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Merus battling cancer

Merus N.V.
Annual Report
31 December 2016

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1. Directors report

1.1 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 Annual Report. We have derived the consolidated statement of profit or loss and comprehensive loss data and the statement of financial position data as of December 31, 2016, 2015, and from our audited financial statements included elsewhere in this Annual Report. Our historical results are not necessarily indicative of the results that should be expected in the future.

	Year Ended December 31,	
	2016	2015
	(euros in thousands, except share and per share data)	
Statement of Profit or Loss and Comprehensive Loss Data:		
Revenue	€ 2,719	€ 1,977
Research and development costs	(18,991)	(16,350)
Management and administration costs	(4,258)	(768)
Other expenses	(7,142)	(7,898)
Operating result	(27,672)	(23,039)
Finance income (expenses)	(19,556)	(145)
Result before tax	(47,228)	(23,184)
Other comprehensive income	8	-
Total comprehensive loss for the year	€ (47,220)	€ (23,184)
Basic (and diluted) loss per share ⁽¹⁾	€ (3.57)	€ (3.95)
Weighted average shares outstanding, basic and diluted ⁽²⁾	13,236,649	5,871,248

- (1) Basic loss per share and diluted loss per share are the same because outstanding options would be anti-dilutive due to our net losses in these periods.
- (2) Includes preferred shares issued and outstanding as of December 31, 2015.

	As of December 31,	
	2016	2015
	euros in thousands)	
Statement of Financial Position Data:		
Cash and cash equivalents	€ 56,917	€ 32,851
Total assets	72,310	35,494
Total liabilities	38,280	7,192
Accumulated loss	(107,295)	(63,382)
Total equity (deficit)	34,031	28,302

Exchange Rate Information

Our business is primarily conducted in the European Union, and we maintain our books and records in euros. We have presented our results of operations in euros. In this Annual Report, translations from euros to U.S. dollars were made at the rate of 0.9182 to \$1.00, the official exchange rate quoted as of April 25, 2017 by the European Central Bank. Such U.S. dollar amounts are not necessarily indicative of the amount of U.S. dollars that could actually have been purchased upon exchange of euros at the dates indicated.

The following table presents information on the exchange rates between the euro and the U.S. dollar for the periods indicated:

	<u>Period end</u>	<u>Average for period</u>	<u>Low</u>	<u>High</u>
	(euros per U.S. dollar)			
Year Ended December 31:				
2012.....	0.758	0.778	0.743	0.827
2013.....	0.725	0.753	0.724	0.783
2014.....	0.824	0.754	0.717	0.824
2015.....	0.917	0.901	0.826	0.954
2016.....	0.949	0.907	0.864	0.965
			<u>Low</u>	<u>High</u>
			(euros per U.S. dollar)	
Month Ended:				
October 31, 2016.....			0.8900	0.9198
November 30, 2016.....			0.9013	0.9480
December 31, 2016.....			0.9292	0.9694
January 31, 2017.....			0.9304	0.9629
February 28, 2017.....			0.9252	0.9512
March 31, 2017.....			0.9184	0.9511
April 2017 (through April 25).....			0.9182	0.9454

1.2 Risk management and control systems

In its review of our internal control over financial reporting in connection with the annual audit for 2016, our management identified the following material weaknesses:

- insufficient accounting resources required to fulfill IFRS and SEC reporting requirements, and
- insufficient comprehensive IFRS accounting policies and financial reporting procedures.

As a result, our management concluded that our disclosure controls and procedures were not effective as of December 31, 2016. We are continuing to conduct a thorough review of our accounting resources and accounting policies and financial procedures. Following this review, management will develop a remediation plan to address the material weaknesses identified by management.

1.3 Risk factors

You should carefully consider the risks and uncertainties described below and the other information in this Annual Report. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occur.

1.3.1 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 €47.0 million, and €23.2 million for the years ended December 31, 2016, and 2015 respectively. As of December 31, 2016, we had an accumulated loss of €107.3 million. Our losses have resulted principally from expenses incurred in research and development of our bispecific antibody candidates and from general and

administrative 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 the Phase 1/2 clinical trial of MCLA-128, our lead bispecific antibody candidate;
- conduct the Phase 1 clinical trial of MCLA-117, our second bispecific antibody candidate;
- continue the research and development of our other bispecific antibody candidates, including completing pre-clinical studies and commencing clinical trials for MCLA-158;
- seek to enhance our technology platform, which generates our pipeline of Biclomics, and discover and develop additional bispecific antibody candidates;
- seek regulatory approvals for any bispecific 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 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, safety issues or other regulatory challenges.

To date, we have financed our operations primarily through the initial public offering of our common shares, private placements of equity securities, upfront and milestone payments, funding from patient organizations and governmental bodies and borrowings from bank and bridge loan financings. We have devoted a significant portion of our financial resources and efforts to developing our Biclomics technology platform, identifying potential bispecific antibody candidates and conducting pre-clinical studies and initiating our clinical trials of MCLA-128 and MCLA-117. We are in the early stages of development of our bispecific antibody candidates, and we have not completed development of any Biclomics or any other drugs or biologics.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our bispecific antibody candidates, discovering and developing additional bispecific 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 U.S. Food and Drug Administration, or the FDA, or the European Medicines Agency, or 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 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 the Phase 1/2 clinical trial of MCLA-128 and the Phase 1 clinical trial of MCLA-117, and continue to research, develop and initiate clinical trials of MCLA-158 and our other bispecific 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 clinical development plans, we expect our existing cash and cash equivalents to last well into 2019. For this assessment, we have taken into consideration the proceeds from the initial public offering of our common shares, which closed in May 2016, as well as the payments we have received in 2017 under our collaboration agreement with Incyte Corporation. 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 the Phase 1/2 clinical trial of MCLA-128 and the Phase 1 clinical trial of MCLA-117;
- the success of our collaboration with Incyte Corporation, or 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 bispecific antibody candidates, including MCLA-158;
- the costs, timing and outcome of regulatory review of any of our bispecific antibody candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our bispecific 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 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, 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 under a collaboration agreement, completion of pre-clinical studies and clinical trials of, receipt of marketing approvals for, establishment of commercial manufacturing capabilities 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, 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 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 technology platform is an unproven, novel approach to the production of molecules for therapeutic intervention.

We have not, nor to our knowledge has any other company, 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 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 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 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 raw materials or products.

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 who may derive selective and meaningful benefit from the bispecific antibody candidates we are developing. In collaboration with partners, 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 medical devices and typically require separate regulatory approval prior to commercialization. We intend to develop companion diagnostics in collaboration with third parties and are dependent on the scientific insights and sustained cooperation and effort of our third-party collaborators in developing and obtaining approval for these companion diagnostics. We and our collaborators may encounter difficulties in developing and obtaining approval for the 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 the 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 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 and our other bispecific antibody candidates, building our intellectual property portfolio, developing our supply chain, planning our business, raising capital and providing general and administrative support for these operations. We commenced the Phase 1/2 clinical trial of MCLA-128, our lead bispecific antibody candidate, in February 2015, and commenced the Phase 1 clinical trial of MCLA-117, our second bispecific antibody candidate, in May 2016, but have not completed any clinical trials for any bispecific antibody candidate. We have not yet demonstrated our ability to successfully complete any Phase 1 clinical trial, 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 public equity or debt financing or other sources, 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 and we may raise additional capital through the sale of equity or convertible debt securities. In such an event, 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. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

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

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. Moreover, the terms of any financing may adversely affect the holdings or the rights of our shareholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our common shares to decline. The sale of additional equity or convertible securities would dilute all of our shareholders. The incurrence of indebtedness could result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or others at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or bispecific antibody candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

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. Almost all 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;
- 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 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.

1.3.2 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 and MCLA-117, are prolonged or delayed, we or our 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 our 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 initiated a Phase 1/2 clinical trial of MCLA-128 in February 2015 and a Phase 1 clinical trial of MCLA-117 in May 2016, and we are planning to initiate clinical trials for our 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 contract research organizations, or 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 enrolment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients and volunteers 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, as applicable, to suspend or terminate a trial if we or our collaborators 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 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 the 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 lead bispecific antibody candidate, MCLA-128, for the treatment of various solid tumors. To date, patients treated with MCLA-128 have experienced mild to moderate adverse reactions that may be related to the treatment, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. There have been two serious adverse events in the Phase 1/2 clinical trial of MCLA-128, reported as infusion-related reactions one of which was readily reversible and the other, an allergic reaction, which resulted in death in a patient with significant underlying comorbidities. Patients treated with our bispecific antibody candidates require pre-treatment with corticosteroids to mitigate potential side effects.

In May 2016, we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-117. To date, in this ongoing clinical study in patients with acute myeloid leukemia, no serious adverse events have been reported attributed to the drug. 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 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. In the Phase 1 clinical trial of MCLA-128 that we commenced in February 2015, we plan to enroll up to 200 patients with various solid tumors that are relapsed or refractory to at least one prior regimen of available standard treatment or for whom no curative therapy is available. In the Phase 1 clinical trial of MCLA-117 that

commenced in May 2016, we plan to enroll up to 50 adult patients with AML. Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

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 and delay or potentially jeopardize our ability to commence product sales and generate revenue. 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;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, the EMA or comparable foreign regulatory authorities for approval;
- 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 bispecific antibody candidates.

A key element of our strategy is to use and expand our Biclomics technology platform to build a pipeline of bispecific antibody candidates and progress these bispecific 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 bispecific 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 bispecific 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 bispecific 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 collaboration partners may engage in misconduct or other improper activities, including noncompliance with 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 collaboration partners 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.

1.3.3 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 50% 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;
- new requirements to report certain financial arrangements with physicians and certain others, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;

- 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;
- creation of the Independent Payment Advisory Board which has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and those recommendations could have the effect of law unless overruled by a supermajority vote of Congress; 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.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes 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 2025 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 will pay 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 bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain products. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our bispecific antibody candidates or additional pricing pressures.

Individual states in the United States have also become increasingly aggressive 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.

The policies of 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 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation, but it has not yet been implemented and its ultimate implementation is unclear. 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.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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, that could 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. Notably, on January 30, 2017, an executive order was issued, applicable to all executive agencies, including the FDA, that requires that for each notice of proposed rulemaking or final regulation to be issued in fiscal year 2017, the agency shall identify at least two existing regulations to be repealed, unless prohibited by law. These requirements are referred to as the "two-for-one" provisions. This Executive Order includes a budget neutrality provision that requires the total incremental cost of all new regulations in the 2017 fiscal year, including repealed regulations, to be no greater than zero, except in limited circumstances. For fiscal years 2018 and beyond, the Executive Order requires agencies to identify regulations to offset any incremental cost of a new regulation and approximate the total costs or savings associated with each new regulation or repealed regulation. In interim guidance issued by the Office of Information and Regulatory Affairs within OMB on February 2, 2017, the administration indicates that the "two-for-one" provisions may apply not only to agency regulations, but also to significant agency guidance documents. Moreover, on February 24, 2017, an Executive Order was issued requiring each agency to designate a regulatory reform officer and create a regulatory reform task force to evaluate existing regulations and make recommendations regarding their repeal, replacement, or modification. 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.

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 whistle-blower 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 Non-discrimination 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 pre-empted 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.

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, 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.

1.3.4 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, any collaborators may decide to market and sell products that compete with the bispecific antibody candidates that we have agreed to license to them, 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, 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 MCLA-117 for the treatment of AML. Even if we are able to obtain orphan designation for MCLA-117 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 for MCLA-117 for the treatment of AML, we may never 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 collaboration partners 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 collaboration partner, 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 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 law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

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, or that the FDA will not consider our bispecific antibody candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. 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.

1.3.5 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 requires 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. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

The collaboration and license agreement, or the Collaboration Agreement, with Incyte Corporation, or 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 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 collaboration partner, we may need to seek additional financing to support the research and development of any terminated products so that we may continue development activities, or we may be forced to discontinue development of terminated products, each of which could have a material adverse effect on our business.

Under the Collaboration Agreement, we are dependent upon Incyte to successfully develop and commercialize 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, in December 2016, we entered into the Collaboration Agreement with Incyte to develop and commercialize up to eleven bispecific antibody candidates. In addition, in April 2014, we entered into a strategic research and license agreement with ONO Pharmaceutical Co., Ltd., or 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.

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 collaboration partner devotes to the product development program;
- the collaboration partner may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaboration partner 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 collaboration partner'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. We have contracted with biopharmaceutical CMOs Boehringer Ingelheim for the manufacturing of MCLA-128 and MCLA-117 and CMC Biologics for the manufacturing of MCLA-158. 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 NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMP for the manufacture of our bispecific antibody candidates. If our contract manufacturers 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 no control over the ability of our contract manufacturers 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 suppliers 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 manufacturers to purchase from third-party suppliers the materials necessary to produce our bispecific antibody candidates for our 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. 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, any significant delay in the supply of a bispecific antibody candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our bispecific antibody candidates. If our manufacturers 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.

1.3.6 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 Biclomics 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 technology, including our bispecific antibody and antibody candidates, products and methods used to manufacture those antibody and antibody candidates, the methods for treating patients using those products, 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 collaboration partners 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 collaboration partners 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 collaboration partners' 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 collaboration partners to narrow the scope of the claims of our or our licensors', licensees' or collaboration partners' 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 bispecific antibody candidates, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaboration partners' 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. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

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 in order 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 required to pay us any license fees. In addition, however, 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 products 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 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 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 novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. 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 would 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 methods or products 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 technology. 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 pending patent applications held by third parties that may be construed 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 statutes, 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 gain 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, products or the use of our products.

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 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 licensors' or collaboration 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, such as if Regeneron Pharmaceuticals, Inc. is successful in an appeal of its lawsuit alleging that we are infringing its U.S. Patent No. 8,502,018.

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. For example, we are involved in litigation with Regeneron in which Regeneron has alleged that we are infringing one of its patents. The trial court has entered judgment stating that we are not infringing Regeneron's patent and that Regeneron's patent is invalid. Further, the trial court ruled and entered judgment that Regeneron's patent was procured through inequitable conduct and is unenforceable. Regeneron appealed all three decisions. On February 13, 2017, the United States Court of Appeals for the Federal Circuit held oral argument on these judgments. A decision is expected by mid-2017. The European counterpart of this patent has been reinstated with amended claims by the Technical Board of Appeal for the European Patent Office, or EPO, after an appeal by Regeneron. Regeneron also initiated a lawsuit against us in the Netherlands which has been stayed. For further descriptions of these legal proceedings, see "Business—Legal Proceedings."

Our involvement in litigation, and in any interferences, opposition 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 current and 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 use 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 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, including, but not limited to Regeneron.

We cannot assure you that we will ultimately prevail if any of this third-party intellectual property is asserted against us, or in the current U.S. or Dutch patent infringement lawsuits. Further, Regeneron has raised opposition proceedings against our patent estate in jurisdictions including Europe, Japan and Australia. The European and Japanese patent oppositions have been resolved in our favor and the outcome of the Australian opposition is expected in the first half of 2017. A notice of appeal was filed by Regeneron at the EPO to appeal the outcome of the European proceedings. Similarly, we cannot assure you that we will ultimately prevail in these opposition proceedings brought by Regeneron against our intellectual property.

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, we could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce 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 will likely 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 our applicable bispecific antibody candidate or program.

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 or trade names 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 and trade names, which we need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks 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.

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. 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 licensors' or collaboration 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 licensors or collaboration 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 licensors' or collaboration 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 evidentiary standard in USPTO proceedings compared to the evidentiary standard 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 collaboration partners or licensors, and the enforcement or defense of our issued patents.

Additionally, the U.S. Supreme Court has ruled on several patent cases, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on 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 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 and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors 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. 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 licensors or collaboration partners 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.

Our information technology systems could face serious disruptions that could adversely affect our business.

Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties to manufacture our product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

1.3.7 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 management board. For example, our founder and Chief Executive 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.

1.3.8 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 board 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 The NASDAQ Global Market, or 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 management board 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.

We estimate that our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, for the year ended December 31, 2016 was €1.8 million and will be between €1.0 million and €2.0 million per year going forward. However, 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 will be required to furnish a report by our management board on our internal control over financial reporting with our next 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 achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we need to 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 conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective 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 identified material weaknesses in our internal control over financial reporting that 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.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. However, for as long as we are an “emerging growth company,” our independent registered public accounting firm will not be required to test the effectiveness of our internal control over financial reporting in connection with an auditor attestation pursuant to Section 404. While our management will be required to assess the effectiveness of our internal controls annually, an independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. In its review of our internal control over financial reporting in connection with the annual audit for 2016, our management identified the following material weaknesses: insufficient accounting resources required to fulfill IFRS and SEC reporting requirements and the absence of comprehensive IFRS accounting policies and financial reporting procedures. As a result, our management concluded that our disclosure controls and procedures were not effective as of December 31, 2016. We are continuing to conduct a thorough review of our internal control over financial reporting. Following this review, management intends to develop a plan to address the material weaknesses identified by management. See “Item 15 Controls and Procedures.” If the material weaknesses identified by our management are not remediated, or 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, these material weaknesses, and any resulting restatements, could cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

Members of our management board, members of our supervisory board, and certain shareholders affiliated with members of our supervisory board 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, 2016, our management board, supervisory board and shareholders affiliated with members of our supervisory board, in the aggregate, owned approximately 39% 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 supervisory 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.

In addition, in the event we receive an offer from a third party to acquire us or prior to our soliciting an offer from, or negotiating terms with, any third party, with respect to a sale or license of two of our undisclosed product candidates in pre-clinical development, we must first notify one of our existing shareholders of such opportunity and negotiate in good faith with such shareholder the terms of a purchase or license agreement for such

product candidates. This obligation may have the effect of delaying or preventing a change in control of us that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for your 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 a lock-up agreement and 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 management board and supervisory board.

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 management board or supervisory board. These provisions include:

- the authorization of a class of preferred shares that may be issued to a friendly party;
- staggered four-year terms of our supervisory board members, whereby reappointment is limited to two times;
- a provision that our management board and supervisory 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 supervisory board); 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 management board that has been approved by our supervisory board.

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

We adopted an anti-takeover measure pursuant to which our management board may, subject to supervisory board approval but without shareholder approval, issue (or grant the right to acquire) cumulative preferred shares. We may issue an amount of cumulative preferred shares up to 100% of our issued capital immediately prior to the issuance of such cumulative preferred shares. In such event, the cumulative preferred shares (or right to acquire cumulative preferred shares) will be issued to a separate, special purpose foundation, which will be structured to operate independently of us. We have granted a right to acquire such number of cumulative preferred shares as we may issue to such special purpose foundation.

The cumulative 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, cumulative 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 cumulative preferred shares will have both a liquidation and dividend preference over our common shares and

will accrue cash dividends at a fixed rate. The management board may issue these cumulative 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. If the management board determines to issue the cumulative preferred shares to such a foundation, 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.

We do not expect to pay cash dividends in the foreseeable future.

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 management board, which proposal is subject to the approval of the supervisory board 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.

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 management board (if the management 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 management board and supervisory 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 management board and supervisory board are required by Dutch law to consider the interests of our company, its shareholders, its employees and other stakeholders, in all cases with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, the interests of our shareholders.

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

We are subject to the Dutch Corporate Governance Code, or the DCGC. The DCGC contains both principles and best practice provisions for management boards, supervisory boards, 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 management board and our supervisory 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. Substantially all of our assets are located outside the United States. The majority of our management board members and supervisory board members reside 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 management board or supervisory 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 Securities Exchange Act of 1934, as amended, or 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 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) a majority of our common shares must be either directly or indirectly owned 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 supervisory 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 the current taxable year and for our taxable year ended December 31, 2016. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that the U.S. Internal Revenue Service, or the IRS, will not take a contrary position. 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, 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. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined below under “Item 10.E Taxation”) holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See “Item 10.E Taxation.”

1.4 Information on the Company

1.4.1 History and Development of the Company

We were incorporated as Merus B.V. under the laws of the Netherlands on June 16, 2003 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*). Upon the initial public offering of our common shares on May 19, 2016, we converted to a Dutch public company with limited liability (*naamloze vennootschap*) and changed our name to Merus N.V. Our principal executive offices are located at Yalelaan 62, 3584 CM Utrecht, The Netherlands. Our telephone number at this address is +31 30 253 8800. Our website address is 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 National Corporate Research, Ltd., whose address is 10 E. 40th Street, 10th floor, New York, New York 10016.

In May 2016, we completed the initial public offering of our common shares, or IPO. In connection with our IPO, our common shares were listed on The NASDAQ Global Market under the symbol “MRUS.” See “Item 14.E. Use of Proceeds” for more information on our IPO.

Our principal capital expenditures for the years ended December 31, 2016, and 2015 were €0.5 million, and €0.1 million respectively. These capital expenditures primarily consisted of laboratory equipment and leasehold improvements. 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. We anticipate our capital expenditure in 2017 to be financed from the cash flows from operating activities, proceeds of our initial public offering and our collaboration with Incyte Corporation. For more information on our capital expenditures, see Note 7 to the consolidated financial statements.

1.4.2 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, are generated from our technology platform. By binding to two different targets, Biclomics can be designed to simultaneously 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. In our pre-clinical studies, our bispecific antibody candidates were effective in killing tumor cells, a result that we believe supports their potential efficacy in the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our lead bispecific antibody candidate, MCLA-128, for the treatment of HER2-expressing solid tumors, and we expect to report top-line results from this trial in the second half of 2017. In May 2016, we commenced a Phase 1 clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML. 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 colorectal cancer, and plan to submit a Clinical Trials Application, or CTA, to the European Medicines Agency, or EMA, by the end of 2017 to initiate a Phase 1/2 clinical trial in Europe. Additionally, we have several other bispecific antibody candidates in pre-clinical development that bind to combinations of immunomodulatory molecules, including PD-1 and PD-L1, both of which we believe play a significant role in treating cancer. Each of these bispecific 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 Biclomics technology platform enables rapid functional screening of large collections of Biclomics which allows us to identify lead candidates with multiple mechanisms of action. The Biclomics 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.

Our lead bispecific antibody candidate, MCLA-128, is currently in a Phase 1/2 clinical trial in Europe for the treatment of various solid tumors, including breast, gastric and ovarian cancers. We believe MCLA-128 has the potential to be a more effective treatment of HER2-expressing solid tumors than existing therapies due to its ability to inhibit cellular growth factor receptors on tumor cells and simultaneously involve immune system cells to attack tumor cells. MCLA-128 is designed to bind to and block growth factor receptors known as HER2 and HER3, as well as recruit immune killer cells, such as NK cells and macrophages. In our pre-clinical studies, MCLA-128 was more effective in inhibiting heregulin-driven tumor growth than HER2 or HER3 mAbs, as well as their combinations and a combination of currently approved HER2 mAbs. The production of heregulin, which is the ligand for HER3, has been widely shown to cause cancer cells to grow and become resistant to treatment with HER2-targeted therapies. Our Phase 1/2 clinical trial of MCLA-128 will assess its safety, tolerability and anti-tumor activity. In the dose escalation phase of the trial, the recommended dose of MCLA-128 was established. In this ongoing study, preliminary data showed that MCLA-128 is well tolerated with a very good safety profile. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies. We expect to report top-line results from the Phase 1/2 trial in the second half of 2017.

Our second bispecific antibody candidate, MCLA-117, is currently in a Phase 1 clinical trial in Europe for the treatment of AML. 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 binds 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 U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA. We expect to report top-line results from this Phase 1/2 trial in the first half of 2018. We are also currently evaluating MCLA-117 for the treatment of myelodysplastic syndrome, or MDS, in pre-clinical studies.

In addition to MCLA-128 and MCLA-117, we are developing MCLA-158, a bispecific antibody candidate that is designed to bind to cancer stem cells expressing Lgr5 and EGFR, for the potential treatment of colorectal cancer. We are conducting pre-clinical studies of MCLA-158 and plan to submit a CTA to the EMA by the end of 2017 to initiate a Phase 1/2 clinical trial in Europe. 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.

Our Strategy

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

- ***Rapidly develop our lead bispecific antibody candidate, MCLA-128, for the treatment of solid tumors.*** We are developing MCLA-128 for the treatment of patients with HER2-expressing solid tumors, including breast, colorectal, ovarian, endometrial, 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. In this ongoing study, preliminary data showed that MCLA-128 is well tolerated with a very good safety profile. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies. We submitted an IND application to the FDA for MCLA-128 in the fourth quarter of 2016 to expand the Phase 1/2 clinical trial to a site in the United States. We expect to report top-line data from this Phase 1/2 trial in the second half of 2017. If the results of the Phase 1/2 clinical trial are favorable, we intend to commence a single agent and/or combination Phase 2 clinical trial in the United States for MCLA-128. 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 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. We expect to report top-line results from this Phase 1 trial in the first half of 2018. If the results of this clinical trial are favorable, we intend to submit an IND to the FDA and initiate a Phase 2 clinical trial in the United States. 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 are also currently evaluating MCLA-117 for the treatment of MDS in pre-clinical studies.
- ***Accelerate the internal discovery and development of additional immunotherapeutic bispecific antibody candidates.*** We believe we are well positioned to expand our pipeline of Biclomics for the treatment of other forms of cancer. Our platform enables rapid functional screening of large collections of Biclomics which allows us to identify lead candidates with multiple mechanisms of action that have the potential to kill tumor cells with high potency. We are currently evaluating Biclomics that target various combinations of checkpoint inhibitory molecules, such as PD-1, PD-

immunomodulatory monoclonal antibodies and (4) CAR-T and TCR therapies. While each of these therapies varies in its mechanism of action, these therapies 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 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, 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 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

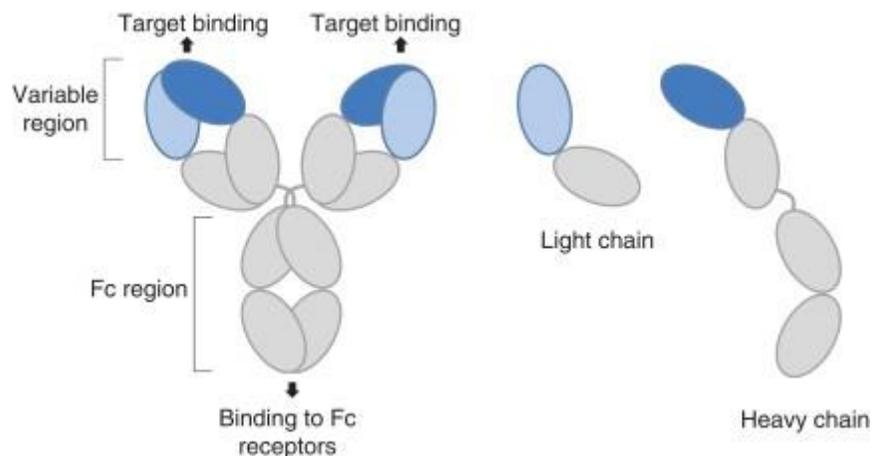
early-stage clinical trials, CAR-T and TCR therapies have been observed to have anti-tumor activity in a narrow spectrum of hematologic cancers.

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 antibody dependent cytotoxicity, or ADCC. The Fc region can be modified to enhance ADCC so as to generate a more potent immune response against a particular target.

Our Biconics Platform

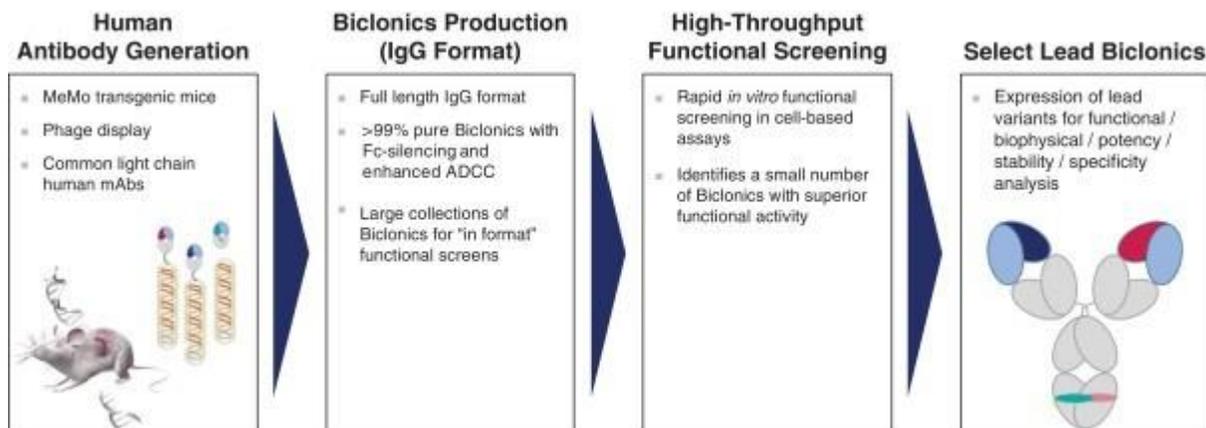
We have a pipeline of Biconics generated from our technology platform. Our platform enables the rapid identification of immunotherapeutics with the potential to produce tumor cell-killing activity, and allows for the flexible and rapid generation of Biconics against any particular target pair.

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. 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. Biclomics can be designed to prevent the blocking of T-cells by cancer cells while retaining the advantages of specific targeting in the tumor environment.
- ***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. Biclomics 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. Biclomics 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 Biclomics for clinical development takes approximately 12 months and is illustrated below. We use our human antibody generation and Biclomics production technologies to rapidly build large collections of Biclomics directed against particular target pairs. We then test these collections in cell-based functional assays to identify Biclomics that have differentiated modes of action. We select the most potent Biclomics and evaluate them in multiple in vitro and in vivo assays to identify lead candidates for clinical development.

Selection of Lead Biconics



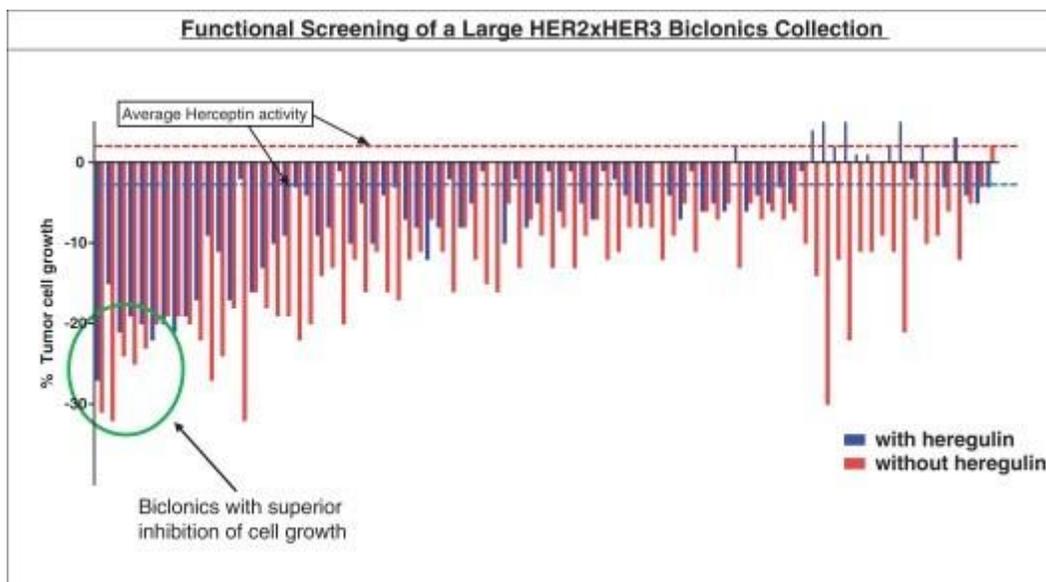
Our Biconics technology platform includes the following:

- **Human antibody generation.** Our human antibody platform is comprised of transgenic mice, which we refer to as MeMo, which are used to generate human antibodies and phage display for the generation of panels of common light chain human mAbs. MeMo harnesses the power of the *in vivo* immune system to directly yield antibodies with high potency, specificity, solubility and low immunogenicity. Using our human antibody generation 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, are ready to be inserted into the Biconics format.
- **The full-length Immunoglobulin G format.** The Biconics format retains 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. Biconics consist of two different heavy chains that need to stably form, or heterodimerize, inside a manufacturing cell line. We insert 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 all human antibodies derived from MeMo is designed to have the heavy chains pair with the correct, common light chain to 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 Biconics are bispecific heterodimeric IgG antibodies that closely mimic IgG antibodies that are produced naturally by the immune system.

The Biconics format enables 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 Biconics that are enhanced for ADCC, resulting in the improved ability to recruit NK cells and macrophages. This ADCC enhancement has been made to our lead bispecific antibody candidate, MCLA-128. In order to improve safety and tolerability, we can modify our Biconics 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 Biconics 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.** The panels of target-specific human antibodies are introduced as pairs of DNA constructs into mammalian cells. The common light chain format and modified Fc region of the IgG antibody ensure the secretion of pure Biclomics 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 identify Biclomics with differentiated modes of action.

For example, the chart below shows the results of a pre-clinical study in which 495 different Biclomics targeting HER2 and HER3 were functionally screened against tumor cell samples, with and without heregulin present. From the 80 candidates depicted in the chart, 40 exhibited superior inhibition of cell growth compared to Herceptin, 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:

- **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 greater than 99.8% 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

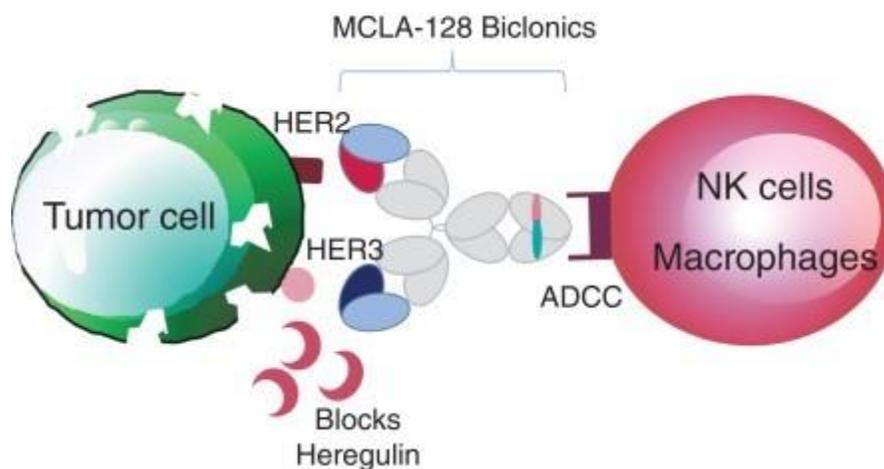
Our lead bispecific antibody candidate, MCLA-128, commenced a Phase 1/2 clinical trial in Europe for the treatment of patients with solid tumors in February 2015. Additionally, we commenced a Phase 1 clinical trial in Europe of our second bispecific antibody candidate, MCLA-117, for the treatment of patients with AML in May 2016, and we have several other bispecific antibody candidates in pre-clinical development, including MCLA-158 for which we intend to submit a CTA to the EMA by the end of 2017 to initiate a Phase 1/2 clinical trial in Europe.

MCLA-128

MCLA-128 is an ADCC-enhanced Biclomics that is designed to bind to HER2 and HER3-expressing solid tumor cells, including breast, colorectal and ovarian 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 to HER2-targeted therapies 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 Mechanism of Action



We believe that MCLA-128 has the potential to be a more effective treatment of HER2-expressing solid tumors than existing therapies due to its ability to inhibit cellular growth factor receptors on tumor cells and simultaneously recruit cells of the immune system to attack tumor cells.

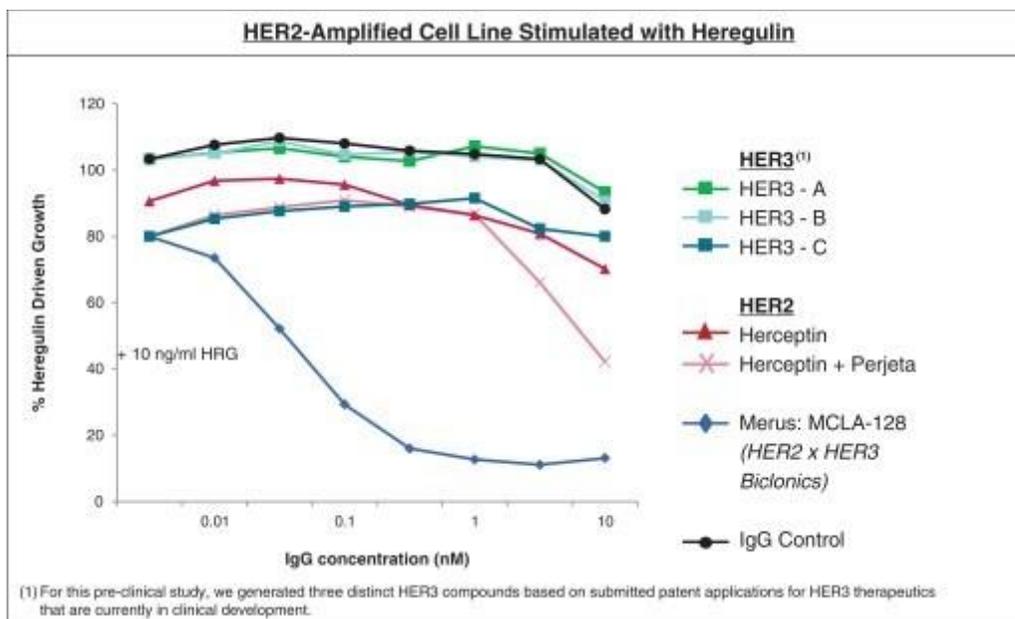
Market Overview

The National Cancer Institute estimates that 246,660 new cases of female breast cancer, 134,490 new cases of colorectal cancer, 224,390 new cases of lung cancer, 22,280 new cases of ovarian cancer, 76,960 new cases of bladder cancer and 26,370 new cases of stomach cancer were diagnosed in the United States in 2016. Based on a market survey we commissioned from Specialized Medical Services-oncology BV in 2012, we estimate that HER2 is expressed in 28% of cases of breast cancer, 34% of cases of colorectal cancer, 22% of cases of lung cancer, 25% of cases of ovarian cancer, 45% of cases of bladder cancer and 23% of cases of stomach cancer. Herceptin, Avastin, and Erbitux are drugs commonly prescribed for the treatment of these types of cancers. Worldwide sales of these drugs in 2014 were approximately \$6.8 billion, \$7.0 billion and \$1.9 billion, respectively.

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).

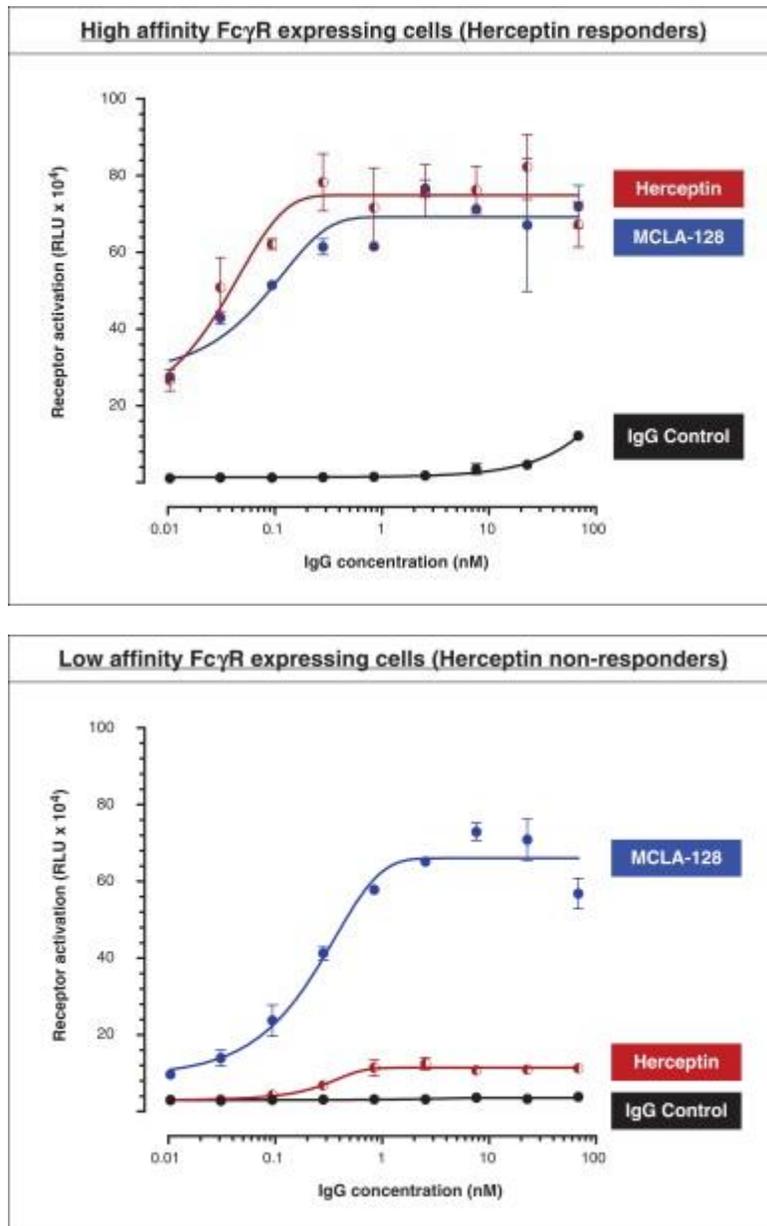
As shown in the chart below, the administration of MCLA-128 reduced heregulin-driven tumor growth at significantly lower concentrations than mAbs targeting HER2 or HER3 and the combination of Herceptin and Perjeta.



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.

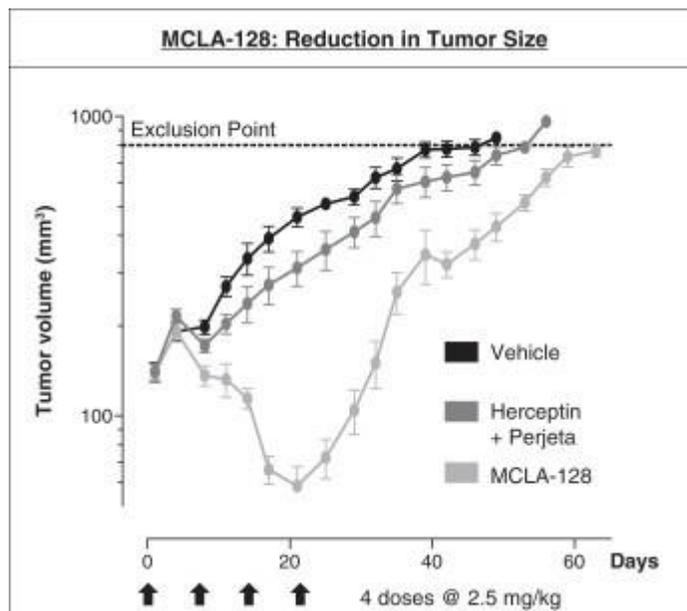
We also studied the ADCC activity of MCLA-128 in cell lines expressing different types of Fc receptors. As shown in the two charts below, because MCLA-128 is ADCC enhanced, it was able to bind and activate Fc receptors required for the recruitment of immune killer cells regardless of the receptor affinity 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)

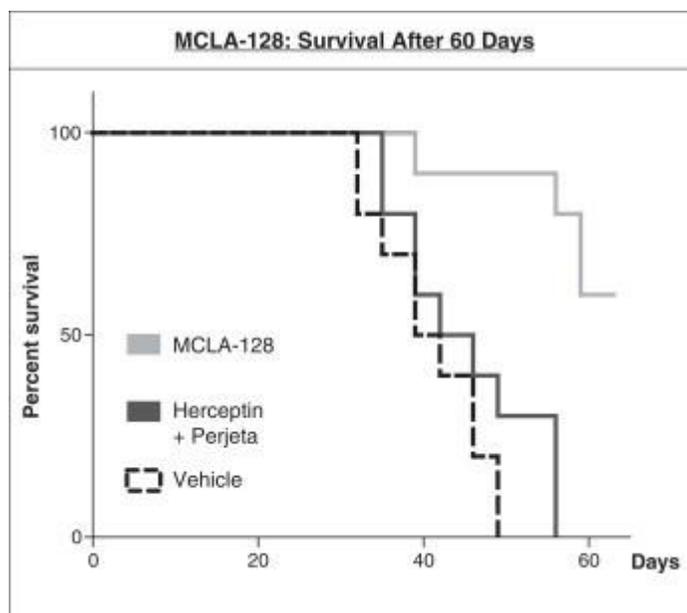


In the pre-clinical studies, we also compared the ability of MCLA-128 to inhibit the in vivo growth of cell lines such as JIMT-1, which is an aggressive breast cancer line resistant to HER2-targeted therapies. In these studies, we administered four doses of MCLA-128 at 2.5 mg/kg. The MCLA-128-treated 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 are currently being conducted to evaluate whether tumor suppression can be sustained by continuing treatment over the 60 day observation period. In addition, 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 a favorable

safety profile and early positive data of efficacy. 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. We intend to enroll up to 200 evaluable patients with breast, ovarian endometrial and non-small cell lung cancers in Part 2 of this trial, to further study the safety, tolerability and clinical efficacy of MCLA-128. The trial is designed to enroll patients with solid tumors that are relapsed or refractory to at least one prior regimen of available standard treatment or for whom no curative therapy is available. We plan to conduct the trial in at least six clinical sites.

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.

The primary endpoint of Part 1 of our clinical trial was to determine the maximum tolerated dose and/or the maximum recommended dose of MCLA-128. The secondary endpoints of Part 1 consisted of:

- the pharmacodynamic, or PD, response to MCLA-128 in tumor tissue and/or surrogate tissues;
- the PK profile, including total exposure, maximum concentration clearance, volume of distribution and half-life;
- the serum concentration of anti-drug antibodies to MCLA-128; and
- the frequency and nature of adverse events.

We also evaluated other anti-tumor parameters, such as:

- the objective response rate, or ORR, which is the proportion of patients in whom a complete response or partial response was observed;
- the clinical benefit rate, or CBR, which is the proportion of patients in whom a complete response, partial response, or stable disease was observed (where the stable disease duration is a minimum of 16 weeks/4 months) according to standard criteria;
- the duration of response, or DOR, which is the time from the initial response until documented tumor progression;
- progression free survival, or PFS, which is the time from treatment initiation to objective tumor progression or death from any cause; and
- patient survival rates.

As of March 31, 2017, we have enrolled a total of 26 patients in the trial. In this ongoing study, preliminary data has shown that MCLA-128 is well tolerated with a very good safety profile. To date, patients treated with MCLA-128 have experienced mild to moderate adverse reactions that may be related to treatment, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. There have been two serious adverse events, reported as infusion-related reactions one of which was readily reversible and the other, an allergic reaction, which resulted in death in a patient with significant underlying comorbidities. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies.

We expect to report interim safety and efficacy results from Part 2 of this trial in the first half of 2017. However, interim results of a clinical trial do not necessarily predict final results. If the results of the Phase 1/2 clinical trial are favorable, we intend to expand the current clinical trial or commence a new single agent and/or combination Phase 2 clinical trial in the United States and EU.

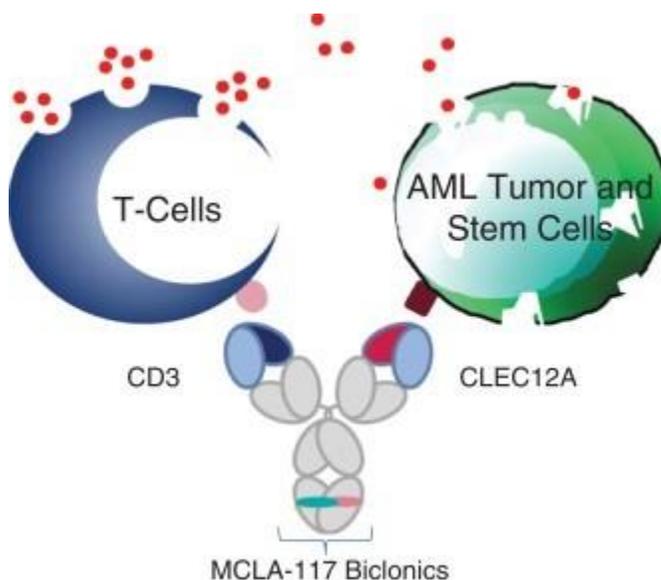
MCLA-117

MCLA-117 for AML

MCLA-117 is a Biconics 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 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



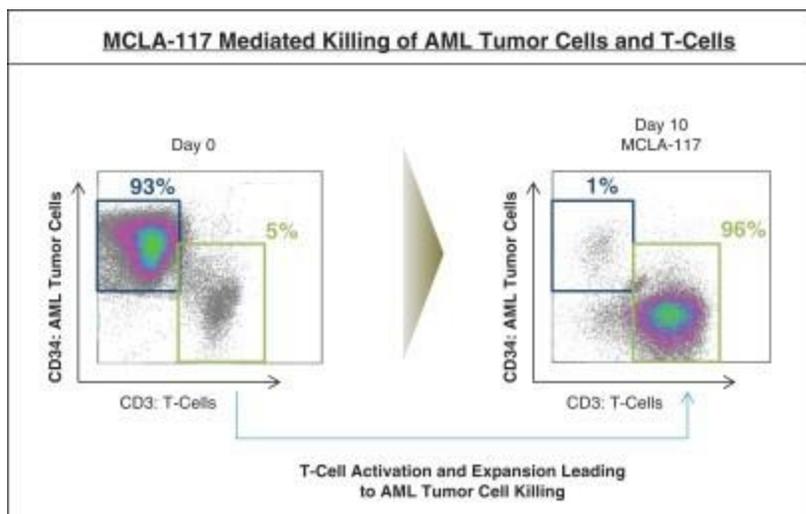
Unlike some other bispecific antibody formats, the full-length IgG format of MCLA-117 and its associated longer half-life keeps it from having to be administered through continuous infusion using infusion pumps. In addition, through Fc-silencing, MCLA-117 is designed to avoid binding to Fc receptors 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 Biclomics for CLEC12A and a relatively low affinity for CD3. In these studies, MCLA-117 recruits 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 Biclomics that does not bind to CLEC12A but retains 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 effectively 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 Biclomics 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 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. For the Phase 1 clinical trial, we plan 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. We expect to enroll approximately 50 patients in this trial, consisting of up to 31 patients in Part 1, the dose escalation phase, and up to 15 patients in Part 2, the safety dose expansion phase. 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. The secondary endpoints include:

- the assessment of the PK profile of an MCLA-117 intravenous infusion as a single agent;
- the investigation of the PD effects of MCLA-117;
- the determination of incidence and serum titer of anti-drug antibodies against MCLA-117; and
- the evaluation of the preliminary efficacy and anti-leukemic activity of MCLA-117.

We expect to report interim safety and preliminary activity results from Part 1 of this Phase 1 trial by the end of 2017. However, interim results of a clinical trial do not necessarily predict final results.

We expect to report top-line data from this Phase 1 trial in the first half of 2018. If the results of the clinical trial are favorable, we intend to submit an IND to the FDA and initiate a Phase 2 clinical trial in the United States. We believe MCLA-117 may qualify for orphan drug designation in the United States and in Europe for the treatment of AML, and we plan to seek orphan drug designation from the FDA and the EMA for the treatment of AML.

MCLA-117 for MDS

We are also currently evaluating MCLA-117 for the treatment of MDS in pre-clinical studies. 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 on 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 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 more than 500 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 EGFR-targeting mAbs, such as cetuximab, and small molecule inhibitors of the PI3K and MAPK signaling pathways in inhibiting the growth of patient-derived colorectal cancer organoids. In our cell culture 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 plan to continue to conduct pre-clinical studies on MCLA-158 and to submit a CTA to the EMA by the end of 2017 to initiate a Phase 1/2 clinical trial for MCLA-158 in Europe.

Other Bispecific Antibody Candidates

MCLA-134

MCLA-134 is a Biclomics that is designed to bind to a combination of two immunomodulatory targets expressed by T-cells, PD-1 and TIM-3. MCLA-134 is designed to activate unresponsive tumor infiltrating T-cells to kill cancer cells.

MCLA-145

MCLA-145 is a Biclomics that is designed to bind to a tumor-associated target with an immunomodulatory target involved in checkpoint inhibition. MCLA-145 is designed to simultaneously reverse immune system suppression at the tumor site while attracting immune effector cells to directly kill the targeted tumor. MCLA-145 is being developed under our collaboration with Incyte Corporation.

Pre-Clinical Discovery Programs

We intend to leverage our Biclomics technology platform to identify multiple additional bispecific antibody candidates and advance them to clinical development. Each of these bispecific 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. We are currently evaluating Biclomics that target combinations of checkpoint inhibitory molecules, such as PD-1, PD-L1 and other checkpoint inhibitors, as well as combinations of checkpoint inhibitory and co-stimulatory molecules, and combinations of molecules present on cancer stem cells. 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 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 preclinical programs, or Program 1, 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 Program 1, 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. In addition, if Program 1 fails to complete IND-enabling toxicology studies successfully, we will be granted an additional option to co-fund development of a specified program other than Program 1 in exchange for a share of profits in the United States. 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 Program 1, 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 Program 1, 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 we have no 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 bispecific antibody candidates, if approved, based on our Biclomics technology platform with 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 €34.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved three of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €1.8 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. 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.

Manufacturing

Our Biclomics technology platform relies on third parties for biological materials. We currently generate batches of lead bispecific antibody candidates in our own laboratories for initial pre-clinical studies using standardized procedures. 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 raw materials, but we have contracted biopharmaceutical CMOs Boehringer Ingelheim for the manufacturing of MCLA-128 and MCLA-117 and CMC Biologics for the manufacturing of MCLA-158. We believe that the standardized Biclomics manufacturing process can be transferred to a number of other CMOs for the production of clinical and commercial supplies of our Biclomics 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 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 sale 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 novel forms of 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, 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., OncoMed Pharmaceuticals, Inc., Genmab A/S, MacroGenics, Inc., Merrimack Pharmaceuticals, Inc., Regeneron Pharmaceuticals, Inc. and Xencor, Inc. These bispecific antibody candidates in development 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 bispecific antibody candidates that are important to the development and implementation of our business.

As of April 15, 2017, 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 MCLA-128 composition of matter and methods of using MCLA-128 to treat subjects (at risk of) having a ErbB-2 and/or ErbB3 positive tumor. In addition, 3 priority patent application filings covering further methods of using MCLA-128 to treat patients were filed on March 31, 2017.

As of April 15, 2017, 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 other foreign countries with an expected expiry not earlier than September 27, 2033. In addition, we filed a second PCT application related to MCLA-117 on July 10, 2016, which is expected to enter national phases in 2017. Claims are directed 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.

As of April 15, 2017, our patent portfolio related to our bispecific antibody candidate MCLA-158 consists of one PCT filed on October 21, 2016 and is expected to enter national phases in the United States, Europe and approximately 14 other foreign countries with an expiry no earlier than October 23, 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.

As of April 15, 2017, our patent portfolio related to our MeMo mouse consists of four pending U.S. applications, 11 issued foreign patents including one issued European patent that has been validated in many countries, and 12 pending foreign applications, all with an expected expiry not earlier than June 29, 2029. Claims are directed to a common light chain mouse and methods of producing antibodies by exposing the mouse to an antigen. Opposition against our issued Australian, European and Japanese patents have been filed by Regeneron Pharmaceuticals, Inc. The European and Japanese oppositions have been resolved in our favor, and, Regeneron has filed a notice of appeal against the decision of the European Opposition Division. The outcome of the Australian opposition is expected in the first half of 2017.

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 technology platforms and ongoing development of our bispecific 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 technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business. 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.”

We also rely on trade secret protection for our confidential and proprietary information. Although we take steps to protect our confidential and proprietary information as trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, such agreements provide that all inventions conceived by the individual while providing services to us are assigned to us.

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 investigational new drug, or IND, application, 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, 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. 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 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 and potent, or effective, for its intended use, and has an acceptable purity profile, 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 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. To date, only five biosimilars have been licensed under the BPCIA, although numerous biosimilars have been approved in Europe. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars.

Biosimilarity, which requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity, and potency, can be shown through analytical studies, animal studies, and a clinical 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.

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

The FDA has generally required companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic simultaneously 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, including the Final HIPAA Omnibus Rule published on January 25, 2013, 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 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.

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.

We expect that other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare findings, 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 bills 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 aggressive 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 created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This 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 2025 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.

Corporate Social Responsibility

We are committed to conducting our business in compliance with all applicable environmental and workplace health and safety laws and regulations. We strive to provide a safe and healthy work environment for our employees, senior management, members of the Management Board and Supervisory Board, consultants of the Company and others temporarily assigned to perform work or services for the Company and to avoid adverse impact and injury to the environment and the communities in which we conduct our business. Achieving this goal is the responsibility of the Company and all of the employees, senior management, members of the Management Board and Supervisory Board, consultants of the Company and others temporarily assigned to perform work or services for the Company jointly.

1.4.3 Organizational Structure

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

1.5 Operating and Financial Review and Prospects

1.5.1 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, are generated from our technology platform. By binding to two different antigens, or targets, Biclomics can be designed to simultaneously 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. In our pre-clinical studies, our bispecific antibody candidates were effective in killing tumor cells, a result that we believe supports their potential efficacy in the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our lead bispecific antibody candidate, MCLA-128, for the treatment of HER2-expressing solid tumors, and we expect to report top-line results from this trial in the second half of 2017. In May 2016, we commenced a Phase 1/ clinical trial of our second

bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML. We are also developing MCLA-158 for the potential treatment of colorectal cancer, and plan to submit a Clinical Trial Application to the European Medicines Agency by the end of 2017 to initiate a Phase ½ clinical trial in Europe. Additionally, we have several other bispecific antibody candidates in pre-clinical development that bind to combinations of immunomodulatory molecules.

Since our inception in June 2003, we have devoted a significant portion of our financial resources and efforts to developing our Biclomics technology platform, identifying potential bispecific antibody candidates and conducting pre-clinical studies and initiating and conducting our clinical trials of MCLA-128 and MCLA-117. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations through (i) the initial public offering of our common shares, (ii) private placements of equity securities, (iii) upfront, milestone and expense reimbursement payments received from our collaborators under our research and license agreements, (iv) funding from patient organizations and governmental bodies and (v) bank and bridge loans. Since our inception, we have raised net proceeds of \$53.3 million from the initial public offering of our common shares, gross proceeds of €171.3 million from private placements of equity securities, received aggregate gross proceeds of €125.9 million from our collaborators, received €4.2 million in grants from patient organizations and governmental bodies and received €1.5 million in proceeds from bank loan financings. As of December 31, 2016, we had cash and cash equivalents of €56.9 million.

In December 2016, we 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 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 Collaboration Agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120 million. For more on the Collaboration Agreement, see “Collaboration Agreements” below. In connection with the Collaboration 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.

In May 2016, we completed the initial public offering of our common shares 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 August 2015, we entered into a subscription agreement pursuant to which we sold an aggregate of 3,482,550 of our Class C preferred shares to new and existing investors for aggregate gross proceeds of €41.6 million and our €8.0 million existing convertible bridge loan fully converted into 667,334 Class C preferred shares in connection with the consummation of the first tranche of this private placement. In connection with the initial public offering of our common shares, all of the Class C preferred shares converted to common shares.

We are a clinical-stage company and have not generated any revenue from product sales. Our ability to generate revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our bispecific antibody candidates. Since our inception, we have incurred significant operating losses. For the years ended December 31, 2016 and 2015, we incurred net losses of €47.2 million and €23.2 million, respectively. As of December 31, 2016, we had an accumulated loss of €107.3 million.

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. In addition, we may incur expenses in connection with the in-license or acquisition of additional bispecific antibody candidates. Furthermore, we expect to continue to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

As a result, we will need 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 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 clinical development plans, we expect our existing cash and cash equivalents to last well into 2019. For this assessment, we have taken into consideration the proceeds from the initial public offering of our common shares, which closed in May 2016, as well as the payments we have received in 2017 under our collaboration agreement with Incyte Corporation.

1.5.2 Collaboration Agreements

As part of our business strategy, we intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Biclomics 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 bispecific antibody candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

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 preclinical programs, or Program 1, 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 Program 1, 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. In addition, if Program 1 fails to complete IND-enabling toxicology studies successfully, we will be granted an additional option to co-fund development of a specified program other than Program 1 in exchange for a share of profits in the United States. 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 Program 1, 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 Program 1, 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 we have no 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 Pharmaceutical Co., Ltd., or 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 €34.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved two of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €1.8 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.

1.5.3 Financial Operations Overview

Revenue

To date, our revenue has consisted principally of license revenue and collaboration revenue and revenue from several government grants, primarily with respect to research and development activities related to the use of our Biclomics technology in various indication areas. For 2016, and 2015, all of our license revenue and collaboration revenue was generated under our agreements with ONO. Our research and license agreements comprise elements of upfront license fees, milestone payments based on development and sales and royalties based on product sales. In addition, our research and license agreement contemplates our involvement in the ongoing

research and development for some of our partnered bispecific antibody candidates, for which ONO provides funding for the services rendered.

Our grant income is related to subsidies received from various institutions that support research and development organizations. The grants are obtained for specific research projects and require upfront application. We currently have three research and development grants for which a total consideration of €1.4 million was recognized.

We have no products approved for sale. Other than the sources of revenue described above, we do not expect to receive any revenue from any bispecific antibody candidates that we develop, including MCLA-128 and MCLA-117 and our pre-clinical 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.

Research and Development Costs

Research and development costs consist principally of:

- salaries for research and development staff and related expenses, including share-based compensation expenses;
- costs for production of preclinical compounds and drug substances by contract manufacturers;
- fees and other costs paid to contract research organizations, or CROs, in connection with additional preclinical testing and the performance of clinical trials;
- costs of related facilities, materials and equipment;
- 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 incur various external expenses under our research and license agreements for material and services consumed in the development of our partnered bispecific antibody candidates. Under our research and license agreements, ONO reimburses us for these external expenses and compensates us for time spent on the project by our employees. We recognize these reimbursements and compensation as revenue. External expenses that are not reimbursed are recognized as research and development expenses in the period in which they are incurred. Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. Government grants to cover research and development expenses incurred are recognized as revenue proportionally over the periods during which the related research and development expenses are incurred.

We expect our total research and development expenses in 2017 will be approximately €39.9 million and will primarily relate to the following key programs:

- *MCLA-128.* In February 2015, we commenced a Phase 1/2 clinical trial in Europe of MCLA-128 in patients with HER-2 expressing solid tumors, including breast cancer, colorectal cancer and ovarian cancer. We anticipate that our research and development expenses will increase substantially as we continue to enroll patients for the trial.
- *MCLA-117.* In May 2016, we commenced a Phase 1 clinical trial in Europe of MCLA-117 in patients with AML. We anticipate that our research and development expenses will increase substantially in connection with the commencement of this trial.

- *Other development programs.* Our other research and development expenses relate to our pre-clinical studies of our other bispecific antibody candidates, MCLA-158, MCLA-134 and MCLA-145, as well as other early research projects. These expenses primarily consist of costs for production of the pre-clinical compounds and generating clinical grade material as well as costs paid to CROs in conjunction with pre-clinical studies.

For the years ended December 31, 2016, and 2015, we spent €19.0 million, and €16.4 million respectively, on research and development costs. For the same time periods, we spent €6.7 million, and €3.2 million on MCLA-128, respectively, and €3.3 million, and €6.6 million, on MCLA-117, respectively. Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials.

Research and development expenses are expected to increase as we advance the clinical development of MCLA-128 and MCLA-117 and further advance the research and development of our pre-clinical 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 or any other bispecific antibody candidate that we may develop in the future.

Any of these variables with respect to the development of MCLA-128, MCLA-117 or any other bispecific antibody candidate that we may develop could result in a significant change in the costs and timing associated with the development of MCLA-128, MCLA-117 or such other bispecific antibody candidate. For example, if the FDA, the EMA or other regulatory authority were to require us to conduct pre-clinical 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.

Management and Administration Costs

Our management and administration costs consist principally of salaries for employees other than research and development staff, including 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. In addition, we expect to grant share-based compensation awards to key management personnel and other employees.

Other Expenses

Other expenses consist principally of:

- professional fees for auditors and other 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;
- information technology services; 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. These public company-related increases include costs of additional legal fees, accounting and audit fees, management board and supervisory board liability insurance premiums and costs related to investor relations.

Finance Income (Expenses)

Finance income consists of interest earned on our cash and cash equivalents. Finance expenses consist primarily of interest accrued on our outstanding indebtedness.

1.5.4 Results of Operations

Comparison of Years Ended December 31, 2015 and 2016

The below table summarizes our results of operations for the years ended December 31, 2015 and 2016.

	Year Ended December 31	
	2016	2015
	(euros in thousands)	
Revenue	€ 2,719	€ 1,977
Research and development costs	(18,991)	(16,350)
Management and administration costs	(4,258)	(768)
Other expenses	(7,142)	(7,898)
Operating result	(27,672)	(23,039)
Finance income (expenses)	(19,556)	(145)
Result after taxation	(47,228)	(23,184)
Other comprehensive income	8	-
Total comprehensive loss for the year	<u>€ (47,220)</u>	<u>€ (23,184)</u>

Revenue

Revenue increased €0.7 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The increase was primarily attributable to the €0.7 million increase in grant revenue, mainly related due to additional research activities performed under the FP7 grant, a research grant provided by the European Union.

Research and Development Costs

Research and development costs increased €2.6 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The increase was primarily due to the following:

- a decrease of €3.9 million related to our MCLA-117 program, due primarily to higher manufacturing costs at our CRO in 2015;
- an increase of €3.5 million in expenses in connection with various pre-clinical and discovery programs; and
- an increase of €2.1 million related to our MCLA-128 program, due primarily to lower manufacturing costs at our CRO and costs associated with pre-clinical studies.
- An increase of €0.9 million relates to additional payroll expenses in research & development due to increased staffing and additional equity compensation expense.

Management and Administration Costs

Management and administration costs increased €3.5 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The increase was primarily attributable to an increase in employee headcount and compensation-related expenses for non-research and development personnel, including an increase in share-based compensation.

Other Expenses

Other expenses decreased €0.8 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease was primarily attributable to a decrease of €2.9 million in professional fees for legal services partially offset by an increase of €2.1 million in other general expenses partially as a result of the IPO.

Finance Income/ (Expenses)

Financial expenses are mainly related to the accounting impact on the financial derivative recognized under the Incyte collaboration. As a result of the agreement an additional loss of €19.2 million was included related to the revaluation of the obligation to deliver shares to Incyte in 2017. Finance income increased €0.2 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015, due to a decrease in financial expense of €0.1 million from the repayment of a bridge loan between our Series B and Series C Preferred Shares, as well as an increase of interest income of €0.1 million due to improved cash balance.

Critical Accounting Policies and Significant Judgments and Estimates

Our operating and financial review is based on our financial statements, which we have prepared in accordance with IFRS as issued by the EU. 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. 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.

Our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this Annual Report. 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.

Research and Development

We incur research and development expenses related to our clinical and pre-clinical drug development programs. Expenditure on research activities is recognized as an expense in the period in which it is incurred.

Research and development expenses (or from the development phase of an internal project) 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.

The above criteria for capitalization of development costs have not been met and therefore, all development expenditures relating to internally generated intangible assets to date have been expensed when incurred.

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses. This process involves reviewing quotations and contracts, identifying services that have been performed on our behalf, 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 majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each statement of financial position date in our 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 and make adjustments if necessary. The significant estimates in our accrued research and development expenses are related to fees paid to CROs in connection with research and development activities for which we have not yet been invoiced. We base our expenses related to CROs on our estimates of the services received and efforts expended pursuant to quotes and contracts with CROs that conduct research and development on our behalf.

The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepayment expense accordingly.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and could result in us reporting amounts that are too high or too low in any particular period.

Share-Based Compensation

We maintain share option programs that entitle key management personnel, staff and consultants providing similar services to purchase 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.

The options granted under the share option programs 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 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. The options granted are exercisable once vested. Options will lapse on the eighth anniversary of the date of grant for options granted under the 2010 Option Plan and on the tenth anniversary of the date of grant for the options granted under the 2016 Option Plan

The option exercise price of each option is specified in the applicable notice of grant and equals either the fair market value per common share as determined at the date of grant or another price determined by our supervisory board when granting the options. Each option is exercisable at such times and subject to such terms and conditions as specified in the applicable notice of grant. We may, in the event of a change of control of our company, decide to exchange, cancel and settle in cash and/or accelerate the vesting of the outstanding options or our supervisory board may consider other appropriate steps with respect to the outstanding options.

Share-based compensation reflects the compensation expense of our share option programs granted to employees or others providing similar services, which are measured at the grant date fair value of the options. The compensation expense is spread over the vesting period in accordance with each separate vesting tranche of the options granted, taking into consideration actual and expected forfeitures at each reporting date and at the respective vesting dates. The grant date fair value share-based compensation is recognized as an expense.

Prior to the IPO, we estimated the fair value of each share option grant using the Black-Scholes option-pricing model for members of our executive management team, which includes our management board and other key personnel, or a binomial option pricing model for other participants, including supervisory board members. Service and non-market performance conditions attached to the transactions were not taken into account in measuring fair value. Following our IPO, we use a binomial option pricing model for all participants. The share based payments compensation expenses has been adjusted to reflect the use of the binomial option pricing model for all participants.

The assumptions we used to determine the fair value of share options granted are as follows, presented on a weighted average basis:

	Year ended December 31,			
	2016		2015	
	Executives	Other	Executives	Other
Expected volatility (weighted-average)	95.30%	97.15%	94.85%	94.85%
Expected life (weighted-average)	10 years	8-10 years	4 years	8 years
Expected dividends	0%	0%	0%	0%
Risk-free interest rate (based on government bonds)	1.84%-1.86%	0.10%-1.87%	0.16% -0.70%	0.16% -0.70%

These assumptions represented our best estimates, but the estimates involve inherent uncertainties and the application of our judgment.

The options outstanding at December 31, 2016 had exercise prices in the range of €1.93 to €16.85 per share. On October 5, 2015, we amended the exercise price of all options granted under the 2010 Option Plan prior to January 2015 to be €1.93 per share to reflect the relative decrease in estimated fair value for each common share. As a result, we recognized an additional share option expense that was immaterial.

Since we were a private company prior to the closing of the initial public offering of our common shares, company-specific historical and implied volatility information is not available. Expected volatility was therefore estimated based on the observed daily share price returns of publicly traded peer companies over a historic period equal to the period for which expected volatility was estimated. The group of comparable listed companies were publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and were selected taking into consideration the availability of meaningful trading data history and market capitalization. We will continue to use this group for calculation of expected volatility data until sufficient historical market data is available for estimating the volatility of our common shares.

Since the options are not transferable, the participants will tend to exercise the options prior to the maturity date. Expected early exercises have been incorporated in the option valuation by assuming that the participants will exercise the options if the share price increases to two times the exercise price at a future point in time.

Valuation of Our Common Shares

Prior to the initial public offering of our common shares, the fair value of our common shares was determined by our 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 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.

The “prior sale of company stock” method, a form of the market approach, had been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm’s length sales of our equity securities. Considerations factored into the analysis included: the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the relationship of the parties involved, the risk-free rate, the timing compared to the common shares valuation date and the financial condition and our structure at the time of the sale. As such, the value per share was benchmarked to the external transactions of our securities and external financing rounds. Throughout this period, a number of financing rounds were held, which resulted in the issuance of preferred shares. The preferred shares were transacted with numerous existing and new investors, and therefore the pricing in these financing rounds was considered a strong indication of fair value.

Given that there were multiple classes of equity, the hybrid method was applied in order to allocate equity to the various equity classes. The hybrid method is a hybrid between the probability-weighted expected return method, or PWERM, and the Option Pricing Method, or OPM, which estimates the probability weighted value across certain exit scenarios, but uses the OPM to estimate the remaining unknown potential exit scenarios. As a part of this analysis, we estimated cumulative probabilities of 65% and 35% of an initial public offering and for a sale of our company, respectively, from September 2014 onwards. Prior to this date, we estimated cumulative probabilities of 32.5% and 67.5% of an initial public offering and for a sale of our company, respectively. A discount for lack of marketability, or DLOM, was applied, corresponding to the time to exit under the various scenarios to reflect the increased risk arising from the inability to readily sell the shares. When assessing the DLOM, the Black-Scholes

option pricing model was used. Under this method, the cost of the put option, which can hedge the price change before the privately held shares can be sold, was considered as the basis to determine the DLOM.

Upon the commencement of public trading of our common shares in May 2016 in connection with the initial public offering of our common shares, estimates by our management board and our supervisory board are no longer necessary to determine the fair value of common shares.

Income Taxes

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

No tax charge or income was recognized during the reporting periods since we are in a loss-making position and have a history of losses. We have tax loss carry-forwards of €101.1 million, and €76.5 million as of December 31, 2016, 2015, respectively. As a result of Dutch income tax law, tax loss carry-forwards are subject to a time limitation of nine 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 or tax credits only to the extent the relevant fiscal unity has sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal unity. Our judgment is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” For qualifying profits, we effectively owe only 5% income tax, instead of the general tax rate of 25.0%, which results in an estimated effective tax rate of 10%. The agreement with the tax authorities was originally signed for the years 2011 to 2015 and was subsequently extended through the year 2019.

Recent Accounting Pronouncements

We refer to Note 4 to our audited financial statements for the year ended December 31, 2016 for a discussion of new standards and interpretations not yet adopted by us.

1.6 Financial Instruments

Financial Risk Management

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

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 customers and investments in debt securities. The carrying amount of financial assets represents the maximum credit exposure.

	<u>2016</u>	<u>2015</u>
Balance per December 31 in thousands of euros		
Financial asset (derivative)	11,847	-
Trade receivables	205	-
Restricted cash	167	218
Cash and cash equivalents	56,917	32,851
	<u>69,139</u>	<u>33,069</u>

At year-end, there is no significant concentration of credit risk at any of the counterparties regarding financial instruments and cash and cash equivalents. Cash balances are held at banks with credit ratings varying between A and AA.

The ageing of trade and other receivables that were not impaired was as follows:

	<u>2016</u>	<u>2015</u>
Balance per 31 December in thousands of euros		
Neither past due nor impaired	205	-
Past due	-	-
	<u>205</u>	<u>-</u>

There is no allowance for impairment.

Liquidity Risk

Prudent liquidity risk management implies maintaining sufficient funds and marketable securities.

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:

December 31, 2016	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
			(Euros in thousands)			
Non-derivative financial liabilities						
Secured bank loans	486	526	190	181	155	-
Trade and other payables	5,978	5,978	5,978	-	-	-
	<u>6,464</u>	<u>6,504</u>	<u>6,168</u>	<u>181</u>	<u>155</u>	<u>-</u>
 December 31, 2015						
	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
			(Euros in thousands)			
Non-derivative financial liabilities						
Secured bank loans	653	709	193	186	330	-
Trade and other payables	5,926	5,926	5,926	-	-	-
	<u>6,579</u>	<u>6,635</u>	<u>6,119</u>	<u>186</u>	<u>330</u>	<u>-</u>

The secured bank loans have an interest rate that is fixed until March 2017. The interest payable on the loans in the table above assumes continuation of this interest rate. These amounts may change as market interest rates change.

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 is limited and originates from foreign exchange and interest risks. Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies.

Exposure to interest rate risk

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

	Carrying amount	
	2016	2015
Balance per December 31 in thousands of euros		
Fixed-rate instruments		
Financial liabilities	(486)	(653)
Variable rate instruments		
Cash and cash equivalents	56,917	32,851

Due to the limited impact of changes in interest rates on the Company no sensitivity data is provided.

Accounting classifications and fair values

The Company classifies financial assets and financial liabilities into the loans and receivables and other financial liability categories only, with the exception of the derivative recognized as a result of the Incyte collaboration and share Subscription agreement, we refer to note 24. These financial assets and financial liabilities are not measured at fair value and as such information on the fair value hierarchy is omitted. The carrying amount of the financial assets and financial liabilities is a reasonable approximation of the fair value.

The fair value of the derivative related to the Incyte collaboration and share Subscription agreement is recorded using Level 2 inputs. For determining the fair value the Company has used as valuation technique the Bloomberg forward pricing model. In this valuation the inputs used are related to the foreign exchange component (spot prices of EUR and USD), closing stock prices of the Company, as well as discount rates to reflect the time value of money (limited).

1.7 Liquidity and Capital Resources

Sources of Funds

Since our inception in 2003, we have devoted substantially all of our resources to developing our 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. To date, we have financed our operations through the initial public offering of our common shares, private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborators under our research and license agreements, as well as funding from patient organizations, governmental bodies and bank and bridge loans. Since

our inception, we have raised net proceeds of \$53.3 million from the initial public offering of our common shares, gross proceeds of €171.3 million from private placements of equity securities, received aggregate gross proceeds of €125.9 million from our collaborators, received €4.2 million in grants from patient organizations and governmental bodies and received €1.5 million in proceeds from bank loan financings

In December 2005, we entered into a loan and security agreement with Coöperatieve Rabobank Utrechtse Heuvelrug U.A., or Rabobank, which provided for total borrowings of €1.5 million. Under the loan and security agreement, we were obligated to make monthly payments of €14,000 until November 2019, the maturity date. The loan bore interest at an annual rate equal to 3.55% until March 31, 2017 at which time the loan was repaid in full. In connection with our entry into the loan and security agreement, we also provided security to Rabobank in the form of (i) a right of pledge on the account of €500,000, in our name in a new savings account for the benefit of Rabobank, and (ii) a suretyship (borgstelling) of €1,000,000 in the framework of the Small and Medium Business Guarantee Decision (Innovative Guaranteed Credit) (Besluit Borgstelling Midden- en Kleinbedrijf (Innovatief Borgstellingskrediet)). The pledged amount decreased in relation to the outstanding balance of the loans. As of December 31, 2016, an amount of €167,000 (2015: €218,000) has been included as restricted cash on our statement of financial position in connection with this pledge. The pledge was terminated on March 31, 2017 in connection with our repayment in full of the loan.

As of December 31, 2016, we had cash and cash equivalents of €56.9 million. In December 2016, we entered into a collaboration and license agreement, or the Collaboration Agreement, and a share subscription agreement, or the Share Subscription Agreement, with Incyte Corporation, or Incyte. In January 2017, we received an upfront payment of \$120.0 million (€110.2 million) from Incyte pursuant to the Collaboration Agreement and \$80.0 million (€73.5 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).

We have no ongoing material financing commitments, such as lines of credit or guarantees that are expected to affect our liquidity over the next five years, other than leases.

Cash Flows

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

	Year Ended December 31,	
	2016	2015
	(euros in thousands)	
Net cash used in operating activities	€ (25,733)	€ (23,031)
Net cash used in investing activities	(408)	(53)
Net cash from financing activities	50,201	54,367
Net (decrease) increase in cash and cash equivalents	<u>€ 24,060</u>	<u>€ 31,283</u>

The increase in net cash used in operating activities to €25.7 million for the year ended December 31, 2016 from €22.9 million for the year ended December 31, 2015 was primarily due to higher research and development expenses and changes in working capital.

The increase in net cash used in investing activities to €0.4 million for the year ended December 31, 2016 from €0.05 million for the year ended December 31, 2015 was primarily due to an increase in investments in laboratory equipment and office equipment.

The decrease in net cash from financing activities to €50.2 million for the year ended December 31, 2016 from €54.4 million for the year ended December 31, 2015 was primarily due to the bridge loan financing between the Series B and Series C preferred shares.

Operating and Capital Expenditure Requirements

We have not achieved profitability since our inception and, as of December 31, 2016, we had an accumulated loss of €107.3 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 and MCLA-117 and 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 Phase 1/2 clinical trial of MCLA-128, our lead bispecific antibody candidate;
- conduct the Phase 1 clinical trial of MCLA-117, our second bispecific antibody candidate;
- continue the research and development of our other bispecific antibody candidates, including completing pre-clinical studies and commencing clinical trials for our third bispecific antibody candidate, MCLA-158;
- seek to enhance our technology platform, which generates our pipeline of Biclronics, and discover and develop additional bispecific 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;
- add clinical, scientific, operational, financial 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 any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Based on our current clinical development plans, we expect our existing cash and cash equivalents to last well into 2019. For this assessment, we have taken into consideration the proceeds from the initial public offering of our common shares, which closed in May 2016, as well as the payments we have received in 2017 under our collaboration agreement with Incyte Corporation. In December 2016, we entered into the Collaboration Agreement and 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 Collaboration Agreement and \$80.0 million (€73.5 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 (€187.0 million). In our opinion, our working capital is sufficient for our present requirements. 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 and our pre-clinical 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 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 bispecific 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 pre-clinical 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.

Solvency

The solvency ratio calculated as total equity divided by total of equity and liabilities amounted to 47.2% compared to 79.7% in prior year. The solvency was negatively impacted due to the derivative that was recognized in relation to the collaboration agreement with Incyte as was disclosed in Note 24 to the consolidated financial statements.

1.8 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 “Item 4.B.—Business Overview,” “Item 5.A.—Operating Results,” and “Item 5.B.—Liquidity and Capital Resources.”

1.9 Off-Balance Sheet Arrangements

During the periods presented, we did not and do not currently have any off-balance sheet arrangements.

We lease approximately 11,130 square feet of office and laboratory space in Utrecht, the Netherlands. This facility serves as our corporate headquarters and central laboratory facility. The lease for this space expires on April 22, 2021. We also plan to lease office space in Boston, Massachusetts to serve as our U.S. headquarters; however, no lease has been entered into at this time.

The table below summarizes our contractual obligations at December 31, 2016.

	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 ⁽¹⁾	€2,321	€423	€966	€932	€-
Debt obligations ⁽²⁾	€526	€190	€181	€155	€-
Total	€2,847	€613	€1,147	€1,087	€-

(1) Amounts in the table reflect payments due for our office and laboratory facility in Utrecht, Netherlands.

(2) Reflects the contractually required principal and interest payments payable pursuant to our security and loan agreement with Rabobank. On March 31, 2017, we repaid the loan in full and have no continuing obligations under the security and loan agreement.

1.10 Directors, Senior Management and Employees

The following table presents information about our management board, key employees and supervisory board, including their ages as of the date of this Annual Report:

Name	Age	Gender	Nationality	Position
<i>Management Board Members</i>				
Ton Logtenberg, Ph.D.	58	Male	Dutch	Chief Executive Officer
Shelley Margetson	46	Female	British	Chief Operating Officer
<i>Key Employees</i>				
John Crowley	43	Male	U.S	Chief Financial Officer
Hui Liu, Ph.D.	44	Male	U.S	Chief Business Officer
L. Andres Sirulnik, M.D, Ph.D..	50	Male	U.S	Chief Medical Officer
Mark Throsby, Ph.D.	50	Male	Australian	Chief Scientific Officer
<i>Supervisory Board Members</i>				
Mark Iwicki	50	Male	U.S.	Chairman of the Board
Wolfgang Berthold, Ph.D.	70	Male	German/U.S	Member
Lionel Carnot	49	Male	French/Swiss	Member
John de Koning, Ph.D.	48	Male	Dutch	Member
Anand Mehra, M.D.	41	Male	U.S.	Member
Jack Nielsen	53	Male	Danish	Member
Gregory Perry	56	Male	U.S.	Member

Unless otherwise indicated, the current business addresses for the members of our management board and supervisory board is c/o Merus N.V., Yalelaan 62, 3584 CM Utrecht, The Netherlands.

The management board positions are evenly divided between men and women. The Company is making an effort to increase the number of women on the supervisory board, and is intending to focus on female candidates for supervisory positions. The main focus will continue to be on ensuring that those persons best qualified for a position on the supervisory board, irrespective of their gender, are nominated.

Board Structure

We have a two-tier board structure consisting of a management board (*raad van bestuur*) and a separate supervisory board (*raad van commissarissen*).

Management Board

The management board is in charge of managing the company under the supervision of the supervisory board. Pursuant to our Articles of Association, the supervisory board determines the number of management board members and nominates members for shareholder approval at a general meeting of shareholders. Under our Articles of Association, such nomination is binding, but shareholders may resolve to render the nomination to be non-binding by the vote of a majority of a quorum, consisting of at least two-thirds of the votes cast representing more than half of the issued share capital. If a nomination is rendered non-binding, a new nomination shall be made each time by the supervisory board. Shareholders may suspend or remove any management board member at a general meeting. In addition, the supervisory board may at any time suspend a management board member, and such suspension can be lifted by shareholders at a general meeting.

Our Articles of Association provide that the management board shall draw up rules concerning the organization, decision-making and other internal matters of the management board. In performing their duties, the management board members are required to observe and comply with such rules.

The following is a brief summary of the business experience of the members of our management board.

Ton Logtenberg, Ph.D. has served as our Chief Executive Officer and a management board member since co-founding our company in June 2003. 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. Dr. Logtenberg holds a Ph.D. in medical biology from Utrecht University.

Shelley Margetson has served as our Chief Operating Officer since November 2016 and a management board member since June 2012. From October 2010 to November 2016, Ms. Margetson served as our Chief Financial Officer. Her responsibilities include human resources, legal and internal operations. Prior to joining Merus, from June 2006 to October 2010, Ms. Margetson served as vice president of finance of PanGenetics B.V., a therapeutic antibody development company that specializes in research of antibodies. Ms. Margetson has worked in the biotechnology industry since 2001 for companies located in the United Kingdom, France and the Netherlands. Ms. Margetson holds a B.A. in business economics from the Higher Economics School, is an Associate of the Chartered Institute of Management Accountants, and holds the Chartered Global Management Accountants designation.

Key Employees

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

John Crowley has served as our Chief Financial Officer since November 2016. His responsibilities include accounting, financial planning and analysis, tax, treasury and investor relations. From September 2013 to November 2016, he served as Corporate Senior Vice President, Corporate Controller and Chief Accounting Officer of Charles River Laboratories, Inc., a pre-clinical and clinical service provider for the pharmaceutical industry. Prior to Charles River Laboratories, he was the Vice President, Corporate Controller and Chief Accounting Officer of Ironwood Pharmaceuticals, Inc. from March 2012 to September 2013, and held senior corporate finance positions at Vertex Pharmaceuticals, Inc. from April 2010 to March 2012, and Sunovion Pharmaceuticals, Inc. from April 2008 to April 2010. Mr. Crowley holds B.S. degrees in both economics and accountancy from Babson College and is a Certified Public Accountant.

Hui Liu, Ph.D. has served as our Chief Business Officer since December 2015. His responsibilities include all aspects of business development, including in- and out- licensing, acquisitions and alliance management. Prior to joining Merus, Dr. Liu served as Vice President and Global Head, Business Development & Licensing, Oncology at Novartis AG, a pharmaceutical company, from 2013 to 2015, and as Vice President and Global Head, Business Development & Licensing, Vaccines & Diagnostics, from 2009 to 2012. Prior to Novartis, Dr. Liu held various management positions at Pfizer, Inc., a pharmaceutical company, from 2004 to 2009 and at Pfizer, Inc. and its

predecessor company Warner-Lambert from 1997 to 2001. From 2001 to 2004, Dr. Liu was an investment banker at Goldman Sachs and Citigroup. Dr. Liu holds a Ph.D. in molecular biology and an M.B.A. in finance from the University of Michigan and a B.S. in biology from Peking University.

Andres Sirulnik, M.D., Ph.D. has served as our Chief Medical Officer since October 2016. His responsibilities include clinical strategy and development. Prior to joining Merus, Dr. Sirulnik was at Novartis Pharmaceuticals from 2008 to 2016, most recently serving as Vice President – Senior Global Clinical Program Head and Research Physician in Oncology Clinical Development. From 2003 to 2008, Dr. Sirulnik was an attending physician in the leukemia program at Dana Farber Cancer Institute and Instructor in Medicine at Harvard Medical School where he focused his research and clinical work in rare hematologic malignancies. Dr. Sirulnik received his medical degree from the University of Buenos Aires, Argentina, and his Ph.D. in medicine and molecular biology at the University of Cambridge, England.

Mark Throsby, Ph.D. has served as our Chief Scientific Officer since January 2013 and previously served as our Chief Operating Officer from October 2008 to January 2013. His responsibilities include strategic scientific leadership, management of discovery, pre-clinical research and translational research, business development support, external collaborations and partnerships management. Before joining Merus, from October 2000 to October 2008, he served as a senior scientist and then as director of antibody discovery for Crucell N.V., a biotechnology company specializing in vaccines and biopharmaceutical technology. Dr. Throsby holds a Ph.D. in neuro-immunology from Monash University.

Supervisory Board

Our supervisory board supervises the management board and the general course of affairs of the company. The supervisory board gives advice to the management board and is guided by the interests of the business when performing its duties. The management board communicates regularly with the supervisory board. Members of the supervisory board are appointed by shareholders at a general meeting upon a binding nomination of the supervisory board. The nominating and corporate governance committee of the supervisory board recommends members for nomination to the supervisory board. The members of the supervisory board are not authorized to represent us in dealings with third parties.

Our supervisory board must consist of at least three members, up to a maximum of seven members. A supervisory board member must be an individual. The supervisory board determines the number of supervisory board members pursuant to our Articles of Association. The general meeting appoints our supervisory board members at general meetings of shareholders and may at any time suspend or remove any supervisory board member. The general meeting can only appoint a supervisory board member upon a binding nomination of the supervisory board. The general meeting may resolve to render the nomination to be non-binding by a majority of at least two-thirds of the votes cast representing more than half of the issued share capital. If a nomination is rendered non-binding, a new nomination shall be made each time by the supervisory board. If the nomination comprises one candidate for a vacancy, a resolution concerning the nomination will result in the appointment of the candidate, unless the nomination is rendered non-binding.

The term of appointment of our supervisory board members is up to four years. Supervisory board members may be re-appointed twice for additional terms of four years each.

Currently, certain members of our supervisory board are not independent within the means of the DCGC. These supervisory board members are Lionel Carnot, John de Koning, Anand Mehra and Jack B. Nielsen. These supervisory board members are representatives of (and/or employed by) some of our shareholders. We have the intention to increase the number of independent members on our supervisory board over time.

The supervisory board meets as often as a supervisory board member deems necessary or as often as the management board shall request. At a meeting of the supervisory board, each supervisory board member has a right to cast one vote. All resolutions by the supervisory board are adopted by an absolute majority of the votes cast. In the event the votes are equally divided, the chairman has the deciding vote. A supervisory board member may grant another supervisory board member a written proxy to represent him at the meeting, but a supervisory board member cannot represent more than one supervisory board member.

Our supervisory board can pass resolutions outside of meetings, provided that (i) the resolution is adopted in writing, (ii) all supervisory board members are familiar with the resolution to be passed and (iii) there are no objections to this decision making process.

There is no retirement age requirement for our supervisory board under our Articles of Association.

Our Articles of Association provide that our supervisory board shall draw up rules concerning the organization, decision-making and other internal matters of the supervisory board and its committees. In performing their duties, the supervisory board members are required to observe and comply with such rules.

The following is a brief summary of the business experience of our supervisory board members.

Mark Iwicki serves as Chairman of our supervisory board and has been a member of the supervisory board since June 2015. Mr. Iwicki also serves as the chief executive officer and chairman of the board of directors of Kala Pharmaceuticals, Inc. and as a member of the boards of directors of Aimmune Therapeutics, Inc., Nimbus Therapeutics, TARIS Biomedical and Oxeia Biopharmaceuticals. 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.

Wolfgang Berthold, Ph.D. has been a member of the supervisory board since September 2010. Dr. Berthold has held senior positions at Boehringer Ingelheim, GMBH, and BiogenIdec International, CH (now Biogen, Inc.), where he was responsible for various aspects of manufacturing operations, process development and facilities and engineering. He has over 30 years of experience in the industry. Since 2011, Dr. Berthold has served as president of Berthold BioPharm Consulting GmbH, Switzerland, a biotechnology consulting company. From February 2000 until March 2011, Dr. Berthold held positions of increasing seniority at BiogenIdec International, CH, including serving as its Chief Technology Officer. During that time, Dr. Berthold also served on the executive board of BiogenIdec International GMBH from February 2009 until his retirement in March 2011. Dr. Berthold holds a Ph.D. in biochemistry from the University of London.

Lionel Carnot was nominated to serve as a member of the supervisory board by Bay City Capital Coöperatief U.A., one of our shareholders, and has been a member of the supervisory board since January 2010. Mr. Carnot is a managing director at Bay City Capital LLC, a global life sciences investment firm, a position he has held since March 2005. Mr. Carnot currently serves on the boards of directors of Tallikut Pharmaceuticals and Interleukin Genetics, Inc. Mr. Carnot holds an M.B.A. with distinction from INSEAD and an M.S. with honors in molecular biology from the University of Geneva.

John de Koning, Ph.D. was nominated to serve on the supervisory board by Coöperatief LSP IV U.A., one of our shareholders, and has been a member of the supervisory board since January 2010. Dr. de Koning has been a partner at Life Sciences Partners since January 2006. Dr. de Koning currently serves on the boards of several private companies. Previously, he served on the supervisory boards of BMEYE (acquired by Edwards Lifesciences), Prosenza (acquired by BioMarin) and Skyline Diagnostics, and as a non-executive director on the boards of arGEN-X, Pronota (now 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 the supervisory board by Sofinnova Venture Partners IX, L.P., one of our shareholders, and has been a member of the supervisory board since August 2015. Dr. Mehra has been with 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 Vicept 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., Aclaris Therapeutics, Inc. and Marinus Pharmaceuticals 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.

Jack B. Nielsen was nominated to serve on the supervisory board by Novo A/S, one of our shareholders, and has been a member of the supervisory board since August 2015. Mr. Nielsen has worked within Novo A/S and its venture activities since 2001 in several roles. Novo A/S is a Denmark limited liability company that manages investments and financial assets. Since January 2016, Mr. Nielsen has been employed by Novo A/S as a senior partner. From 2012 through 2015, he was employed as a partner at Novo A/S, and from 2006 to 2012, Mr. Nielsen was employed as a partner by, and helped establish, Novo Ventures (US) Inc., which provides certain consultancy services to Novo A/S. Mr. Nielsen previously served as a member of the board of directors of Akebia Therapeutics, Inc. from 2013 to June 2015. He currently serves on the board of directors of a number of private companies in the biopharmaceutical and biotechnology industries. Mr. Nielsen holds an M.Sc. in chemical engineering and an M.S. in management of technology from the Technical University of Denmark.

Gregory Perry has been a member of the supervisory board since May 2016. Mr. Perry has been the Chief Financial and Administrative Officer of Aegerion Pharmaceuticals, Inc., a biopharmaceutical company, since July 2015. Prior to joining Aegerion Pharmaceuticals, Mr. Perry served as Chief Financial and Business Officer of Eleven Biotherapeutics, Inc., a biopharmaceutical company, from December 2013 to July 2015, as interim Chief Financial Officer of InVivo Therapeutics Holding Corp., a biotechnology company, from September 2013 to December 2013, and as Chief Financial Officer of ImmunoGen, Inc., a biopharmaceutical company, from January 2009 to September 2013. Mr. Perry served as a director of Ocata Therapeutics, Inc. from December 2011 to February 2016, when it was acquired by Astellas Pharma Inc. Mr. Perry holds a B.A. in economics and political science from Amherst College.

Family Relationships

There are no family relationships among any of the members of our supervisory board, members of our management board and our key employees.

Compensation of Management Board Members

The following table sets forth the approximate remuneration paid during our 2016 fiscal year to our management board members.

Name and Principal Position	Salary	Option Awards⁽¹⁾	Non-Equity Incentive Plan Compensation	All Other Compensation⁽²⁾	Total
Ton Logtenberg, Ph.D. Chief Executive Officer	€ 369,204	€907,236	€ 147,680	€ 17,717	€ 1,441,837
Shelley Margetson..... Chief Operating Officer	€ 198,987	€164,547	€ 84,000	€ 6,152	€ 453,686

- (1) Amount shown represents the aggregate option cost recognized in the consolidated statement of profit or loss. For a description of the assumptions used in valuing these awards, see note 14 to our financial statements included elsewhere in this Annual Report. During 2016, no options to purchase common shares were granted to our management board members.
- (2) Amount shown represents pension contributions made by us.

Remuneration Policy of Management Board Members

In connection with our initial public offering, the shareholders adopted our policy concerning the compensation of the management board members in accordance with the relevant statutory requirements of Dutch law. Pursuant to this policy, the compensation of the management board members is determined by the supervisory board, with assistance from the compensation committee, pursuant to our Articles of Association and Dutch law.

The remuneration policy for the management board members provides the supervisory board with a framework within which the supervisory board determines the remuneration of the management board members,

which consists of base compensation, short-term incentive compensation, long-term equity incentive compensation under our 2016 Incentive Award Plan, or the 2016 Plan, and pension benefits, each as further described below.

Base Compensation

We pay our management board members a base salary to compensate them for the satisfactory performance of services rendered to our company. Base salary is intended to provide a fixed component of compensation reflecting the executive's level of responsibility and performance. Our management board members' base salaries for 2016 are set forth in the table above entitled "Compensation of Management Board Members."

Short-Term Incentive Plan

We maintain a short-term incentive plan pursuant to which we may grant our employees, including our management board members, incentive cash bonuses based upon corporate and/or individual performance. The remuneration policy for the management board members currently provides that the annual cash bonuses will be based upon the achievement of set financial targets, non-financial and personal goals and company milestones for the period. Achievement of the targets are measured following year-end and the actual bonus amounts are determined by the supervisory board.

The corporate objectives set for 2016 pursuant to our short-term incentive plan accounted for 60% of the management board members' bonus opportunity and were generally related to clinical developments, intellectual property, business developments and funding initiatives. Individual objectives are established annually for each management board member and, in 2016, accounted for 40% of the management board members' bonus opportunity. The actual bonus amounts paid to our management board members for 2016 are set forth in the table above entitled "Compensation of Management Board Members".

Long-Term Incentive Plans

2010 Option Plan

In 2010, we established the Merus B.V. 2010 Employee Option Plan, or the 2010 Option Plan, under which certain participants (key management personnel, including our management board members and key employees, supervisory board members, staff and consultants) were granted the right to acquire (non-voting) depositary receipts, or Depositary Receipts, issued in respect of our common shares and/or cash settled instruments the value of which was linked to our common shares. Under these programs, holders of vested options were entitled to purchase Depositary Receipts for shares at the exercise price determined at the date of grant.

Upon the exercise or award or vesting of a non-cash settled award under the 2010 Option Plan, common shares were issued to the Foundation. The purpose of the Foundation was to facilitate administration of share-based compensation awards and pool the voting interests of the underlying shares. The Foundation thereupon granted a Depositary Receipt for each issued common share to the person entitled to such common share under an award. The Depositary Receipt holder was entitled to any dividends or other distributions paid on the shares for which the Depositary Receipts were granted. The voting rights attached to the shares were exercised by the Foundation at its own discretion. The Depositary Receipt holders did not have meeting rights: they were not entitled to attend a general meeting of shareholders or to cast a vote.

In connection with our initial public offering, we transferred the common shares held by the Foundation to the relevant depositary holders and cancelled the corresponding Depositary Receipts. The Foundation was then dissolved and deregistered. Furthermore, we amended the 2010 Option Plan to reflect that an option entails the right of the holder to purchase common shares rather than Depositary Receipts.

The options granted under the 2010 Option Plan vest in installments over a four-year period from the grant date. 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting

commencement date. The options granted are exercisable once vested. Options will lapse on the eighth anniversary of the date of grant.

Following our initial public offering, we no longer make grants under the 2010 Option Plan. However, the 2010 Option Plan continues to govern the terms and conditions of the outstanding awards granted under it.

2016 Incentive Award Plan

In connection with our initial public offering, we adopted and our shareholders approved the 2016 Plan under which we may grant cash and equity-based incentive awards to eligible service providers, including our management board members, in order to attract, retain and motivate the persons who make important contributions to our company.

The material terms of the 2016 Plan are summarized below.

Eligibility and Administration

Our employees, consultants, management board members and supervisory board members, and employees and consultants of our subsidiaries, if any, are eligible to receive awards under the 2016 Plan. The 2016 Plan is administered by our supervisory board with respect to members of the management board and by our management board with respect to any other service providers who are not members of the supervisory board, each of which may delegate its duties and responsibilities to one or more committees of our supervisory board, management board and/or officers (referred to collectively as the plan administrator below), subject to the limitations imposed under the 2016 Plan, our Articles of Association and applicable laws. The plan administrator has the authority to take all actions and make all determinations under the 2016 Plan, to interpret the 2016 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2016 Plan as it deems advisable. The plan administrator also has the authority to determine which eligible service providers receive awards, grant awards and set the terms and conditions of all awards under the 2016 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2016 Plan. Notwithstanding the foregoing, all actions taken by the management board under the 2016 Plan shall be subject to the conditions and limitations set forth in the management board rules of procedures.

Shares Available for Awards

An aggregate of 1,277,778 common shares were initially available for issuance under the 2016 Plan. The number of shares initially available for issuance is increased by an annual increase on January 1 of each calendar year beginning in 2017 and ending in and including 2026, equal to the least of (A) 4% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (B) a smaller number of shares determined by our supervisory board. No more than 1,277,778 common shares may be issued under the 2016 Plan upon the exercise of incentive stock options. Shares issued under the 2016 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares.

If an award under the 2016 Plan expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, canceled without having been fully exercised or forfeited, any unused shares subject to the award will again be available for new grants under the 2016 Plan. Awards granted under the 2016 Plan in substitution for any options or other stock or stock-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the shares available for grant under the 2016 Plan, but will count against the maximum number of shares that may be issued upon the exercise of incentive stock options.

Awards

The 2016 Plan provides for the grant of stock options, including incentive stock options, or ISOs, and nonqualified stock options, or NSOs, stock appreciation rights, or SARs, restricted stock, dividend equivalents, restricted stock units, or RSUs, and other stock or cash based awards. Certain awards under the 2016 Plan may constitute or provide for payment of "nonqualified deferred compensation" under Section 409A of the Internal

Revenue Code of 1986, as amended. All awards under the 2016 Plan will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of each award type follows.

- *Stock Options and SARs.* Stock options provide for the purchase of common shares in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Internal Revenue Code are satisfied. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The plan administrator will determine the number of shares covered by each option and SAR, the exercise price of each option and SAR and the conditions and limitations applicable to the exercise of each option and SAR. Unless otherwise determined by the plan administrator, the exercise price of a stock option or SAR will not be less than 100% of the fair market value of the underlying share on the grant date (or 110% in the case of ISOs granted to certain significant shareholders), except with respect to certain substitute awards granted in connection with a corporate transaction. The term of a stock option or SAR may not be longer than ten years (or five years in the case of ISOs granted to certain significant shareholders).
- *Restricted Stock and RSUs.* Restricted stock is an award of nontransferable common shares that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs are contractual promises to deliver common shares in the future, which may also remain forfeitable unless and until specified conditions are met and may be accompanied by the right to receive the equivalent value of dividends paid on common shares prior to the delivery of the underlying shares. The plan administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted stock and RSUs will be determined by the plan administrator, subject to the conditions and limitations contained in the 2016 Plan.
- *Other Stock or Cash Based Awards.* Other stock or cash based awards are awards of cash, fully vested common shares and other awards valued wholly or partially by referring to, or otherwise based on, common shares or other property. Other stock or cash based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The plan administrator will determine the terms and conditions of other stock or cash based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance Criteria

The plan administrator may select performance criteria for an award to establish performance goals for a performance period. Performance criteria under the 2016 Plan may include, but are not limited to, the following: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including but not limited to gross profits, net profits, profit growth, net operation profit or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on shareholders' equity; total shareholder return; return on sales; costs, reductions in costs and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human resources management; supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including

those measuring liquidity, activity, profitability or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to the company's performance or the performance of a subsidiary, division, business segment or business unit of the company or a subsidiary, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies. When determining performance goals, the plan administrator may provide for exclusion of the impact of an event or occurrence which the plan administrator determines should appropriately be excluded, including, without limitation, non-recurring charges or events, acquisitions or divestitures, changes in the corporate or capital structure, events unrelated to the business or outside of the control of management, foreign exchange considerations, and legal, regulatory, tax or accounting changes.

Certain Transactions

In connection with any spin-off, change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2016 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2016 Plan and replacing or terminating awards under the 2016 Plan. In addition, in the event of certain non-reciprocal transactions with our shareholders, the plan administrator will make equitable adjustments to the 2016 Plan and outstanding awards as it deems appropriate to reflect the transaction.

Plan Amendment and Termination

The plan administrator may amend or terminate the 2016 Plan at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2016 Plan, may materially and adversely affect an award outstanding under the 2016 Plan without the consent of the affected participant and shareholder approval will be obtained for any amendment to the extent necessary to comply with our Articles of Association or applicable laws. Further, the plan administrator cannot, without the approval of our shareholders, amend any outstanding stock option or SAR to reduce its price per share or cancel any outstanding stock option or SAR in exchange for cash or another award under the 2016 Plan with an exercise price per share that is less than the exercise price per share of the original stock option or SAR. The 2016 Plan will remain in effect until the tenth anniversary of the date our shareholders approved the 2016 Plan, unless earlier terminated by the plan administrator. No awards may be granted under the 2016 Plan after its termination.

Foreign Participants, Claw-Back Provisions, Transferability and Participant Payments

The plan administrator may modify awards granted to participants who are employed outside the Netherlands or establish subplans or procedures to address differences in laws, rules, regulations or customs of such foreign jurisdictions. All awards will be subject to any company claw-back policy as set forth in such claw-back policy or the applicable award agreement. Except as the plan administrator may determine or provide in an award agreement, awards under the 2016 Plan are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the plan administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2016 Plan, and exercise price obligations arising in connection with the exercise of stock options under the 2016 Plan, the plan administrator may, in its discretion, accept cash, wire transfer or check, common shares that meet specified conditions, a promissory note, a "market sell order," such other consideration as the plan administrator deems suitable or any combination of the foregoing.

Board Practices.

Conflict of interest procedures are incorporated in the management board's and supervisory board's rules of procedure. There have been no transactions during 2016, and there are currently no transactions, between Merus

N.V. or any of its subsidiaries, and any other significant shareholder, and any supervisory board member or any relative or spouse thereof other than ordinary course compensation arrangements.

Our supervisory board is comprised of seven members and in accordance with the composition profile as adopted by the supervisory board. Each supervisory board member is elected for a term of up to four years. A supervisory board member may be re-appointed for up to two subsequent terms. Supervisory board members must retire periodically in accordance with a rotation plan. Our supervisory board members do not have a retirement age requirement under our Articles of Association. Our supervisory 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 supervisory board and the period each member has served in that term are as follows:

<u>Name</u>	<u>Year Current Term Began</u>	<u>Year Current Term Expires</u>
Mark Iwicki	2015	2020
Wolfgang Berthold, Ph.D.	2010	2017
Lionel Carnot	2010	2018
John de Koning, Ph.D.	2010	2017
Anand Mehra, M.D.	2015	2019
Jack Nielsen	2015	2018
Gregory Perry	2016	2020

There are no arrangements or understanding between us and any of the members of our supervisory board providing for benefits upon termination of their service.

During 2016 the supervisory board extensively discussed the following key topics:

- (Pre)clinical research updates
- Business development objectives and strategy
- Initial Public Offering
- Litigation procedures

In addition meetings were held to discuss:

- Budget process and budget
- Quarterly results and press releases

In 2016, the supervisory board at least once discussed the company's strategy, the main risks related to the company's business, the management board's evaluation of the risk management and control system and possible significant changes thereto.

During 2016, we performed extensive risk assessment procedures, which will be presented to and discussed with the supervisory board in 2017.

In 2016 the supervisory board had 4 meetings. The meetings were very well attended (92%) by the supervisory board members.

Activities of and evaluation by the supervisory directors

The supervisory board performs evaluations related to the functioning of the supervisory board, its committees, the individual members and the chairpersons of the supervisory board and the committees, as well as the functioning of the management board and its individual members. The composition of both boards, and the desired profile, composition and competence were also evaluated. The supervisory board has embedded this evaluation process in its ordinary course of business.

Committees of the Supervisory Board

The supervisory board has established an Audit Committee, Compensation Committee, and Nominating and Corporate Governance Committee, which operate pursuant to written charters adopted by our supervisory board.

Audit Committee

The audit committee, which consists of Gregory Perry, Lionel Carnot and John de Koning, assists the supervisory board 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 full supervisory board on at least an annual basis;
- reviewing and discussing with the management board, the supervisory 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 reviewed the need of an internal audit function. Due to the size of the Company, it was concluded that there is currently no need to appoint an internal auditor.

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 board being present.

Compensation Committee

The compensation committee, which consists of Mark Iwicki, Jack Nielsen and Anand Mehra, assists the supervisory board in determining management board compensation. Mr. Nielsen serves as Chairman of the committee. The compensation committee prepares a proposal for the supervisory board concerning the compensation of each of our management board members 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 board compensation;
- evaluating each management board member's performance in light of such policies and reporting to the supervisory board;
- analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of the management board members;

- recommending any equity long-term incentive component of each management board member's compensation in line with the remuneration policy and reviewing our management board compensation and benefits policies generally; and
- reviewing and assessing risks arising from our compensation policies and practices.

Nominating and Corporate Governance Committee

The nominating and corporate governance committee, which consists of Mark Iwicki, Anand Mehra and John de Koning, assists our supervisory board in identifying individuals qualified to become members of our supervisory board and management board consistent with criteria established by our supervisory board and in developing our corporate governance principles. Dr. Mehra serves as Chairman of the nominating and corporate governance committee.

The nominating and corporate governance committee's responsibilities include:

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

1.11 Employees

As of December 31, 2016, we had 51 employees, 20 of whom hold M.D. or Ph.D. degrees. Forty-three of our employees work in research and development and eight work in management and administrative areas. All of our employees are located in the Netherlands except for three 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 are in the process of establishing a workers' council for our employees.

Major Shareholders

The following table sets forth information relating to the beneficial ownership of our common shares as of April 15, 2017 by:

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

The number of common shares beneficially owned by each entity, person, management board member or supervisory board member is determined in accordance with the rules of the 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 April 15, 2017 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 April 15, 2017 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 April 15, 2017, we had 19,391,513 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
5% or Greater Shareholders		
Incyte Corporation ⁽¹⁾	3,200,000	16.5%
Novartis Bioventures Ltd. ⁽²⁾	2,181,320	11.2%
Bay City Capital Coöperatief U.A. ⁽³⁾	2,101,320	10.8%
Aglaia Oncology Fund B.V./Aglaia Oncology Seed Fund B.V. ⁽⁴⁾	1,109,145	5.7%
Johnson & Johnson Innovation - JJDC, Inc. ⁽⁵⁾	1,195,943	6.2%
Pfizer, Inc. ⁽⁶⁾	1,142,548	5.9%
Sofinnova Venture Partners IX, L.P. ⁽⁷⁾	1,401,403	7.2%
Novo A/S ⁽⁸⁾	1,410,417	7.3%
Baker Brothers Life Sciences L.P. ⁽⁹⁾	1,160,014	6.0%
Coöperatief LSP IV U.A. ⁽¹⁰⁾	1,225,661	6.3%
Management Board Members and Supervisory Board Members		
Ton Logtenberg, Ph.D. ⁽¹¹⁾	288,180	1.5%
Shelley Margetson ⁽¹²⁾	37,329	*
Mark Iwicki ⁽¹³⁾	35,385	*
Wolfgang Berthold, Ph.D. ⁽¹⁴⁾	17,650	*
Lionel Carnot ^{(3), (15)}	2,105,884	10.9%
John de Koning, Ph.D. ⁽¹⁵⁾	4,564	*
Anand Mehra, M.D. ^{(7), (15)}	1,405,967	7.2%
Jack Nielsen.....	-	*
Gregory Perry ⁽¹⁵⁾	4,564	*

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

- (1) Consists of 3,200,000 common shares held directly by Incyte Corporation (“Incyte”). As of April 2017, the board of directors of Incyte is comprised of the following individuals: Hervé Hoppenot, Julian C. Baker, Jean-Jacques Bienaimé, Paul A. Brooke, Paul J. Clancy, Wendy Dixon, PhD and Paul A. Friedman MD. Incyte is a publicly-traded company. Beneficial ownership information is based on a Schedule 13G filed with the SEC on January 23, 2017. Incyte’s address is 1801 Augustine Cut-Off, Wilmington, DE 19803.
- (2) Consists of 2,181,320 common shares held directly by Novartis Bioventures Ltd. (“Novartis”). Novartis AG is the indirect parent of Novartis and may be deemed to share beneficial ownership of these securities. The board of directors of Novartis is comprised of Simon Zivi, Michael Jones and Timothy Faries. Beneficial ownership information is based on a Schedule 13G filed with the SEC on June 3, 2016. Novartis’ mailing address is 131 Front Street, Hamilton, Bermuda HM12.
- (3) Consists of 2,101,320 common shares held directly by Bay City Capital Coöperatief U.A. (“COOP”). Bay City Capital Fund V, L.P. (“Fund V”) and 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. Bay City Capital LLC (“BCC LLC”, and together with COOP, Fund V, Fund V-SBS, and BCCM V, “Bay City Capital”) is the adviser and manager of BCCM V. Because COOP requires two members, BCCM V and BCC LLC represent Fund V and Fund V-SBS, respectively, as members of COOP. Thus, BCCM V and BCC LLC share voting and investment power over the shares held by COOP. Lionel Carnot, a member of our supervisory board, is a member of BCCM V and is employed as a managing director of BCC LLC 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 May 27, 2016. Bay City Capital’s mailing address is De Boelelaan 7, 1083 HJ Amsterdam, Netherlands.
- (4) Consists of (a) 711,854 common shares held directly by Aglaia Oncology Fund B.V. (“AOF”) and (b) 397,291 common shares held directly by Aglaia Oncology Seed Fund B.V. (“AOSF”). AOSF is a wholly owned subsidiary of AOF. Aglaia BioMedical Ventures B.V. (“ABV”) is the sole director of AOF and AOSF. The managing directors of ABV are Mark Krul and Karl Rothweiler. ABV, Mark Krul and Karl Rothweiler may be deemed to beneficially own the shares held directly by AOF and AOSF. Beneficial ownership information is based on a Schedule 13G filed with the SEC on February 10, 2017. The address for each of these entities is Professor Bronkhorstlaan 10, Building 92, 3723 MB Bilthoven, Netherlands.
 - (5) Consists of 1,195,943 common shares held directly by Johnson & Johnson Innovation - JJDC, Inc. (“JJDC”). JJDC is a wholly-owned subsidiary of Johnson & Johnson (“J&J”). JJDC and J&J have shared voting and dispositive power over the shares and J&J may be deemed to indirectly beneficially own the shares. Beneficial ownership information is based on a Schedule 13G filed with the SEC on January 18, 2017. The address of JJDC is One Johnson & Johnson Plaza, New Brunswick, NJ 08933.
 - (6) Consists of 1,142,548 common shares held directly by Pfizer Inc. (“Pfizer”). As of April 2017, the board of directors of Pfizer is comprised of the following individuals: Dennis A. Ausiello, Ronald E. Blacklock, W. Don Cornwell, Joseph J. Echevarria, Frances D. Fergusson, Helen H. Hobbs, James M. Kilts, Shantanu Narayan, Suzanne Nora Johnson, Ian C. Read, Stephen W. Sanger and James C. Smith. Pfizer is a publicly-traded company. Beneficial ownership information is based on a Schedule 13G filed with the SEC on June 6, 2016. Pfizer’s address is 235 East 42nd Street, New York, NY 10017.
 - (7) Consists of 1,401,403 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 supervisory 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 a Schedule 13D filed with the SEC on May 27, 2016. The address for Sofinnova VP and Sofinnova Management is 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, California 94025.
 - (8) Consists of 1,410,417 common shares held directly by Novo A/S, a Danish limited liability company wholly owned by the Novo Nordisk Foundation. Novo A/S, through its Board of Directors (the “Novo Board”), has the sole power to vote and dispose of the shares owned by Novo A/S. The Novo Board, which is comprised of Sten Scheibye, Göran Ando, Jeppe Christiansen, Steen Riisgaard and Per Wold-Olsen, may exercise voting and dispositive control over the shares only with the support of a majority of the Novo Board. As such, no individual member of the Novo Board is deemed to hold any beneficial ownership or reportable pecuniary interest in the Novo shares. Beneficial ownership information is based on a Schedule 13D filed with the SEC on March 3, 2017. The address of Novo A/S is Tuborg Havnevej 19, 2900 Hellerup, Denmark.
 - (9) 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.
 - (10) 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 supervisory 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.

- (11) Consists of (a) 160,814 common shares held by BioPhrase, B.V. ("BioPhrase"), Dr. Logtenberg's personal holding company, (b) 6,542 common shares held by Dr. Logtenberg, and (c) 120,824 options to purchase common shares held by Dr. Logtenberg that vest within 60 days following April 15, 2017.
- (12) Consists of 9,334 common shares and 27,995 options to purchase common shares that vest within 60 days following April 15, 2017.
- (13) Consists of 35,385 options to purchase common shares that vest within 60 days following April 15, 2017.
- (14) Consists of 17,650 options to purchase common shares that vest within 60 days following April 15, 2017.
- (15) Consists of [4,564] options to purchase common shares that vest within 60 days following April 15, 2017.

To our knowledge, and other than changes in percentage ownership as a result of the shares issued in connection with our initial public offering, there has been no significant change in the percentage ownership held by the major shareholders listed above since January 1, 2016, except as discussed under the heading "related Party Transactions."

Registration Rights

Registration Rights Agreement with Incyte

In connection with the Collaboration 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.

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.

Dividend Distribution Policy

We have never paid or declared any cash dividends on our common shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Under Dutch law, a Dutch public company with limited liability (naamloze vennootschap) may only pay dividends if the shareholders' equity (eigen vermogen) exceeds the sum of the paid-up and called-up share capital plus the reserves required to be maintained by Dutch law or our Articles of Association. Subject to such restrictions, any future determination to pay dividends will be at the discretion of our general meeting upon the proposal of the management board, which proposal is subject to the approval of the supervisory board. Any future approval will depend upon the supervisory board's review of a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors the supervisory board deems relevant.

Significant Changes

In December 2016, we 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 preclinical programs, or Program 1, 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 Program 1, 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 products arising from one specified program, and subject to certain conditions, to a second specified program, in each case in 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. In addition, if Program 1 fails to complete IND-enabling toxicology studies successfully, we will be granted an additional option to co-fund development of a specified program other than Program 1 in exchange for a share of profits in the United States. 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 Program 1, 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 Program 1, 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 we have no 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 also entered into a Share Subscription Agreement, or the Subscription Agreement, with Incyte. Pursuant to the Subscription Agreement, we agreed to sell 3,200,000 of our common shares, or the Shares, to Incyte at a price per share of \$25.00, for an aggregate purchase price of \$80 million, representing 19.9% of our pre-transaction issued and outstanding common shares. The consummation of the transactions contemplated by the Subscription Agreement were subject to the early termination or expiration of the waiting period under the HSR Act, no termination or breach that is continuing of the Collaboration Agreement, and the satisfaction or waiver of customary closing conditions. On January 20, 2017, HSR clearance was received and on January 23, 2017, or the Closing Date, the transactions under the Subscription Agreement were closed.

Pursuant to the Subscription Agreement, for a specified period that may terminate earlier upon the occurrence of certain events related to an acquisition of us or the termination of the Collaboration Agreement, referred to as the Standstill Period, Incyte has agreed, subject to certain exceptions, that it will not, directly or indirectly, increase its percentage ownership of our voting securities, make or solicit proxies or seek to influence the voting of our securities, seek to influence or control our management, make a proposal or offer to acquire us or our assets, or seek to effect a change of control of us or other similar extraordinary transactions.

Incyte has also agreed that for a period ending on the earlier of 18 months after the Closing Date or the end of the Standstill Period, referred to as the Lock-Up Period, it will not, subject to certain exceptions, sell or otherwise transfer or agree to transfer the Shares. In addition, if the Standstill Period has not been terminated early, for a period of three years after the end of the Lock-Up Period, Incyte will be restricted from selling or otherwise transferring

more than one-third of the Shares during any 12-month period or ten percent of the Shares during any three-month period, unless we consent otherwise. Incyte has further agreed that during the Standstill Period, it will vote all of the voting securities that it holds in accordance with the recommendation of a majority of our supervisory board. However, Incyte may vote its securities at its own discretion for certain extraordinary matters, including a change in control of us.

We have also agreed to customary resale registration rights with respect to the Shares, however, any such resales will be subject to the Lock-Up Period and volume limitations on sale and transfer of the Shares described above.

1.12 The Offer and sting

Our common shares have been listed on The NASDAQ Global Market under the symbol “MRUS” since May 19, 2016. Prior to that date, there was no public trading market for our common shares. Our initial public offering was priced at \$10.00 per common share on May 19, 2016. The following table sets forth for the periods indicated the high and low sales prices per common share as reported on The NASDAQ Global Market:

	Price Per Common Share	
	High	Low
Year Ended December 31,		
2016 (from May 19, 2016 through December 31, 2016).....	\$ 22.19	\$ 7.26
Quarter Ended		
Second Quarter 2016 (beginning May 19)	\$ 10.89	\$ 7.26
Third Quarter 2016.....	\$ 16.98	\$ 8.42
Fourth Quarter 2016.....	\$ 22.19	\$ 13.13
First Quarter 2017	\$ 33.63	\$ 20.55
Second Quarter 2017 (through April 25)	\$ 25.44	\$ 18.79
Month of		
October 2016.....	\$ 19.63	\$ 15.56
November 2016.....	\$ 17.95	\$ 14.85
December 2016	\$ 22.19	\$ 13.13
January 2017	\$ 27.36	\$ 20.55
February 2017	\$ 26.25	\$ 22.90
March 2017	\$ 33.63	\$ 23.28
April 2017 (through April 25).....	\$ 25.44	\$ 18.79

Memorandum and Articles of Association

The information in response to this item is contained under the caption “Description of Share Capital and Articles of Association” in our final prospectus filed with the Securities and Exchange Commission on May 20, 2016 and is incorporated herein by reference.

Underwriting Agreement

We entered into an underwriting agreement with Citigroup Global Markets, Inc. and Jefferies LLC, as representatives of the underwriters, on May 18, 2016, for the initial public offering of our common shares. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

License and Collaboration Agreements

In addition, we have entered into license and collaboration agreements with Incyte Corporation and ONO Pharmaceuticals, Inc. Information on these agreements may be found in this Annual Report under “Item 4—Information on the Company—Collaboration Agreements” and is incorporated herein by reference.

Employment Agreements

We have entered into employment agreements with our management board members and our Chief Financial Officer.

Ton Logtenberg, Chief Executive Officer and Management Board Member

We have entered into an employment agreement, as amended from time to time, with Ton Logtenberg pursuant to which Dr. Logtenberg serves as our Chief Executive Officer. The agreement is for an unspecified term and may be terminated by either Dr. Logtenberg or the company subject to the applicable statutory notice periods; provided that, the agreement will automatically terminate without notice at the end of the month in which Dr. Logtenberg reaches the age at which he is entitled to pension under Dutch law. Pursuant to the employment agreement, Dr. Logtenberg is entitled to an annual base salary of no less than \$463,000 USD, effective January 1, 2017, and may earn an annual cash incentive award based on performance with a target value equal to 50% of his annual base salary. Dr. Logtenberg is also entitled to certain other benefits, including health and disability benefits, reimbursement for commuting expenses and participation in the company's pension plan.

If Dr. Logtenberg's employment is terminated by the company without cause or due to Dr. Logtenberg's resignation for good reason, then subject to his executing a general release of claims and continued compliance with the company's proprietary information agreement, Dr. Logtenberg will be entitled to receive (i) base salary continuation payments for 6 months and (ii) potential accelerated vesting of any portion of his option awards that are unvested as of the date of his termination. If Dr. Logtenberg's employment is terminated without cause or due to Dr. Logtenberg's resignation for good reason within 12 months following a change in control, then subject to his executing a general release of claims and continued compliance with the proprietary information agreement, Dr. Logtenberg will be entitled to receive (i) a lump sum payment equal to six months of his base salary and 50% of his target annual bonus and (ii) accelerated vesting of any portion of his unvested equity awards, except that performance based equity awards will only vest subject to the attainment of the applicable performance goals.

The agreement contains restrictive covenants which restrict Dr. Logtenberg's ability to compete with us for a period of 24 months following his termination of employment or solicit our employees for a period of 12 months following termination. In the event Dr. Logtenberg violates these restrictive covenants, he will be subject to a penalty of €25,000 for each violation and an additional penalty of €1,000 for each day the violation continues.

The agreement also contains covenants regarding protection of our confidential information, violation of which subjects Dr. Logtenberg to the same penalties as described above, and ownership of intellectual property.

Shelley Margetson, Chief Operating Officer and Management Board Member

We have entered into an employment agreement, as amended from time to time, with Shelley Margetson pursuant to which Ms. Margetson serves as our Chief Operating Officer. The agreement is for an unspecified term and may be terminated by us or by Ms. Margetson subject to the applicable statutory notice periods. Pursuant to the employment agreement, Ms. Margetson is entitled to an annual base salary of no less than \$300,000 USD, effective November 1, 2016, and may earn an annual cash incentive award based on performance with a target value equal to 35% of her annual base salary. Ms. Margetson is also entitled to certain other benefits, including disability benefits, reimbursement for commuting expenses and relocation costs and participation in a pension scheme.

If Ms. Margetson's employment is terminated by the company without cause or due to Ms. Margetson's resignation for good reason, then subject to her executing a general release of claims and continued compliance with the company's proprietary information agreement, Ms. Margetson will be entitled to receive (i) base salary continuation payments for 6 months and (ii) potential accelerated vesting of any portion of her option awards that are unvested as of the date of her termination. If Ms. Margetson's employment is terminated without cause or due to Ms. Margetson's resignation for good reason within 12 months following a change in control, then subject to her executing a general release of claims and continued compliance with the proprietary information agreement, Ms. Margetson will be entitled to receive (i) a lump sum payment equal to six months of her base salary and 50% of her target annual bonus and (ii) accelerated vesting of any portion of her unvested equity awards, except that performance based equity awards will only vest subject to the attainment of the applicable performance goals.

The agreement contains restrictive covenants which restrict Ms. Margetson's ability to compete with the company for a period of 12 months following termination. Ms. Margetson is subject to a penalty of €10,000 for each violation of this covenant and an additional fine of €1,000 for each day the violation continues. Ms. Margetson is also prohibited from performing outside activities with another employer or client during the course of her employment with us and is subject to a per violation fine of €5,000 and per day fine of €1,000 for failure to comply.

The agreement also contains covenants regarding Ms. Margetson's protection of our confidential information for a period of 5 years following her termination, violation of which subjects her to penalties of €50,000 for each violation and €1,000 for each day the violation continues, and ownership of intellectual property.

John Crowley, Chief Financial Officer

On October 5, 2016, we and our wholly-owned subsidiary Merus US, Inc. entered into an employment agreement with John Crowley. Pursuant to the employment agreement, Mr. Crowley agreed to serve as our Executive Vice President and Chief Financial Officer and Merus US effective as of November 1, 2016. The employment agreement provides for an initial annual base salary of \$362,500 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 35% of Mr. Crowley's annual base salary. Mr. Crowley received a one-time signing bonus in an amount equal to \$100,000; provided that, if Mr. Crowley is terminated for cause or resigns without good reason, in either case, within one year of his commencement of employment, Mr. Crowley must repay the full amount of the signing bonus. If Mr. Crowley's employment is terminated by Merus US without cause or due to Mr. Crowley's resignation for good reason, then subject to his executing a general release of claims and continuing compliance with the Company's proprietary information agreement, Mr. Crowley will be entitled to receive (i) base salary continuation payments for 6 months and (ii) potential accelerated vesting of any portion of his initial option award that is unvested as of the date of his termination. If Mr. Crowley's employment is terminated without cause or due to Mr. Crowley's resignation for good reason within 12 months following a change in control of us, then subject to his executing a general release of claims and continuing compliance with the proprietary information agreement, Mr. Crowley will be entitled to receive (i) a lump sum payment equal to six months of his base salary and 50% of his target annual bonus; (ii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to nine months, and (iii) accelerated vesting of any portion of his unvested equity awards, except that performance-based equity awards will only vest subject to the attainment of the applicable performance goals.

Indemnification Agreements

We have entered into indemnification agreements with our management board and supervisory board members. Information on the indemnification agreements may be found in this Annual Report under "Item 7—Major Shareholders and Related Party Transactions—Indemnification Agreements" and is incorporated herein by reference.

Registration Rights Agreements

We have entered into registration rights agreements with Incyte under the Share Subscription Agreement and with certain of our shareholders under a Registration Rights Agreement. Information on the indemnification agreements may be found in this Annual Report under "Item 7—Major Shareholders and Related Party Transactions—Registration Rights" and is incorporated herein by reference.

Lease

On April 22, 2016, we entered into a lease agreement with Stichting Incubator Utrecht for approximately 11,130 square feet of office and laboratory space in Utrecht, the Netherlands. The lease has a term of five years and expires on April 22, 2021. The agreed rental price is €402 thousand per year.

Exchange Controls.

Under the existing laws of the Netherlands, there are no exchange controls applicable to the transfer to persons outside of the Netherlands of dividends or other distributions with respect to, or of the proceeds from the sale of, shares of a Dutch company.

1.13 Controls and Procedures.

Our management, with the participation of our principal executive officer and principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a- 15(e) and 15d- 15(e) under the Securities Exchange Act of 1934, as amended and the relevant Dutch regulations), as of the end of the period covered by the Annual Report. Based on such evaluation, our principal executive officer and principal financial officer have concluded that as of such date, our disclosure controls and procedures were not effective as a result of the material weaknesses in internal control over financial reporting described below.

Material Weaknesses in Internal Control Over Financial Reporting.

The Annual Report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of our registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies. Neither we nor our independent registered public accounting firm have undertaken a comprehensive assessment of our internal control over financial reporting for purposes of identifying material weaknesses, significant deficiencies and control deficiencies in our internal control over financial reporting. However, as part of the preparation process for providing a management's assessment regarding internal control over financial reporting in the future, our management identified the following material weaknesses:

- insufficient accounting resources required to fulfill IFRS and SEC reporting requirements; and
- insufficient comprehensive IFRS accounting policies and financial reporting procedures.

Remediation of Material Weaknesses

To remediate the material weaknesses described above and enhance our internal control over financial reporting, our management is continuing to conduct a thorough review of our internal controls over our accounting resources and accounting policies and financial procedures. Following this review, management will develop a remediation plan to address the material weaknesses in our accounting resources related to IFRS and SEC reporting requirements and insufficient comprehensive IFRS accounting policies and financial procedures.

We believe it is possible that, had we performed a formal assessment of our internal control over financial reporting or had our independent registered public accounting firm performed an audit of our internal control over financial reporting, additional material weaknesses may have been identified.

Changes in Internal Control Over Financial Reporting.

Other than as discussed above, there has been no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) during the period covered by this annual report that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting.

1.14 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 management board may, subject to supervisory board approval but without shareholder approval, issue (or grant the right to acquire) cumulative preferred shares. We may issue an amount of cumulative preferred shares up to 100% of our issued capital immediately prior to the issuance of such cumulative preferred shares. In such event, the cumulative preferred shares (or right to acquire cumulative preferred shares) will be issued to a separate, special purpose foundation, which has been structured to operate independently of us. We have

granted a right to acquire such number of cumulative preferred shares as we may issue to such special purpose foundation.

1.15 Supervisory Board Report

The members of the supervisory board wish to thank all Merus employees and the management board for the progress made during 2016 toward achieving Merus' strategic goals. We would also like to thank our shareholders, customers, business partners and other stakeholders for honoring Merus with their continued collaboration and trust.

General

The supervisory board follows the principle of increasing shareholder value as the members represent the interests of all stakeholders, including shareholders. Merus is committed to a corporate governance structure that best suits its business and stakeholders, and that complies with relevant rules and regulations. Merus has endorsed the Dutch Corporate Governance Code effective January 1, 2004. The Dutch Code was last amended on December 8, 2016 and is applicable as from January 1, 2017. Our policy is to follow the guidelines of Good Practice of Corporate Governance as described in the Dutch Corporate Governance Code, although some deviations may result from the impact of factors such as legal requirements imposed on Merus or industry standards.

Merus is also subject to the rules regarding Corporate Governance set by NASDAQ, where depository receipts for its common shares are listed. Merus believes all of its operations are carried out in accordance with legal frameworks, including Dutch Corporate Law and U.S. laws and regulations. Merus's common shares are registered and traded in the U.S. on the NASDAQ Global Select Market. For a more detailed description on corporate governance please refer to Chapter 3 of the Annual Report.

Our supervisory board supervises the management board and the general course of affairs of the company. The supervisory board gives advice to the management board and is guided by the interests of the business when performing its duties. The management board communicates regularly with the supervisory board. Members of the supervisory board are appointed by shareholders at a general meeting upon a binding nomination of the supervisory board. The nominating and corporate governance committee of the supervisory board recommends members for nomination to the supervisory board. The members of the supervisory board are not authorized to represent us in dealings with third parties.

Meetings and activities of the supervisory board

The supervisory board held 4 meetings in 2016, The meetings were very well attended (92%) by the supervisory board members.

In 2016, the supervisory board spent a considerable period of time discussing (pre-) clinical research updates, business developments objectives and strategy, Initial Private Offering and litigation procedures. In addition meetings were held to discuss the budget process and budget, the quarterly results and press releases.

The supervisory board performs evaluations related to the functioning of the supervisory board, its committees, the individual members and the chairpersons of the supervisory board and the committees, as well as the functioning of the management board and its individual members. The composition of both boards, and the desired profile, composition and competence were also evaluated. The supervisory board has embedded this evaluation process in its ordinary course of business.

Composition of management board and supervisory board

Taking into account the legislation that re-entered into force in the Netherlands on April 13, 2017 and concerning the composition of the companies' management board and supervisory board, we highlight that the composition of the management board is currently equally divided in male and female. We further note that the members of the supervisory board are currently all male. Nonetheless, the Company believes that the composition of its supervisory board has a broad diversity of experience, expertise and backgrounds, and that the backgrounds and

qualifications of the supervisory directors, considered as a group, provide a significant mix of experience, knowledge, abilities and independence that we believe will allow our supervisory board to fulfill its responsibilities and properly execute its duties. In the future, the Company does not rule out appointing females to achieve a balanced distribution of seats.

Our supervisory board is comprised of seven members and in accordance with the composition profile as adopted by the supervisory board. Each supervisory board member is elected for a term of up to four years. A supervisory board member may be re-appointed for up to two subsequent terms. Supervisory board members must retire periodically in accordance with a rotation plan. Our supervisory board members do not have a retirement age requirement under our Articles of Association. Our supervisory 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.

Currently, certain members of our supervisory board are not independent within the means of the Dutch Corporate Governance Code. These supervisory board members are Lionel Carnot, John de Koning, Anand Mehra and Jack B. Nielsen. These supervisory board members are representatives of (and/or employed by) some of our shareholders. We have the intention to increase the number of independent members on our supervisory board over time.

For further details and biographies of the member of the supervisory board see Chapter 2.10 of the Directors Report.

Remuneration of the supervisory board

In May 2016, the company established the Supervisory Board Remuneration Program. As part of this program, the members of the supervisory board are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as annual awards, subject to approval of the general meeting of shareholders.

Consistent with market practice in the U.S., supervisory board members receive rights to acquire depository receipts for common shares in the company's capital as part of their remuneration. In connection with this offering, we expect to adopt a Supervisory Board Compensation Program, which will provide for cash and equity compensation to our supervisory board members. Refer to Note 21 to the consolidated financial statements for further information on supervisory board compensation

Committees of the supervisory board

The supervisory board has established an audit committee, compensation committee, and nominating and corporate governance committee, which operate pursuant to written charters adopted by our supervisory board. Refer to Chapter 1.10 of the Directors Report.

Financial statements and audits

In this Annual Report, the financial statements for 2016 are presented as prepared by the management board, audited by KPMG. We have reviewed the financial statements, and the management report. We have no objections, thus we concur with the results of the audit, and it has been approved by the supervisory board. In closing, the supervisory board would like to again thank all Merus employees for their dedication and hard work during 2016.

Utrecht, the Netherlands, May 5, 2017

Mark Iwicki

Chairman of the Supervisory Board, on Behalf of the full Supervisory Board.

1.16. Corporate Governance Report

General

Since our initial public offering and listing on the NASDAQ on 19 May 2016, we are required to comply with the Dutch Corporate Governance Code which applies to all Dutch companies listed on a regulated stock exchange (in The Netherlands or elsewhere).

The full text of the Dutch Corporate Governance Code can be found at the website of the Monitoring Commission Corporate Governance Code (www.mccg.nl)

Because of our listing on the NASDAQ we are also required to comply with the US Sarbanes-Oxley Act of 2002, and the rules and regulations from the US Securities and Exchange Commission ('SEC'). The Company qualifies as a non-accelerated emerging growth company.

However, we are a foreign private issuer. As a result, in accordance with NASDAQ rules, we comply with home country governance requirements and certain exemptions thereunder rather than complying with NASDAQ corporate governance standards. 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 in the United States. 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). As permitted by the listing requirements of NASDAQ, we have also opted out of the requirements of NASDAQ Listing Rule 5605(d), which requires an issuer to have a compensation committee that consists entirely of independent directors, and NASDAQ Listing Rule 5605(e), which requires an issuer to have independent director oversight of director nominations. In addition, we have opted out of 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 Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

Dutch Corporate Governance Code

The management board and supervisory board are responsible for the corporate governance structure and are responsible to ensure that the practices and procedures of the company comply with both Dutch and corporate governance requirements. The DCGC contains both principles and best practice provisions for management boards, supervisory boards, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. As a Dutch company, we are subject to the DCGC and are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting NASDAQ requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report. We acknowledge the importance of good corporate governance. However, at this stage, we do not comply with all the provisions of the DCGC, to a large extent because such provisions conflict with or are inconsistent with the corporate governance rules of NASDAQ and U.S. securities laws that apply to us, or because such provisions do not reflect best practices of global companies listed on NASDAQ. The discussions below summarize the most important differences between our expected governance structure following this offering and the principles and best practices of the DCGC:

- *The company shall have an internal risk management and control system that is suitable for the company (section II.1.3 of the DCGC)*

We are currently in the process of reviewing and implementing such internal risk management and control system that is suitable for us. We intend to comply with this best practice provision as soon as reasonably possible.

- *The best practice provisions regarding the grant of options, such as that they shall, in any event, not be*

exercised in the first three years after the date of granting and the number of options to be granted shall be dependent on the achievement of challenging targets specified beforehand, (section II.2.4 and II.2.6 of the DCGC),

The options granted under the 2010 Option 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 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. The options granted are exercisable once vested. 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 (or five years in the case of ISOs granted to certain significant shareholders). 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.

- *Shares granted to management board members without financial consideration shall be retained for a period of at least five years or until at least the end of the employment, if this period is shorter (section II.2.5 of the DCGC.)*

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

- *Neither the exercise price of options granted nor the other conditions may be modified during the term of the options, except in so far as prompted by structural changes relating to the shares or the company in accordance with established market practice. (section II.2.7 of the DCGC).*

In October 2015, the exercise price of options granted prior to January 2015 under the 2010 Option Plan was amended. In addition, in connection with the IPO, the 2010 Option Plan was amended to reflect that an option entails the right of the holder to purchase common shares rather than depositary receipts as we are no longer a private company, but a public company with publicly traded shares.

- *All supervisory board members, with the exception of not more than one person, shall be independent within the meaning of the DCGC (section III.2.1 of the DCGC).*

Currently, certain members of our supervisory board are not independent within the meaning of the DCGC. These supervisory board members are representatives of (and/or employed by) some of our shareholders. Although we have the intention to increase the number of independent members on our supervisory board over time, it is our view that given the nature of our business and the practice in our industry and considering our shareholder structure, it is justified that only three supervisory board members will be independent. We may need to deviate from the DCGC's independence definition for supervisory board members either because such provisions conflict with or are inconsistent with the corporate governance rules of NASDAQ and U.S. securities laws that apply to us, or because such provisions do not reflect best practices of global companies listed on NASDAQ. We may need to further deviate from the DCGC's independence definition for supervisory board members when looking for the most suitable candidates. For example, a future supervisory board candidate may have particular knowledge of, or experience in our industry, but may not meet the definition of independence in the DCGC. As such background is very important to the efficacy of our supervisory board, our supervisory board may decide to nominate candidates for appointment who do not fully comply with the criteria as listed under best practice provision III.2.2 of the DCGC.

- *A supervisory board member may not be granted any shares and/or rights to shares by way of*

remuneration. Any shares held by a supervisory board member in the company on whose board he sits are long-term investments (section III.7.1 of the DCGC).

Consistent with market practice in the U.S., our supervisory board members receive rights to acquire depositary receipts for shares in our capital as a part of their remuneration. In connection with these rights, we expect to adopt a Supervisory Board Compensation Program, which will provide for cash and equity compensation to our Supervisory Board members. Refer to Note 21 to the consolidated financial statements for further information on management board and supervisory board compensation.

Although the DCGC discourages such remuneration, we believe that such remuneration is appropriate due to our listing on NASDAQ.

- *The cancellation of the binding nature of a nomination for the appointment of a member of the management board or the supervisory board and/or a resolution to dismiss a member of the management board or of the supervisory board by an absolute majority of the votes cast (Section IV.1.1 of the DCGC)*

Our Articles of Association provide that the binding nomination of the supervisory board for the appointment of a member of the management board or the supervisory board may be overruled by the general meeting with a majority of at least two third of the votes cast representing more than half of the issued share capital. The dismissal of a member of the management board or supervisory board also requires a majority of two third of the votes cast representing more than half of the issued share capital.

- *The company shall formulate an outline policy on bilateral contacts with the shareholders and publish this policy on its website (section IV.3.13 of the DCGC).*

We believe we should be reluctant in maintaining bilateral contracts with some of our shareholders. However, we are still considering this topic and if we believe such bilateral contracts should be entered into with the shareholders, we shall formulate an outline policy and publish such policy on our website.

Other Codes of Conduct or Corporate Governance Practices

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, senior management, members of the management board and supervisory board, consultants of the Company and others temporarily assigned to perform work or services for the Company. The most current version of the Code of Conduct is available on our website at www.merus.nl. Our management board is responsible for administering the Code of Conduct. The management board is allowed to amend, alter or terminate the Code of Conduct, but only with the approval of the supervisory board.

General meeting of shareholders

The Company's general meeting of shareholders (the "General Meeting") may be held in Utrecht, Amsterdam, Rotterdam, Haarlemmermeer (Schiphol) or The Hague, the Netherlands.

The Company must hold at least one General Meeting each year, to be held within six months after the end of our fiscal year. This annual General Meeting shall be called by the management board or the supervisory board in accordance with applicable law. In addition, a General Meeting must also be held within three months if our management board has determined it to be likely that the Company's equity has decreased to an amount equal to or lower than half of its paid up and called up capital. If the management board and the supervisory board have failed to ensure that a General Meeting as referred to in the preceding sentences is held in a timely fashion, each shareholder and other person entitled to attend General Meetings may be authorized by the Dutch court to convene the General Meeting.

Our management board or supervisory board may convene extraordinary General Meetings whenever our respective board so decides. One or more shareholders and/or others entitled to attend General Meetings, alone or jointly representing at least 10% of our issued share capital, may on their application, be authorized by the Dutch court to convene a General Meeting. The Dutch court will disallow the application if it does not appear that the

applicants have previously requested that the management board or supervisory board convene a General Meeting and the management board or supervisory board has not taken the necessary steps so that such General Meeting could be held within six weeks after the request.

General Meetings are convened in the manner and with reference to applicable law and stock exchange requirements, with due observance of a convening notice of at least 15 days, by a notice which includes (i) the subjects to be discussed, (ii) the place and time of the General Meeting, (iii) the procedures for participation in the General Meeting and the exercise of voting rights in person or by proxy, and (iv) such other items as must be included in the notice pursuant to applicable law and stock exchange rules. One or more shareholders and/or others entitled to attend General Meetings, alone or jointly representing at least 3% of the issued share capital, have the right to request the inclusion of additional items on the agenda of General Meetings. Such requests must be made in writing, substantiated and received by us no later than on the 60th day before the day of the relevant General Meeting. No resolutions are to be adopted on items other than those which have been included on the agenda.

Under the DCGC, shareholders and others entitled to attend General Meetings who wish to exercise their rights to request the convening of a General Meeting or to put matters on the agenda, as discussed above, should first consult our management and supervisory board. If the envisaged exercise of such rights might result in a change to the Company's strategy, the DCGC allows the management and supervisory board to invoke a reasonable response period of up to 180 days. If invoked, such response period should be used for further deliberation and constructive consultation and explore alternatives. The response period may be invoked only once for any given General Meeting and shall not apply (i) in respect of a matter for which a response period has been previously invoked, or (ii) if a shareholder holds at least 75% of the Company's issued share capital as a consequence of a successful public bid.

Regardless of who would be entitled to attend the General Meeting in the absence of a record date as set forth in the applicable provisions of the Dutch Civil Code, persons entitled to attend the General Meeting are those who, on the record date (if determined by the management board), have voting rights and/or meeting rights with respect to a class of shares of the Company and have been registered as such in a register designated by the management board for that purpose. The record date (if determined by the management board) must be the 28th day prior to that of the General Meeting concerned.

Admission to the General Meeting shall be given to the persons who have pre-registered for the General Meeting in the period between the record date for the General Meeting and the meeting itself.

The Company's articles of association do not attribute specific powers to the General Meeting, in addition to those which follow from Dutch law.

2. FINANCIAL STATEMENTS 2016

2.1 Consolidated statement of financial position

After appropriation of the result for the year

	Notes	December 31, 2016	December 31, 2015
(euros in thousands)			
Non-current assets			
Property, plant and equipment	6	648	325
Intangible assets	7	374	435
Restricted cash	12	167	218
		<u>1,189</u>	<u>978</u>
Current assets			
Financial asset	9	11,847	—
Trade and other receivables	10	2,357	1,665
Cash and cash equivalents		56,917	32,851
		<u>71,120</u>	<u>34,516</u>
Total assets		<u><u>72,310</u></u>	<u><u>35,494</u></u>
Shareholders' equity			
Issued and paid-in capital	14	1,448	775
Share premium account		139,878	90,909
Accumulated loss		(107,295)	(63,382)
Total equity		<u>34,031</u>	<u>28,302</u>
Non-current liabilities			
Borrowings	12	319	486
Deferred revenue	13	30,206	390
Current liabilities			
Borrowings	12	167	167
Trade payables		2,298	2,419
Taxes and social security liabilities		29	142
Deferred revenue	13	1,610	223
Other liabilities and accruals	11	3,650	3,365
		<u>7,754</u>	<u>6,316</u>
Total liabilities		<u>38,280</u>	<u>7,192</u>
Total equity and liabilities		<u><u>72,310</u></u>	<u><u>35,494</u></u>

2.2 Consolidated Statement of Profit or Loss and Comprehensive Loss

	Notes	<u>2016</u>	<u>2015</u>
(Euros in thousands, except per share data)			
Revenue	15	<u>2,719</u>	1,977
		2,719	1,977
Research and development costs.....	16	(18,991)	(16,350)
Management and administration costs	16	(4,258)	(768)
Other expenses	16	<u>(7,142)</u>	<u>(7,898)</u>
Total operating expenses		(30,391)	(25,016)
Operating result		(27,672)	(23,039)
Finance income	18	88	50
Finance costs.....	18	<u>(19,644)</u>	<u>(195)</u>
Total finance income (expenses)		(19,556)	(145)
Result before tax		(47,228)	(23,184)
Income tax expense.....	9	<u>—</u>	<u>—</u>
Result after taxation		(47,228)	(23,184)
Exchange differences from translation of foreign operations		8	—
Other comprehensive income		<u>8</u>	<u>—</u>
Total comprehensive loss for the year		<u>(47,220)</u>	<u>(23,184)</u>
Basic (and diluted) loss per share ⁽¹⁾⁽²⁾	19	<u>(3.57)</u>	<u>(3.95)</u>

The results for the year and the comprehensive loss for the year are fully attributable to the owners of the Company.

- (1) The basic (and diluted) loss per share is adjusted based on the reverse share split with reference to note 14 regarding the capital reorganization.
- (2) For the periods included in these financial statements, the share options are not included in the diluted loss per share calculation as the Company was loss-making in all these periods. Due to the anti-dilutive nature of the outstanding options, basic and diluted loss per share is equal.

2.3 Consolidated Statement of Changes in Equity

	Note	Common share capital	Class A Pref. share capital	Class B Pref. share capital	Class C Pref. share capital	Common share premium	Class A Pref. share premium	Class B Pref. share premium	Class C Pref. share premium	Accumulated loss	Total equity
(euros in thousands)											
Balance at January 1, 2015		30	21	231	—	1,564	1,334	34,026	—	(40,765)	(3,559)
Result.....		—	—	—	—	—	—	—	—	(23,184)	(23,184)
Other comprehensive income		—	—	—	—	—	—	—	—	—	—
Total comprehensive loss		—	—	—	—	—	—	—	—	(23,184)	(23,184)
Transactions with owners of the Company:											
Issuance of shares (net).....	14	—	—	120	373	—	—	4,880	49,105	—	54,478
Equity settled shared-based payments	17	—	—	—	—	—	—	—	—	567	567
Total contributions by and distributions to owners of the Company		—	—	120	373	—	—	4,880	49,105	567	55,045
Balance at December 31, 2015		30	21	351	373	1,564	1,334	38,906	49,105	(63,382)	28,302
Balance at January 1, 2016		30	21	351	373	1,564	1,334	38,906	49,105	(63,382)	28,302
Result.....		—	—	—	—	—	—	—	—	(47,228)	(47,228)
Other comprehensive loss.....		—	—	—	—	—	—	—	—	8	8
Total comprehensive loss		—	—	—	—	—	—	—	—	(47,220)	(47,220)
Transactions with owners of the Company:											
Issuance of shares (net).....	14	673	—	—	—	50,478	—	—	—	—	51,151
IPO expenses		—	—	—	—	(1,509)	—	—	—	—	(1,509)
Conversion preference shares	14	745	(21)	(351)	(373)	89,345	(1,334)	(38,906)	(49,105)	—	—
Equity settled shared-based payments	17	—	—	—	—	—	—	—	—	3,307	3,307
Total contributions by and distributions to owners of the Company		1,418	(21)	(351)	(373)	138,314	(1,334)	(38,906)	(49,105)	3,307	52,949
Balance at December 31, 2016		1,448	—	—	—	139,878	—	—	—	(107,295)	34,031

2.4 Consolidated Statement of Cash flows as of December 31

	<i>Note</i>	<u>2016</u>	<u>2015</u>
		(euros in thousands)	
Cash flows from operating activities			
Result after taxation		(47,228)	(23,184)
Adjustments for:			
Change in fair value derivative	18	19,213	—
Unrealized foreign exchange results	18	365	—
Depreciation and amortization	7, 8	234	193
Share option expenses	17	3,307	567
Net finance (income) expenses	18	(33)	145
		<u>(24,142)</u>	<u>(22,279)</u>
Changes in working capital:			
Trade and other receivables	10	(1,365)	(816)
Trade payables		(121)	10
Other liabilities and accruals.....	11	286	461
Deferred revenue.....	13	(223)	(223)
Tax and social security liabilities.....		(113)	11
Cash used in operating activities		<u>(25,678)</u>	<u>(22,836)</u>
Interest paid.....	18	(55)	(195)
Taxes paid.....	9	—	—
Net cash used in operating activities		<u>(25,733)</u>	<u>(23,031)</u>
Cash flows from investing activities			
Acquisition of property, plant and equipment.....	7	(496)	(103)
Interest received	10, 18	88	50
Net cash used in investing activities		<u>(408)</u>	<u>(53)</u>
Cash flows from financing activities			
Proceeds from issuing shares	14	50,547	46,478
Prepaid share issuance costs	10	(230)	—
Proceeds from borrowings	14	—	8,000
Repayment of borrowings.....	12	(167)	(166)
Changes in restricted cash.....	12	51	55
Net cash from financing activities		<u>50,201</u>	<u>54,367</u>
Net increase/(decrease) in cash and cash equivalents		<u>24,060</u>	<u>31,283</u>
Effects of exchange rate changes on cash and cash equivalents		6	—
Cash and cash equivalents as at January 1		<u>32,851</u>	<u>1,568</u>
Cash and cash equivalents as at December 31		<u><u>56,917</u></u>	<u><u>32,851</u></u>

2.5 Notes to the Consolidated Financial Statements

1. General Information

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 in Boston, Massachusetts, United States. These audited consolidated financial statements as at and for the twelve-month period ended December 31, 2016 comprise Merus N.V. and Merus US, Inc. (together, the “Company”).

On May 24, 2016, Merus N.V. closed its initial public offering of 5,500,000 common shares and, upon the underwriters’ exercise of their option to purchase additional shares on May 26, 2016, issued an additional 639,926 of its common shares, at a price to the public of US\$10.00 per share (the “IPO”). Net proceeds to Merus N.V. after deducting underwriting discounts and commissions and offering expenses were US\$53.3 million. On May 19, 2016, Merus N.V.’s common shares were listed on The NASDAQ Global Market (“NASDAQ”). In connection with the IPO, Merus N.V.’s legal structure under Dutch law was changed from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) to a public company with limited liability (*naamloze vennootschap*). In addition, in connection with the IPO, all of Merus N.V.’s preferred shares converted into common shares.

Merus N.V. was incorporated in the Netherlands, with its statutory seat in Utrecht. In connection with becoming a public company, on May 19, 2016, Merus N.V.’s name changed from “Merus B.V.” to “Merus N.V.” The address of Merus N.V.’s registered office is Yalelaan 62, 3584 CM Utrecht, the Netherlands (KVK# 30189136).

2. Basis of Preparation

These consolidated financial statements have been authorized for issuance on April 27, 2017. Certain prior year information has been reclassified to conform to current period presentation.

Statement of Compliance

These consolidated financial statements (“the financial statements”) have been prepared in accordance with International Financial Reporting Standards (“IFRS”) as issued by the International Accounting Standards Board.

The financial statements have been prepared under the historical cost convention unless otherwise stated in the below accounting policies.

Functional and Presentation Currency

The financial statements are presented in euros, which is the Company’s functional and presentation currency. All amounts are rounded to the nearest thousands of euros, except as otherwise indicated.

Going Concern

During the year ended December 31, 2016, the Company suffered losses from its operations, which further weakened the shareholders’ equity (not considering the impact of the IPO).

The Company expects to incur significant expenses and operating losses for the foreseeable future as its bispecific antibody candidate’s advance from discovery through preclinical development and into clinical trials, and it seeks regulatory approval and pursues commercialization of any approved bispecific antibody candidate. In addition, the Company may incur expenses in connection with the licensing or acquisition of additional bispecific antibody candidates.

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 or debt financings or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company's inability to raise capital as and when needed would have a negative impact on the financial condition and ability to pursue its business strategy. The Company will need to generate significant revenue to achieve profitability and may never do so.

Based on the Company's current clinical development plans, it expects its existing cash balance to last well into 2019. For this assessment the Company takes into consideration its existing cash and cash equivalents, including funds raised from the IPO, which closed in May 2016, as well as the new funding in 2017 through the collaboration with Incyte Corporation (as included under Note 24 "Subsequent events").

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 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 in the twelve month period ended December 31, 2016. Therefore, all development expenditures relating to internally generated intangible assets in the twelve month period ended December 31, 2016 were expensed as incurred.

Income Tax

The criteria for the recognition of unused tax losses are disclosed in Note 3 "Significant accounting policies". As at December 31, 2016, deferred tax assets have not been recognized in respect of tax losses, because the Company has no history of generating taxable profits and there is no convincing evidence that sufficient taxable profit will be available against which the tax losses can be utilized. The amount of the unutilized tax losses is disclosed in Note 9.

Accounting for Upfront License Fees

The Company entered into a research and license agreement with ONO Pharmaceuticals Co., Ltd ("ONO") in April 2014. In connection with this arrangement, the Company received an upfront fee, which relates to the integrated package of deliverables under the contract (one single performance obligation). The applicable period over which to recognize the upfront payment is a significant judgment. Revenue related to this upfront fee is deferred and amortized on a straight-line basis over the contract period, as that is the period over which the Company provides its integrated service activities to ONO.

Equity Settled Share-Based Payments

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

- (a) the exercise price of the option;
- (b) the expected life of the option;

- (c) the current value of the underlying shares;
- (d) the expected volatility of the share price;
- (e) the dividends expected on the shares; and
- (f) the risk-free interest rate for the life of the option.

For the Company's share option plans, management's judgment is that the Black-Scholes valuation model and the binomial option pricing model are the most appropriate methods for determining the fair value of the Company's share options considering the terms and conditions attached to the grants made and to reflect 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 shares and the expected volatility of that share value 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 was set by considering the historic share price volatility of a set of peer companies for 2016. For post-IPO valuations, the continuous yield on U.S. Treasury Bills with a term to maturity comparable to the expected life of the options, as published by the U.S. Department of Treasury, was 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 14 to the financial statements.

3. Significant Accounting Policies

The accounting policies set out below have been consistently applied to all periods presented in these 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 Group, consisting of Merus N.V. and its wholly owned subsidiary Merus US, Inc. The Group 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. At December 31, 2016, the net equity of Merus US, Inc amounted to €150 thousand, which also reflected the profit for the period from incorporation to December 31, 2016.

(ii) Loss of control

When the Group 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

Intra-group balances and transactions, and any unrealized income and expenses arising from intra-group transactions, are eliminated. Unrealized gains arising from transactions with equity-accounted investees are eliminated against the investment to the extent of the Group'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.

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 expenditure that is directly attributable to the acquisition of the items. Depreciation of property, plant and equipment is charged 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 expenditure is capitalized only when the expenditure will increase the future economic benefit of the asset. All other expenditures are expensed in the profit or loss and comprehensive income or loss.

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

- Plant and equipment: 5 years
- 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.

(a) Patents

Patents acquired separately by the Company are reported at cost less accumulated amortization and accumulated impairment losses. Amortization is charged on a straight-line basis over the shorter of their estimated economic or legal lives. The estimated useful life and amortization method are reviewed at the end of each annual reporting period, with the effect of any changes in estimates being accounted for on a prospective basis.

(b) *Research and Development*

The Company incurs research and development expenses related to its clinical trials and preclinical drug development programs. Development expenses are defined as expenses incurred to achieve technical and commercial feasibility. Expenditure on research activities is 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 loans and receivables. The Company classifies non-derivative financial liabilities into the other financial liabilities category.

(c) *Non-Derivative Financial Assets and Financial Liabilities*

The Company initially recognizes loans and receivables issued on the date when they are originated. 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 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.

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.

(d) Loans and Receivables

These assets are initially recognized at fair value plus any directly attributable transaction costs. Subsequent to initial recognition, they are measured at amortized cost using the effective interest method.

(e) Non-Derivative Financial Liabilities

Non-derivative financial liabilities are initially recognized 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.

Borrowing Costs

Borrowing costs are related to the interest expense on loans and are expensed in the period in which they are incurred.

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 includes deposits held with financial institutions with original maturities of less than three months.

Treatment of equity issuance cost

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

- incremental costs that are directly attributable to issuing new shares were initially recognized as prepaid expenses and were deducted from equity (net of any income tax benefit); costs that relate to listing on NASDAQ, or are otherwise not incremental and directly attributable to issuing new shares, were directly recorded as an expense in the statement of profit or loss and comprehensive loss; and
- costs that relate to both share issuance and listing were 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

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.

In assessing collective impairment, the Company uses historical information on the timing of recoveries and the amount of loss incurred, and makes an adjustment if current economic and credit conditions are such that the actual losses are likely to be greater or lesser than suggested by historical trends.

An impairment loss is calculated as the difference between an asset's carrying amount and the present value of the estimated future cash flows discounted at the asset's original effective interest rate. Losses are recognized in profit or loss and reflected in an allowance account. When the Company considers that there are no realistic prospects of recovery of the asset, the relevant amounts are written off. 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

Revenue is recognized to the extent that it is probable that the economic benefits will flow to the Company and the revenue can be reliably measured.

Fees and Royalties

Fees and royalties paid for the use of the Company's assets (such as patents) are normally recognized in accordance with the substance of the agreement. As a practical matter, this may be on a straight-line basis over the life of the agreement, for example, when a licensee has the right to use certain technology for a specified period of time.

An assignment of rights for a fixed fee or non-refundable guarantee under a non-cancellable contract which permits the licensee to exploit those rights freely and the licensor has no remaining obligation to perform is, in substance, a

sale. In some cases, whether or not a license fee or royalty will be received is contingent on the occurrence of a future event. In such cases, revenue is recognized only when it is probable that the fee or royalty will be received which is normally when the event has occurred.

Services

Revenues from services rendered are recognized in the profit or loss account in proportion to the stage of completion of the transaction at the reporting date. The stage of completion is assessed by reference to assessments of the work performed.

Government Grants

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 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.

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 research and development activities (as defined in the WBSO Act). Under this Act, a contribution is paid towards the labor costs of employees directly involved in research and development. The contribution is in the form of a reduction of payroll taxes. Subsidies relating to labor costs are deferred and recognized in the income statement as negative labor costs over the period necessary to match them with the labor costs that they are intended to compensate (see Note 17).

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 is recognized as an expense, 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 directors, 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 profit or 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 income;
- interest expense; 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 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. 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.

4. New Standards and Interpretations Not Yet Adopted

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2017, and have not been applied in preparing these financial statements. Those which may be relevant to the Company are set out below. The Company does not plan to adopt these standards early.

IFRS 9 Financial Instruments

IFRS 9, published in July 2014, replaces the existing guidance in IAS 39 Financial Instruments: Recognition and Measurement. IFRS 9 includes revised guidance on the classification and measurement of financial instruments, including a new expected credit loss model for calculating impairment on financial assets and the new general hedge accounting requirements. It also carries forward the guidance on recognition and derecognition of financial instruments from IAS 39.

IFRS 9 is effective for annual reporting periods beginning on or after January 1, 2018, with early adoption permitted. The Company is assessing the potential impact on its financial statements resulting from the application of IFRS 9. The Company has identified the accounting areas which will be impacted by the new standard, and is anticipating having a full assessment done in the second half of 2017.

IFRS 15 Revenue from Contracts with Customers

IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognized. It replaces existing revenue recognition guidance, including IAS 18 Revenue, IAS 11 Construction Contracts and IFRIC 13 Customer Loyalty Programs.

IFRS 15 is effective for annual reporting periods beginning on or after January 1, 2018, with early adoption permitted.

The Company is assessing the potential impact on its financial statements resulting from the application of IFRS 15. The Company is modeling the transition alternatives and has not finalized its decision regarding the method of

implementation. The Company is in the process of reviewing its contracts and practices as compared to the new guidance and is working through implementation steps and continues to evaluate its procedural and related system requirements related to the provisions of this standard. In 2017, the Company will be rewriting its revenue recognition accounting policy and drafting new revenue disclosures to reflect the requirements of this standard. The Company is currently evaluating the impact that this guidance will have on its consolidated financial statements.

IFRS 16 Leases

The IASB has issued a new standard on leases that will require lessees to recognize most leases on their balance sheets as lease liabilities with a corresponding right-of-use asset. The IASB has set an effective date to apply the new standard for periods beginning on or after January 1, 2019. The Company has identified known lease agreements and has started working on determining the impact on the financial statements. Additionally, the Company is assessing all effective agreements to determine whether there are embedded leases included under the definition as included under IFRS 16. The Company anticipates finalizing its assessment in the first half of 2017.

5. Segment Reporting

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

6. Property, Plant and Equipment

Movements in property, plant and equipment were as follows:

	Plant and equipment	Other fixed assets	Total
	(euros in thousands)		
Balance as at January 1, 2015			
Costs	259	1,201	1,460
Accumulated depreciation	(145)	(962)	(1,107)
Book value.....	<u>114</u>	<u>239</u>	<u>353</u>
Changes in book value			
Additions	66	48	114
Depreciation	(27)	(111)	(138)
Disposals (Cost)	-	(29)	(29)
Disposals (Accumulated depreciation).....	-	24	24
Balance.....	<u>39</u>	<u>(68)</u>	<u>(29)</u>
Balance as at December 31, 2015			
Costs	325	1,220	1,545
Accumulated depreciation	(171)	(1,049)	(1,220)
Book value	<u>154</u>	<u>171</u>	<u>325</u>
Changes in book value			
Additions	330	166	496
Depreciation	(56)	(118)	(173)
Disposals (Cost)	(6)	-	(6)
Disposals (Accumulated depreciation).....	6	-	6
Balance.....	<u>274</u>	<u>48</u>	<u>323</u>
Balance as at December 31, 2016			
Costs	649	1,386	2,035

Accumulated depreciation	<u>(221)</u>	<u>(1,166)</u>	<u>(1,387)</u>
Book value	<u>428</u>	<u>220</u>	<u>648</u>

7. Intangible Assets

The intangible assets relate to acquired intellectual property rights.

The movements are as follows:

	<u>2016</u>	<u>2015</u>
	<i>(euros in thousands)</i>	
Balance as at January 1		
Historical cost	860	860
Accumulated amortization	(425)	(363)
Book value	435	497
Capital expenditures	-	-
Amortization charge for the year	(61)	(62)
Book value as at December 31, 2016	374	435
Balance as at December 31		
Historical cost	860	860
Accumulated amortization	(486)	(425)
Book value	374	435

On January 23, 2009, the Company purchased the patents regarding the recombinant production of mixtures of antibodies from Crucell Holland B.V. The majority of the patents was filed by Crucell Holland B.V. on July 15, 2003 and had an economic life of 20 years. Therefore, the Company is amortizing the cost over the remaining economic life of 14 years after acquisition.

8. Taxation

Deferred tax assets have not been recognized in respect of tax losses, because the Company has no history of generating taxable profits and at the balance sheet date, there is no convincing evidence that sufficient taxable profit will be available against which the tax losses can be utilized. As at December 31, 2016, the tax losses carried forward amounted to €101.1 million as compared to €76.5 million at December 31, 2015.

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. For the qualifying profits under the Dutch jurisdiction, the Company effectively owes only 5% income tax, instead of the general tax rate of 25%, which results in an estimated effective tax rate of 10%. Taxable profits will only qualify for the Innovations Box once the tax losses carried forward are completely utilized. Since the Company is loss-making, no income tax is recognized in profit or loss. Taking into account the general tax rate applicable in the Netherlands of 25%, the income tax benefit that has not been recognized in 2016 amounts to €6.4 million (2015: € 6.9 million)

9. Financial asset

As discussed in Note 24, on December 20, 2016, the Company entered into a collaboration and license agreement and share subscription agreement with Incyte. As these contracts are denominated in USD the Company determined that the forward to sell its own shares (derivative), on which the Company became committed to on December 20, 2016, qualifies as a derivative financial instrument which is recognized in the statement of financial position as at December 31, 2016. The fair value of the derivative at December 20, 2016 and December 31, 2016 amounts to € 31.4 million and €11.8 million, respectively. The Company measured the derivative using significant observable inputs (Level 2).

10. Trade and Other Receivables

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

	Balance per December 31	
	2016	2015
	(euros in thousands)	
Trade receivables	205	-
VAT receivable	782	296
Prepaid general expenses	382	136
Prepaid pension costs.....	463	364
Prepaid share issuance costs	230	814
Interest bank	32	45
Grant receivable.....	24	-
Other receivables	239	10
	<u>2,357</u>	<u>1,665</u>

VAT receivable relates to value added tax receivable from the Dutch tax authorities based on the tax application for the third and fourth quarter of 2016.

Prepaid expenses reflected above in the form of prepaid general expenses, prepaid pension costs and prepaid share issuance costs consist of expenses that were paid during the reporting period, but are related to activities taking place in the subsequent year.

11. Other Liabilities and Accruals

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

	Balance per December 31	
	2016	2015
	(euros in thousands)	
Accrued auditor's fee	282	335
Accrual for holiday expenses	-	50
Personnel	220	141
R&D studies	1,256	741
IP – Legal fee	114	170
Bonuses	768	391
Subsidy advance received	224	1,294
Other accruals	786	243
	<u>3,650</u>	<u>3,365</u>

The R&D studies relate to accrued expenses for research and development expenses.

The bonuses relate to the employee bonuses for the financial year 2016, which are paid out annually in February.

The other accruals include a total amount of €0.6 million related to legal expenses with regard to the Incyte collaboration as disclosed under Note 24.

12. Borrowings

Rabobank

The Company entered into a financing agreement with Rabobank Utrechtse Heuvelrug U.A. ("Rabobank") on December 29, 2005, which provides for total borrowings of €1.5 million for the financing of its business activities. The duration of this agreement is 12 years.

Under the agreement, the loans were to be repaid in monthly instalments of €14 thousand, beginning on January 31, 2009. Repayments were deferred in January 2010 for a period of two years. Repayment recommenced in January 2012. The loans bore interest at an annual rate equal to 4.45% and were fixed until April 1, 2016. At that date, the interest rate was fixed at 3.55% until March 31, 2017 at which time the loan was repaid in full

In connection with the financing agreement, the following securities have been issued:

- a right of pledge on the account of €500 thousand, in the Company's name in a new savings account for the benefit of Rabobank; and
- a suretyship of €1 million within the framework of the Royal Decree "Borgstelling MKB-krediet."

The pledged amount decreased in relation to the outstanding balance. Per December 31, 2016, an amount of €167 thousand (2015: €218 thousand) related to the abovementioned pledge, has been included as non-current assets on the balance sheet. The pledge was terminated on March 31, 2017 in connection with the repayment in full by the Company of the loan.

Movements in the Company's borrowings with the Rabobank were as follows:

	(euros in thousands)
Balance December January 1, 2015.....	819
Short term portion January 1, 2015	(167)
Long term portion January 1, 2015.....	652
Repayments	(166)
Balance December 31, 2015	653
Short term portion December 31, 2015	(167)
Long term portion December 31, 2015.....	486
Balance January 1, 2016.....	653
Repayments	(167)
Balance December 31, 2016.....	486
Short term portion December 31, 2016	(167)
Long term portion December 31, 2016.....	319

13. Deferred Revenue

On April 8, 2014, the Company entered into a research and license agreement with ONO. As part of this agreement, the Company received a non-refundable upfront payment of €1.0 million. This upfront payment is being amortized on a straight-line basis, and presented as revenue, over a period from April 8, 2014 through September 30, 2018, the end of the research term. The Company is eligible to receive milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under this agreement, if any, the Company is also eligible to receive a mid-single digit royalty on net sales. ONO also provides funding for the Company's 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. In addition, the company has recognized additional deferred revenue as a result of the collaboration and share subscription agreement with Incyte. The included deferred revenue is resulting from the derivative resulting from the agreement.

As discussed in Note 24, on December 20, 2016, the Company entered into a collaboration and license agreement and share subscription agreement with Incyte. As these contracts are denominated in USD the Company determined that the forward to sell its own shares (derivative), on which the Company became committed to on December 20, 2016, qualifies as a derivative financial instrument which is recognized in the statement of financial position as at December 31, 2016. As the derivative is linked to the collaboration agreement and no consideration was paid or received on December 20, 2016, the Company recorded a liability (deferred revenue) in its statement of financial position for the same amount as the fair value of the forward at initial recognition. The liability (deferred revenue)

will be amortized over the period of continuing involvement under the collaboration and license agreement, starting on January 21 2017, the day when the agreements became irrevocable.

Deferred revenue is as follows:

<i>Balance per December 31 (euros in thousands)</i>	<u>2016</u>	<u>2015</u>
Deferred revenue – current portion.....	1,610	223
Deferred revenue	30,206	390
	<u>31,816</u>	<u>613</u>

Of the total deferred revenue balance per December 31, 2016 an amount of €31.4 million was related to the Incyte collaboration agreement.

14. Shareholders' Equity

On May 6, 2016, the general meeting of shareholders of the Company 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. 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.

Issued and Paid-in Share Capital

All issued shares have been fully paid in cash.

Common Shares

For the twelve month period ended December 31, 2016, 18,283 options were exercised at an exercise price of €1.93 per share. As a result, 18,283 common shares were issued, share capital increased by €1,645 and share premium increased by €33,641. For the twelve month period ended December 31, 2015, no options were exercised.

As a result of the IPO, all issued and paid-in preferred shares were converted to common shares. The conversion ratio was a one-for-one conversion, taking into consideration the reverse share split that became effective on May 6, 2016. During the twelve month period ended December 31, 2016, a total of €1.5 million was paid related to costs that are directly attributable to issuing the new shares. Of this amount, a total of €0.8 million was paid in previous reporting periods.

Situation as at December 31, 2016

At December 31, 2016, a total of 16,085,851 common shares were issued and fully paid in cash.

At December 31, 2015, a total of 4,149,884 Class C preferred shares, 3,899,104 Class B preferred shares, 229,055 Class A preferred shares and 337,562 common shares with a nominal value of € 0.09 each were issued and paid up.

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 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 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 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, 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 will be made under the 2016 Plan.

As part of the 2016 Plan, the Company also established the Supervisory Board Remuneration Program. As part of this program, the members of the supervisory board are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as annual awards, subject to approval of the shareholders.

The initial awards granted under the Supervisory Board Remuneration 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 67% 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 Supervisory Board member is entitled to over his/her remaining term. Since these subsequent awards are subject to shareholder approval, the grant date is not yet established and expenses are based on an estimated grant date fair value. The estimated grant date fair value is updated each reporting period until the grant date has been established. Once the grant date has been established, the estimated fair value is revised so that the expense recognized is based on the actual grant date fair value of the awards granted.

Measurement of Fair Values of the Equity-settled Share-based Payment Arrangements

The fair value of the employee share options has been measured using the binomial option pricing model, including supervisory board members). Service and non-market performance conditions attached to the transactions were not taken into account in measuring fair value.

The number of options outstanding as at December 31 was as follows:

Group of employees entitled	December 31, 2016	December 31, 2015
Executives.....	1,117,289	743,428
Other employees	92,427	96,371
Supervisory Board members.....	185,128	113,890
Total.....	1,394,844	953,689

The inputs used in the measurement of the fair values and the related fair values at the grant dates were as follows for the options granted during the twelve-month period ended December 31, 2016.

	2016		2015	
	Executives	Other	Executives	Other
	€	€	€	€
Fair value at grant date	9.97-11.03	5.74-5.79	3.98-5.76	4.03-5.06
Share price at grant date	15.24-16.85	8.46-8.87	6.12-7.20	5.94-7.20
Exercise price	15.24-16.85	8.46-8.87	1.93-7.20	1.93-7.20
Expected volatility				
(weighted-average)	95.30%	97.15%	94.85%	94.85%
Expected life	10 years	8-10 years	4 years	8 years
Expected dividends.....	0%	0%	0%	0%
Risk-free interest rate				
(based on government	1.84%-1.86	0.10%-1.87	0.16%-0.70	
bonds)	%	%	%	0.16-0.70%

The table above does not include the subsequent awards to the Supervisory Board. The inputs used in the measurement of the fair values will be included once the subsequent award options will be granted upon approval by the shareholders at the annual general meeting of shareholders.

(f) Reconciliation of outstanding share options

The number and weighted average exercise prices of share options granted under the share option programs were as follows:

	2016		2015	
	Weighted average exercise price	Number of options	Weighted average exercise price	Number of options
	(€)		(€)	
Outstanding at January 1	5.35	953,689	5.15	192,276
Forfeited during the year	6.07	(31,351)	1.93	(1,033)

Expired during the year	11.95	(5,454)	4.18	(9,216)
Exercised during the year	1.93	(18,283)	-	-
Granted during the year	14.74	496,243	5.99	771,662
Outstanding at December 31....	8.69	1,394,844	5.35	953,689
		<u>418,453</u>		<u>157,562</u>

The options outstanding at December 31, 2016 had an exercise price in the range of €1.93 to €16.85 (2015: €1.93 to €13.50) and a weighted-average remaining contractual life of 6.68 years (2015: 3.63 years). On October 5, 2015, the Company amended the exercise price of options granted under the 2010 Option plan prior to January 2015, to be €1.93, which has been reflected in the weighted average exercise price of the options outstanding at December 31, 2015.

Expense Recognized in Profit or Loss

For details on the related option expenses recognized as employee benefit expenses, see Note 17.

15. Revenue

(euros in thousands)

	<u>2016</u>	<u>2015</u>
ONO Pharmaceutical Co., Ltd. – research funding	1,332	1,315
Smithkline Beecham- exclusivity fee	-	-
Income from grants on research projects	1,387	662
	<u>2,719</u>	<u>1,977</u>

Revenue for the year ended December 31, 2016 was €2.7 million, as a result of one research milestone reached by the Company for which an amount of €0.7 million (2015: €1.1 million) was paid by ONO. Additionally, the Company received an amount of €0.4 million revenue from a new consultancy agreement that was signed with ONO on March 7, 2016. A further €0.2 million of deferred revenue at December 31, 2015 was recognized in 2016 (2015: €0.2 million) in accordance with the agreement signed between the parties in 2014. Additionally, the Company recognized an amount of €1.4 million in grant income (2015: €0.7 million).

Merus currently has three active grants consisting of cash allowances for specific research and development projects. For two of the grants, the Company has reporting obligations at the end of the grant contract term. The unconditional receipt of the grant allowances is dependent on the final review of the reporting provided by Merus at the end of the contract term.

16. Total Operating Expenses

	<u>2016</u>	<u>2015</u>
Manufacturing costs	3,162	5,878
IP and license costs	1,167	1,112
Personnel related R&D	3,852	3,166
Other research and development costs	10,810	6,194
<i>Total research and development costs</i>	<u>18,991</u>	<u>16,350</u>
Management and administration costs	4,258	768
Litigation costs	1,490	4,419
Other operating expenses	5,652	3,479
<i>Total other expenses</i>	<u>7,142</u>	<u>7,898</u>

Total operating expenses 30,391 25,016

Manufacturing cost decreased in 2016 due to relatively low manufacturing activity in 2016. In 2016 one program was developed, compared to two in 2015.

Personnel related expenses mainly increased due to the increase in staff as well as additional expenses resulting from the implementation of the new option plan as well as the modification of the 2016 Plan, as described in Note 14.

Other operating expenses mainly consist of legal expenses amounting to €2.0 million (2015: €1.2 million), expenses related to the finance function of €1.4 million (2015: €0.9 million) and expenses related to facilities of €0.9 million (2015: €0.5 million).

Litigation costs were lower in 2016 when compared to 2015 as a result of lower litigation activity with regard to the Regeneron litigation as described below.

The other operating expenses relate to general and administrative expenses related to regular operations of the Company.

A breakdown of other research and development costs is presented as follows:

	<u>2016</u>	<u>2015</u>
Discovery and pre-clinical costs	5,185	2,534
Clinical costs	3,409	1,883
Consumables.....	1,055	979
Other research and development costs.....	1,161	798
<i>Total other research and development costs</i>	<u>10,810</u>	<u>6,194</u>

Other research and development costs consist mainly of consultancy expenses related to R&D activities, which cannot be specifically allocated to a research project.

On March 11, 2014 Regeneron Pharmaceuticals Inc. (“Regeneron”) filed a complaint in the United States District Court for the Southern District of New York (the “Court”), alleging that the Company was infringing on one or more claims in Regeneron’s U.S. Patent No. 8,502,018, entitled “Methods of Modifying Eukaryotic Cells.” On July 3, 2014, the Company filed a response to the complaint, denying Regeneron’s allegations of infringement and raising affirmative defenses, and filed counterclaims seeking, among other things, a declaratory judgment that the Company did not infringe the patent and that the patent was invalid. The Company subsequently filed amended counterclaims during the period from August to December 2014, seeking a declaratory judgment of unenforceability of the patent due to Regeneron’s commission of inequitable conduct.

On November 21, 2014, the Court found that there was clear and convincing evidence that a claim term present in each of the patent claims was indefinite and granted the Company’s proposed claim constructions. On February 24, 2015, the Court entered partial judgment in the proceeding, on the grounds that the Company did not infringe each of the patent claims, and that each of the patent claims were invalid due to indefiniteness. On November 2, 2015, the Court found Regeneron had withheld material information from the United States Patent and Trademark Office during prosecution of the patent, and Regeneron had engaged in inequitable conduct and affirmative egregious misconduct in connection with the prosecution of the patent. On December 18, 2015, Regeneron filed an appeal of the Court’s decision which is currently pending. On February 13, 2017, the United States Court of Appeals for the Federal Circuit held oral argument. A decision is expected by mid-2017.

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 opposed the 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. The Company believes that its current business operations do not infringe the patent reinstated

to Regeneron with amended claims because it believes it has not used the technology or methods claimed under the amended claims. The Dutch litigation procedure is stayed.

The costs incurred in the above litigation and opposition (€1.5 million in 2016; €4.4 million in 2015) are included in the statement of profit or loss and comprehensive loss for the period.

A part from the above mentioned litigation procedures, a number of opposition proceedings are currently ongoing between the Company and Regeneron. The Company has opposed granted European patents owned by Regeneron related to transgenic mice technology. Regeneron has opposed granted patents owned by Merus, in Europe, Japan and Australia. The oppositions in Europe and Japan have been resolved in the Company's favor and a resolution on the opposition in Australia is expected in the second half of 2017. Based on the current facts and circumstances no provision has been recognized under IAS 37.

Operating expenses presented by nature are outlined below:

	<u>2016</u>	<u>2015</u>
	(Euros in thousands)	
Costs of outsourced work	3,162	5,878
Other external costs	18,885	15,012
Employee benefits	8,110	3,933
Depreciation and amortization.....	234	193
Total operating expenses	<u>30,391</u>	<u>25,016</u>

The increase in other external cost is mainly due to the increase in clinical and preclinical operations. The other external costs consist mainly of preclinical costs of €5.2 million (2015: €2.5 million), clinical costs of €3.4 million (2015: €1.9 million) and IP costs of €2.7 million (2015: €5.5 million).

17. Employee Benefits

Details of the employee benefits are as follows:

	<u>2016</u>	<u>2015</u>
	(Euros in thousands)	
Salaries and wages	5,166	3,204
WBSO subsidy.....	(1,721)	(348)
Social security premiums.....	382	238
Health insurance	27	31
Pension costs.....	507	241
Stock award expense.....	3,307	567
Other personnel expense	442	-
	<u>8,110</u>	<u>3,933</u>

The option expenses included in personnel expenses were €3.3 million in the twelve month period ended December 31, 2016 (2015: €0.6 million). Refer to Note 14 for a detailed explanation on the option cost for the Company. Of the total option expense €2.0 million is included under management and administration costs and €1.3 million is included under research and development costs (personnel related R&D).

The WBSO ("*afdrachtvermindering speur- en ontwikkelingswerk*") is a Dutch fiscal facility that provides subsidies to companies, knowledge centers and self-employed people who perform research and development activities (as defined in the WBSO Act). Under this Act, a contribution is paid towards the labor costs of employees directly involved in research and development. The contribution is in the form of a reduction of payroll taxes and social security contributions. Subsidies relating to labor costs are deferred and recognized in the income statement as

negative labor costs over the period necessary to match them with the labor costs that they are intended to compensate. The increase in the WBSO subsidy is due to the increase in staff as well as amendment of the WBSO regulation to be compensated fully through wage tax, which is beneficial for Merus N.V.

The average number of personnel during the year was approximately 40 (2015: 32), all employed in the Netherlands, with the exception of an average of two employees employed in the United States. Employees are principally employed in the area of research and development. A total of 11 employees that are devoted to activities other than research and development are included under management and administration costs.

18. Finance Income and Expense

	<u>2016</u>	<u>2015</u>
	(Euros in thousands)	
Interest income and similar income	88	50
Interest expenses and similar expenses.....	(19,644)	(195)
	<u>(19,556)</u>	<u>(145)</u>

As discussed in Note 24, on December 20, 2016, the Company entered into a collaboration and license agreement and share subscription agreement with Incyte. As these contracts are denominated in USD the Company determined that the forward to sell its own shares (derivative), on which the Company became committed to on December 20, 2016, qualifies as a derivative financial instrument which is recognized in the statement of financial position as at December 31, 2016. The interest expense and similar expenses include an amount of €19.2 million related to the revaluation of this derivative.

19. Loss per share

19.1.1 *Basic and Diluted Loss per Share*

Basic loss per share is calculated by dividing the loss attributable to equity holders of the Company by the weighted average numbers of shares outstanding during the year.

	<u>2016</u>	<u>2015</u>
	(Euros in thousands, except per share data)	
Loss attributable to equity holders of the Company	(47,220)	(23,184)
Weighted average number of shares	13,236,649	5,871,237
Basic (and diluted) loss per share (€ per share)	<u>(3.57)</u>	<u>(3.95)</u>

19.1.2 *Diluted Loss per Share*

For the periods included in these financial statements, the share options are not included in the diluted loss per share calculation as the Company was loss-making in all these periods. Due to the anti-dilutive nature of the outstanding options, basic and diluted loss per share is equal.

19.1.3 *Dividends per Share*

The Company did not declare dividends for any of the years presented in these financial statements.

20. Financial Instruments

Financial Risk Management

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

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.

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

	<u>2016</u>	<u>2015</u>
Balance per December 31 in thousands of euros		
Financial asset (derivative)	11,847	-
Trade receivables	205	-
Restricted cash	167	218
Cash and cash equivalents	56,917	32,851
	<u>69,136</u>	<u>33,069</u>

At year-end for each of 2016 and 2015, there was no significant concentration of credit risk at any of the counterparties regarding financial instruments and cash and cash equivalents. Cash balances are held at banks with credit ratings varying between A and AA.

The aging of trade and other receivables that were not impaired was as follows:

	<u>2016</u>	<u>2015</u>
Balance per December 31 in thousands of euros		
Neither past due nor impaired	205	-
Past due	-	-
	<u>205</u>	<u>-</u>

There is no allowance for impairment.

Liquidity Risk

Prudent liquidity risk management implies maintaining sufficient funds and marketable securities.

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:

December 31, 2016	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
			(Euros in thousands)			
Non-derivative financial liabilities						
Secured bank loans	486	526	190	181	155	-
Trade and other payables	5,978	5,978	5,978	-	-	-
	<u>6,464</u>	<u>6,504</u>	<u>6,168</u>	<u>181</u>	<u>155</u>	<u>-</u>
December 31, 2015						
	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
Non-derivative financial liabilities			(Euros in thousands)			

Secured bank loans	653	709	193	186	330	-
Trade and other payables	5,926	5,926	5,926	-	-	-
	<u>6,579</u>	<u>6,635</u>	<u>6,119</u>	<u>186</u>	<u>330</u>	<u>-</u>

The secured bank loans have an interest rate that is fixed until March 2017. The interest payable on the loans in the table above assumes continuation of this interest rate. These amounts may change as market interest rates change.

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 is limited and originates from foreign exchange and interest risks. Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies.

(g) Exposure to interest rate risk

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

	<u>Carrying amount</u>	
	<u>2016</u>	<u>2015</u>
<i>Balance per December 31 in thousands of euros</i>		
Fixed-rate instruments		
Financial liabilities	(486)	(653)
Variable rate instruments		
Cash and cash equivalents	56,917	32,851

Due to the limited impact of changes in interest rates on the Company no sensitivity data is provided.

Accounting classifications and fair values

The Company classifies financial assets and financial liabilities into the loans and receivables and other financial liability categories only, with the exception of the derivative recognized as a result of the Incyte collaboration and share Subscription agreement, we refer to Note 24. These financial assets and financial liabilities are not measured at fair value and as such information on the fair value hierarchy is omitted. The carrying amount of the financial assets and financial liabilities is a reasonable approximation of the fair value.

The fair value of the derivative related to the Incyte collaboration and share Subscription agreement is recorded using Level 2 inputs. For determining the fair value the Company has used as valuation technique the Bloomberg forward pricing model. In this valuation the inputs used are related to the foreign exchange component (spot prices of EUR and USD), closing stock prices of the Company, as well as discount rates to reflect the time value of money (limited).

21. Compensation of Management Board and Supervisory Board

Management Board

In 2016, the following amounts were charged to the profit and loss statement for the remuneration of the statutory directors:

Amounts in Euros

Name	Gross Salary	Bonus	Pension	Option cost	Total
Ton Logtenberg, CEO	€369,204	€147,820	€17,717	€907,236	€1,441,977
Shelley Margetson, COO.....	198,987	84,000	6,152	164,547	453,686
Total.....					1,895,663

In 2016, there were no options granted to the statutory directors.

In 2015, the following amounts were charged to the statement of profit or loss for the remuneration of the statutory directors:

Name	Gross Salary	Bonus	Pension	Option cost	Total
(Amounts in Euros)					
Ton Logtenberg, CEO	€236,032	€89,072	€18,591	€1,910,204	€2,253,899
Shelley Margetson, COO.....	159,749	37,365	13,824	284,938	495,876
Total.....					2,749,775

As at December 31, 2016, Ton Logtenberg holds 376,912 options (2015: 376,912) with an average exercise price of €2.98 (2015: €5.35) and Shelley Margetson holds 59,330 options (2015: 64,886) with an average exercise price of €3.69 (2015: €4.70).

On October 27, 2016, the Company appointed Andres Sirulnik as its Chief Medical Officer (CMO). A total of 219,890 options over common shares were granted to Dr. Sirulink with an exercise price of €16.85 per option.

On November 1, 2016, the Company appointed John Crowley as its Chief Financial Officer. A total of 183,241 options over common shares were granted to Mr. Crowley with an exercise price of €15.24 per option.

On October 5, 2015, the Company amended the exercise price of options granted under the 2010 Option plan prior to January 2015, to be €1.93. Those option holders that had already exercised options under this plan were reimbursed the excess paid over €1.93 per share. This amounted in a total reimbursement of €60,935.

The remainder of management personnel has received the following remuneration for the year 2016.

Remuneration	2016	2015
(Amounts in Euros)		
Short term employment benefits.....	1,139,763	190,763
Post-employment benefits	18,720	11,671
Other long term benefits	-	-
Termination benefits.....	-	-
Share based payments.....	1,195,876	57,065
Total.....	2,354,359	259,499

Some of the key management personnel have long term benefits in the form of life and long term disability insurance policies which have been effected in their name as well as severance conditions in case of termination without cause or leave for 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 Group during the year.

Supervisory Board

In May 2016, the Company established the Supervisory Board Remuneration Program. As part of this program, the members of the supervisory board are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as annual awards, subject to approval of the shareholders.

In 2016, the following amounts were charged to the statement of profit or loss and comprehensive loss for the remuneration of the (former) members of the Supervisory Board:

Name	Cash		Total
	compensation	Option cost	
(Amounts in Euros)			
Mark Iwicki	€50,394	€183,367	€233,761
Wolfgang Berthold	19,850	50,928	70,778
Lionel Carnot	24,852	66,959	91,811
John de Koning	26,230	37,000	63,230
Anand Mehra	26,938	84,703	111,641
Gregory Perry	28,356	97,365	125,721
Total	<u>176,620</u>	<u>520,322</u>	<u>696,942</u>

In 2015, the following amounts were charged to the statement of profit or loss and comprehensive loss for the remuneration of the (former) members of the Supervisory Board:

Name	Cash		Total
	compensation	Option cost	
(Amounts in Euros)			
Mark Iwicki	€26,325	€115,380	€141,705
Wolfgang Berthold	-	15,475	15,475
Gabriele Dallmann (*)	11,000	5,795	16,795
Gerard van Odijk (*)	-	16,298	16,298
Total	<u>37,235</u>	<u>152,948</u>	<u>190,273</u>

(*) former board member

The other members of the Supervisory Board did not receive any remuneration from the Company.

As at December 31, members of the Supervisory Board held the following number of options:

Name	December 31, 2016		December 31, 2015	
	Number	Average exercise price	Number	Average exercise price
Mark Iwicki	73,576	€6.57	73,576	€6.57
Wolfgang Berthold	26,724	€3.02	14,168	€1.93
Lionel Carnot	17,000	€8.87	-	-
John de Koning	17,000	€8.87	-	-
Anand Mehra	17,000	€8.87	-	-
Gregory Perry	17,000	€8.87	-	-
Gabriele Dallmann (*)	16,828	€3.24	4,272	€1.93
Gerard van Odijk (*)	-	-	21,874	€1.93
Total	<u>185,128</u>	<u>€7.21</u>	<u>113,890</u>	<u>€4.93</u>

(*) former board member

22. Related party disclosures

In the twelve month period ended December 31, 2016 and 2015, the Management Board and other senior management received regular salaries, bonuses and contributions to post-employment schemes as well as non-cash compensation as disclosed in Note 21.

Additionally, selected members of the Supervisory Board received compensation for their services in the form of cash compensation as well as non-cash compensation, as disclosed in Note 21.

The following shareholders currently hold a position in the Supervisory Board:

- Bay City Capital Coöperatief U.A.
- Coöperatief LSP IV U.A.
- Novo A/S
- Sofinnova Venture Partners IX, L.P.

The following shareholders filed a form 13-D to reflect ownership in the Company of more than 5%

- Bay City Capital Coöperatief U.A.
- Coöperatief LSP IV U.A.
- Novo A/S
- Sofinnova Venture Partners IX, L.P.

The following shareholders filed a form 13-G to reflect ownership of the Company of more than 5%

- Novartis Bioventures Ltd
- Pfizer Inc
- Johnson and Johnson
- Aglaia Oncology Fund B.V.
- Baker Bros. Advisors LP

In connection with the collaboration with Incyte Corporation described in Note 24, Incyte Corporation acquired an ownership of more than 5% in the Company on January 23, 2017.

23. Operating leases

Rent

Merus N.V. had a contract for the rent of facilities with the University of Utrecht, seated in Utrecht. The contract expired on December 31, 2015. The total annual obligation was €256 thousand. While Merus N.V. was awaiting the completion of a new office building, the contract for the lease of the facilities was extended at the agreed rental price. Merus N.V. ended the contract with a month's notice in December 2016. On April 22, 2016, Merus N.V. closed a new lease agreement with Stichting Incubator Utrecht for a new office building. The agreement term is for five years and expires in the fourth quarter of 2021. If the lease is not terminated by Merus, it will be automatically renewed for a period of two years. The agreed rental price is €402 thousand per year. The Company moved into the new office building in November 2016. In the twelve month period ending December 31, 2016, the Company recognized an amount of €270 thousand for rent and service charges related to the abovementioned buildings.

24. Subsequent events

On December 20, 2016, the Company entered into a Collaboration and License Agreement and Share Subscription Agreement with Incyte Corporation ("Incyte") focused on the research, discovery and development of bispecific

antibodies utilizing the Company's proprietary Bionics® technology platform. The Collaboration and License Agreement grants Incyte the exclusive rights for up to eleven bispecific antibody research programs, including two of the Company's current preclinical immuno-oncology discovery programs. The agreements became effective in January 2017.

Under the terms of the collaboration, Incyte paid to the Company an upfront payment of \$120 million in January 2017. In addition, Incyte purchased 3.2 million shares of the Company's common shares at \$25 per share, for a total equity investment of \$80 million. Please refer to the disclosure included in Note 6 Financial Assets as well as Note 13 Deferred revenue for further disclosure on the transactions recognized in the financial year 2016.

The parties have agreed to collaborate on the development and commercialization of up to 11 bispecific antibody programs. For one current preclinical program, the Company will retain all rights to develop and commercialize approved products in the United States, and Incyte will develop and commercialize approved products arising from the program outside the United States. Following any regulatory approval of a product candidate for this particular pre-clinical program, each company has agreed to pay the other tiered royalties ranging from 6% to 10% on net sales of products in their respective territories.

The Company also has the option to co-fund development of product candidates arising from two other programs. For any program for which the Company exercises its co-development option, the Company would be responsible for 35% of global development costs in exchange for a 50% share of U.S. profits and losses and tiered royalties ranging from 6% to 10% on ex-U.S. sales by Incyte for these programs. The Company also has the right to elect to provide up to 50% of detailing activities for product candidates arising from one of these programs in the United States.

For each of the other eight programs, Incyte has agreed to independently fund all development and commercialization activities. For these programs, the Company will be eligible to receive potential development, regulatory and sales milestone payments of up to \$350 million per program, which could result in an aggregate milestone opportunity of approximately \$2.8 billion if all development, regulatory and sales milestones are achieved across all such eight other programs in all territories. The Company will also be eligible to receive tiered royalties ranging from 6% to 10% on global sales of any approved products under these eight programs.

The Company will retain rights to both of its clinical candidates and MCLA-158, as well as its technology platform and future programs emerging from the Company's platform that are outside the scope of the agreement.

On March 30, 2017, the Company repaid the loan from the Rabobank. At the repayment date the total outstanding balance of the loan amounted to €0.5 million. As a result of the repayment the pledge associated with the loan was removed.

2.6 The Company Financial Statements

2.7 Statement of Financial Position

	Notes	December 31, 2016	December 31, 2015
(euros in thousands)			
Non-current assets			
Financial assets	2	287	-
Property, plant and equipment	3	644	325
Intangible assets	4	374	435
Restricted cash	16	167	218
		<u>1,472</u>	<u>978</u>
Current assets			
Financial asset	2	11,847	-
Trade and other receivables	6	2,318	1,665
Cash and cash equivalents		56,587	32,851
		<u>70,752</u>	<u>34,516</u>
Total assets		<u>72,224</u>	<u>35,494</u>
Shareholders' equity			
Issued and paid-in capital	10	1,448	775
Share premium account		139,878	90,909
Legal reserve		238	-
Accumulated loss		(107,533)	(63,382)
Total equity		<u>34,031</u>	<u>28,302</u>
Non-current liabilities			
Borrowings	8	319	486
Deferred revenue	9	30,206	390
Current liabilities			
Borrowings	12	167	167
Trade payables		2,282	2,419
Taxes and social security liabilities		31	142
Deferred revenue	9	1,610	223
Other liabilities and accruals	7	3,578	3,365
		<u>7,668</u>	<u>6,316</u>
Total liabilities		<u>38,193</u>	<u>7,192</u>
Total equity and liabilities		<u>72,224</u>	<u>35,494</u>

2.8 Statement of Profit or Loss

	Notes	2016	2015
(Euros in thousands, except per share data)			
Revenue	11	<u>2,719</u>	<u>1,977</u>
		2,719	1,977
Research and development costs	12	(18,909)	(16,350)
Management and administration costs	12	(2,400)	(768)
Other expenses	12	(9,382)	(7,898)
Total operating expenses		<u>(30,691)</u>	<u>(25,016)</u>
Operating result		<u>(27,972)</u>	<u>(23,039)</u>
Finance income	14	88	50
Finance costs	14	(19,624)	(195)
Total finance income (expenses)		<u>(19,537)</u>	<u>(145)</u>
Result before tax		<u>(47,508)</u>	<u>(23,184)</u>
Income tax expense	5	-	-
Result after taxation		<u>(47,508)</u>	<u>(23,184)</u>
Result from foreign exchange differences		9	-
Result from subsidiary		279	-
Other comprehensive income		<u>288</u>	<u>-</u>
Total comprehensive loss for the year		<u>(47,220)</u>	<u>(23,184)</u>

The results for the year and the comprehensive loss for the year are fully attributable to the owners of the Company.

2.9 Statement of Changes to Equity

Note	Common share capital	Class A Pref. share capital	Class B Pref. share capital	Class C Pref. share capital	Common share premium	Class A Pref. share premium	Class B Pref. share premium	Class C Pref. share premium	Currency translation differences	Prepaid issuance cost	Accumulated loss	Total equity
Legal Reserves												
(euros in thousands)												
Balance at January 1, 2015	30	21	231	-	1,564	1,334	34,026	-	-	-	(40,765)	(3,559)
Result	-	-	-	-	-	-	-	-	-	-	(23,184)	(23,184)
Transactions with owners of the Company:												
Issuance of shares (net).....	-	-	120	373	-	-	4,880	-	-	-	-	54,478
Equity settled shared-based payments ...	-	-	-	-	-	-	-	-	-	-	567	567
Total contributions by and distributions to owners of the Company	-	-	120	373	-	-	4,880	49,105	-	-	567	55,045
Balance at December 31, 2015	30	21	351	373	1,564	1,334	38,906	49,105	-	-	(63,382)	28,302
Balance at January 1, 2016	30	21	351	373	1,564	1,334	38,906	49,105	-	-	(63,382)	28,302
Result	-	-	-	-	-	-	-	-	-	-	(47,508)	(47,508)
Other comprehensive loss.....	-	-	-	-	-	-	-	-	-	-	288	288
Total comprehensive loss	-	-	-	-	-	-	-	-	-	-	(47,220)	(47,220)
Transactions with owners of the Company:												
Net Current Periodic Change									8	230	(238)	-
Issuance of shares (net).....	673	-	-	-	50,478	-	-	-	-	-	-	51,151
IPO expenses	-	-	-	-	(1,509)	-	-	-	-	-	-	(1,509)
Conversion preference shares.....	745	(21)	(351)	(373)	89,345	(1,334)	(38,906)	(49,105)	-	-	-	-
Equity settled shared-based payments ...	-	-	-	-	-	-	-	-	-	-	3,307	3,307
Total contributions by and distributions to owners of the Company	1,418	(21)	(351)	(373)	138,314	(1,334)	(38,906)	(49,105)			3,307	52,949
Balance at December 31, 2016	1,448	-	-	-	139,878	-	-	-	8	230	(107,533)	34,031

2.10 Statement of Cash Flows

	<u>2016</u>	<u>2015</u>
Cash flows from operating activities	Euros in thousands	
Result after taxation.....	(47,508)	(23,184)
Adjustments for:		
Change in fair value of derivative	19,213	-
Unrealized foreign exchange results	389	-
Depreciation and amortization.....	234	193
Share option expenses	3,307	567
Net finance (income) expenses.....	(65)	145
Changes in working capital:	(24,430)	(22,279)
Trade and other receivables	(1,326)	(816)
Trade payables.....	(137)	10
Other liabilities and accruals	216	461
Deferred revenue	(223)	(223)
Tax and social security liabilities	(111)	11
Cash used in operating activities	(26,011)	(22,836)
Interest paid	(55)	(195)
Taxes paid.....	-	-
Net cash used in operating activities	(26,066)	(23,031)
Cash flows from investing activities		
Acquisition of property, plant and equipment ...	(496)	(103)
Interest received.....	88	50
Net cash used in investing activities	(408)	(53)
Cash flows from financing activities		
Proceeds from issuing shares.....	50,547	46,478
Prepaid share issuance costs	(230)	-
Proceeds from borrowings	-	8,000
Repayment of borrowings.....	(167)	(166)
Changes in restricted cash	51	55
Net cash from financing activities	50,201	54,367
Net increase/(decrease) in cash and cash equivalents.....	23,727	31,283
Effects of exchange rate changes on cash and cash equivalents	9	-
Cash and cash equivalents as at January 1	32,851	1,568
Cash and cash equivalents as at December 31	56,587	32,851

2.11 Notes to the Company Financial Statements

A. Significant accounting policies

Basis of preparation

Merus' parent 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 parent company financial statements are the same as those applied in the consolidated financial statements and are deemed incorporated and repeated herein by reference (see Note 4 to the consolidated financial statements). A description of the Company's activities and structure is included in the consolidated financial statements.

Investments in subsidiaries

Investments in subsidiaries are accounted for using the equity method accounting policies as described in Note 4 to the consolidated financial statements.

Presentation of Company Financial Statements

The structure of the Company statement of financial position and Company statement of profit or loss are aligned as much as possible with the consolidated statements in order to achieve optimal transparency between the Consolidated Financial Statements and the Company Financial Statements. Consequently, the presentation of the Company financial statements deviates from Dutch regulations.

Additional information

For 'Additional information' within the meaning of Section 2:392 of the Dutch Civil Code, please refer to section 2.12 Independent auditors report, of this Annual Report.

Employees

The average number of personnel during the year was approximately 40 (2015: 32), all employed in the Netherlands, with the exception of an average of two employees employed in the United States. Employees are principally employed in the area of research and development. A total of eleven 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 management board and the supervisory board and the parent company's share based compensation plans, see Notes 21 and Note 14 to the consolidated financial statements.

Notes to the Statement of Financial Position

B. Financial Assets

Please refer to Note 9 of the Consolidated Financial Statements for a further disclosure on the derivative related to the Incyte collaboration.

Movement in subsidiaries

Balance as at January 1	2016	2015
Costs	-	-

Result on subsidiary	279	-
Revaluation on foreign operation	9	
	<hr/>	<hr/>
Book value as at December 31	288	-
	<hr/> <hr/>	<hr/> <hr/>

Merus US, Inc. was founded on March 1, 2016. Merus N.V. has a 100% subsidiary in Merus US, Inc. The equity of Merus US, Inc. at December 31, 2016 amounted to €287 thousand.

C. Property, Plant and Equipment

Movements in property, plant and equipment were as follows:

<i>(euros in thousands)</i>	Plant and equipment	Other fixed assets	Total
Balance as at January 1, 2015			
Costs	259	1,201	1,460
Accumulated depreciation	(145)	(962)	(1,107)
	<hr/>	<hr/>	<hr/>
Book value	114	239	353
	<hr/>	<hr/>	<hr/>
Changes in book value			
Additions	66	48	114
Depreciation	(27)	(111)	(138)
Disposals (Cost)	-	(29)	(29)
Disposals (Accumulated depreciation)	-	24	24
	<hr/>	<hr/>	<hr/>
Balance	39	(68)	(29)
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Balance as at December 31, 2015			
Costs	325	1,220	1,545
Accumulated depreciation	(171)	(1,049)	(1,220)
	<hr/>	<hr/>	<hr/>
Book value	154	171	325
	<hr/>	<hr/>	<hr/>
Changes in book value			
Additions	330	163	493
Depreciation	(56)	(118)	(174)
Disposals (Cost)	(6)	-	(6)
Disposals (Accumulated depreciation)	6	-	6
	<hr/>	<hr/>	<hr/>
Balance	274	45	319
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>
Balance as at December 31, 2016			
Costs	649	1,383	2032
Accumulated depreciation	(221)	(1,166)	(1,387)
	<hr/>	<hr/>	<hr/>
Book value	428	217	645
	<hr/> <hr/>	<hr/> <hr/>	<hr/> <hr/>

D. Intangible Assets

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

E. Taxation

Please refer to Note 8 of the consolidated financial statements for a detailed disclosure on the taxation.

F. Trade and Other Receivables

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

Balance per December 31 ***(euros in thousands)***

	2016	2015
Trade receivables	205	-
VAT receivable	782	296
Prepaid general expenses	381	136
Prepaid pension costs	463	364
Prepaid share issuance cost	229	814
Interest bank	32	45
Intercompany receivables	20	-
Other receivables	206	10
	<u>2,318</u>	<u>1,665</u>

Taxation and social security premiums receivable relate to value added tax receivable from the Dutch tax authorities based on the tax application for the third and fourth quarter of 2016.

Prepaid expenses reflected above in the form of prepaid general expenses, prepaid pension costs and prepaid IPO costs consist of expenses that were paid during the reporting period, but are related to activities taking place in the subsequent year.

G. Other Liabilities and Accruals

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

Balance per December 31 ***(euros in thousands)***

	2016	2015
Accrued auditor's fee	282	335
Accrual for holiday expenses	-	50
Personnel	176	141
R&D studies	1,256	741
IP – Legal fee	114	170
Bonuses	768	391
Subsidy advance received	201	1,294
Other accruals	781	243
	<u>3,578</u>	<u>3,365</u>

The R&D studies relate to accrued expenses for research and development projects.

The bonuses relate to the employee bonuses for the financial year 2016, which are paid out annually in February.

The other accruals include a total amount of €0.6 million related to legal expenses with regard to the Incyte collaboration as disclosed under Note 24.

H. Borrowings

Please refer to Note 12 to the consolidated financial statements for further information on the borrowings.

I. Deferred Revenue

Please refer to Note 13 to the consolidated financial statements for further information on deferred revenue.

J. Shareholders' Equity

Please refer to Note 14 to the consolidated financial statements for further information on equity.

K. Revenue

Please refer to Note 15 to the consolidated financial statements for further information on revenue.

L. Total Operating Expenses

	<u>2016</u>	<u>2015</u>
Manufacturing costs	3,162	5,878
IP and license costs	1,167	1,112
Personnel related R&D	3,770	3,166
Other research and development costs	10,810	6,194
<i>Total research and development costs</i>	<u>18,909</u>	<u>16,350</u>
Management and administration costs	2,400	768
Litigation costs	1,490	4,419
Other operating expenses	7,892	3,479
<i>Total other expenses</i>	<u>9,382</u>	<u>7,898</u>
Total operating expenses	<u>30,691</u>	<u>25,016</u>

Please refer to Note 16 to the consolidated financial statements for additional disclosure on the research and development expenses.

Personnel related expenses mainly increased due to the increase in staff as well as additional expenses resulting from the implementation of the 2016 option plan as well as the modification of the 2016 option plan, as described in Note 14 to the consolidated financial statements.

Litigation costs were lower in 2016 when compared to 2015 as a result of lower litigation activity with regard to the Regeneron litigation as described in Note 16 to the consolidated financial statements.

The other operating expenses relate to general and administrative expenses related to regular operations of the Company.

Operating expenses presented by nature are outlined below:

<i>Euros in thousands</i>	<u>2016</u>	<u>2015</u>
Costs of outsourced work	3,162	5,878
Other external costs	18,743	15,012
Employee benefits	6,170	3,933
Intercompany charges	2,381	-
Depreciation and amortization	234	193
Total operating expenses	<u>30,690</u>	<u>25,016</u>

The increase in other external cost is mainly due to the increase in clinical and preclinical operations.

M. Employee Benefits

Details of the employee benefits are as follows:

<i>Euros in thousands</i>	<u>2016</u>	<u>2015</u>
Salaries and wages	3,306	3,204
WBSO subsidy	(1,721)	(348)
Social security premiums	349	238
Health insurance	-	31
Pension costs	507	241
Stock award expense	3,307	567
Other personnel expense	422	-
	<u>6,170</u>	<u>3,933</u>

Refer to Note 14 to the consolidated financial statements for a detailed explanation on the option cost for the Company.

N. Finance Income and Expense

	<u>2016</u>	<u>2015</u>
<i>Euros in thousands</i>		
Interest income and similar income	88	50
Interest expenses and similar expenses	<u>(19,624)</u>	<u>(195)</u>
	<u>(19,537)</u>	<u>(145)</u>

The interest expenses and similar expenses include a total of €20.1 million related to the derivative resulting from the Incyte collaboration as described in Note 18 and Note 24 to the consolidated financial statements.

O. Loss per share

Please refer to Note 19 to the consolidated financial statements for the loss per share information.

P. Financial Instruments

Refer to Note 20 to the consolidated financial statements for further information on financial risk management, liquidity risk and market risk.

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

	<u>2016</u>	<u>2015</u>
Balance per December 31 in thousands of euros		
Financial asset (derivative).....	11,847	-
Trade receivables.....	205	-
Restricted cash.....	167	218
Cash and cash equivalents.....	<u>56,587</u>	<u>32,851</u>
	<u>68,806</u>	<u>33,069</u>

At year-end for each of 2016 and 2015, there was no significant concentration of credit risk at any of the counterparties regarding financial instruments and cash and cash equivalents. Cash balances are held at banks with credit ratings varying between A and AA.

The aging of trade and other receivables that were not impaired was as follows:

	<u>2016</u>	<u>2015</u>
<i>Balance per December 31 in thousands of euros</i>		
Neither past due nor impaired.....	205	-
Past due.....	-	-
	<u>205</u>	<u>-</u>

There is no allowance for impairment.

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:

December 31, 2016

	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
	(Euros in thousands)					
Non-derivative financial liabilities						
Secured bank loans	486	526	190	181	155	-
Trade and other payables	5,892	5,892	5,892	-	-	-
	<u>6,378</u>	<u>6,418</u>	<u>6,082</u>	<u>181</u>	<u>155</u>	<u>-</u>

December 31, 2015

	<u>Carrying amount</u>	<u>Total</u>	<u>< 12 months</u>	<u>1 - 2 years</u>	<u>2 - 5 years</u>	<u>More than 5 years</u>
	(Euros in thousands)					
Non-derivative financial liabilities						
Secured bank loans	653	709	193	186	330	-
Trade and other payables	5,926	5,926	5,926	-	-	-
	<u>6,579</u>	<u>6,635</u>	<u>6,119</u>	<u>186</u>	<u>330</u>	<u>-</u>

The secured bank loans have an interest rate that is fixed until March 2017. The interest payable on the loans in the table above assumes continuation of this interest rate. These amounts may change as market interest rates change.

Exposure to interest rate risk

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

	<u>Carrying amount</u>	
	<u>2016</u>	<u>2015</u>
Balance per December 31 in thousands of euros		
Fixed-rate instruments		
Financial liabilities	(486)	(653)
Variable rate instruments		
Cash and cash equivalents	56,587	32,851

Due to the limited impact of changes in interest rates on the Company no sensitivity data is provided.

Accounting classifications and fair values

The Company classifies financial assets and financial liabilities into the loans and receivables and other financial liability categories only, with the exception of the derivative recognized as a result of the Incyte collaboration and share Subscription agreement, we refer to note 24. These financial assets and financial liabilities are not measured at fair value and as such information on the fair value hierarchy is omitted. The carrying amount of the financial assets and financial liabilities is a reasonable approximation of the fair value.

The fair value of the derivative related to the Incyte collaboration and share Subscription agreement is recorded using Level 2 inputs. For determining the fair value the Company has used as valuation technique the Bloomberg forward pricing model. In this valuation the inputs used are related to the foreign exchange component (spot prices

of EUR and USD), closing stock prices of the Company, as well as discount rates to reflect the time value of money (limited).

Q. Compensation of Management Board and Supervisory Board

Refer to Note 21 to the consolidated financial statements for further information on management board and supervisory board compensation.

R. Related party disclosures

Refer to Note 22 to the consolidated financial statements for further information on related party transactions.

S. Operating leases

Refer to Note 23 to the consolidated financial statements for further information on operating leases.

T. 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	2016	2015
Audit Fees.....	€ 1,001,000	€ 661,000
Audit-Related Fees	-	-
Tax Fees.....	10,000	28,000
All Other Fees.....	-	-
Total Fees	€ 1,011,000	€ 689,000

Audit Fees

Audit fees consist of fees billed for the audit of our annual consolidated financial statements, the review of the interim consolidated financial statements, and related services that are normally provided in connection with registration statements, including the registration statement for our initial public offering.

Audit-Related Fees

Audit-related fees consist of specified procedures related to the filings of the quarterly financial information as well as assistance during the IPO. Included in the 2016 audit-related fees is €498,000 of fees billed in connection with our initial public offering in May 2016.

Tax Fees

Tax fees consist of fees for professional services, including tax consulting and compliance performed by KPMG Accountants N.V.

All Other Fees

We did not incur any other fees in 2016 or 2015.

U. Appropriation of Results

“It is proposed that the 2016 loss of €47,508 be 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.

V. Subsequent Events

Refer to Note 24 to the consolidated financial statements for further information on subsequent events.

2.12 Other information

Independent auditor's report

Report on the accompanying financial statements 2016



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Special rights of control under the Company's articles

Not applicable. The Company's articles do not grant any party special rights of control (*zeggenschap*) in respect of the Company

Shares carrying limited economic entitlement

The cumulative preferred shares in the Company's capital carry a limited (but preferential) entitlement to the Company's profit, reserves and liquidation proceeds. As at December 31, 2016, no cumulative preferred shares in the Company's capital were issued.