company recognizes rental expense on a straight-line basis over the lease term and records the difference between rent expense and the amount currently payable as deferred rent, as a component of other liabilities and accruals. For the years ended December 31, 2018 and 2017 the Company recognized €1.3 million and €0.6 million, respectively, for rent and service charges related to the leased office space. In addition, the Company has provided deposits totaling €0.3 million and €0.1 million included in other assets as of December 31, 2018, and December 31, 2017, respectively.

Future minimum lease payments under these leases as of December 31, 2018 are as follows:

Less than one year.....	1,579
Between one and five years .....	3,106
More than five years .....	—
<b>Total.....</b>	<b>4,685</b>

The Company is contractually obligated to return leased space in good order, repair and condition excluding ordinary wear and tear upon termination of the lease agreement. The Company's asset retirement obligations were not significant as of December 31, 2018 and 2017.

The Company's contractual obligations associated with non-real estate leases were not significant as of December 31, 2018 and 2017.

In March 2019, the Company entered in a lease agreement for approximately 7,583 square feet of office space in Cambridge, Massachusetts. Refer to Note 22 for further details.

### *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 collaboration encompasses up to 11



independent programs, including some of the Company's current preclinical immuno-oncology discovery programs. For one of the current programs, concerning MCLA-145, the Company retains the exclusive right to develop and commercialize products and product candidates in the U.S., while Incyte has the exclusive right to develop and commercialize products and product candidates arising from such program outside the U.S. For MCLA-145, the Company and Incyte will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in the respective territories. 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 with respect to MCLA-145, the content and timing of decisions made by the regulators, the reimbursement and competitive landscape around MCLA-145 and other factors.

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, 2018, 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.

During 2018, the Company entered into certain contracts to purchase property, plant and equipment in 2019 for €0.6 million.

#### ***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 hold 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, 2018 and 2017.

### *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.” In 2015, the trial court entered judgments finding that the Company does not infringe the claims of the Patent No. 8,502,018, that the patent is invalid, and that the patent was procured through inequitable conduct and is unenforceable. On July 27, 2017 the U.S. Court of Appeals for the Federal Circuit affirmed the trial court’s conclusion that Regeneron engaged in inequitable conduct before the U.S. Patent and Trademark Office while prosecuting the Patent No. 8,502,018 and affirmed that the Patent No. 8,502,018 is unenforceable. On December 26, 2017, the Federal Circuit denied Regeneron’s petition for rehearing and rehearing en banc seeking a review of that decision and on October 1, 2018, the Supreme Court of the U.S. denied Regeneron’s petition for certiorari, rendering the case finally resolved in the Company’s favor.

On March 26, 2018, the trial court granted the Company’s motion for attorneys’ fees, expert fees, and costs associated with the Company’s defense of the above litigation, and ordered the parties to address the amount of the award. The Company provided a detailed explanation of its attorneys’ fees, expert fees, and costs of such award, which Regeneron responded to, seeking a reduction of the amount. The matter was fully briefed as of May 18, 2018, and the court issued an Order on June 25, 2018, which published on July 10, 2018, granting the Company’s motion for \$8,332,453.46 in attorneys’ fees, \$465,390.34 in expert fees, and \$1,717,100.69 in litigation expenses and costs, along with pre- and post-judgment interest. Regeneron appealed the decision awarding attorneys’ fees to the Company to the Federal Circuit, filing its opening brief on November 7, 2018.

On March 11, 2014, Regeneron served a writ in the Netherlands alleging that the Company was infringing one or more claims in their European patent EP 1 360 287 B1. The Company had opposed that patent in June 2014. On September 17, 2014, Regeneron’s patent EP 1 360 287 B1 was revoked in its entirety by the European Opposition Division of the European Patent Office (the “EPO”). In Europe, an appeal hearing occurred in October and November 2015 at the Technical Board of Appeal for the EPO at which time the patent was reinstated to Regeneron with amended claims. On October 2, 2017, the Company filed an appeal with the Technical Board of Appeal for the EPO to address whether the patent having claims amended during the course of opposition complies with Art. 84 EPC, Art. 123(2) EPC and Rule 80 EPC. On May 25, 2018, at Regeneron’s request, a hearing before the Technical Board of Appeals for the EPO was scheduled for September 13, 2018, to address whether the description of EP 1 360 287 B1 patent having claims amended during the course of opposition complies with Art. 84 EPC, Art. 123(2) EPC and Rule 80 EPC. The Technical Board of Appeals provided preliminary views on the matter on August 23, 2018, after which the Company’s appeal filed on October 2, 2017 was withdrawn on September 5, 2018.

The costs incurred in the above litigation and opposition were €1.4 million and €1.0 million for the years ended December 31, 2018 and 2017, respectively.

Regeneron also previously raised opposition proceedings against certain of the Company’s patents in jurisdictions including Europe, Japan and Australia.

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.

On April 5, 2018, an unnamed third party and Regeneron filed notices of opposition against the Company's EP 2604625 patent, entitled "Generation of Binding Molecules," in the EPO. The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron will no longer be pursuing this opposition pursuant to December 20, 2018 settlement. On August 20, 2018, the Company timely responded to these submissions, with proceedings to be ongoing with respect to the unnamed third party. An opposition hearing is scheduled for June 2019. 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.

## **22. Subsequent events**

In March 2019, Merus US, Inc. entered in a lease agreement for approximately 7,583 square feet of office space in Cambridge, Massachusetts. The lease has a term of seven years and expires on April 1, 2026. The lease provides for escalating rent each year, with total cash payments of approximately \$4.9 million, or €4.2 million, payable over the lease term.

## 12.2 Company Financial Statements

### Company Statement of Financial Position

*After appropriation of the result for the year*

	Notes	December 31, 2018	December 31, 2017 Restated
(euros in thousands)			
<b>Non-current assets</b>			
Financial fixed assets .....	2	947	433
Property, plant and equipment, net .....	3	2,417	1,163
Intangible assets, net .....	4	2,445	312
Non-current investments .....	5	14,324	6,232
Other assets .....		953	123
		<u>21,086</u>	<u>8,263</u>
<b>Current assets</b>			
Trade and other receivables .....	6	11,502	12,406
Current investments .....	5	43,374	33,216
Cash and cash equivalents .....		141,614	141,821
		<u>196,490</u>	<u>187,443</u>
<b>Total assets</b> .....		<u>217,576</u>	<u>195,706</u>
<b>Shareholders' equity</b>			
Issued and paid-in capital .....	9	2,102	1,749
Share premium account .....		264,854	213,618
Legal reserves .....		133	97
Accumulated loss .....		(175,220)	(158,872)
Total shareholders' equity .....		<u>91,869</u>	<u>56,592</u>
<b>Non-current liabilities</b>			
Deferred revenue .....	8	97,675	112,551
<b>Current liabilities</b>			
Trade payables .....		3,807	2,749
Taxes and social security liabilities .....		169	49
Deferred revenue .....	8	16,934	15,935
Other liabilities and accruals .....	7	7,122	7,830
		<u>28,032</u>	<u>26,563</u>
<b>Total liabilities</b> .....		<u>125,707</u>	<u>139,114</u>
<b>Total shareholders' equity and liabilities</b> .....		<u>217,576</u>	<u>195,706</u>

## Company Statement of Profit or Loss and Comprehensive Loss

	Notes	2018	2017
		2018	Restated
(euros in thousands)			
<b>Revenue</b> .....	10	<u>31,448</u>	<u>21,915</u>
		31,448	21,915
Research and development costs .....		(45,197)	(33,074)
Management and administration costs.....		(7,025)	(11,165)
Other expenses .....		<u>(18,785)</u>	<u>(13,250)</u>
<b>Total operating expenses</b> .....	11	<u>(71,007)</u>	<u>(57,489)</u>
<b>Operating result</b> .....		<u>(39,559)</u>	<u>(35,574)</u>
Finance income .....	13	7,752	1,077
Finance costs.....	13	(4)	(30,245)
Other income .....	13	7,095	—
<b>Total other income (expense)</b> .....		<u>14,843</u>	<u>(29,168)</u>
Result on subsidiary.....	2	<u>481</u>	<u>57</u>
<b>Result before taxation</b> .....		<u>(24,235)</u>	<u>(64,685)</u>
Income tax expense.....	14	—	—
<b>Result after taxation</b> .....		<u>(24,235)</u>	<u>(64,685)</u>
<b>Total comprehensive loss for the period</b> .....		<u>(24,235)</u>	<u>(64,685)</u>

The results for the year and the comprehensive loss for the year are fully attributable to the owners of the Company.

## Notes to the Company Financial Statements

### 1. Significant accounting policies

#### Basis of preparation

Merus N.V.'s company financial statements have been prepared in accordance with Part 9, Book 2 of the Dutch Civil Code. In accordance with subsection 8 of section 362, Book 2 of the Dutch Civil Code, the recognition and measurement principles applied in these company financial statements are the same as those applied in the consolidated financial statements (see Note 3 to the consolidated financial statements, included in section 12.1 of this report).

For a description of the impact of the adoption of new accounting standards on the company financial statements see Note 4 to the consolidated financial statements, included in section 12.1 of this report). 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 company 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 recognised in the translation reserve within equity.

#### Additional information

For 'Additional information' within the meaning of Section 2:392 of the DCC, please refer to section 13 (Other Information), of this report.

#### Employees

The average number of personnel during the year was approximately 73 (2017: 59), of which one is employed outside The Netherlands (2017: 0 employees). Employees are principally employed in the area of research and development. A total of 9 employees (2017: 21 employees) that are devoted to activities other than research and development are included under management and administration costs.

For information on the remuneration of the board and the company's share based compensation plans, see Note 12 and Note 19 and to the consolidated financial statements (included in section 12.1 of this report). The board remuneration and the company's share based compensation are entirely recorded in Merus N.V.

### 2. Financial fixed assets

#### Subsidiaries

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

	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Balance as at January 1 .....	433	287
Result on subsidiary .....	481	57

Exchange differences .....	<b>33</b>	89
Balance as at December 31 .....	<b>947</b>	433

The equity of Merus US, Inc. at December 31, 2018 amounted to €947 thousand (December 31, 2017: €433 thousand).

### 3. Property, Plant and Equipment

Movements in property, plant and equipment were as follows:

	<b>Plant and equipment</b>	<b>Other fixed assets</b>	<b>Total</b>
	(euros in thousands)		
<b>Balance as at January 1, 2017</b>			
Costs .....	649	1,383	2,032
Accumulated depreciation .....	(221)	(1,167)	(1,388)
Book value .....	<u>428</u>	<u>216</u>	<u>644</u>
<b>Changes in book value</b>			
Additions .....	663	111	774
Depreciation .....	(186)	(69)	(255)
Disposals (Cost).....	(51)	(1,086)	(1,137)
Disposals (Accumulated depreciation).....	51	1,086	1,137
Balance .....	<u>477</u>	<u>42</u>	<u>519</u>
<b>Balance as at December 31, 2017</b>			
Costs .....	1,261	408	1,669
Accumulated depreciation .....	(356)	(150)	(506)
Book value .....	<u>905</u>	<u>258</u>	<u>1,163</u>
<b>Changes in book value</b>			
Additions .....	1,499	300	1,799
Depreciation .....	(448)	(97)	(545)
Balance .....	<u>1,051</u>	<u>203</u>	<u>1,254</u>
<b>Balance as at December 31, 2018</b>			
Costs .....	<b>2,760</b>	<b>708</b>	<b>3,468</b>
Accumulated depreciation .....	<b>(804)</b>	<b>(247)</b>	<b>(1,051)</b>
Book value .....	<u><b>1,956</b></u>	<u><b>461</b></u>	<u><b>2,417</b></u>

### 4. Intangible Assets

Please refer to Note 6 of the consolidated financial statements (included in section 12.1 of this report) for a detailed disclosure on the intangible assets.

### 5. Financial assets

#### Investments (non-current and current)

The Company's investments include investments in commercial paper, debt securities issued by several public corporations and the U.S. Treasury. 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 original investment date are classified as non-current.

Investments as of December 31, 2018 and 2017 consisted of the following:

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Commercial paper.....	<b>€ 20,727</b>	€ 14,700
U.S. Treasury securities.....	<b>6,733</b>	9,177
Corporate fixed income bonds.....	<b>14,185</b>	7,886
Agency bonds.....	<b>1,729</b>	1,453
<i>Current investments</i> .....	<b>43,374</b>	<b>33,216</b>
Corporate fixed income bonds.....	<b>14,324</b>	6,232
<i>Non-current investments</i> .....	<b>14,324</b>	<b>6,232</b>
Total investments.....	<b>€ 57,698</b>	<b>€ 39,448</b>

The Company first began its investment program during the fourth quarter of 2017. During the years ended December 31, 2018 and 2017, the Company purchased investments totaling €68.7 million and €40.2 million, respectively, which are held and denominated in U.S. dollars. During the years ended December 31, 2018 and 2017, the Company received proceeds of €53.7 million and €0, respectively, relating to investment maturities. As a result of the fluctuation in foreign currency between the euro and U.S. dollar, the Company recorded foreign currency exchange net gains of €2.8 million as a component of finance income for the year ended December 31, 2018. For the year ended December 31, 2017, the Company recorded foreign currency exchange net losses of €0.8 million as a component of finance expense.

## 6. Trade and Other Receivables

All trade and other receivables are short-term and due within 1 year.

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Trade receivables.....	<b>€ 2,690</b>	€ 1,594
Unbilled receivables.....	<b>236</b>	710
VAT receivable.....	<b>891</b>	582
Prepaid expenses.....	<b>2,684</b>	392
Prepaid pension costs.....	<b>—</b>	838
Interest receivable.....	<b>207</b>	168
Intercompany receivable.....	<b>4,618</b>	8,074
Other receivables.....	<b>176</b>	48
	<b>€ 11,502</b>	<b>€ 12,406</b>



Trade and unbilled receivables relate primarily to invoicing for cost reimbursements relating to the Incyte collaboration and license agreement, ONO research and license agreement and Sincere research and license agreement. VAT receivable relates to a value added tax receivable from the Dutch tax authorities based on the tax application for the fourth quarter of 2018. The Company is evaluating if the benefits of claiming foreign VAT are favorable compared to the related costs and expects to finalize the assessment and conclude in the course of 2019.

Prepaid expenses consist of expenses that were paid but are related to activities taking place in subsequent periods and prepaid taxes. The increase in prepaid expenses at December 31, 2018 relates primarily to advance payments made to contract research and contract manufacturing organizations in support of the Company's preclinical, clinical trial, and contract manufacturing activities.

Intercompany receivables relates to the intercompany receivable from Merus US, Inc.

#### 7. Other Liabilities and Accruals

All amounts are short-term and payable within 1 year.

	<b>Balance per December 31,</b>	
	<b>2018</b>	<b>2017</b>
	<b>(euros in thousands)</b>	
Audit fees.....	€ 167	€ 96
Personnel-related .....	477	350
Accrued bonus .....	867	842
R&D costs.....	4,409	5,272
IP legal fee .....	204	509
Subsidy advance received.....	42	224
Other accruals.....	956	537
	<u>€ 7,122</u>	<u>€ 7,830</u>

Accrued R&D costs relate to third-party contract costs for preclinical studies and clinical trial activities and related contract manufacturing expenses. The decrease in R&D costs is due to the timing of invoices received.

Accrued bonuses relate to employee bonuses for the financial year 2018, which were paid out in February 2019.

Subsidy advances received relate to active grants where the Company has received cash in excess of allowances, which is required to be repaid or recognized as grant revenue when the relevant reimbursable costs are incurred as services are performed.

#### 8. Deferred Revenue

Please refer to Note 11 to the consolidated financial statements (included in section 12.1 of this report) for further information on deferred revenue.

#### 9. Shareholders' Equity

The legal reserve as of December 31, 2018 relates to accumulated foreign exchange differences on the Company's subsidiary (December 31, 2017: €0.1 million).

It is proposed that the loss for the year ended December 31, 2018, of €24.3 million is charged to the accumulated deficit. In anticipation of the decision to be taken by the general meeting of shareholders, this proposal has already been reflected in the statement of financial position.

Please refer to Note 12 to the consolidated financial statements (included in section 12.1 of this report) for further information on equity.

## 10. Revenue

Please refer to Note 13 to the consolidated financial statements (included in section 12.1 of this report) for further information on revenue.

## 11. Total Operating Expenses

	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Manufacturing costs.....	€ 18,914	€ 13,567
IP and license costs.....	1,852	1,858
Personnel related R&D.....	5,698	5,698
Other R&D costs.....	18,733	11,951
<i>Total R&amp;D costs</i> .....	<u>45,197</u>	<u>33,074</u>
<i>Management and administration costs</i> .....	<u>7,025</u>	<u>11,165</u>
Litigation costs.....	1,425	1,039
Other operating expenses.....	17,360	12,211
<i>Total other expenses</i> .....	<u>18,785</u>	<u>13,250</u>
<b>Total operating expenses</b> .....	<u>€ 71,007</u>	<u>€ 57,489</u>

Operating expenses presented by nature are outlined below:

	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Contract manufacturing.....	€ 18,914	€ 13,567
Other external and outsourced costs.....	30,996	21,391
Employee costs and related benefits.....	13,577	17,493
Intercompany charges.....	6,884	4,721
Depreciation and amortization.....	636	317
<b>Total operating expenses</b> .....	<u>€ 71,007</u>	<u>€ 57,489</u>

Please refer to Note 14 to the consolidated financial statements (included in section 12.1 of this report) for additional disclosure on operating expenses.

## 12. Employee Benefits

Details of the employee benefits are as follows:

	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Salaries and wages.....	€ 6,728	€ 6,419
WBSO subsidy.....	(4,257)	(3,523)

Social security premiums.....	679	496
Health insurance .....	(16)	24
Pension costs.....	688	628
Share-based compensation.....	7,925	12,815
Other personnel expense.....	1,830	634
	<u>€ 13,577</u>	<u>€ 17,493</u>

Refer to Note 12 to the consolidated financial statements (included in section 12.1 of this report) for a detailed explanation on the share-based compensation expense for the Company.

### 13. Other Income (Expense)

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

	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Finance income		
Interest and related income.....	€ 1,655	€ 1,077
Net gain on foreign exchange.....	6,097	—
	7,752	1,077
Other income .....	7,095	—
Finance costs		
Interest and other expenses.....	(4)	(190)
Net loss on foreign exchange.....	—	(19,330)
Derivative financial instrument expense.....	—	(10,725)
	(4)	(30,245)
	<u>€ 14,843</u>	<u>€ (29,168)</u>

Refer to Note 16 to the consolidated financial statements (included in section 12.1 of this report) for a detailed explanation on other income and expense for the Company.

### 14. Taxation

Refer to Note 7 to the consolidated financial statements (included in section 12.1 of this report) for a detailed disclosure on the taxation.

### 15. Financial Instruments

Refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on financial risk management.

#### Credit Risk

Refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on credit risk.

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

	<u>Balance per December 31,</u>	
	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
<b>Financial Assets</b>		
Trade and unbilled receivables .....	€ 2,926	€ 2,304

Investments .....	57,698	39,448
Cash and cash equivalents .....	141,614	141,821
	<u>€ 202,238</u>	<u>€ 183,573</u>

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. Besides, since Merus 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 18 to the consolidated financial statements (included in section 12.1 of this report) for further information the Company's exposure to credit risk.

The aging of trade and unbilled receivables was as follows:

	<u>Balance per December 31,</u>	
	<u>2018</u>	<u>2017</u>
	(euros in thousands)	
Neither past due nor impaired.....	€ 2,926	€ 2,304
Past due.....	—	—
	<u>€ 2,926</u>	<u>€ 2,304</u>

There is no allowance for impairment.

### Liquidity Risk

Refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on liquidity risk.

The following are the remaining contractual maturities of financial liabilities at the reporting date. The amounts are gross and undiscounted, and include estimated interest payments and excluding the impact of netting agreements:

<b>December 31, 2018</b>						
	<u>Carrying amount</u>	<u>Total</u>	<u>&lt; 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
	(euros in thousands)					
<b>Non-derivative financial liabilities</b>						
Trade payables .....	3,807	3,807	3,807	—	—	—
Other liabilities and accruals.....	7,122	7,122	7,122	—	—	—
	<u>10,929</u>	<u>10,929</u>	<u>10,929</u>	<u>—</u>	<u>—</u>	<u>—</u>
<b>December 31, 2017</b>						
	<u>Carrying amount</u>	<u>Total</u>	<u>&lt; 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
	(euros in thousands)					
<b>Non-derivative financial liabilities</b>						
Trade payables .....	2,749	2,749	2,749	—	—	—
Other liabilities and accruals.....	7,879	7,879	7,879	—	—	—
	<u>10,628</u>	<u>10,628</u>	<u>10,628</u>	<u>—</u>	<u>—</u>	<u>—</u>

## Market Risk

Refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on market risk.

### *Foreign currency risk*

Refer to Note 18 to the consolidated financial statements (included in section 12.1 of this report) for further information the Company's exposure to foreign currency risk.

### *Exposure to interest rate risk*

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

	<u>As per December 31,</u>	
	<u>2018</u>	<u>2017</u>
<b>Carrying amount</b>	<b>(euros in thousands)</b>	
<b>Fixed-rate instruments</b>		
Investments .....	€ 57,698	€ 39,448
<b>Variable rate instruments</b>		
Cash and cash equivalents .....	€ 141,614	€ 141,821

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 18 to the consolidated financial statements (included in section 12.1 of this report) for further information on classification and measurement of financial instruments.

## 16. Board Compensation and Key Management Personnel

Refer to Note 19 to the consolidated financial statements (included in section 12.1 of this report) for further information on Board of Directors and key management personnel compensation.

The cash compensation to Non-Executive Directors disclosed in Note 19 to the consolidated financial statements (included in section 12.1 of this report) fully consists of amounts of periodically paid remuneration.

## 17. Related party disclosures

Refer to Note 20 to the consolidated financial statements (included in section 12.1 of this report) for further information on related party transactions. In addition, the Company identified a related party relationship with its subsidiary, Merus US, Inc. The Company incurred €6.9 million of expenses related to recharges by Merus US, Inc. (2017: €4.7 million), the Company's intercompany receivable as of year end is disclosed in Note 6.

## 18. Operating leases

Refer to Note 21 to the consolidated financial statements (included in section 12.1 of this report) for further information on operating leases.

## 19. 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:

Fee Category	2018	2017
Audit Fees .....	€ 945,000	€1,034,000
Audit-Related Fees .....	115,875	210,000
Tax Fees.....	—	—
All Other Fees.....	2,500	—
Total Fees.....	€1,063,375	€1,244,000

### Audit Fees

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

Audit related fees relate to assurance services related to registration statements and a specific research grant.

### Tax Fees

Tax fees consist of fees for professional services, including tax consulting and compliance. We did not incur any tax fees in 2018 or 2017.

### All Other Fees

All other fees consist of fees for accounting research tools.

## 20. Subsequent events

There are no subsequent events for Merus N.V. at the date of this report.

Utrecht, May 22, 2019

The Board of Directors:

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T. Logtenberg

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R. Greig

---

J. de Koning

---

M. Iwicki

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L. Kanavy

---

A. Mehra

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G. Perry

**13 OTHER INFORMATION**

**13.1 Independent auditor's report**





# Independent auditor's report

To: the General Meeting of Shareholders and the Audit Committee of Merus N.V.

## **Report on the audit of the financial statements 2018 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 31 December 2018, 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 31 December 2018, 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 2018 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, 2018;
- 2 the following consolidated statements for 2018: profit and 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 company statement of financial position as December 31, 2018;
- 2 the company statement of profit or loss and comprehensive loss for 2018; 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 'Wet toezicht accountantsorganisaties' (Wta, Audit firms supervision act), 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***

<b>Materiality</b>
— Materiality of EUR 900 thousand — 3.0% of result before taxation (excluding finance cost)
<b>Group audit</b>
— Full scope audit of all group entities
<b>Key audit matters</b>
— Accounting of research and development costs
<b>Opinion</b>
— Unqualified





## ***Materiality***

Based on our professional judgment we determined the materiality for the financial statements as a whole at EUR 900 thousand (2017: EUR 600 thousand). The materiality is determined with reference to result before taxation (3.0%), adjusted for finance cost. We consider 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 qualitative reasons for the users of the financial statements.

We agreed with the Audit Committee and the Board of Directors that misstatements in excess of EUR 45 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 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 audit focused on both Merus N.V. and Merus US, Inc, for which we perform 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 of 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.

## ***Consideration of fraud in the audit of financial statements***

In accordance with the Dutch Standards on Auditing we are responsible for obtaining reasonable assurance that the financial statements taken as a whole are free from material misstatement, whether caused by fraud or error. In determining the audit procedures we will make use of the evaluation of management in relation to fraud risk management (prevention, detection and response), including ethical standards to create a culture of honesty.

In our process of identifying fraud risks we assessed fraud risk factors, which we discussed with management and the audit committee. Fraud risk factors are events or conditions that indicate an incentive or pressure to commit fraud or provide an opportunity to commit fraud.

Based on the auditing standards we addressed the following presumed fraud risk that was relevant to our audit:

— fraud risk in relation to management override of controls

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 revenue and reimbursement of expenses are limited and/or non-complex.



Our audit procedures included an evaluation of the internal controls relevant to mitigate these risks and supplementary substantive audit procedures, including detailed testing of journal entries and source documentation in relation to amongst others research and development expenses and non-routine transactions.

Our audit procedures differ from a specific forensic fraud investigation, which investigation often has a more in-depth character.

### ***Consideration of laws and regulations in the audit of financial statements***

We identified laws and regulations that could reasonably be expected to have a material effect on the financial statements from our general and sector experience, through discussion with management and the Audit Committee and discussed the policies and procedures regarding compliance with laws and regulations. We communicated identified laws and regulations within our audit 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:

- the Company is subject to laws and regulations that directly affect the financial statements, such as relevant tax laws and financial reporting standards and we assessed the extent of compliance with these laws and regulations as part of our procedures on the related financial statement items; and
- the Company is subject to other, sector specific, laws and regulations where the consequences of non-compliance could have a material effect on amounts or disclosures in the financial statements, for instance if the Company's products don't 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 these laws and regulations to inquiry of the directors, those charged with governance and other management and inspection of (board) minutes and regulatory and legal correspondence, if any. These are part of our procedures on the related financial statement items.

We are not responsible for preventing non-compliance and cannot be expected to detect non-compliance with all laws and regulations.

### ***Our key audit matters***

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements. We have communicated the key audit matters 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 of research and development costs

### Description

Research and Development (R&D) costs incurred, amounting to € 46.7 million (2017: € 34.1 million) relate to research projects which is the primary business of the company in its current development phase. In 2018 research and development costs significantly increased in line with the progress of the studies and clinical trials. As a result of the size of the transactions and the increased complexity of the related arrangements, we have considered the accounting of research and development costs as key audit matter, specifically the risks related to the recognition, measurement and classification of accruals and prepayments related to R&D expenses originating from vendors that perform clinical and manufacturing services.

### Our response

Our audit procedures included test of details in order to verify the completeness, accuracy and existence of the recorded expenses and related accruals and prepayments. Among others, for specific vendors and suppliers, we have assessed the accounting of significant or complex contracts, performed specific item testing on accruals and prepayments, and performed cut-off procedures for an extended period before and after the balance sheet date. Furthermore, we have assessed and re-performed management's procedures related to the accuracy and completeness of the accruals, prepayments and related classification of expenses.

### Our observation

The results of our procedures performed on management's accounting of 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 that consists of:

- the Dutch statutory board report;
- the other information pursuant to Part 9 of Book 2 of the Dutch Civil Code;

Based on the following procedures performed, we conclude that the other information:

- is consistent with the financial statements and does not contain material misstatements;
- 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 substantially 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 Dutch statutory board report in accordance with Part 9 of Book 2 of the Dutch Civil Code and the other information pursuant to 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 2018 on July 26, 2018, 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 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 appendix of this auditor's report. This description forms part of our auditor's report.



Amstelveen, May 22, 2019

KPMG Accountants N.V.

B.S. Geerling RA

Appendix: Description of our responsibilities for the audit of the financial statements



KPMG Accountants N.V., registered with the trade register in the Netherlands under number 33263683, is a member firm of the KPMG network of independent companies affiliated with KPMG International Cooperative ("KPMG International"), a Swiss entity.



## Appendix to our auditor's report on the financial statements 2018 of Merus N.V.

We have exercised professional judgement and have maintained professional scepticism throughout the audit, in accordance with Dutch Standards on Auditing, ethical requirements and independence requirements. Our audit included among others:

- identifying and assessing the risks of material misstatement of the financial statements, whether due to fraud or error, designing and performing audit procedures responsive to those risks, and obtaining audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than the risk resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control;
- obtaining an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control;
- evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by the board of directors;
- concluding on the appropriateness of the board of directors' use of the going concern basis of accounting, and based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the board of directors' 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.

Because we are ultimately responsible for the opinion, we are also responsible for directing, supervising and performing the group audit. In this respect we have determined the nature and extent of the audit procedures to be carried out for group components. Decisive were the size and/or the risk profile of the group components or operations. On this basis, we selected group components for which an audit or review had to be carried out on the complete set of financial information or specific items.

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.





### **13.2 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.

### **13.3 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, 2018, no preferred shares in the Company's capital were issued.

### **13.4 Branches**

The Company has no branch offices.

### **13.5 Material subsequent events**

See Note 22 (*Subsequent events*) to the Consolidated Financial Statements for an overview of events which do not need to be discussed in the Company's statutory annual accounts and which might influence the Company's outlook.

