

As confidentially submitted to the Securities and Exchange Commission on September 8, 2015  
 This draft registration statement has not been publicly filed with the United States Securities and Exchange Commission and all information herein remains strictly confidential.

Registration No. 333-

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

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

**Merus B.V.\***

(Exact Name of Registrant as Specified in its Charter)

Not Applicable

(Translation of Registrant's Name into English)

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

2834  
 (Primary Standard Industrial Classification  
 Code Number)

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

Padualaan 8 (postvak 133)  
 3584 CH Utrecht, the Netherlands  
 +31 30 253 8800

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

Peter N. Handrinos  
 Nathan Ajiashvili  
 Latham & Watkins LLP  
 John Hancock Tower  
 200 Clarendon Street  
 Boston, Massachusetts 02116  
 +1 617 948 6000

Tom van Wijngaarden  
 Eversheds B.V.  
 De Cuserstraat 85a  
 1081 CN Amsterdam  
 PO Box 7902  
 1008 AC Amsterdam, the Netherlands  
 +31 20 5600 600

Roel Botter  
 Van Doorne N.V.  
 Jachthavenweg 121  
 1081 KM Amsterdam  
 P.O. Box 75265  
 1070 AG Amsterdam, the Netherlands  
 +31 20 6789 123

Divakar Gupta  
 Marc Recht  
 Brian F. Leaf  
 Cooley LLP  
 1114 Avenue of the Americas  
 New York, NY 10036-7798  
 +1 212 479 6000

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

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

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

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

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

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price(1)(2)	Amount of Registration Fee(3)
Common shares, nominal value €0.05 per share	\$	\$

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

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

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

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

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

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

SUBJECT TO COMPLETION, DATED \_\_\_\_\_, 2015

PRELIMINARY PROSPECTUS

# Merus

## Shares

# Merus B.V.

## Common Shares

\$ \_\_\_\_\_ per share

This is the initial public offering of our common shares. We are selling \_\_\_\_\_ of our common shares in this offering. We currently expect the initial public offering price to be between \$ \_\_\_\_\_ and \$ \_\_\_\_\_ per share.

We have granted the underwriters an option to purchase up to \_\_\_\_\_ additional common shares to cover over-allotments.

We intend to apply to have our common shares listed on The NASDAQ Global Market under the symbol "MRUS."

**Investing in our common shares involves risks. See "[Risk Factors](#)" beginning on page 12.**

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and will be eligible for reduced public company disclosure requirements. See "Summary—Implications of Being an Emerging Growth Company and a Foreign Private Issuer."

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

	Per Share	Total
Public Offering Price	\$ _____	\$ _____
Underwriting Discount(1)	\$ _____	\$ _____
Proceeds to Merus (before expenses)	\$ _____	\$ _____

(1) We refer you to "Underwriting" beginning on page 156 for additional information regarding underwriting compensation.

The underwriters expect to deliver the shares to purchasers on or about \_\_\_\_\_, 2015 through the book-entry facilities of The Depository Trust Company.

**Citigroup**

**Jefferies**

**Guggenheim Securities**

**Wedbush PacGrow**

\_\_\_\_\_, 2015

## Table of Contents

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

---

### TABLE OF CONTENTS

<a href="#">PRESENTATION OF FINANCIAL AND OTHER INFORMATION</a>	ii
<a href="#">CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS</a>	ii
<a href="#">SUMMARY</a>	1
<a href="#">RISK FACTORS</a>	12
<a href="#">MARKET AND INDUSTRY DATA</a>	56
<a href="#">TRADEMARKS, SERVICE MARKS AND TRADENAMES</a>	56
<a href="#">EXCHANGE RATE INFORMATION</a>	57
<a href="#">USE OF PROCEEDS</a>	58
<a href="#">DIVIDEND POLICY</a>	59
<a href="#">CAPITALIZATION</a>	60
<a href="#">DILUTION</a>	62
<a href="#">SELECTED FINANCIAL DATA</a>	64
<a href="#">MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS</a>	65
<a href="#">BUSINESS</a>	80
<a href="#">MANAGEMENT</a>	113
<a href="#">PRINCIPAL SHAREHOLDERS</a>	123
<a href="#">RELATED PARTY TRANSACTIONS</a>	125
<a href="#">DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION</a>	128
<a href="#">SHARES ELIGIBLE FOR FUTURE SALE</a>	145
<a href="#">MATERIAL TAX CONSIDERATIONS</a>	147
<a href="#">UNDERWRITING</a>	156
<a href="#">EXPENSES OF THE OFFERING</a>	162
<a href="#">LEGAL MATTERS</a>	163
<a href="#">EXPERTS</a>	163
<a href="#">ENFORCEMENT OF CIVIL LIABILITIES</a>	164
<a href="#">WHERE YOU CAN FIND MORE INFORMATION</a>	165
<a href="#">INDEX TO FINANCIAL STATEMENTS</a>	F-1

---

**For investors outside the United States: Neither we nor the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction, other than the United States, where action for that purpose is required. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of our common shares and the distribution of this prospectus outside the United States.**

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

## ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms “Merus,” the “Company,” “we,” “us” and “our” in this prospectus refer to (i) Merus B.V., together with its subsidiaries, prior to the conversion of Merus B.V. into Merus N.V. and (ii) Merus N.V., together with its subsidiaries, after giving effect to the conversion of Merus B.V. into Merus N.V., and such conversion is expected to occur immediately prior to the consummation of this offering.

## PRESENTATION OF FINANCIAL AND OTHER INFORMATION

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of the financial statements were prepared in accordance with generally accepted accounting principles in the United States. We present our financial statements in euros and in accordance with IFRS. We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them. All references in this prospectus to “\$,” “US\$,” “U.S.,” “U.S. dollars,” “dollars” and “USD” mean U.S. dollars and all references to “€” and “euros,” mean euros, unless otherwise noted.

Prior to the consummation of this offering, we intend to convert from a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*), Merus B.V., to a public company with limited liability (*naamloze vennootschap*), Merus N.V. The audited financial statements for the years ended and as of December 31, 2014 and 2013 are the financial statements for Merus B.V.

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

Forward-looking statements appear in a number of places in this prospectus and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements are subject to risks and uncertainties, and actual results may differ materially from those expressed or implied in the forward-looking statements due to various important factors, including, but not limited to, those identified under the section titled “Risk Factors” in this prospectus. Forward-looking statements include, but are not limited to, statements about:

- our operations as a clinical-stage company with limited operating history and a history of operating losses;
- the initiation, timing, progress and results of clinical trials of our bispecific antibody candidates, including statements regarding when results of the trials will be made public;
- our plans to pursue research and development of our lead bispecific antibody candidate, MCLA-128, for the treatment of patients with various solid tumors;
- our plans to pursue research and development of our second bispecific antibody candidate, MCLA-117, for the treatment of patients with acute myeloid leukemia, or AML;
- the potential advantages of MCLA-128 for the treatment of patients with various solid tumors;
- the potential advantages of MCLA-117 for the treatment of patients with AML;
- the timing or likelihood of regulatory filings and approvals for any bispecific antibody candidates;

## Table of Contents

- our ability to establish sales, marketing and distribution capabilities;
- our ability to establish and maintain manufacturing arrangements for our bispecific antibody candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our bispecific antibody candidates and technology;
- our ability to defend against any claims by third parties that we are infringing upon their intellectual property rights;
- our expectations regarding the use of proceeds from this offering;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the rate and degree of market acceptance of our bispecific antibody candidates;
- the impact of government laws and regulations on our business;
- our competitive position; and
- other risk factors discussed under “Risk Factors.”

Forward-looking statements speak only as of the date they are made, and we do not undertake any obligation to update them in light of new information or future developments or to release publicly any revisions to these statements in order to reflect later events or circumstances or to reflect the occurrence of unanticipated events.

## SUMMARY

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

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. We have a pipeline of full-length human bispecific antibodies, which we refer to as Biclonics, generated from our technology platform. Biclonics can be designed 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 various solid tumors, and we expect to report top-line results from this trial in the first half of 2017. In the first quarter of 2016, we expect to commence a Phase 1/2 clinical trial with our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML. Additionally, we have several bispecific antibody candidates in pre-clinical development that bind to combinations of immunomodulatory molecules, including programmed death receptor-1, or PD-1, and programmed death-ligand 1, or PD-L1, both of which we believe play a significant role in treating cancer.

By binding to two different antigens, or targets, we believe Biclonics may provide several advantages over existing cancer therapeutics, including greater potency and lower toxicity. Our Biclonics technology platform enables rapid functional screening of large collections of Biclonics to identify lead candidates with multiple mechanisms of action. The Biclonics format retains the Immunoglobulin G, or IgG, format of conventional monoclonal antibodies, or mAbs, and is designed to preserve its key features, including stability, long half-life and low immunogenicity, in our bispecific antibody candidates. We leverage industry-standard manufacturing processes and infrastructure to efficiently produce Biclonics.

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, colorectal 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 natural killer, or 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 binding molecule, or 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 early stages of the dose escalation, we have observed a measurable positive effect in 3 out of 12 evaluable patients treated to date with MCLA-128. In two patients, the disease did not progress, a condition defined as stable disease. For the third patient, we observed reduction in size and disappearance of some metastatic lesions with no new tumors appearing to date, and this result is defined as a partial response. We expect to report top-line results from the Phase 1/2 trial in the first half of 2017.

Our second bispecific antibody candidate, MCLA-117, is expected to commence a Phase 1/2 clinical trial in Europe for the treatment of AML in the first quarter of 2016. AML generally has a poor prognosis and clinical and pre-clinical studies suggest that treatment-resistant leukemic stem cells are a potential cause of disease

## Table of Contents

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 are also currently evaluating MCLA-117 for the treatment of myelodysplastic syndrome, or MDS, in pre-clinical studies.

Our management team has a broad range of experience in research and late-stage clinical development in the fields of antibody engineering, immunology and medical oncology. 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. Dr. Logtenberg has authored more than 80 scientific publications and is named as an inventor on 20 patent applications and patent families in the field of antibody engineering.

### Our Product Pipeline

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

Bispecific Antibody Candidate	Targets	Indication	Pre-Clinical	IND / CTA	Phase 1 / 2
MCLA-128	HER2, HER3	Breast cancer <sup>(1)</sup>	████████████████████	████████████████████	████████████████████
		Colorectal cancer <sup>(1)</sup>	████████████████████	████████████████████	████████████████████
		Ovarian cancer <sup>(1)</sup>	████████████████████	████████████████████	████████████████████
MCLA-117	CD3, CLEC12A	AML	████████████████████	████████████████████	
		MDS	████████████████████		
MCLA-134	PD-1, TIM-3	Various solid tumors	████████████████████		
MCLA-114	CD3, undisclosed	Multiple myeloma	████████████████████		
MCLA-145	PD-L1, undisclosed	Various solid tumors	████████████████████		
Potential for Multiple Programs Leveraging Biclonics Technology Platform	Combinations including checkpoint inhibitory, co-stimulatory and cancer stem cell targets	Various solid and hematological tumors	████████████████████		

<sup>(1)</sup> Based on the results of our Phase 1/2 trial for MCLA-128, we may choose to evaluate the use of MCLA-128 for the treatment of additional solid tumors in the future.

### Our Biclonics Platform

We have a pipeline of Biclonics 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 Biclonics against any particular target pair.

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

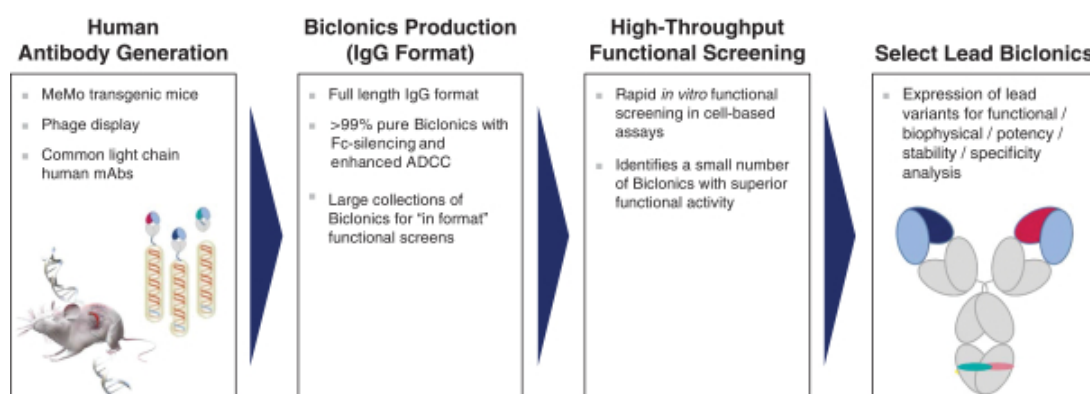
- **Blocking combinations of growth factor receptors that drive tumor cell growth and relapse while simultaneously recruiting immune effector cells through enhanced ADCC.** Biclonics may be generated for different combinations of growth factor receptors that play a role in tumors with different

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 antibody-dependent cellular cytotoxicity, or 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 can be 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 revive T-cells to kill tumor cells. 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 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 tumor cells. 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 Biclomics





Our Biclomics technology platform includes the following:

- **Human antibody generation.** We use our human antibody generation technology, comprised of our proprietary transgenic mice, which we refer to as MeMo, 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 Biclomics format.
- **The full-length Immunoglobulin G format.** The Biclomics format retains several of the favorable attributes of conventional human IgG mAbs, including their stability and predictability during manufacturing and their long half-life and low immunogenicity during treatment of patients.
- **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 constant 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.

#### 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 peptides.** 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 peptides, or 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 heterodimer 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 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 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 and ovarian cancers. We commenced a Phase 1/2 clinical trial of MCLA-128 in February 2015. 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 with the intent of seeking orphan drug designation from the FDA and the EMA. We intend to submit a Clinical Trial Application, or CTA, to the EMA by the end of 2015. 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 Biclonics for the treatment of other forms of cancer. Our platform enables rapid functional screening of large collections of Biclonics to identify lead candidates with multiple mechanisms of action that have the potential to kill tumor cells with high potency. We are currently evaluating Biclonics that target various combinations of checkpoint inhibitory, co-stimulatory and cancer stem cell targets.
- **Seek strategic collaborative relationships.** We intend to seek strategic collaborations to facilitate the capital-efficient development of our Biclonics technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We believe these collaborations could potentially provide significant funding to advance our bispecific antibody candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

### Financing History

Since inception, we have financed our operations primarily through a series of private placements of our Class A, Class B and Class C preferred shares with a number of European and U.S.-based venture capital firms, providing total gross proceeds of €91.3 million in the aggregate.

In August 2015, we entered into a subscription agreement pursuant to which we sold an aggregate of 6,268,579 of our Class C preferred shares for aggregate consideration of €41.6 million and fully converted our €8.0 million convertible bridge loan into 1,201,201 Class C preferred shares in connection with the consummation of the first tranche of the private placement, or the Class C Financing. See “Related Party Transactions—Convertible Bridge Loan and Class C Preferred Share Financing.”

All of our outstanding Class A, Class B and Class C preferred shares will be automatically converted into common shares on a -for- basis upon the closing of this offering.

### Corporate Information

We were incorporated under the laws of the Netherlands on June 16, 2003 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*), and prior to the consummation of this offering, we intend to convert to a Dutch public company with limited liability (*naamloze vennootschap*). Our principal executive offices are located at Padualaan 8 (postvak 133), 3584 CH Utrecht, the Netherlands. Our telephone number at this address is +31 30 253 8800.

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

### **Risks Associated with Our Business**

Our business is subject to a number of risks of which you should be aware before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth under the “Risk Factors” section of this prospectus in deciding whether to invest in our securities. Among these important risks are the following:

- We have a limited operating history, have incurred significant losses since our inception, expect to incur losses for the foreseeable future and may never achieve or maintain profitability.
- We will need additional funding to complete the development of our bispecific antibody candidates and commercialize our products, if approved, and 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.
- The Biclomics technology platform is an unproven novel approach to the production of molecules for therapeutic intervention.
- We are very early in our development efforts and our bispecific antibody candidates, including MCLA-128 and MCLA-117, may not be successful in clinical trials and, as a result, may never be approved as marketable therapeutics.
- 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.
- We may encounter regulatory changes that delay or impede our development and commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials and to manufacture our bispecific antibody candidates for pre-clinical and clinical testing, and those third parties may not perform satisfactorily, which could delay our product development activities.
- If we are unable to adequately protect our technology, or to secure and maintain freedom to operate and/or issue patents protecting our bispecific antibody candidates, others could preclude us from commercializing our technology and products and/or compete against us more directly, which would have a material adverse impact on our business, results of operations, financial condition and prospects.
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.
- The rights of shareholders in companies subject to Dutch corporate law differ in material respects from the rights of shareholders of corporations incorporated in the United States.

### **Implications of Being an Emerging Growth Company and a Foreign Private Issuer**

We are an “emerging growth company” as defined in the Jumpstart Our Business Startups Act, or JOBS Act. As such, we are eligible, for up to five years, to take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not emerging growth companies. These exemptions include:

- the option to present only two years of audited financial statements and only two years of related Management’s Discussion and Analysis of Financial Condition and Results of Operations in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002;

- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- we are not required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency” and “say-on-golden parachutes;” and
- we are not required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

We may take advantage of these provisions until the last day of our fiscal year following the fifth anniversary of the completion of this offering or such earlier time that we are no longer an emerging growth company. As a result, the information we provide to our shareholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are choosing to irrevocably opt out of this extended transition period and as a result, we will comply with new or revised accounting standards on the relevant dates on which adoption of such standards is required for non-emerging growth companies. Under federal securities laws, our decision to opt out of the extended transition period is irrevocable.

We will remain an emerging growth company until the earliest of: (i) the last day of the first fiscal year in which our annual gross revenues exceed \$1 billion; (ii) the last day of the fiscal year following the fifth anniversary of the date of this offering; (iii) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur if the aggregate market value of our common shares that is held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (iv) the date on which we have issued more than \$1 billion in non-convertible debt securities during any three-year period.

Upon consummation of this offering, we will report under the Exchange Act as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, for as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- 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
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specific information, or current reports on Form 8-K, upon the occurrence of specified significant events.

Both foreign private issuers and emerging growth companies are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an emerging growth company, but remain a foreign private issuer, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an emerging growth company nor a foreign private issuer.

**THE OFFERING**

Common shares offered by us	common shares
Common shares to be outstanding after this offering	common shares ( common shares if the underwriters exercise their option to purchase additional common shares from us in full)
Option to purchase additional shares	We have granted the underwriters an option to purchase up to additional common shares from us within 30 days of the date of this prospectus.
Use of proceeds	We estimate that the net proceeds to us from this offering will be approximately \$ million, assuming an initial public offering price of \$ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We intend to use the net proceeds from this offering, together with our cash and cash equivalents on hand, to fund research and development efforts for our bispecific antibody candidates and the remainder for working capital and other general corporate purposes. See “Use of Proceeds.”
Dividend 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.
Risk factors	See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should consider before deciding to invest in our common shares.
Listing	We intend to apply to list our common shares on The NASDAQ Global Market, or NASDAQ, under the symbol “MRUS”.

The number of our common shares to be outstanding after this offering is based on common shares outstanding as of June 30, 2015, after giving effect to the Class C Financing and the automatic conversion of all of our outstanding preferred shares into an aggregate of common shares upon the closing of this offering, and excludes:

- common shares issuable upon the exercise of share options outstanding as of June 30, 2015 at a weighted average exercise price of € per share; and
- common shares reserved for future issuance under our employee share option programs as described in “Management—Long-Term Incentive Plans.”

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

- the consummation of the Class C Financing;
- the automatic conversion of all of our outstanding preferred shares into an aggregate of common shares upon the closing of this offering;
- no exercise of the outstanding options described above after , 2015;

[Table of Contents](#)

- our conversion into a public company with limited liability (*naamloze vennootschap*) under the laws of the Netherlands and the amendment of our Articles of Association as adopted by our general meeting of shareholders prior to the consummation of this offering;
- no exercise by the underwriters of their option to purchase additional common shares in this offering; and
- an initial public offering price of \$        per share, which is the midpoint of the price range set forth on the cover page of this prospectus.

## SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of comprehensive loss data for the years ended December 31, 2014 and 2013 and the statement of financial position data as of December 31, 2014 from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

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

	<u>Year Ended December 31,</u>	
	<u>2014</u>	<u>2013</u>
(euros in thousands, except share and per share data)		
<b>Statement of Comprehensive Loss Data:</b>		
Revenue	€ 1,303	€ 558
Costs of outsourced work and other external costs:		
Research and development costs	(14,099)	(6,054)
Other operating expenses	(1,203)	(1,294)
Personnel expenses	(3,168)	(2,852)
Depreciation and amortization	(253)	(264)
Operating loss	(17,420)	(9,906)
Finance income and expense	11	(2)
Net loss and comprehensive loss	<u>€ (17,409)</u>	<u>€ (9,908)</u>
Net loss per share, basic and diluted	€ (3.42)	€ (2.75)
Weighted average common shares outstanding, basic and diluted	5,093,258	3,603,827
Pro forma net loss per share, basic and diluted (unaudited)(1)		
Pro forma weighted average common shares outstanding, basic and diluted (unaudited)(1)		

- (1) Pro forma to reflect the automatic conversion of our Class A, Class B and Class C preferred shares into common shares on a -for- basis upon the closing of this offering. Pro forma basic net loss per share and diluted net loss per share are the same because outstanding options would be anti-dilutive due to our net loss in this period.

	<u>As of December 31, 2014</u>		
	<u>Actual</u>	<u>Pro Forma(1)</u>	<u>Pro Forma As Adjusted(2)</u>
(euros in thousands)			
<b>Statement of Financial Position Data:</b>			
Cash and cash equivalents	€ 1,841	€	€
Total assets	3,540		
Total liabilities	7,099		
Accumulated deficit	(40,765)		
Total equity (deficit)	(3,559)		

- (1) The pro forma balance sheet data give effect to (i) the sale by us of 6,268,579 Class C preferred shares in August 2015 for gross proceeds of €41.6 million, (ii) the borrowing of our €8.0 million convertible bridge loan in June 2015 and the subsequent conversion of such loan into 1,201,201 Class C preferred shares in

connection with the consummation of the Class C Financing and (iii) the automatic conversion of all of our preferred shares outstanding, including the preferred shares issued in the Class C Financing, into an aggregate of            common shares in connection with the closing of this offering. See “Related Party Transactions—Convertible Bridge Loan and Class C Preferred Share Financing.”

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



## RISK FACTORS

*You should carefully consider the risks and uncertainties described below and the other information in this prospectus before making an investment in our common shares. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common shares could decline and you could lose all or part of your investment. This prospectus also contains forward-looking statements that involve risks and uncertainties. See “Cautionary Statement Regarding Forward-Looking Statements.” Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.*

### Risks Related to Our Business and Industry

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

We are a clinical-stage immuno-oncology company with a limited operating history. We have incurred net losses of €17.4 million and €9.9 million for the years ended December 31, 2014 and 2013, respectively. As of December 31, 2014, we had an accumulated deficit of €40.8 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;
- continue the research and development of our other bispecific antibody candidates, including completing pre-clinical studies and commencing clinical trials for our second bispecific antibody candidate, MCLA-117;
- seek to enhance our technology platform, which generates our pipeline of Biclonics, 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 transition to 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 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 Biclonics technology platform, identifying potential bispecific antibody candidates and conducting pre-clinical studies and initiating our clinical trial for MCLA-128. We are in the early stages of development of our bispecific antibody candidates, and we have not completed development of any Biclonics or any other drugs or biologics.

## [Table of Contents](#)

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 additional bispecific antibody candidates, obtaining regulatory approval for these bispecific antibody candidates and manufacturing, marketing and selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

Because of the numerous risks and uncertainties associated with pharmaceutical product and biological development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. If we are required by the FDA, the EMA or other regulatory authorities to perform studies in addition to those we currently anticipate, or if there are any delays in completing our clinical trials or the development of any of our bispecific antibody candidates, our expenses could increase and 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. A decline in the market price of our common shares also could cause you to lose all or a part of your investment.

***Even if this offering is successful, 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 continue to research, develop and initiate clinical trials of MCLA-117 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, upon the closing of this offering, we expect 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.

We expect that our existing cash, cash equivalents and investments, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least . 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;
- 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-117;
- the costs, timing and outcome of regulatory review 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;

## Table of Contents

- 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 entering into licensing or collaboration arrangements for bispecific antibody candidates, although we currently have no commitments or agreements to complete any such transactions.

***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 and any strategic partners we may have 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 lead bispecific antibody candidate, MCLA-128, is in a Phase 1/2 clinical trial, while our remaining bispecific antibody candidates are still in pre-clinical development. 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 license to others, 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 the collaboration, 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, 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 European Union, or 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.***

Our Biclomics technology platform generates bispecific antibodies that are designed to eradicate tumor cells by blocking receptors that drive tumor cell growth and survival and/or simultaneously recruiting and activating various killer cells in the immune system. We have not, nor to our knowledge has any other company, received regulatory approval for a therapeutic based on a full-length human 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 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. All but one of our bispecific antibody candidates, MCLA-128, are still in pre-clinical development. We recently commenced the Phase 1/2 clinical trial of MCLA-128, our lead bispecific antibody candidate, but have not completed any clinical trials for this or any other 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 shareholders, including purchasers of common shares in this offering, 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 a combination of the net proceeds of this offering, together with our existing cash and cash equivalents. In order to accomplish our business objectives and further develop our product pipeline, however, we will 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 stockholders and

## [Table of Contents](#)

the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. 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 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 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 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. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

**Risks 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, 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 for MCLA-128 in February 2015, and although 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 obtain regulatory approval to commence a trial;
- 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 or failure to obtain institutional review board, or IRB, approval at each site;

## Table of Contents

- delays in or failure to recruit suitable patients to participate in a trial;
- 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;
- manufacturing sufficient quantities of bispecific antibody candidate for use in clinical trials;
- 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;
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires;
- 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;
- changes in regulatory requirements, policies and guidelines;
- lower than anticipated retention rates of patients and volunteers in clinical trials;
- 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;
- delays in establishing the appropriate dosage levels in clinical trials;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results; and
- the quality or stability of the bispecific antibody candidate falling below acceptable standards.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Review Committee, or DRC, or Data Safety Monitoring Board, or DSMB, for such trial or by the FDA 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 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 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 are conducted in countries outside the EU and the United States, which 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 or other comparable foreign authorities. In February 2015, we commenced a Phase 1/2 clinical trial 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. Patients treated with our bispecific antibody candidates may require pre-treatment with corticosteroids to mitigate potential side effects. While we have not yet initiated clinical trials for our other bispecific antibody candidates, as is the case with all oncology products, it is possible that there may be side effects associated with their use. 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 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;

## [Table of Contents](#)

- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

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

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

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For the clinical trial we recently launched in February 2015, we plan to enroll up to 120 patients with advanced solid tumors. 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

## [Table of Contents](#)

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 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 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 or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that 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 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 or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;

## [Table of Contents](#)

- 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 or elsewhere;
- the FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with partners; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

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 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 Europe, 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. 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 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.

#### **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 a number of legislative and regulatory 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, as of 2014, has authority to recommend certain changes to the Medicare program that could result in reduced payments for prescription drugs and

## [Table of Contents](#)

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.

At this time, the full effect that the ACA would have on our business remains unclear.

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 2024 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 may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. The U.S. Department of Health and Human Services, or HHS, has set a goal of moving 30% of Medicare payments to alternative payment models by 2016 and 50% of Medicare payments into these alternative payment models by the end of 2018. 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



## [Table of Contents](#)

service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our bispecific antibody candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. 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 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, which impose criminal and civil penalties, and includes the civil False Claims Act, through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent 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;

## [Table of Contents](#)

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- the U.S. federal Food, Drug and Cosmetic Act, or FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians, other healthcare providers, and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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 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 to be not 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.

## 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 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, our collaborators may decide to market and sell products that compete with the bispecific antibody candidates that we have agreed to license to it, 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 by 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 Europe, 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 designations.

***The successful commercialization of our bispecific antibody candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate 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.

## [Table of Contents](#)

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 our lead bispecific antibody candidates are still in 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 partners.***

We have never commercialized a bispecific antibody candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for our bispecific antibody candidates that our collaborators have licensed under our collaboration, 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 a 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.

## 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 European Economic Area, or 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.



***Independent clinical investigators and CROs that we engage to conduct our clinical trials may not devote sufficient time or attention to our clinical trials or be able to repeat their past success.***

We expect to continue to depend on independent clinical investigators and CROs to conduct our clinical trials. CROs may also assist us in the collection and analysis of data. There is a limited number of third-party service providers that specialize or have the expertise required to achieve our business objectives. Identifying, qualifying and managing performance of third-party service providers can be difficult, time consuming and cause delays in our development programs. These investigators and CROs will not be 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. Further, the FDA and other regulatory authorities require that we comply with standards, commonly referred to as current Good Clinical Practice, or cGCP, for conducting, recording and reporting clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial subjects are protected. Failure of clinical investigators or CROs to meet their obligations to us or comply with cGCP procedures could adversely affect the clinical development of our bispecific antibody candidates and harm our business.

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

Our product development programs and the potential commercialization of our 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 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;

## [Table of Contents](#)

- 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. For the manufacturing of MCLA-128 and MCLA-117, we have contracted with Boehringer Ingelheim, a biopharmaceuticals CMO, for their production. 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 the regulatory requirements, known as cGMPs, 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, 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.

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

***We rely on patents and other intellectual property rights to protect our 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 our bispecific antibody candidates, methods used to manufacture those products and the methods for treating patients using those products, 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

## [Table of Contents](#)

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 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 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, 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 products 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 products or elements thereof, our manufacture or uses relevant to our development plans, the targets of 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

## [Table of Contents](#)

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 defenses against such claims, including defenses under safe harbors designed to protect activity undertaken to obtain federal regulatory approval of a drug, like 35 U.S.C. § 271(e) and similar foreign statutes, patent invalidity and/or unenforceability. However, if such 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 may have filed patent applications or have patents on aspects of the targets or their uses, and there can be no assurance we will not need to seek licenses from such third parties or have such patents asserted against us.

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 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

## [Table of Contents](#)

industries, including the 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. Currently, we are defending against a lawsuit filed by Regeneron Pharmaceuticals Inc. in the United States, in which it has alleged that we have infringed its U.S. Patent No. 8,502,018 entitled “Methods of Modifying Eukaryotic Cells.” A further description of this litigation is found below under the section “Business—Legal Proceedings.” The European equivalent of this patent has been successfully opposed by us and is currently under appeal by Regeneron. Regeneron also initiated a lawsuit against us in the Netherlands which has been stayed pending conclusion of the European opposition.

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 time 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 Pharmaceuticals Inc. 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 patent infringement lawsuit recently filed by Regeneron Pharmaceuticals Inc.

### ***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

## [Table of Contents](#)

similar legislation in the EU. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced, possibly materially.

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

We generally file our first patent application (*i.e.*, priority filing) at the European Patent Office, or the EPO. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within twelve 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.



## [Table of Contents](#)

- 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 addition, the America Invents Act, or the AIA, has been recently enacted in the United States, resulting in significant changes to the U.S. patent system.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned 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. A third party that files a patent application in the USPTO after that date but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by the third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application, but circumstances could prevent us from promptly filing patent applications on our inventions.

Among some of the other changes introduced by the AIA are 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 United States 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 implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.

## [Table of Contents](#)

The USPTO recently developed new regulations and procedures to govern administration of the AIA, and many of the substantive changes to patent law associated with the AIA, and, in particular, the first to file provisions, only became effective on March 16, 2013. Accordingly, it is not clear what, if any, impact the AIA will have on the operation of our business. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our or our licensors' or collaboration partners' patent applications and the enforcement or defense of our or our licensors' or collaboration partners' issued patents, all of which could have an adverse effect on our business and financial condition.

Additionally, the U.S. Supreme Court has ruled on several patent cases in recent years, such as *Association for Molecular Pathology v. Myriad Genetics, Inc. (Myriad I)*, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, and *Alice Corporation Pty. Ltd. v. CLS Bank International*, 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 U.S. Patent and Trademark Office, 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, the complexity and uncertainty of European patent laws has also increased in recent years. For example, the EPC was amended in April 2010 by limiting 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 changes could limit 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 advisors 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.***

Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. A significant disruption in the availability of our information technology and other internal infrastructure systems could cause interruptions in our collaborations with our partners and delays in our research and development work.

#### **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.

## [Table of Contents](#)

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.

### **Risks Related to the Offering and 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 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 incur significant legal, accounting and other expenses that we did not incur as a private company. Prior to the consummation of this offering, we intend to convert to a Dutch public company with limited liability (*naamloze vennootschap*). 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 devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified members of our management board and supervisory board.

Overall, we estimate that our incremental costs resulting from operating as a public company, including compliance with these rules and regulations, may be between € million and € million per year. 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. However, 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 will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that 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.

***There has been no public market for our common shares prior to this offering, and an active market in the shares may not develop in which investors can resell our common shares.***

Prior to this offering, there has been no public market for our common shares. We cannot predict the extent to which an active market for our common shares will develop or be sustained after this offering, or how the development of such a market might affect the market price for our common shares. The initial public offering price of our common shares in this offering will be agreed upon between us and the underwriters based on a number of factors, including market conditions in effect at the time of the offering, which may not be indicative of the price at which our shares will trade following completion of the offering. Investors may not be able to sell their shares at or above the initial public offering price.

***Certain of our existing shareholders and members of our management board will continue to own a majority of our common shares and as a result, will be able to exercise significant control over us, and your interests may conflict with the interests of our existing shareholders.***

Following completion of this offering, our existing shareholders are expected to own approximately % 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 you 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 and dilute shareholders.***

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. Following the completion of this offering, we will have common shares outstanding (assuming no exercise of the underwriters' option to purchase additional common shares from us) based on common shares outstanding as of June 30, 2015 and additional common shares issuable upon the conversion of all of our outstanding preferred shares into common shares after giving effect to the Class C Financing. This includes the issuance and sale of shares in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. Approximately % of the shares outstanding will be held by existing shareholders. A significant portion of these shares will be subject to the lock-up agreements described in the "Underwriting" section of this prospectus. If, after the end of such lock-up agreements, these shareholders sell substantial amounts of shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. We also intend to enter into a registration rights agreement upon the consummation of this offering pursuant to which we will agree 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 intend to register all common shares that we may issue under our equity compensation plans. Once we register these common shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

***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;

## [Table of Contents](#)

- staggered four-year terms of our supervisory board members;
- 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 have 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, newly established foundation, which will be structured to operate independently of us.

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 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 will 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 will be structured to operate independently of us.

### ***If you purchase common shares in this offering, you will suffer immediate dilution of your investment.***

The assumed initial public offering price of our common shares is substantially higher than the pro forma net tangible book value per common share. Therefore, if you purchase common shares in this offering, you will pay a price per share that substantially exceeds our pro forma net tangible book value per common share after this offering. To the extent outstanding options are exercised, you will incur further dilution. Based on the assumed initial public offering price of \$      per share, which is the midpoint of the range set forth on the cover page of this prospectus, you will experience immediate dilution of \$      per share, representing the difference between our pro forma net tangible book value per share after giving effect to this offering and the assumed initial public offering price. In addition, purchasers of common shares in this offering will have contributed approximately      % of the aggregate price paid by all purchasers of our common shares but will own only approximately      % of our common shares outstanding after this offering. See "Dilution."

### ***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***

Our management board will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common shares. The failure by our management board to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common shares to decline

## [Table of Contents](#)

and delay the development of our bispecific antibody candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

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

We have not paid any 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 dividends will not be paid until we have an established revenue stream to support continuing dividends. Payment of 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 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 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). See "Description of Share Capital and Articles of Association—Comparison of Dutch Corporate Law and Our Articles of Association and U.S. Corporate Law—Preemptive Rights." 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.

### ***Upon the consummation of this offering, we will be a Dutch public company with limited liability (naamloze vennootschap). The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.***

Upon the consummation of this offering, we will be 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, your interests as a shareholder. See "Description of Share Capital and Articles of Association—Corporate Governance."

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

Upon the consummation of this offering, we will be a Dutch public company with limited liability (*naamloze vennootschap*) and will be subject to the Dutch Corporate Governance Code, or 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,



## [Table of Contents](#)

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 independency 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. See “Description of Share Capital and Articles of Association—Dutch Corporate Governance Code.” This may affect your rights as a shareholder and you 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. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

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. 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. 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*).

Based on the lack of a treaty as described above, U.S. investors may not be able to enforce against 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 any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

### ***We will be 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.***

Upon the consummation of this offering, we will 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 and although we are subject to Dutch laws and regulations with regard to such matters and intend to furnish quarterly financial information to the SEC, 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 Securities and

## [Table of Contents](#)

Exchange Commission, or 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, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

***As a foreign private issuer and as permitted by the listing requirements of NASDAQ, we will 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 will 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. For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association—Corporate Governance.” Accordingly, you 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. We may no longer be a foreign private issuer as of June 30, 2016 (the end of our second fiscal quarter in the fiscal year after this offering), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of January 1, 2016. In order to maintain our current status as a foreign private issuer, either (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 required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. 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 any June 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an “emerging growth company” as of the following December 31 (our 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 we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls 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. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal controls could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

***If securities or industry analysts do not publish research, or 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may

## [Table of Contents](#)

never, publish research on us. If no or too few securities or industry analysts commence coverage on us, the trading price for our common shares would likely be negatively affected. In the event securities or industry analysts initiate coverage, 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 expect to be a “passive foreign investment company,” or PFIC, for the current taxable year or in the foreseeable future. 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. Furthermore, a separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. Accordingly, we cannot assure you that we will not be a PFIC for our current taxable year or any future taxable year. 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. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined below under “Material Tax Considerations— Material U.S. Federal Income Tax Considerations for U.S. Holders”) holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See “Material Tax Considerations— Material U.S. Federal Income Tax Considerations for U.S. Holders —Passive Foreign Investment Company Rules.”

## **MARKET AND INDUSTRY DATA**

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

## **TRADEMARKS, SERVICE MARKS AND TRADENAMES**

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

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

**EXCHANGE RATE INFORMATION**

Our business is primarily conducted in the EU, and we maintain our books and records in euros. We have presented our results of operations in euros. In this prospectus, translations from euros to U.S. dollars were made at the rate of €0.892 to \$1.00, the official exchange rate quoted as of August 31, 2015 by the European Central Bank. Such U.S. dollar amounts are not necessarily indicative of the amounts 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>
	<u>(euros per U.S. dollar)</u>			
<b>Year Ended December 31:</b>				
2010	0.748	0.754	0.687	0.837
2011	0.773	0.718	0.672	0.776
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
<b>Month Ended:</b>				
January 31, 2015	0.885	0.859	0.824	0.893
February 28, 2015	0.830	0.881	0.874	0.890
March 31, 2015	0.922	0.923	0.890	0.947
April 30, 2015	0.892	0.928	0.892	0.948
May 31, 2015	0.912	0.897	0.876	0.921
June 30, 2015	0.894	0.892	0.877	0.914
July 31, 2015	0.912	0.909	0.894	0.923
August 31, 2015	0.892	0.899	0.869	0.919

## USE OF PROCEEDS

We estimate that the net proceeds to us from this offering will be approximately \$ \_\_\_\_\_, assuming an initial public offering price per share of \$ \_\_\_\_\_, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and expenses of the offering that are payable by us. Each \$1.00 increase (decrease) in the assumed initial public offering price per share would increase (decrease) our net proceeds, after deducting the estimated underwriting discounts and commissions and expenses, by \$ \_\_\_\_\_, assuming that the number of common shares offered by us, as set forth on the cover of this prospectus, remains the same. Each increase (decrease) of \_\_\_\_\_ common shares in the number of common shares offered by us would increase (decrease) our net proceeds, after deducting the estimated underwriting discounts and commissions and expenses, by approximately \$ \_\_\_\_\_ million, assuming no change in the assumed initial public offering price per share.

As of June 30, 2015, we had cash and cash equivalents of € \_\_\_\_\_ million. We intend to use the net proceeds from this offering, together with our cash and cash equivalents on hand, to fund research and development efforts for our bispecific antibody candidates and the remainder of any net proceeds for working capital and other general corporate purposes.

This expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional businesses, technologies, products or assets, although currently we have no specific agreements, commitments or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the costs necessary to develop bispecific antibody candidates can be difficult. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from pre-clinical studies and any ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties for our bispecific antibody candidates and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

Based on our planned use of the net proceeds of this offering and our current cash and cash equivalents described above, we estimate that such funds will be sufficient to enable us to fund our operating expenses and capital expenditure requirements through at least \_\_\_\_\_. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds from this offering in short- and intermediate-term interest-bearing obligations and certificates of deposit.

## **DIVIDEND 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, we may only pay dividends if our 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.



## CAPITALIZATION

The table below sets forth our cash and cash equivalents and capitalization as of December 31, 2014 derived from our audited financial statements included elsewhere in this prospectus:

- on an actual basis;
- on a pro forma basis to give effect to: (i) the consummation of the Class C Financing; (ii) the automatic conversion of all outstanding preferred shares, including the preferred shares issued in the Class C Financing, into an aggregate of \_\_\_\_\_ common shares upon the closing of this offering; and (iii) the amendment of our Articles of Association as adopted by our general meeting of shareholders in connection with this offering; and
- on a pro forma as adjusted basis to give further effect to the issuance and sale of \_\_\_\_\_ common shares in this offering at the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Investors should read this table in conjunction with our audited financial statements included in this Prospectus as well as “Use of Proceeds,” “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

<u>(euro in thousands)</u>	<b>December 31, 2014</b>		
	<b>Actual</b>	<b>Pro Forma</b>	<b>Pro Forma As Adjusted(1)</b>
Cash and cash equivalents	€ 1,841	€	€
Total debt, including current portion	€ 819		
Shareholders’ equity:			
Issued capital:			
Common shares	30		
Class A preferred shares	21		
Class B preferred shares	231		
Class C preferred shares	—		
Share premium	36,924		
Accumulated deficit	(40,765)		
Total equity (deficit)	(3,559)		
Total capitalization	€ (2,740)	€	€

- (1) A \$1.00 increase or decrease in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, share premium, total shareholders’ equity and total capitalization by approximately € \_\_\_\_\_ million, assuming the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated underwriting discounts and commissions. An increase or decrease of 1,000,000 shares in the number of common shares offered by us, as set forth on the cover page of this prospectus, would increase or decrease the pro forma as adjusted amount of each of cash and cash equivalents, share premium, total shareholders’ equity and total capitalization by approximately € \_\_\_\_\_ million, assuming no change in the assumed initial public offering price of \$ \_\_\_\_\_ per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting the estimated underwriting discounts and commissions.

---

[Table of Contents](#)

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

- common shares issuable upon the exercise of share options outstanding as of December 31, 2014 at a weighted average exercise price of € per share; and
- common shares reserved for future issuance under our equity incentive plan as of December 31, 2014 as described in “Management—Long-Term Incentive Plans.”

## DILUTION

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

At December 31, 2014, we had a historical net tangible book value of \$(4.4) million (€(3.6) million), corresponding to a net tangible book value of \$(0.79) per share (€(0.64) per share). Net tangible book value per share represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by the total number of our common shares outstanding at December 31, 2014.

Our pro forma net tangible book value as of December 31, 2014 was \$ million (€ million), corresponding to a pro forma net tangible book value of \$ per share (€ per share). Pro forma net tangible book value per share represents our pro forma net tangible book value divided by the total number of our common shares outstanding at December 31, 2014, after giving effect to: (i) the consummation of the Class C Financing; and (ii) the automatic conversion of all outstanding preferred shares, including the preferred shares issued in the Class C Financing, into an aggregate of common shares upon the closing of this offering.

After giving effect to the sale by us of common shares in this offering at the assumed initial public offering price of \$ per share (€ per share), which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value at December 31, 2014 would have been approximately \$ million (€ million), representing \$ per share (€ per share). This represents an immediate increase in pro forma net tangible book value of \$ per share (€ per share) to existing shareholders and an immediate dilution in net tangible book value of \$ per share (€ per share) to new investors purchasing common shares in this offering at the assumed initial public offering price per share. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

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

	\$	€
Assumed initial public offering price		
Pro forma net tangible book value per share		
Increase in net tangible book value per share attributable to this offering		
Pro forma as adjusted net tangible book value per share		
Dilution per share to new investors		
Percentage of dilution in net tangible book value per share for new investors	%	%

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

Each \$1.00 increase (decrease) in the assumed initial public offering price of \$ per share (€ per share), which is the midpoint of the price range set forth on the cover page of this prospectus, respectively,

## Table of Contents

would increase (decrease) the pro forma as adjusted net tangible book value after this offering by \$            per share (€            per share) and the dilution per share to new investors in the offering by \$            per share (€            per share), assuming that the number of common shares offered by us, as set forth on the cover page of this prospectus, remains the same.

The following table sets forth, on a pro forma basis as of December 31, 2014, giving effect to (i) the consummation of the Class C Financing; and (ii) the automatic conversion of all outstanding preferred shares, including the preferred shares issued in the Class C Financing, into an aggregate of            common shares upon the closing of this offering, the differences between the number of common shares purchased from us, the total consideration paid to us and the average price per share paid by existing shareholders and by new investors purchasing common shares in this offering. The calculation below is based on an assumed initial public offering price of \$            per share (€            per share), which is the midpoint of the estimated price range set forth on the cover page of this prospectus, before deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us:

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

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

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

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

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

- common shares issuable upon the exercise of stock options outstanding as of December 31, 2014 at a weighted average exercise price of €            per share; and
- common shares reserved for future issuance under our equity incentive plan as described in “Management—Long-Term Incentive Plans.”

**SELECTED FINANCIAL DATA**

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere in this prospectus and the “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections of this prospectus. We have derived the statement of comprehensive loss data for the years ended December 31, 2014 and 2013 and the statement of financial position data as of December 31, 2014 and 2013 from our audited financial statements included elsewhere in this prospectus. Our historical results for any prior period are not necessarily indicative of results to be expected in any future period.

We maintain our books and records in euros, and we prepare our financial statements under IFRS, as issued by the IASB.

	<b>Year Ended December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(euros in thousands, except share and per share data)</b>	
<b>Statement of Comprehensive Loss Data:</b>		
Revenue	€ 1,303	€ 558
Costs of outsourced work and other external costs:		
Research and development costs	(14,099)	(6,054)
Other operating expenses	(1,203)	(1,294)
Personnel expenses	(3,168)	(2,852)
Depreciation and amortization	(253)	(264)
Operating loss	(17,420)	(9,906)
Finance income and expense	11	(2)
Net loss and comprehensive loss	€ (17,409)	€ (9,908)
Net loss per share, basic and diluted	€ (3.42)	€ (2.75)
Weighted average common shares outstanding, basic and diluted	5,093,258	3,603,827
	<b>As of December 31,</b>	
	<b>2014</b>	<b>2013</b>
	<b>(euros in thousands)</b>	
<b>Statement of Financial Position Data:</b>		
Cash and cash equivalents	€ 1,841	€ 10,647
Total assets	3,540	12,424
Total liabilities	7,099	4,762
Accumulated deficit	(40,765)	(23,510)
Total equity (deficit)	(3,559)	7,662

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with the information under "Selected Financial Data" and our audited financial statements, including the notes thereto, included in this prospectus. The following discussion is based on our financial information prepared in accordance with IFRS as issued by the IASB, which might differ in material respects from generally accepted accounting principles in other jurisdictions. The following discussion includes forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of many factors, including but not limited to those described under "Risk Factors" and elsewhere in this prospectus.*

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. We have a pipeline of full-length human bispecific antibodies, which we refer to as Biclonics, generated from our technology platform. Biclonics can be designed 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 various solid tumors, and we expect to report top-line results from this trial in the first half of 2017. In the first quarter of 2016, we expect to commence a Phase 1/2 clinical trial with our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML. Additionally, we have several bispecific antibody candidates in pre-clinical development that bind to combinations of immunomodulatory molecules, including PD-1 and PD-L1, which we believe play a significant role in treating cancer.

Since our inception in June 2003, we have devoted a significant portion 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 (i) private placements of equity securities, (ii) upfront, milestone and expense reimbursement payments received from our collaborator under our research and license agreement, (iii) funding from patient organizations and governmental bodies and (iv) bank and bridge loans. Since our inception, we have raised gross proceeds of €91.3 million from private placements of equity securities, received aggregate gross proceeds of approximately €4.1 million from our collaborator, received €3.7 million in grants from patient organizations and governmental bodies and received €1.5 million in proceeds from bank and bridge loan financings. As of December 31, 2014, we had cash and cash equivalents of €1.8 million.

In August 2015, we entered into a subscription agreement pursuant to which we sold an aggregate of 6,268,579 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 1,201,201 Class C preferred shares in connection with the consummation of the first tranche of this private placement.

We are a clinical-stage company and have not generated any revenue from product sales. All of our bispecific antibody candidates other than MCLA-128 are still in pre-clinical development. 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, 2014 and 2013, we incurred net losses of €17.4 million and €9.9 million, respectively. As of December 31, 2014, we had an accumulated deficit of €40.8 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

## [Table of Contents](#)

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, upon closing of this offering, we expect 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.

We expect that our existing cash and cash equivalents, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least . See “—Liquidity and Capital Resources.”

### **Collaboration Agreements**

As part of our business strategy, we intend to seek strategic collaborations to facilitate the capital-efficient development of our Biclonics 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.

#### ***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 Biclonics technology platform with undisclosed targets.

ONO paid us a non-refundable upfront fee of €1.0 million. We are eligible to receive milestone payments upon achievement of specified research and clinical development milestones. As of August 28, 2015, we have achieved two of the specified pre-clinical milestones under this research and license agreement. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. 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.

### **Financial Operations Overview**

#### ***Revenue***

To date, our revenues have 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 Biclonics technology in various indication areas. For 2014, all of our license revenue and collaboration revenue was generated under our agreement with ONO. Our research and license agreement comprises 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 of our partnered bispecific antibody candidates, for which our collaborator provides funding for the services rendered.

## [Table of Contents](#)

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 other 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.

### ***Costs of Outsourced Work and Other External Costs***

Our costs of outsourced work and other external costs since inception have consisted primarily of research and development activities and other operating expenses.

#### *Research and Development Expenses*

Research and development expenses consist primarily of external costs incurred for our research activities, including our discovery efforts, and the development of our bispecific antibody candidates, which include:

- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct research, pre-clinical activities and clinical trials on our behalf as well as contract manufacturing organizations, or CMOs, that manufacture drug products for use in our pre-clinical and clinical trials;
- testing and clinical trials; and
- costs associated with obtaining and maintaining patents and other intellectual property, including litigation costs associated with our alleged patent infringement case with a third party. See “Business—Legal Proceedings.”

We incur various external expenses under our research and license agreement for material and services consumed in the development of our partnered bispecific antibody candidates. Under our research and license agreement, our collaboration partner 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 2015 will be approximately in the range of €        million to €        million and will primarily relate to the following key programs:

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



## [Table of Contents](#)

- *Other development programs.* Our other research and development expenses relate to our pre-clinical studies of our other bispecific antibody candidates, MCLA-134, MCLA-114 and MCLA-145, as well as other early research projects. These expenses primarily consist of costs for production of the pre-clinical compounds and costs paid to CROs in conjunction with pre-clinical studies.

For the years ended December 31, 2014 and 2013, we spent €14.1 million and €6.1 million, respectively, on research and development costs. For the same time periods, we spent €5.0 million and €2.9 million on MCLA-128, respectively, and €0.8 million and €0.3 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 other 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.

### *Other Operating Expense*

Other operating expenses include facility-related costs, materials and equipment for our research and development activities and professional fees for auditing, tax and legal services, advertising costs and information technology expenses.

We expect our other operating expenses will increase in the future as we expand our operating activities and we incur additional costs associated with operating as a public company. We also expect to incur increased external costs to comply with NASDAQ and SEC requirements, as well as other corporate governance, internal controls, investor relations, additional insurance and disclosure requirements applicable to public companies.

### *Personnel Expenses*

Our personnel expenses consist primarily of salaries and related costs, including share-based compensation and travel expenses, for personnel. This includes personnel in research and development, executive, finance,

## [Table of Contents](#)

human resources and administrative support functions. We expect that our personnel expenses will increase in the future as our business expands and as we increase our headcount to support the expected growth in our research and development and operating activities.

### **Finance Income and Expense**

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

## **Results of Operations**

### **Comparison of Years Ended December 31, 2014 and 2013**

The below table summarizes our results of operations for the years ended December 31, 2014 and 2013.

	Year Ended December 31,	
	2014	2013
	(euros in thousands)	
<b>Statement of Comprehensive Loss Data:</b>		
Revenue	€ 1,303	€ 558
Costs of outsourced work and other external costs:		
Research and development costs	(14,099)	(6,054)
Other operating expenses	(1,203)	(1,294)
Personnel expenses	(3,168)	(2,852)
Depreciation and amortization	(253)	(264)
Operating loss	(17,420)	(9,906)
Finance income and expense	11	(2)
Net loss and comprehensive loss	€ (17,409)	€ (9,908)

### **Revenue**

Revenue increased €0.7 million during the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase was primarily attributable to the €0.2 million we received as an upfront payment in connection with entering into the research and license agreement with ONO and €0.5 million we received for research and development services rendered under such agreement.

### **Costs of Outsourced Work and Other External Costs**

Costs of outsourced work and other external costs increased €8.0 million during the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase was primarily attributable to an €8.0 million increase in research and development costs.

### **Research and Development Expenses**

Research and development expenses increased €8.0 million during the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase was primarily due to the following:

- an increase of €2.1 million related to our MCLA-128 program, due primarily to higher manufacturing costs at our CRO and pre-clinical studies;
- an increase of €4.5 million in intellectual property and legal fees associated with an alleged patent infringement case with a third party; and
- an increase of €1.4 million in expenses in connection with various pre-clinical and discovery programs.

## [Table of Contents](#)

### *Other Operating Expenses*

Other operating expenses decreased €0.1 million during the year ended December 31, 2014 as compared to the year ended December 31, 2013. The decrease was primarily attributable to lower fees incurred for external consultants.

### *Personnel Expenses*

Personnel expenses increased €0.3 million during the year ended December 31, 2014 as compared to the year ended December 31, 2013. The increase was primarily due to the hiring of additional employees to support our operations. The average number of personnel during the year ended December 31, 2014 was approximately 32 as compared to approximately 27 during the year ended December 31, 2013.

### *Finance Income and Expense*

Finance income and expense for the years ended December 31, 2014 and 2013 was immaterial.

## **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 private placements of equity securities, upfront, milestone and expense reimbursement payments received from our collaborator under our research and license agreement, as well as funding from patient organizations, governmental bodies and bank and bridge loans. Since our inception, we raised gross proceeds of €91.3 million from private placements of equity securities, received aggregate gross proceeds of approximately €4.1 million from our collaborator, received €3.7 million in grants from patient organizations and governmental bodies and received €1.5 million in proceeds from bank and bridge loan financings.

As of December 31, 2014, we had cash and cash equivalents of €1.8 million.

### *Subsequent Events*

In January 2015, we closed the fifth tranche of our Class B preferred share private placement and sold an aggregate of 2,407,224 Class B preferred shares to existing investors for aggregate gross proceeds of €5.0 million.

In June 2015, in lieu of closing the sixth and seventh tranches of our Class B preferred share private placement, several shareholders granted us an €8.0 million convertible bridge loan until the closure of a subsequent issuance of Class C preferred shares. In August 2015, we entered into a subscription agreement pursuant to which we sold an aggregate of 6,268,579 of our Class C preferred shares to new and existing investors for aggregate gross proceeds of €41.6 million. Pursuant to the terms of the convertible bridge loan, the bridge loan was fully converted into an aggregate of 1,201,201 Class C preferred shares after the closing of the first tranche of the Class C preferred share private placement. See “Related Party Transactions—Convertible Bridge Loan and Class C Preferred Share Financing.”

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.

## [Table of Contents](#)

### **Cash Flows**

The table below summarizes our cash flows for the years ended December 31, 2014 and 2013.

	Year Ended December 31,	
	2014	2013
	(euros in thousands)	
Net cash from operating activities	€(14,587)	€(6,963)
Net cash flow (used in) from investing activities	(86)	5
Net cash from financing activities	5,867	11,842
Net (decrease) increase in cash and cash equivalents	€ (8,806)	€ 4,884

The increase in net cash used in operating activities to €14.6 million for the year ended December 31, 2014 from €7.0 million for the year ended December 31, 2013 was primarily due to higher research and development expenses and changes in working capital.

The decrease in net cash from investing activities to €(86,000) for the year ended December 31, 2014 from €5,000 for the year ended December 31, 2013 was primarily due to investments in laboratory equipment and office equipment in support of our business operating activities.

The decrease in net cash from financing activities to €5.9 million for the year ended December 31, 2014 from €11.8 million for the year ended December 31, 2013 was mainly due to the consummation of a private placement of our Class B preferred shares which resulted in €12.0 million in gross proceeds. In 2014, we consummated the fourth tranche of a private placement of our Class B preferred shares which resulted in €6.0 million in gross proceeds.

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

We have not achieved profitability since our inception and, as of December 31, 2014, we had an accumulated deficit of €40.8 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 other pre-clinical programs. In addition, upon the closing of this offering, we expect 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;
- continue the research and development of our other bispecific antibody candidates, including commencing clinical trials for MCLA-117;
- seek to enhance our Biclomics technology platform and discover and develop additional bispecific antibody candidates;
- seek regulatory approvals for any bispecific antibody candidates that successfully competes 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 transition to a public company; and

## Table of Contents

- 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.

We expect that our existing cash and cash equivalents, together with anticipated net proceeds from this offering, will enable us to fund our operating expenses and capital expenditure requirements through at least . 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 other 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 other 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

## [Table of Contents](#)

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.

### Contractual Obligations and Commitments

The table below summarizes our contractual obligations at December 31, 2014.

	Payments Due by Period				
	Total	Less than 1 year	1 - 3 years	3 - 5 years	More than 5 years
	(euros in thousands)				
Operating lease obligations(1)	€ 256	€ 256	€—	€—	€—
Debt obligations(2)	912	200	193	519	—
Total	€1,168	€ 456	€193	€519	€—

- (1) Amounts in the table reflect payments due for our office space at Utrecht University in Utrecht, Netherlands under an operating lease agreement that expires on December 31, 2015.
- (2) Reflects the contractually required principal and interest payments payable pursuant to our bank loan.

We entered into a loan and security agreement with the Rabobank Utrechtse Heuvelrug U.A. on December 29, 2009, which provided for total borrowings of €1.5 million. Under the loan and security agreement, we are obligated to make monthly payments of €14,000 until November 2019, the maturity date. The loans bear interest at an annual rate equal to 4.45% until April 1, 2016 and thereafter, at our option, at a fixed or variable rate to be agreed.

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 Borgsellingskrediet)*).

### Off-Balance Sheet Arrangements

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

### Quantitative and Qualitative Disclosures About Market Risk

We are exposed to a variety of financial risks. Our overall risk management program seeks to minimize potential adverse effects of these financial risks on our financial performance.

#### **Credit Risk**

We consider all of our material counterparties to be creditworthy. We consider the credit risk for each of our counterparties to be low and do not have a significant concentration of credit risk at any of our counterparties.

#### **Liquidity Risk**

We manage our liquidity risk by maintaining adequate cash reserves at banking facilities, and by continuously monitoring our cash forecasts, our actual cash flows and by matching the maturity profiles of

## [Table of Contents](#)

financial assets and liabilities. We believe that our existing cash and cash equivalents as of December 31, 2014, along with the proceeds from our convertible bridge loan financing, the sale of our preferred shares in each of January and August 2015 and the proceeds from this offering, will be sufficient to meet our projected cash requirements for at least \_\_\_\_\_ from the date of this prospectus.

### **Market Risk**

We are not subject to any significant foreign exchange risk and interest rate risk.

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

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. 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 prospectus.

Our significant accounting policies are more fully described in the notes to our financial statements appearing elsewhere in this prospectus. 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 recognized 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 balance sheet 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

## [Table of Contents](#)

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 depositary receipts for our common shares. Under these programs, holders of vested options are entitled to purchase depositary receipts for common shares at the exercise price determined at the date of grant.

Upon exercise of options, Stichting Administratiekantoor Merus, a Dutch foundation that we utilize to facilitate the administration of share-based compensation awards and refer to as the Foundation, issues to such individuals non-voting depositary receipts representing the underlying common shares, against payment of the option exercise price. The voting rights associated with the common shares remain with the Foundation.

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

For participants who are not members of the supervisory board, a participant who voluntarily leaves employment with the Company is 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. Up to the first anniversary of the date of exercise, the participant has an obligation to offer 100% of his depositary receipts to the Foundation. This obligation for a participant to offer depositary receipts to the Foundation upon resignation is reduced by 25% at each anniversary of the date of exercise, which means that there is no such obligation if a participant leaves after the fourth anniversary of the date of exercise.

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 the 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.



## [Table of Contents](#)

The compensation expense is spread over the vesting period in accordance with each separate vesting tranche of the options granted, taking in 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.

We estimate 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. In addition to the vesting period of the options, the vesting period for the depositary receipts were also taken into account when allocating the fair values of the options granted over the required service period.

The inputs used in the measurement of the fair values and the related fair values at the grant dates were as follows for options granted to members of our executive management team (Black-Scholes formula) and other participants (binominal option pricing model):

	2014		2013	
	Executives	Other	Executives	Other
Fair value at grant date	€ 2.39	€2.45-2.71	€ 2.61	€ 2.92
Share price at grant date	€ 3.70	€3.40-3.70	€ 3.80	€ 3.80
Exercise price	€ 2.58	€ 2.58	€ 2.58	€ 2.58
Expected volatility (weighted-average)	101.1%	101.1%	111.7%	111.7%
Expected life (weighted-average)	4 year	8 year	4 year	8 year
Expected dividends	0%	0%	0%	0%
Risk-free interest rate (based on government bonds)	1.2%	1.0%-1.2%	1.5%	1.5%

The options outstanding at December 31, 2014 had an exercise price in the range of €2.13 to €7.50 (2013: €2.13 to €7.50) and a weighted-average remaining contractual life of 4.4 years (2013: 4.6 years).

The weighted-average share price at the date of exercise for share options exercised in 2014 was €3.40 (2013: €3.80).

Since we are a private company prior to the consummation of this offering, company-specific historical and implied volatility information is not available. Expected volatility is therefore estimated based on the observed daily share price returns of publicly traded peer companies over a historic period equal to the period for which expected volatility is estimated. The group of comparable listed companies are publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and are selected taking into consideration the availability of meaningful trading data history and market capitalization. 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 after the consummation of this offering.

Since the options are not transferable, the participants will tend to exercise the options prior to the maturity date. For participants who are not members of the executive management team, 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. The members of the executive management team are expected to exercise their options immediately after vesting of the final vesting installment.

### **Valuation of Our Common Shares**

The fair value of our common shares is determined by our management board and supervisory board, and takes 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 believe are relevant and which may have changed from the date of the most recent valuation through the date of the grant.

## [Table of Contents](#)

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

- the progress of our research and development programs;
- achievement of enterprise milestones, including entering into collaboration and licensing agreements, as well as funding milestones;
- contemporaneous third-party valuations of our common shares for our most recent share issuances in August 2015;
- our need for future financing to fund operations;
- 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; and
- external market and economic conditions impacting our industry sector.

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. Based on the information available, external transactions of Company shares and external rounds of financing, we have determined that the market approach is the most appropriate method. In addition, the guidance prescribed by the American Institute of Certified Public Accountants, or AICPA, *Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation* has been considered.

The “prior sale of company stock” method, a form of the market approach, has been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm’s length sales of our equity securities. Considerations factored into the analysis include: 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 has been 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 is considered a strong indication of fair value.

Given that there are multiple classes of equity, the hybrid method has been 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 merger and acquisition, 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 merger and acquisition, 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.

## [Table of Contents](#)

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

	2014		2013	
	Weighted average exercise price (in euros)	Number of options	Weighted average exercise price (in euros)	Number of options
Outstanding at January 1	€ 2.93	287,400	€ 2.92	294,872
Forfeited during the year	2.58	(13,562)	2.58	(1,280)
Exercised during the year	2.86	(17,915)	2.56	(25,082)
Granted during the year	2.58	90,173	2.58	18,890
Outstanding at December 31	2.86	346,096	2.93	287,400
Exercisable at December 31	2.97	249,247	3.09	189,683

Estimates by our management board and our supervisory board will not be necessary to determine the fair value of new awards once a public trading market for our common shares has been established in connection with the completion of this offering.

We have granted the following options in the period from January 1, 2013 through December 31, 2014:

	Number of options granted	Exercise price per share	Estimated fair value for each common share	Estimated fair value for each option
		(in euros, except for option data)		
June 17, 2013 (executive management team)	16,000	€ 2.58	€ 3.80	€ 2.61
June 17, 2013 (employees)	2,890	2.58	3.80	2.92
June 17, 2014 (executive management team)	47,250	2.58	3.70	2.39
June 17, 2014 (employees)	15,360	2.58	3.70	2.71
June 17, 2014 (supervisory board)	27,563	2.58	3.40	2.45

### **Income Taxes**

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

No tax charge or income was recognized during the reporting periods since we are in a loss-making position and have a history of losses. We have tax loss carry-forwards of €43.5 million and €28.2 million as of December 31, 2014 and December 31, 2013, respectively. As a result of Dutch income tax law, tax loss carry-forwards are subject to a time limitation of nine years. We do not assume that the public trading of our shares as such will negatively affect the tax loss carry-forward position of the Company.

Deferred income tax assets are recognized for tax losses and other temporary differences to the extent that the realization of the related tax benefit through future taxable profits is probable. We recognize deferred tax assets arising from unused tax losses or tax credits only to the extent the relevant fiscal unity has sufficient taxable temporary differences or if there is convincing other evidence that sufficient taxable profit will be available against which the unused tax losses or unused tax credits can be utilized by the fiscal unity. Our judgment is that sufficient convincing other evidence is not available and therefore, a deferred tax asset is not recognized.

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the "Innovation Box." For the

---

## [Table of Contents](#)

qualifying profits, we effectively owe only 5% income tax, instead of the general tax rate of 25%, which results in an estimated effective tax rate of 10%. The benefits of the Innovation Box will take effect once the tax losses of the Company have been fully recaptured. The agreement with the tax authorities is currently signed for the years 2011 to 2015 but is expected to be extended.

### **Recent Accounting Pronouncements**

We refer to Note 5 to our audited financial statements for the year ended December 31, 2014 for a discussion of new standards and interpretations not yet adopted by us.

### **JOBS Act Exemptions**

On April 5, 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act for complying with new or revised accounting standards. As a result, an “emerging growth company” can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period for complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

## BUSINESS

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. We have a pipeline of full-length human bispecific antibodies, which we refer to as Biclonics, generated from our technology platform. Biclonics can be designed 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 various solid tumors, and we expect to report top-line results from this trial in the first half of 2017. In the first quarter of 2016, we expect to commence a Phase 1/2 clinical trial with our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML. Additionally, we have several bispecific antibody candidates in pre-clinical development that bind to combinations of immunomodulatory molecules, including PD-1 and PD-L1, which we believe play a significant role in treating cancer.

By binding to two different targets, we believe Biclonics may provide several advantages over existing cancer therapeutics, including greater potency and lower toxicity. Our Biclonics technology platform enables rapid functional screening of large collections of Biclonics to identify lead candidates with multiple mechanisms of action. The Biclonics format retains the IgG format of conventional mAbs and is designed to preserve its key features, including stability, long half-life and low immunogenicity, in our bispecific antibody candidates. We leverage industry-standard manufacturing processes and infrastructure to efficiently produce Biclonics.

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, colorectal 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 early stages of the dose escalation, we have observed a measurable positive effect in 3 out of 12 evaluable patients treated to date with MCLA-128. In two patients, the disease did not progress, a condition defined as stable disease. For the third patient, we observed reduction in size and disappearance of some metastatic lesions with no new tumors appearing to date, and this result is defined as a partial response. We expect to report top-line results from the Phase 1/2 trial in the first half of 2017.

Our second bispecific antibody candidate, MCLA-117, is expected to commence a Phase 1/2 clinical trial in Europe for the treatment of AML in the first quarter of 2016. AML generally has a poor prognosis and 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 are also currently evaluating MCLA-117 for the treatment of MDS in pre-clinical studies.

## 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 and ovarian cancers. We commenced a Phase 1/2 clinical trial of MCLA-128 in February 2015. In the early stages of the dose escalation phase of the trial, we have observed a measurable positive effect in 3 out of 12 evaluable patients treated to date with MCLA-128. If the Phase 1/2 trial results are favorable, we plan to submit an IND application to the FDA for MCLA-128 and initiate a Phase 2 clinical trial in the United States, as well as to commence a Phase 1/2 combination trial and a Phase 2/3 single agent trial in Europe. 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 intend to submit a CTA to the EMA by the end of 2015. We expect to commence a Phase 1/2 clinical trial of MCLA-117 in the first quarter of 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity. 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, as well as to commence a Phase 1/2 combination trial and a Phase 2/3 single agent trial in Europe. 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 Biclonics for the treatment of other forms of cancer. Our platform enables rapid functional screening of large collections of Biclonics to identify lead candidates with multiple mechanisms of action that have the potential to kill tumor cells with high potency. We are currently evaluating Biclonics that target various 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. We believe that binding to combinations of checkpoint inhibitory and/or co-stimulatory molecules provides Biclonics with the potential to activate tumor-specific T-cells to effectively kill tumor cells. In addition, by developing Biclonics that attack and kill cancer stem cells, we believe that we may be able to eliminate the cells that cause relapse of tumor growth. In addition to these target combinations, we intend to use our platform to evaluate new Biclonics combinations and bring additional bispecific antibody candidates through pre-clinical development into clinical trials.
- **Seek strategic collaborative relationships.** We intend to seek strategic collaborations to facilitate the capital-efficient development of our Biclonics technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We have entered into a collaboration with ONO Pharmaceutical Co., Ltd., a Japanese pharmaceutical company, to develop bispecific antibody candidates based on our Biclonics technology platform and plan to work with other collaborators to validate and expand the use of our Biclonics platform and the development of bispecific antibody candidates. 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.



**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 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 Monoclonal Antibodies.** 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 antibodies 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.

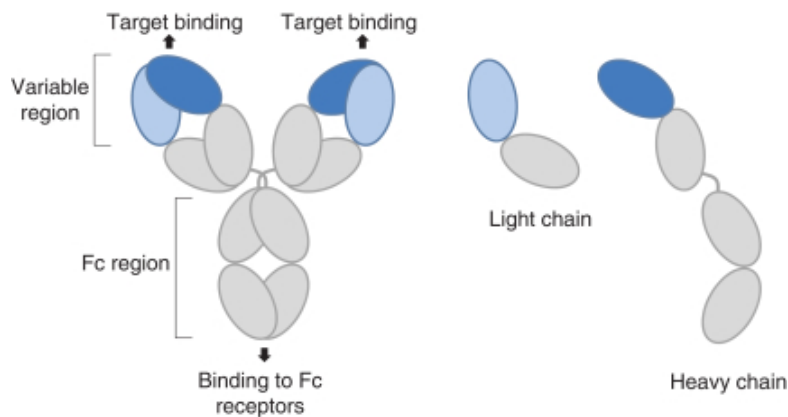
We believe a key limitation of CAR-T and TCR immunotherapies is the need to retrieve non-compromised immune effector cells from a cancer patient, which requires a complex and costly individualized process to develop the therapy. These challenges limit their potential and use in a variety of indications, including 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, or Fc region, 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 resulting in the recruitment and activation of immune effector cells and amplifying the immune response to antigens bound by the variable region of the antibody, a process 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 Biclomics Platform

We have a pipeline of Biclomics 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 Biclomics against any particular target pair.

By binding to two different targets, Biclomics are designed to block receptors that drive tumor cell growth and survival and/or 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:

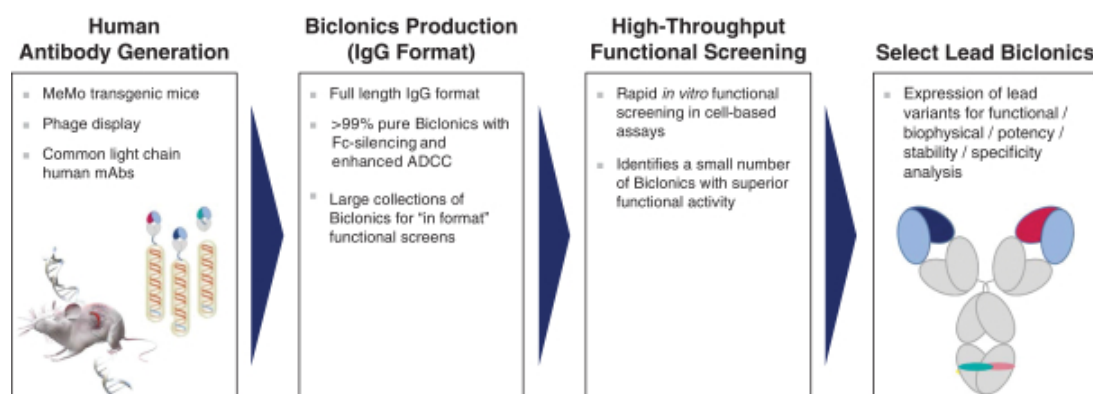
- **Blocking combinations of growth factor receptors that drive tumor cell growth and relapse while simultaneously recruiting immune effector cells through enhanced ADCC.** Biclomics may be generated for different combinations of growth factor receptors that play a role in tumors with different molecular profiles, while a modification in the Fc region of the Biclomics facilitates 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 revive T-cells to kill tumor cells. 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 T-cells.
- **Simultaneously targeting a growth signaling 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 tumor cells. 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 Biclomics



Our Biclomics technology platform includes the following:

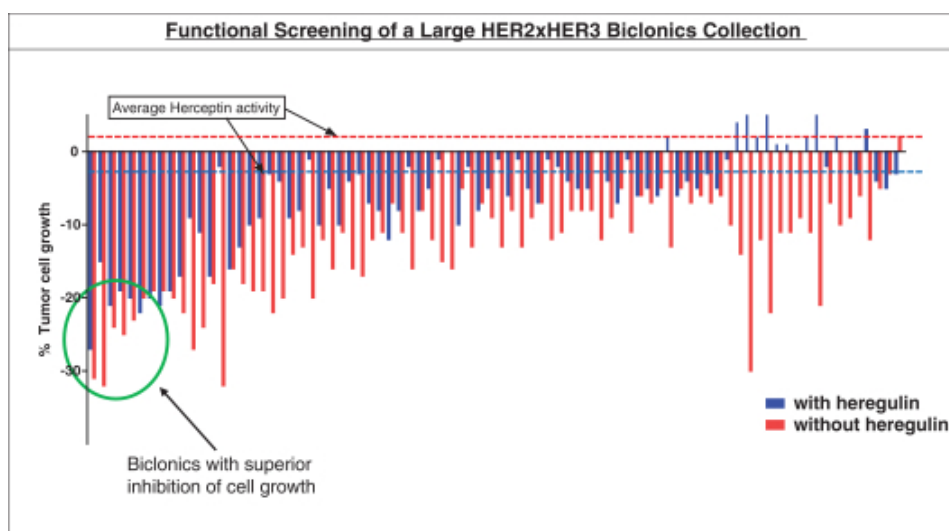
- **Human antibody generation.** We use our human antibody generation technology comprised of our proprietary transgenic mice, which we refer to as MeMo, and phage display, for the generation of panels of common light chain human mAbs. MeMo harnesses the power of the *in vivo* immune system to directly 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 Biclomics format.

- **The full-length Immunoglobulin G format.** The Biclomics format retains several of the favorable attributes of conventional human IgG mAbs, including their stability and predictability during manufacturing and their long half-life and low immunogenicity during treatment of patients. Biclomics 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 Biclomics are bispecific heterodimeric IgG antibodies that closely mimic IgG antibodies that are produced naturally by the immune system.

The Biclomics 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 Biclomics 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 candidate, MCLA-128. In order to improve safety and tolerability, we can modify our Biclomics to prevent the excessive release of signaling proteins called cytokines which can overstimulate the immune system. This process is called Fc-silencing as it blocks the ability of our Biclomics to bind to certain protein receptors on cells, Fc receptors, which are associated with cytokine release. We utilize Fc silencing in our MCLA-117 bispecific antibody candidate.

- **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, as shown in the chart below, the result 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 and were selected in the process leading to identification of the MCLA-128 lead candidate.



## 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 peptides.*** 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 peptides or 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 heterodimer 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 to identify lead candidates with multiple mechanisms of action that have the potential to effectively kill tumor cells. 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 for the treatment of patients with solid tumors in February 2015. Additionally, we expect to commence a Phase 1/2 clinical trial of MCLA-117 for the treatment of patients with AML in the first quarter of 2016, and we have several other bispecific antibody candidates in pre-clinical development.

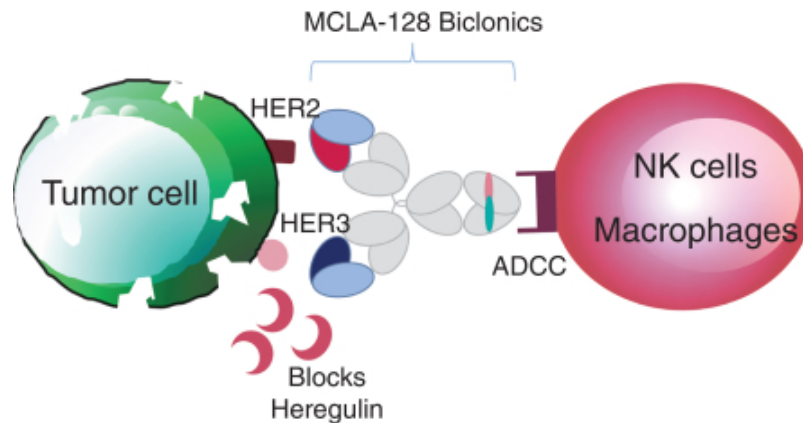
### ***MCLA-128***

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 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.

## [Table of Contents](#)

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 to escape through activation of the HER3/hereregulin pathway. The second mechanism, enhanced ADCC, involves the recruitment 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**

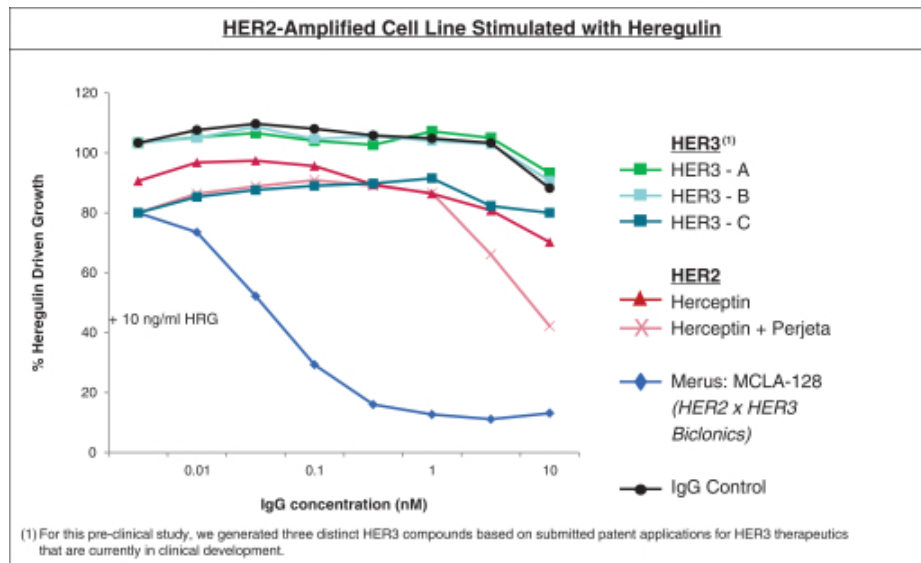


We believe that MCLA-128 has the potential to be a more effective treatment of HER2-expressing solid tumors than existing therapies due to its ability to inhibit cellular growth factor receptors on tumor cells and simultaneously recruit cells of the immune system to attack tumor cells.

#### *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).

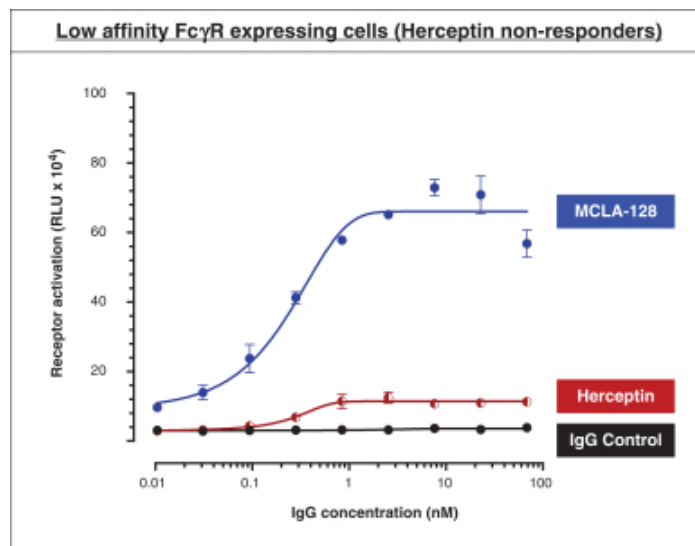
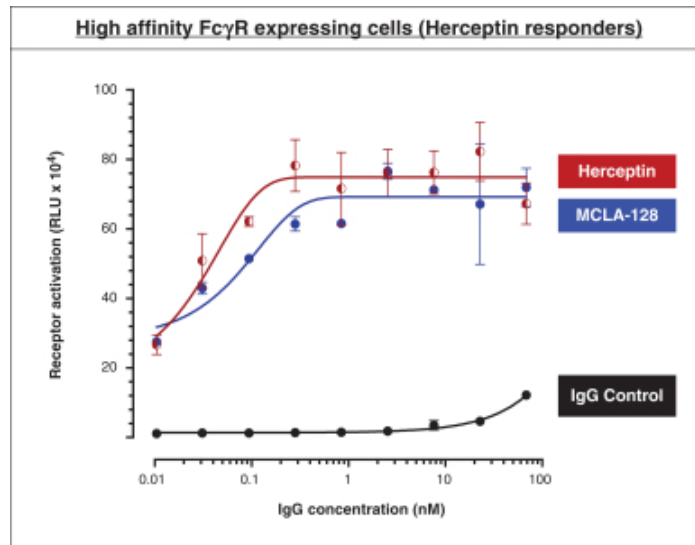
As shown in the chart below, the administration of MCLA-128 reduced heregulin-driven tumor growth at significantly lower concentrations than mAbs targeting HER2 or HER3, and the combination of Herceptin and Perjeta.



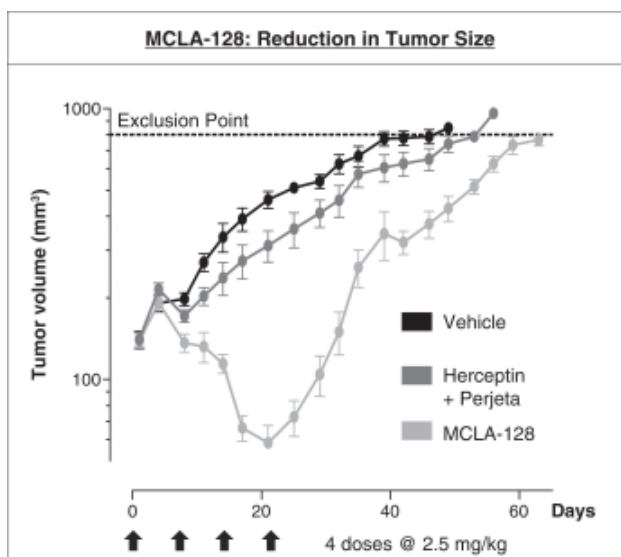
MCLA-128 also blocked phosphorylation and activation of key proteins in the signaling pathways for the cell growth and survival of cancer cell lines, a result that was not observed with the combination of HER2 mAbs, Herceptin and Perjeta.

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.

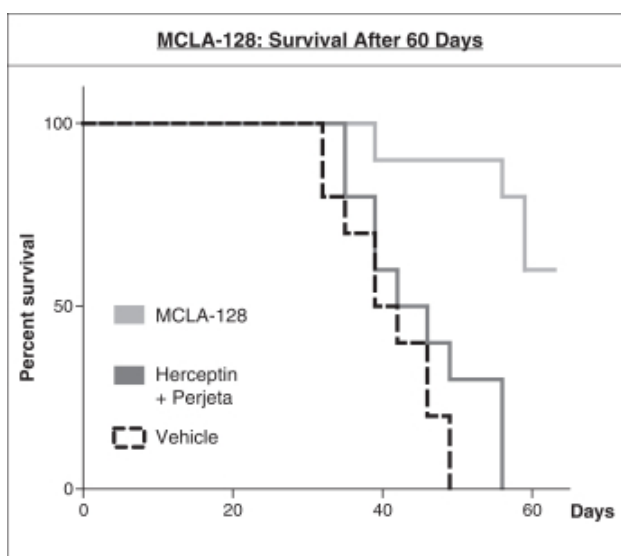
### Fc Receptor Activation by MCLA-128 (FcγR Subtype)



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 graphic 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 did mice receiving either the vehicle or the combination of Herceptin and Perjeta.





*Clinical Development of MCLA-128*

In February 2015, we commenced an open-label Phase 1/2 clinical trial of MCLA-128 for the treatment of HER2-expressing solid tumors. To date, we are currently engaged in the dose escalation phase of the trial and have observed early positive data based on doses below the optimal dose range projected from our pre-clinical studies. We plan to enroll up to 120 patients with breast, gastric, colorectal, lung, pancreatic or ovarian cancers 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 sites in Europe.

The first part of the trial is a dose escalation study, in which we intend to enroll at least 24 evaluable patients, followed by a second part of the trial, in which we intend to enroll up to 68 patients, to further study the safety, tolerability and clinical efficacy of MCLA-128. 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 is to determine the maximum recommended dose of MCLA-128. The secondary endpoints of Part 1 consist of:

- the pharmacodynamic, or PD, response to MCLA-128 in tumor tissue and/or surrogate tissues;
- the pharmacokinetic, or 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 plan to evaluate 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 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.

To date, we have enrolled 12 evaluable patients in the trial. In these patients, the administration of MCLA-128 has been well-tolerated up to a dose of 480 mg, with no reported severe adverse events. The most frequent adverse events in the trial were mild infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. In the early stages of the dose escalation phase of the trial, we have observed a measurable positive effect in 3 out of the 12 evaluable patients treated. In two patients, treated with doses of 80 mg and 240 mg of MCLA-128 respectively, the disease did not progress, a condition defined as stable disease, and the third patient, treated with a dose of 360 mg of MCLA-128, we observed reductions in tumor size and disappearance of some metastatic lesions with no new tumors appearing. This result is defined as a partial response.

In Part 2 of the clinical trial, we plan to treat patients with HER2-expressing cancer cells of different types, with the option to enroll patients with additional tumor types based on ongoing evaluations of safety, as well as

## [Table of Contents](#)

PK, PD and anti-tumor activity data from patients with metastatic or advanced solid tumors enrolled in Part 1. We intend to enroll up to 68 patients in this phase of the trial, consisting of approximately 16 patients with metastatic breast cancer, 12 patients with metastatic colorectal cancer and 16 patients with metastatic ovarian cancer. The primary endpoints of Part 2 of the trial are the frequency and nature of adverse events and the CBR. The secondary endpoints of Part 2 are equivalent to those for Part 1 of the trial.

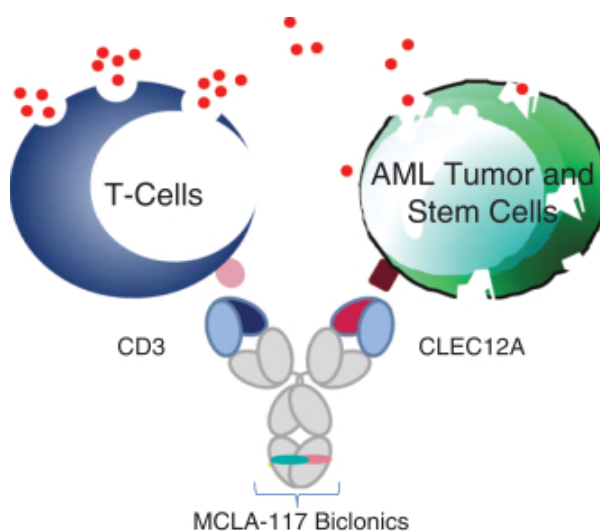
We expect to report top-line data from this Phase 1/2 trial in the first half of 2017. If the Phase 1/2 trial results are favorable, we plan to submit an IND application to the FDA for MCLA-128 and initiate a Phase 2 clinical trial in the United States, as well as to commence a Phase 1/2 combination trial and a Phase 2/3 single agent trial in Europe.

### **MCLA-117**

MCLA-117 is a Biclomics that is designed to bind to CD3, a cell-surface molecule present on all T-cells, and 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, implying 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**



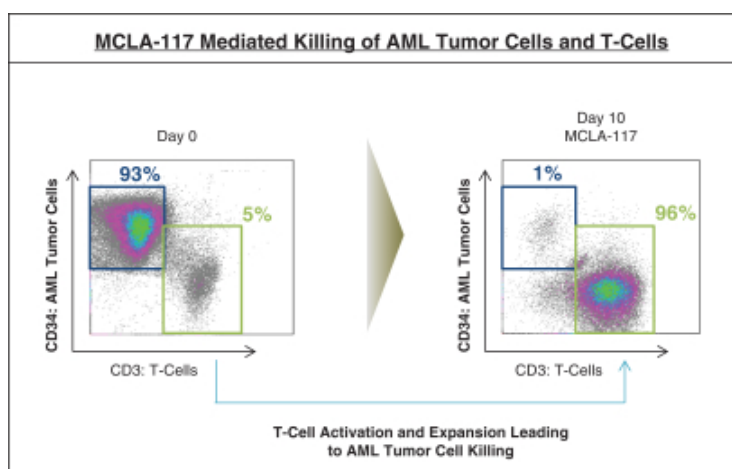
## Table of Contents

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 or to treat minimal residual disease and as rescue therapy for the relapsed/refractory target AML patient population. We intend to explore its use both as a single agent and in combination with commonly used chemotherapy agents and other regimens in 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 Bionics 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 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 efficient killing of AML tumor cells in our pre-clinical studies. An un-manipulated primary blood sample containing both the patients' tumor cells and T-cells was cultured for 10 days with a dosage of 1,000 ng/ml of MCLA-117. At day 10, the percentage of AML tumor cells in the culture dish 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.



We intend to submit a CTA to the EMA by the end of 2015 and to commence a Phase 1/2 clinical trial of MCLA-117 in the first quarter of 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity. For the anticipated Phase 1/2 clinical trial, we plan to enroll adult patients with tumors of all AML subtypes. Patients with relapsed or refractory disease, newly diagnosed, or 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 up to 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. We expect the primary endpoints of the Phase 1/2 trial to be the assessment of the safety and tolerability

## [Table of Contents](#)

of MCLA-117 in order to determine the maximum tolerated dose and frequency of administration and to evaluate the preliminary anti-leukemic activity of MCLA-117 in AML. The secondary endpoints will 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.

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, as well as to commence a Phase 1/2 combination trial and a Phase 2/3 single agent trial in Europe. 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. In addition, we are also currently evaluating MCLA-117 for the treatment of MDS in pre-clinical studies.

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

#### ***MCLA-134***

MCLA-134 is a Biclonics that binds 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-114***

MCLA-114 is a Biclonics that binds to CD3 expressed by T-cells and an undisclosed target expressed by multiple myeloma cells. MCLA-114 is designed to engage T-cells of the immune system to kill multiple myeloma tumor cells. Its mechanism of action is similar to that of MCLA-117.

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

MCLA-145 is a Biclonics that binds 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.

### ***Pre-Clinical Discovery Programs***

We intend to leverage our Biclonics technology platform to identify multiple additional bispecific antibody candidates and advance them to clinical development. 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 Biclonics 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 increase the number of our research collaborations in order to derive further value from our Biclonics platform and more fully exploit its potential.

### ***ONO Pharmaceutical***

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

ONO paid us a non-refundable upfront fee of €1.0 million, and we are eligible to receive milestone payments upon achievement of specified research and clinical development milestones. As of August 28, 2015, we have achieved two of the specified pre-clinical milestones under this research and license agreement. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. 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.

### **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 with Boehringer Ingelheim, a biopharmaceuticals CMO, for the manufacturing of MCLA-128 and MCLA-117. 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.

## [Table of Contents](#)

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 August 28, 2015, our patent portfolio consisted of 7 issued U.S. patents, 14 pending U.S. patent applications, and 26 issued foreign patents including 4 issued European patents that have been validated in many European countries, and 67 pending foreign applications. These patents and patent applications include claims directed to specific bispecific antibody candidates, our technology platform and products based on our technology platform. As of August 28, 2015, our patent portfolio related to our MCLA-128 Biclomics candidate is at the stage of PCT filing (PCT filed 27FEB2015; expiry not earlier than 27FEB2035) and will enter national phases late 2015 or early 2016. 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.

As of August 28, 2015, our patent portfolio related to our MCLA-117 Biclomics candidate consists of 1 PCT application, filed on September 27, 2013, which entered national phases in U.S., Europe and 14 other foreign countries with an expiry not earlier than September 27, 2033. In addition, Merus filed new IP for MCLA-117 on July 10, 2015 which will be followed by a PCT filing no later than July 10, 2016. Claims are directed to MCLA-117 composition of matter and methods of using MCLA-117 in the treatment or prevention of myelodysplastic syndrome, or MDS, chronic myelogenous leukemia, or CML or acute myeloid leukemia, or AML. As of August 28, 2015, our patent portfolio related to our MeMo mouse consists of 4 pending U.S. applications, 9 issued foreign patents including one issued European patent that has been validated in many countries, and 10 pending foreign applications, all with an 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 and European patent has been filed by Regeneron Pharmaceuticals Inc. and is currently ongoing.

## [Table of Contents](#)

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.

### **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;

## [Table of Contents](#)

- 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.



## [Table of Contents](#)

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

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

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

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

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

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

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

After the completion of clinical trials of a biological bispecific antibody candidate, FDA approval of a BLA must be obtained before commercial marketing of the biological product. The BLA must include results of product development, laboratory and animal trials, human trials, information on the manufacture and composition of the product, proposed labeling and other relevant information. In addition, under the Pediatric Research Equity Act, or PREA, a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological bispecific antibody candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug or biological product that includes a new active ingredient, new indication, new dosage form, new dosing regimen or new route of administration 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

## [Table of Contents](#)

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, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. To date, only one biosimilar has 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 which time no similar medicinal product for the same indication may be placed on the market. 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



## [Table of Contents](#)

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 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

## [Table of Contents](#)

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 prohibits 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 or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. 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 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

## [Table of Contents](#)

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 providers, private health insurers and other organizations.

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.

## [Table of Contents](#)

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; 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; and imposed an annual excise tax of 2.3% on any entity that manufactures or imports medical devices.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, 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. 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 2012 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 up to 2% per fiscal year, which went into effect on April 1, 2013 and will stay in effect through 2024 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 and imaging centers.

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.

### **Research and Development**

Our research and development expenses were €14.1 million for the year ended December 31, 2014 and €6.1 million for the year ended December 31, 2013.

### **Employees**

As of June 30, 2015, we had 33 employees, 17 of whom hold M.D. or Ph.D. degrees. Twenty-nine of our employees work in research and development and four work in general and administrative areas. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We are in the process of establishing a workers' council for our employees.

## [Table of Contents](#)

### **Facilities**

We lease approximately 6,800 square feet of office and laboratory space in Utrecht, the Netherlands. This facility serves as our corporate headquarters and central laboratory facility. Our current lease has a term through December 31, 2015, after which it will convert to a lease eligible for renewal every three months.

### **Legal Proceedings**

On March 11, 2014, Regeneron Pharmaceuticals Inc., or Regeneron, filed a complaint in the United States District Court for the Southern District of New York, alleging that we were infringing one or more claims in their U.S. Patent No. 8,502,018, entitled “Methods of Modifying Eukaryotic Cells.” On July 3, 2014, we 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 we did not infringe the patent and that the patent was invalid. We 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 our proposed claim constructions. On February 24, 2015, the Court entered partial judgment in the proceeding, on the grounds that we did not infringe each of the patent claims, and that each of the patent claims were invalid due to indefiniteness. On August 6, 2015, the Court found Regeneron had withheld material information from the USPTO during prosecution of the patent, and Regeneron had engaged in inequitable conduct in connection with the prosecution of the patent.

On March 11, 2014, Regeneron served a writ in the Netherlands alleging that we were infringing one or more claims in their European patent EP 1 360 287 B1. We had opposed that patent in June 2014 and the Dutch litigation is currently stayed. On September 17, 2014, Regeneron’s patent EP 1 360 287 B1 was revoked in its entirety by the European Opposition Division of the European Patent Office, or the EPO. An appeal hearing has been set for October 2015 at the Technical Board of Appeal for the EPO.

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

## MANAGEMENT

### Management Board, Key Employees and Supervisory Board

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

<u>Name</u>	<u>Age</u>	<u>Position</u>
<b>Management Board Members</b>		
Ton Logtenberg, Ph.D.	57	Chief Executive Officer
Shelley Margetson	44	Chief Financial Officer
<b>Key Employees</b>		
Mark Throsby, Ph.D.	48	Chief Scientific Officer
Setareh Shamsili, M.D., Ph.D.	54	Chief Medical Officer
<b>Supervisory Board Members</b>		
Mark Iwicki	48	Chairman of the Board
Wolfgang Berthold, Ph.D.	68	Director
Lionel Carnot	48	Director
Gabriele Dallmann, Ph.D.	55	Director
John de Koning, Ph.D.	46	Director
Florent Gros(1)	47	Director
Anand Mehra, M.D.	39	Director
Jack Nielsen	51	Director

- (1) Florent Gros will resign from the supervisory board contingent upon, and effective immediately prior to, the effectiveness of the registration statement of which this prospectus forms a part.

Unless otherwise indicated, the current business addresses for the members of our management board and supervisory board is c/o Merus B.V., Padualaan 8 (postvak 133), 3584 CH Utrecht, the Netherlands.

### 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.

## [Table of Contents](#)

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 Financial Officer since 2010 and a management board member since 2012. Her responsibilities include financial, treasury, tax, budgeting and external reporting. 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 Accountant, 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.

**Mark Throsby, Ph.D.** has been a Merus employee since October 2008 and has served as our Chief Scientific Officer since 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.

**Setareh Shamsili, M.D., Ph.D.** has served as our Chief Medical Officer and Head of Clinical Development since December 2012. Dr. Shamsili has more than 25 years of experience in general medicine, internal medicine and medical oncology and approximately 12 years of experience in the pharmaceutical industry, including drug development, research and development, medical affairs, drug safety and clinical operation, as well as experience with business development and product portfolio strategy. Prior to joining Merus, Dr. Shamsili worked as an independent oncology consultant from June 2012 to December 2012, and as the Global Medical Leader of Oncology for Astellas Pharma, Inc., from March 2006 to June 2012. Dr. Shamsili holds a Ph.D. in neuro-oncology from Erasmus University Rotterdam, and a Ph.D. in head and neck-oncology and an M.D. from the National University of Medical Sciences, both with distinction.

### **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 by the shareholders. The members of the supervisory board are not authorized to represent us in dealings with third parties.

We have a supervisory board consisting of at least three members, up to a maximum of . A supervisory board member must be an individual. The supervisory board determines the number of supervisory

## Table of Contents

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 by the vote 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 for additional terms.

The supervisory board meets as often as a supervisory board member deems necessary. 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** is Chairman of our supervisory board and has been a member of the supervisory board since June 2015. Mr. Iwicki also serves as the executive 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 has 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 received his 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 Nabsys, Inc., Madrigal Pharmaceuticals, Inc. and Tallikut Pharmaceuticals. Mr. Carnot also serves as a member of the board of directors of 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.

**Gabriele Dallmann, Ph.D.** has been a member of the supervisory board since September 2011. Dr. Dallmann has more than 30 years of experience in regulatory affairs and drug development of medicinal products with a focus on biopharmaceuticals. Dr. Dallmann served at the German Federal Agency for Biopharmaceuticals and Vaccines from 1994 to 2005. She co-founded Biopharma Excellence GbR, a drug development planning consulting company, in October 2013 and co-founded EUCRAF Ltd, or the European Center for Regulatory Affairs, a training firm focusing on regulatory affairs for biopharmaceuticals and drug development, in June 2009. Prior to founding EUCRAF Ltd. and Biopharma-Excellence GbR, Dr. Dallmann founded and served as the chief executive officer of Pharmatching GmbH, from September 2009 to September 2013. Dr. Dallmann has also served on the board of directors of EUCRAF Ltd. since its founding in June 2009 and has served on the board of directors of Biopharma Excellence GbR since its founding in October 2013. Dr. Dallmann has a Ph.D. in immunology from Berlin University and a B.Sc. and M.Sc. in biology from University Leipzig.

**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. Since September 2009, Dr. de Koning has also served as a member of the board of directors of arGEN-X since July 2014. Previously, he served on the supervisory boards of BMEYE (acquired by Edwards Lifesciences), Prosensa (acquired by BioMarin) and Skyline Diagnostics, and as a non-executive director on the boards of Pronota (now MyCartis) and Innovative Biosensors Inc. Dr. de Koning has an M.Sc. in medical biology from Utrecht University and a Ph.D. in oncology from the Erasmus University Rotterdam.

**Florent Gros** was nominated to serve on the supervisory board by Novartis Bioventures Ltd., one of our shareholders, and has been a member of the supervisory board since January 2010. Mr. Gros has served as a managing director of the Novartis Venture Fund, a venture fund investing in life sciences companies, since January 2007 and is an employee of a corporation that is affiliated with Novartis Bioventures Ltd. Previously, Mr. Gros worked in various global leadership positions in intellectual property, venture and transaction matters at Nestlé, Pasteur Merieux Connaught (Sanofi Pasteur) and Novartis. Mr. Gros currently serves on the boards of Anokion S.A., Applied Immune Technologies Ltd., Atlas Genetics Ltd., Gensight S.A., MyoPowers Medical Technologies S.A., Kanyos Bio Inc., Opona Therapeutics Ltd. and Altimune Inc. Mr. Gros is a Kaufmann Fellow (Class of 2012) and received an M.S. in biotechnology engineering from Strasbourg School of Biotechnology in France. He also holds European and French patent law degrees and an M.A. in private law. Mr. Gros will resign from the supervisory board contingent upon, and effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

**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., Aerie Pharmaceuticals Inc. and Marinus Pharmaceuticals Inc. as well as the boards of several private companies. Dr. Mehra received his M.D. from Columbia University's College of Physicians and Surgeons.

## [Table of Contents](#)

**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, and since 2012, he has been employed as a partner based in Copenhagen, Denmark. Novo A/S is a Denmark limited liability company that manages investments and financial assets. From 2006 to 2012, Mr. Nielsen was employed as a partner at Novo Ventures of Novo A/S (US) Inc. in San Francisco, where he established the office 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. He currently serves on the board of directors of a number of private companies in the biopharmaceutical and biotechnology industries. Mr. Nielsen received an M.Sc. in chemical engineering from the Technical University of Denmark, and an M.S. in management of technology from the Technical University of Denmark.

### **Board Composition and Election of Supervisory Board Members After This Offering**

Upon the consummation of this offering, our supervisory board will be comprised of \_\_\_\_\_ members. Each supervisory board member is elected for a term of up to four years. A supervisory board member may be re-appointed for subsequent terms. Supervisory board members must retire periodically in accordance with a rotation plan to be drawn up by the supervisory board. Our supervisory board members do not have a retirement age requirement under our Articles of Association. Our supervisory board members will be elected, or re-elected as the case may be, by our general meeting of shareholders in accordance with the Articles of Association prior to the consummation of this offering to serve until their successors are duly elected and qualified.

We are a foreign private issuer. As a result, in accordance with NASDAQ rules, we will 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. We will also rely on the phase-in rules of the SEC and NASDAQ with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee members within one year of the effectiveness of the registration statement of which this prospectus forms a part. 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 Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events. For an overview of our corporate governance principles, see “Description of Share Capital and Articles of Association.”

***Audit Committee of the Supervisory Board***

The audit committee, which is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, will assist the supervisory board in overseeing our accounting and financial reporting processes and the audits of our financial statements. \_\_\_\_\_ will serve as Chairman of the committee. The audit committee will consist exclusively of members of our supervisory board who are financially literate, and \_\_\_\_\_ is considered an “audit committee financial expert” as defined by the SEC. Our supervisory board has determined that \_\_\_\_\_ satisfies the “independence” requirements set forth in Rule 10A-3 under the Exchange Act. We will rely on the phase-in rules of the SEC and NASDAQ with respect to the independence of our audit committee. These rules require that all members of our audit committee must meet the independence standard for audit committee membership within one year of the effectiveness of the registration statement of which this prospectus forms a part. The audit committee will be governed by a charter that complies with NASDAQ rules.

Upon the completion of this offering, the audit committee will be responsible for:

- 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 and the independent auditor our financial statements and our financial reporting process;
- reviewing our compliance with laws and regulations, including major legal and regulatory initiatives and also reviewing any major litigation or investigations against us that may have a material impact on our financial statements; 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 will meet as often as one or more members of the audit committee deem necessary, but in any event will meet at least four times per year. The audit committee will meet at least once per year with our independent accountant, without our management board being present.

***Compensation Committee of the Supervisory Board***

The compensation committee, which is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, will assist the supervisory board in determining management board compensation. \_\_\_\_\_ will serve as Chairman of the committee. The committee will recommend to the supervisory board for determination the compensation of each of our management board members. Under SEC and NASDAQ rules, there are heightened independence standards for members of the compensation committee, including a prohibition against the receipt of any compensation from us other than standard supervisory board member fees. All of our expected compensation committee members will meet this heightened standard.

Upon the completion of this offering, the compensation committee will be responsible for:

- identifying, reviewing and approving corporate goals and objectives relevant to management board compensation;
- analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of the management board members;

## [Table of Contents](#)

- evaluating each management board member's performance in light of such goals and objectives and determining each management board member's compensation based on such evaluation;
- determining any 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;
- periodically reviewing, in consultation with our Chief Executive Officer, our management succession planning; and
- reviewing and assessing risks arising from our compensation policies and practices for our employees and whether any such risks are reasonably likely to have a material adverse effect on us.

### ***Nominating and Corporate Governance Committee of the Supervisory Board***

The nominating and corporate governance committee, which is expected to consist of \_\_\_\_\_, \_\_\_\_\_ and \_\_\_\_\_, will assist 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. \_\_\_\_\_ will serve as Chairman of the committee.

Upon the completion of this offering, the nominating and corporate governance committee will be responsible for:

- drawing up selection criteria and appointment procedures for supervisory board members and management board members;
- reviewing and evaluating the composition, function and duties of our supervisory board and management board;
- recommending nominees for selection to our supervisory board, its corresponding committees and our management board;
- making recommendations to the supervisory board as to determinations of supervisory board member independence;
- leading the supervisory board in a self-evaluation, at least annually, to determine whether it and its committees are functioning effectively;
- overseeing and recommending for adoption by the general meeting of shareholders the compensation for our supervisory board members; and
- developing and recommending to the supervisory board our rules governing the supervisory board, rules governing the management board and code of business conduct and ethics and reviewing and reassessing the adequacy of such rules governing the supervisory board, rules governing the management board and Code of Business Conduct and Ethics and recommending any proposed changes to the supervisory board.

### **Code of Business Conduct and Ethics**

Upon the consummation of this offering, we will adopt a Code of Business Conduct and Ethics which will cover a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies such as equal opportunity and non-discrimination standards.

### **Management Board Member Employment Agreements**

Each of our management board members has entered into an employment agreement with us for an indefinite period of time.

## **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, staff and consultants) may be 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 is linked to our common shares. Under these programs, holders of vested options are 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 are issued to the Foundation. The purpose of the Foundation is to facilitate administration of share-based compensation awards and pool the voting interests of the underlying shares. The Foundation thereupon grants a Depositary Receipt for each issued common share to the person entitled to such common share under an award. The Depositary Receipt holder is entitled to any dividends or other distributions paid on the shares for which the Depositary Receipts are granted. The voting rights attached to the shares are exercised by the Foundation at its own discretion. The Depositary Receipt holders do not have meeting rights: they are not entitled to attend a general meeting of shareholders or to cast a vote.

The board members of the Foundation are Ton Logtenberg, our Chief Executive Officer, and John de Koning, one of our supervisory board members. The articles of association of the Foundation provide that the board members of the Foundation shall be appointed by the management board of the Foundation.

Under these programs, all options are to be settled by delivery of Depositary Receipts for shares. The options granted under the share option programs vest in installments over a four-year period from the grant date. 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. The options granted are exercisable once vested. Options will lapse on the eighth anniversary of the date of grant.

For participants who are not members of the supervisory board, a participant who voluntarily leaves employment with the Company is 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. Up to the first anniversary of the date of exercise, the participant has an obligation to offer 100% of his Depositary Receipts to the Foundation. This obligation for a participant to offer Depositary Receipts to the Foundation upon resignation is reduced by 25% at each anniversary of the date of exercise, which means that there is no such obligation if a participant leaves after the fourth anniversary of the date of exercise.

### **Compensation of Management Board Members and Supervisory Board Members**

The aggregate compensation, including benefits in kind, accrued or paid to our management board members and supervisory board members with respect to the year ended December 31, 2014, for services in all capacities, was approximately €0.6 million. As of December 31, 2014, we have accrued an amount of €77,500 for bonuses to provide to our management board members in the year 2015. For the year ended December 31, 2014, management board members and supervisory board members were granted an aggregate of 34,688 share options.

Dutch law provides that we must establish a policy in respect of the remuneration of our management board members. The general meeting shall, upon the proposal of the supervisory board, determine our policy concerning the compensation of the management board members pursuant to the relevant statutory requirements.

## [Table of Contents](#)

The compensation of the management board members shall be determined by the supervisory board pursuant to our Articles of Association. The supervisory board shall submit proposals concerning arrangements in the form of shares or rights to subscribe for shares to the general meeting for approval. This proposal must at least include the number of shares or rights to subscribe for shares that may be awarded to the management board members and which criteria apply for such awards or changes thereto.

The remuneration policy for the management board members will provide the supervisory board with a framework within which the supervisory board will determine the remuneration of the management board members. The remuneration policy for the management board members will be adopted by the general meeting upon the proposal of the supervisory board and approved prior to the consummation of this offering. We expect that the remuneration policy for our management board members will provide the supervisory board with the authority to enter into management services agreements with management board members that provide for compensation consisting of base compensation, performance-related variable compensation, long-term equity incentive compensation (as detailed in the terms of the employee share option program described below), pension and other benefits and severance pay and benefits. We expect that the remuneration policy for the management board members will provide that the annual cash bonus payable to management board members may not exceed % of the annual base gross salary and will be based upon the achievement of set financial and operating goals for the period. The bonus payments may be increased in any given year by the supervisory board upon a proposal of the compensation committee based on any exceptional achievements of that management board member. In addition, we expect that the remuneration policy for management board members will allow for cash termination payments, which may not exceed % of the management board member's base salary. We also expect the policy will allow for additional compensation and benefits to our management board members following a change of control.

Under Dutch law, we are not required to establish a remuneration policy for our supervisory board members, and we do not expect to adopt an official remuneration policy as of the date of this prospectus. We expect that remuneration for the supervisory board members will consist of cash and initial and annual equity awards. This is permissible under Dutch law, but constitutes a deviation from best practice provisions III.7.1 of the DCGC. We expect that each supervisory board member will be entitled to an annual retainer of € , provided that the chairman of the supervisory board will be entitled to an annual retainer of € . In addition, the chairman of the audit committee will be entitled to an additional annual retainer of € and the chairmen of the compensation and nomination and corporate governance committees will each be entitled to annual retainers of € . Supervisory board members will also be paid € for each supervisory board meeting attended in person and € for each supervisory board meeting attended by telephone, provided the meeting attended by telephone exceeds 30 minutes. The members of each committee will be paid € for each committee meeting attended in person and € for each committee meeting attended by telephone, provided the meeting attended by telephone exceeds 30 minutes. In addition, we expect that we will grant the chairman of the supervisory board an initial award of stock options to purchase common shares on the date of the consummation of this offering and will grant an initial award of stock options to purchase common shares to any future chairman of the supervisory board on the date of their election as the chairman of the supervisory board. Further, we expect that we will grant each additional supervisory board member an initial award of stock options to purchase common shares on the date of the consummation of this offering and will grant an initial award of stock options to purchase common shares to any future supervisory board members on the date of their election as a supervisory board member. These initial stock options will vest over a -year period in equal installments on the anniversaries of the grant date. In addition, we expect that each supervisory board member will be entitled to an annual grant of stock options, with the chairman of the supervisory board entitled to an annual grant of stock options. These annual awards will vest in four quarterly installments and will be fully vested on the first anniversary of the grant date. Initial awards and annual awards will be granted automatically on the respective dates of issuance based on the approval by the shareholders of the remuneration policy and will not require any further approval by us or the supervisory board or the company. Supervisory board members will also be entitled to be reimbursed for their reasonable expenses incurred in attending meetings of the supervisory board and its committees.

## **Insurance and Indemnification**

Management board members and supervisory board members have the benefit of indemnification provisions set forth in our Articles of Association. These provisions give management board members and supervisory board members the right, to the fullest extent permitted by law, to recover from us amounts, including but not limited to litigation expenses, and any damages they are ordered to pay, in relation to acts or omissions in the performance of their duties. However, no indemnification shall be given to a member of the management board and supervisory board if a Dutch court has established, without possibility for appeal, that the acts or omissions of such indemnified officer that led to the financial losses, damages, suit, claim, action or legal proceedings result from either an improper performance of his duties as an officer of the Company or an unlawful or illegal act; and to the extent that his financial losses, damages and expenses are covered by an insurance policy and the insurer has settled these financial losses, damages and expenses, or has indicated that it would do so. There is generally no entitlement to indemnification for acts or omissions that amount to willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct. In addition, upon the consummation of this offering, we intend to enter into agreements with our management board members and supervisory board members to indemnify them against expenses and liabilities to the fullest extent permitted by law. These agreements will also provide, subject to certain exceptions, for indemnification for related expenses including, among other expenses, attorneys' fees, judgments, penalties, fines and settlement amounts incurred by any of these individuals in any action or proceeding. In addition to such indemnification, we provide our management board members and supervisory board members with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to supervisory board members, management board members or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

**PRINCIPAL SHAREHOLDERS**

The following table sets forth information relating to the beneficial ownership of our common shares as of June 30, 2015, after giving effect to (i) the consummation of the Class C Financing; and (ii) the automatic conversion of all of our outstanding preferred shares into an aggregate of common shares in connection with this offering, as adjusted to reflect the sale of common shares in this offering, by:

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

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 SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to acquire within 60 days of June 30, 2015 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person.

The percentage of shares beneficially owned before the offering is computed on the basis of common shares as of June 30, 2015, after giving effect to (i) the Class C Financing and (ii) the automatic conversion of all of our outstanding preferred shares into an aggregate of common shares in connection with this offering. The percentage of shares beneficially owned after the offering is based on the number of our common shares to be outstanding after this offering, including the common shares that we are selling in this offering, and assumes no exercise of the underwriters' option to purchase additional common shares from us. Common shares that a person has the right to acquire within 60 days of June 30, 2015 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person, except with respect to the percentage ownership of all management board members and supervisory board members as a group. As of June 30, 2015, after giving effect to (i) the Class C Financing and (ii) the automatic conversion of all of our outstanding preferred shares into an aggregate of common shares in connection with this offering, common shares, representing % of our issued and outstanding common shares, were held by U.S. record holders. Unless otherwise indicated below, the address for each beneficial owner listed is c/o Merus B.V., at Padualaan 8 (postvak 133), 3584 CH Utrecht, the Netherlands.

<u>Name and address of beneficial owner</u>	<u>Shares beneficially owned before the offering</u>		<u>Shares beneficially owned after the offering</u>	
	<u>Number</u>	<u>Percent</u>	<u>Number</u>	<u>Percent</u>
<b>5% or Greater Shareholders</b>				
Novartis Bioventures Ltd.(1)		%		%
Bay City Capital Coöperatief U.A.(2)				
Aglaia Oncology Fund B.V./Aglaia Oncology Seed Fund B.V.(3)				
Johnson & Johnson Innovation—JJDC, Inc.(4)				
Pfizer, Inc.(5)				
Sofinnova Venture Partners IX, L.P.(6)				
Novo A/S(7)				
Baker Brothers Life Sciences L.P.(8)				
Coöperatief LSP IV U.A.(9)				



[Table of Contents](#)

<u>Name and address of beneficial owner</u>	<u>Shares beneficially owned before the offering</u>		<u>Shares beneficially owned after the offering</u>	
	<u>Number</u>	<u>Percent</u>	<u>Number</u>	<u>Percent</u>
<b>Management Board Members and Supervisory Board Members</b>				
Ton Logtenberg, Ph.D.				
Shelley Margetson				
Mark Iwicki				
Wolfgang Berthold, Ph.D.				
Lionel Carnot				
Gabriele Dallmann, Ph.D.				
John de Koning, Ph.D.				
Florent Gros				
Anand Mehra, M.D.				
Jack Nielsen				
All management board members and supervisory board members as a group (10 persons)				

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

- (1)
- (2)
- (3)
- (4)
- (5)
- (6)
- (7)
- (8)
- (9)

## RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into since January 1, 2012 with any members of our supervisory board or management board and the holders of more than 5% of our common shares.

### Class B Preferred Share Financing

In April 2012, we issued an aggregate of 1,082,666 Class B preferred shares at a price per share of €7.50 for an aggregate purchase price of €8.1 million.

In September 2013, we issued an aggregate of 1,600,000 Class B preferred shares at a price per share of €7.50 for an aggregate purchase price of €12.0 million.

In August 2014, we issued an aggregate of 800,000 of our Class B preferred shares at a price per share of €7.50 for an aggregate purchase price of €6.0 million.

In January 2015, we issued an aggregate of 2,407,224 of our Class B preferred shares at a price per share of €5.64 for an aggregate purchase price of €5.0 million.

In June 2015, the Class B preferred shareholders waived their rights to the remaining tranches of the Class B preferred share financing.

The following table sets forth the aggregate number of our Class B preferred shares purchased by our management board members, supervisory board members and 5% shareholders and their affiliates. Each preferred share identified in the following table will automatically convert into common shares in connection with this offering.

<u>Participants(1)</u>	<u>Class B Preferred Shares</u>
Novartis Bioventures Ltd.(2)	1,574,039
Bay City Capital Coöperatief U.A.(3)	1,574,039
Johnson & Johnson Innovation—JJDC, Inc.	1,217,636
Pfizer, Inc.	1,049,360
Aglaia Oncology Fund B.V./Aglaia Oncology Seed Fund B.V.	816,287
Coöperatief LSP IV U.A.(4)	787,019

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

(2) Florent Gros, a member of our supervisory board, is a managing director of the Novartis Venture Fund and is an employee of a corporation that is affiliated with Novartis Bioventures Ltd.

(3) Lionel Carnot, a member of our supervisory board, is a managing director of Bay City Capital LLC.

(4) John de Koning, Ph.D., a member of our supervisory board, is a partner of Life Sciences Partners.

### Convertible Bridge Loan and Class C Preferred Share Financing

In June 2015, we entered into a convertible loan agreement with Johnson & Johnson Innovation—JJDC, Inc., an affiliate of Novartis Bioventures Ltd., Coöperatief LSP IV U.A., Bay City Capital Coöperatief U.A., Pfizer, Inc., and Aglaia Oncology Fund B.V., in the amount of €8.0 million with interest at 12% per annum. The convertible loan agreement provided that all principal and interest outstanding on the convertible loan would be converted into shares upon the closing of a Class C preferred share financing round in accordance with the terms and provisions of the convertible loan agreement. As of June 30, 2015, the convertible loan had been drawn in the total amount of €8.0 million.

## [Table of Contents](#)

In August 2015, we entered into a subscription agreement pursuant to which we issued and sold an aggregate of 7,469,780 of our Class C preferred shares at a price per share of €6.66 for an aggregate purchase price of €49.7 million, which includes the contribution of the existing €8.0 million convertible bridge loan and interest thereon. The Class C preferred share financing is divided into two tranches.

In the first tranche, the lenders of the convertible bridge loan agreed to contribute the principal amount of the existing €8.0 million convertible bridge loan and interest thereon and invest, together with certain new investors, an additional €41.6 million in cash.

Pursuant to the terms of the subscription agreement, the second tranche of the Class C preferred share financing will automatically be cancelled upon the closing of this initial public offering.

The following table sets forth the aggregate number of our Class C preferred shares purchased by our management board members, supervisory board members and 5% shareholders and their affiliates. Each Class C preferred share identified in the following table will automatically convert into common shares in connection with this offering.

<u>Participants(1)</u>	<u>Class C Preferred Shares</u>
Sofinnova Venture Partners IX, L.P.(2)	1,275,894
Novo A/S(3)	1,206,300
Baker Brothers Life Sciences L.P.	1,113,508
Novartis Bioventures Ltd.(4)	550,373
Bay City Capital Coöperatief U.A.(5)	550,373
Johnson & Johnson Innovation—JJDC, Inc.	425,754
Aglaia Oncology Fund B.V./Aglaia Oncology Seed Fund B.V.	416,821
Pfizer, Inc.	366,916
Coöperatief LSP IV U.A.(6)	275,186

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

(2) Anand Mehra, M.D., a member of our supervisory board, is a general partner of Sofinnova Ventures.

(3) Jack Nielsen, a member of our supervisory board, is employed as a partner of Novo A/S.

(4) Florent Gros, a member of our supervisory board, is a managing director of the Novartis Venture Fund and is an employee of a corporation that is affiliated with Novartis Bioventures Ltd.

(5) Lionel Carnot, a member of our supervisory board, is a managing director of Bay City Capital LLC.

(6) John de Koning, Ph.D., a member of our supervisory board, is a partner of Life Sciences Partners.

### **Shareholders’ Agreement**

We and all of our then-existing shareholders entered into a shareholders’ agreement on August 20, 2015. While the shareholders’ agreement will terminate upon the closing of this offering, certain provisions of this agreement, including our obligation to enter into a registration rights agreement with certain of our existing shareholders upon the consummation of this offering, will survive upon the closing of the offering.

### **Registration Rights Agreement**

Effective upon the consummation of this offering, we will enter into a registration rights agreement, pursuant to which we will grant demand registration rights, short-form registration rights and piggyback registration rights to certain of our existing shareholders. All fees, costs and expenses of underwritten registrations are expected to be borne by us.

### **Option Plan Foundation**

Our 2010 Option Plan utilizes the Foundation to facilitate administration of share-based compensation awards and pool the voting interests of the underlying shares. Upon the exercise or award or vesting of a non-cash-settled award under the 2010 Option Plan, common shares are issued to the Foundation, which thereupon grants a non-voting depositary receipt representing the underlying common shares against payment of the option exercise price. All options vest 25% on the first anniversary of the grant date and the remaining 75% vest monthly over the next three years, provided that the employee is still employed at the time of vesting. The depositary receipt holder is entitled to any dividends or other distributions paid on the shares for which the depositary receipts are granted. The voting rights attached to the shares are exercised by the Foundation at its own discretion. The depositary receipt holders do not have meeting rights and they are not entitled to attend a general meeting of shareholders or to cast a vote.

The board members of the Foundation are Ton Logtenberg, our Chief Executive Officer, and John de Koning, one of our supervisory board members. The articles of association of the Foundation provide that the board members of the Foundation shall be appointed by the management board of the Foundation.

### **Agreements with Management Board Members**

For a description of our agreements with our management board members, please see “Management—Management Board Member Employment Agreements.”

### **Indemnification Agreements**

We intend to enter into indemnification agreements with our management board members and supervisory board members. The indemnification agreements and our Articles of Association require us to indemnify our management board members and supervisory board members to the fullest extent permitted by law. See “Management—Insurance and Indemnification” for a description of these indemnification agreements.

### **Related Person Transaction Policy**

Prior to the consummation of this offering, we intend to enter into a related person transaction policy.

## DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

### General

We were incorporated on June 16, 2003 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. Prior to the consummation of this offering, we intend to convert into a public company with limited liability (*naamloze vennootschap*) pursuant to a Deed of Amendment and Conversion, and our legal name will be Merus N.V.

We are registered with the Trade Register of the Chamber of Commerce Den Haag, the Netherlands (*handelsregister van de Kamer van Koophandel en Fabrieken Den Haag*) under number 30189136. Our corporate seat is in Utrecht, the Netherlands, and our registered office is Padualaan 8 (postvak 133), 3584 CH Utrecht, the Netherlands.

As of the date of this prospectus, our share capital is divided into several series of preferred shares and common shares. All of our outstanding preferred shares will be converted into common shares upon the closing of this offering. After giving effect to (i) the consummation of the Class C Financing, (ii) the automatic conversion of our outstanding preferred shares into common shares upon the closing of this offering and (iii) this offering, our issued share capital will be € .

After the execution of the Deed of Amendment and Conversion upon the consummation of this offering, our authorized share capital will be € , divided into common shares, each with a nominal value of € and cumulative preferred shares, each with a nominal value of € . We have 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. Under our Articles of Association, the general meeting is authorized to issue common shares and preferred shares, but the general meeting may authorize another body to issue such shares. Subject to the prior approval of the supervisory board, the management board may authorize the issue of an amount of cumulative preferred shares up to 100% of our issued capital immediately prior to the issuance of such preferred shares for a period of five years. In such event, the cumulative preferred shares will be issued to a separate, newly established foundation. If the management board determines to issue the cumulative preferred shares to such a foundation, the foundation's articles of association will 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 will be structured to operate independently of us. Our Articles of Association state that any transfer of preferred shares requires the prior approval of our management board.

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 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 can 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.

Under Dutch law, our authorized share capital is the maximum capital that we may issue without amending our Articles of Association. An amendment of our Articles of Association would require a resolution of the general meeting of shareholders upon proposal by the management board with the prior approval of the supervisory board.

## [Table of Contents](#)

We intend to apply to list our common shares on NASDAQ under the symbol “MRUS.”

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

### **Articles of Association and Dutch law**

Our Articles of Association as are in force as of the date of this prospectus are referred to herein as our “Current Articles.” When we refer to our Articles of Association in this prospectus, we refer to our Articles of Association as they will be in force after the expected execution of the Deed of Amendment and Conversion prior to the consummation of this offering.

Our Current Articles were last amended by Deed of Amendment on August 21, 2015. We shall further amend our Current Articles and convert our Company into a public company with limited liability effective prior to the consummation of this offering. On \_\_\_\_\_, 2015, the general meeting of shareholders, with the prior written approval of the preferred majority of the Class A, Class B and Class C shareholders meeting jointly, resolved to amend the Current Articles and to convert our company into a public company with limited liability (*naamloze vennootschap*), prior to the consummation of this offering. The draft Deed of Amendment and Conversion was made available to the shareholders prior to the date of such resolution and remains available for inspection by interested parties at our offices in Utrecht up to and including the date of consummation of this offering.

Set forth below is a summary of relevant information concerning our share capital and material provisions of our Articles of Association and applicable Dutch law. This summary does not constitute legal advice regarding those matters and should not be regarded as such.

#### ***Amendment of Articles of Association***

The general meeting of shareholders may resolve to amend the Articles of Association, at the proposal of the management board, with the prior approval of the supervisory board. A resolution by the general meeting of shareholders to amend the Articles of Association requires a simple majority of the votes cast.

#### ***Company’s Shareholders’ Register***

Subject to Dutch law and the Articles of Association, we must keep our shareholders’ register accurate and up-to-date. The management board keeps our shareholders’ register and records names and addresses of all holders of shares, showing the date on which the shares were acquired, the date of the acknowledgement by or notification of us as well as the amount paid on each share. The register also includes the names and addresses of those with a right of use and enjoyment (*vruchtgebruik*) in shares belonging to another or a pledge in respect of such shares.

#### ***Corporate Objectives***

Our corporate objectives are: (1) to develop products and services in the area of biotechnology, (2) to finance enterprises and companies, (3) to borrow, to lend to raise funds, including the issue of bonds, promissory notes or other securities or evidence of indebtedness as well as to enter into agreements in connection with the aforementioned, (4) to supply advice and to render services to enterprises and companies with which the Company forms a group and to third parties, (5) to render guarantees, to bind the Company and to encumber its assets for obligations of the companies and enterprises with which it forms a group and on behalf of third parties, (6) to incorporate, to participate in any way whatsoever, to manage and to supervise enterprises and companies

## [Table of Contents](#)

and businesses, (7) to obtain, alienate, manage and exploit registered property and items of property in general, (8) to trade in currencies, securities and items of property in general, (9) to develop and trade in patent, trademarks, licenses, know-how and other industrial property rights, (10) to perform any and all activity of industrial, financial or commercial nature, with all of the foregoing whether independently or in cooperation with third parties and including the performance and support of everything which in the broadest sense is connected directly or indirectly with the above-mentioned objects.

### **Limitation on Liability and Indemnification Matters**

Under Dutch law, management board members, supervisory board members and certain other officers may be held liable for damages in the event of improper or negligent performance of their duties. They may be held jointly and severally liable for damages to the Company and to third parties for infringement of the Articles of Association or of certain provisions of the Dutch Civil Code. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Management board members, supervisory board members and certain other officers are insured under an insurance policy taken out by us against damages resulting from their conduct when acting in the capacities as such directors or officers. In addition, our Articles of Association provide for indemnification of our management board members and supervisory board members, including reimbursement for reasonable legal fees and damages or fines based on acts or failures to act in their duties. No indemnification shall be given to a member of the management board or supervisory board if a Dutch court has established, without possibility for appeal, that the acts or omissions of such indemnified officer that led to the financial losses, damages, suit, claim, action or legal proceedings resulted from either an improper performance of his duties as an officer of the Company or an unlawful or illegal act, and only to the extent that his financial losses, damages and expenses are covered by an insurance and the insurer has settled these financial losses, damages and expenses (or has indicated that it would do so). Furthermore, such indemnification will generally not be available in instances of willful (*opzettelijk*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct unless Dutch law provides otherwise for additional information, please see “Management—Insurance and indemnification.”

### **Shareholders’ Meetings and Consents**

#### *General Meeting*

General meetings of shareholders are held in Utrecht, Amsterdam, Rotterdam, The Hague or in the municipality of Haarlemmermeer (Schiphol Airport), all of which are in the Netherlands. The annual general meeting of shareholders must be held within six months of the end of each financial year. Additional extraordinary general meetings of shareholders may also be held, whenever considered appropriate by the management board or the supervisory board. Pursuant to Dutch law, one or more shareholders, who jointly represent at least one-tenth of the issued capital may request us to convene a general meeting. If we refuse to convene a meeting, such shareholder may, on their application, be authorized by Court to convene a general meeting of shareholders. The Court shall disallow the application if it does not appear that the applicants have previously requested the management board and the supervisory board to convene a general meeting of shareholders and neither the management board nor the supervisory board has taken the necessary steps so that the general meeting of shareholders could be held within six weeks after the request.

General meetings of shareholders can be convened by a notice, which shall include an agenda stating the items to be discussed, including for the annual general meeting of shareholders, among other things, the adoption of the annual accounts, appropriation of our profits and proposals relating to the composition of the management board or supervisory board, including the filling of any vacancies in the management board or supervisory board. In addition, the agenda shall include such items as have been included therein by the management board or supervisory board. The agenda shall also include such items requested by one or more shareholders, and others entitled to attend general meetings of shareholders, representing at least 3% of the issued share capital. Requests must be made in writing and received by the management board at least 60 days before the day of the convocation of the meeting. No resolutions shall be adopted on items other than those which have been included

## [Table of Contents](#)

in the agenda. In accordance with the Dutch Corporate Governance Code, or DCGC, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy, the management board may invoke a response time of a maximum of 180 days until the day of the general meeting of shareholders.

The general meeting is presided over by the chairman of the supervisory board. However, the chairman may charge another person to preside over the general meeting in his place even if he himself is present at the meeting. If the chairman of the supervisory board is absent and he has not charged another person to preside over the meeting in his place, the supervisory board members present at the meeting shall appoint one of them to be chairman. If no members of the supervisory board are present at the general meeting, the general meeting is to be presided over by the chairman of the management board or, if the chairman of the management board is absent, by one of the other management board members designated for that purpose by the management board or, if no member of the management board is present, by any other person appointed by the general meeting. Management board members and supervisory board members may attend a general meeting of shareholders. In these meetings, they have an advisory vote. The chairman of the meeting may decide at its discretion to admit other persons to the meeting.

All shareholders and others entitled to attend general meetings of shareholders are authorized to attend the general meeting of shareholders, to address the meeting and, in so far as they have such right, to vote.

### *Quorum and Voting Requirements*

Each common share confers the right on the holder to cast one vote at the general meeting of shareholders. Shareholders may vote by proxy. The voting rights attached to any shares held by us are suspended as long as they are held in treasury. Nonetheless, the holders of a right of use and enjoyment (*vruchtgebruik*) in shares belonging to another and the holders of a right of pledge in respect of common shares held by us are not excluded from any right they may have to vote on such common shares, if the right of use and enjoyment (*vruchtgebruik*) or the right of pledge was granted prior to the time such common share was acquired by us. We may not cast votes in respect of a share in respect of which there is a right of use and enjoyment (*vruchtgebruik*) or a right of pledge. Shares which are not entitled to voting rights pursuant to the preceding sentences will not be taken into account for the purpose of determining the number of shareholders that vote and that are present or represented, or the amount of the share capital that is provided or that is represented at a general meeting of shareholders.

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. Decisions of the general meeting of shareholders are taken by an absolute majority of votes cast, except where Dutch law or the Articles of Association provide for a qualified majority or unanimity.

### ***Management Board Members and Supervisory Board Members***

#### *Election of Management Board Members and Supervisory Board Members*

Under our Articles of Association, the management board members and supervisory board members are appointed by the general meeting of shareholders upon nomination by our supervisory board. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of shareholders overrules the binding nomination, the supervisory board shall make a new nomination.



*Duties and Liabilities of Management Board Members and Supervisory Board Members*

Under Dutch law, the management board is responsible for our management, strategy, policy and operations. The supervisory board is responsible for supervising the conduct of and providing advice to the management board and for supervising our business generally. Furthermore, each management board member and supervisory board member has a duty to act in the corporate interest of the company. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, whereby the circumstances generally dictate how such duty is to be applied. Any resolution of the management board regarding a significant change in our identity or character requires shareholder approval.

***Dividends and Other Distributions***

*Amount Available for Distribution*

We may only make distributions to our shareholders if our shareholders' equity exceeds the sum of the paid-in and called-up share capital plus the reserves as required to be maintained by Dutch law or by the Articles of Association. Under the Articles of Association, a dividend is first paid out of the profit, if available for distribution, on any preferred shares. After that, the management board shall determine which part of the remaining profit shall be added to our reserves. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders. However, a distribution to the holders of common shares can only be resolved upon by the general meeting upon a proposal of the management board, subject to the approval of the supervisory board.

We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board is permitted, subject to certain requirements and subject to approval of the supervisory board, to declare interim dividends without the approval of the general meeting of shareholders.

Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distributions not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

We do not anticipate paying any cash dividends for the foreseeable future.

*Exchange Controls*

Under 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.

*Squeeze out Procedures*

Pursuant to Section 92a, Book 2, Dutch Civil Code, a shareholder who for his own account contributes at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Enterprise Chamber and can be instituted by means of a writ of summons served upon each of the minority shareholders in accordance with the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer

becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

#### *Obligation to Disclose Holdings and Transactions*

Pursuant to the Dutch Financial Markets Supervision Act (*Wet op het financieel toezicht*), or FMSA, any management board member or supervisory board member and any other person who has managerial or co-managerial responsibilities in respect of us or who has the authority to make decisions affecting our future developments and business prospects and who may have regularly access to inside information relating, directly or indirectly, to us, must give written notice to the Netherlands Authority for the Financial Markets, or NAFM, by means of a standard form of any transactions conducted for his own account relating to our shares or in financial instruments the value of which is also based on the value of our shares.

Furthermore, in accordance with the FMSA and the regulations promulgated thereunder, certain persons who are closely associated with members of our supervisory board or any of the other persons as described above, are required to notify the NAFM of any transactions conducted for their own account relating to our shares or in financial instruments the value of which is also based on the value of our shares. The FMSA and the regulations promulgated thereunder cover the following categories of persons: (1) the spouse or any partner considered by national law as equivalent to the spouse, (2) dependent children, (3) other relatives who have shared the same household for at least one year at the relevant transaction date, and (4) any legal person, trust or partnership whose, among other things, managerial responsibilities are discharged by a person referred to under (1), (2) or (3) above or by the relevant supervisory board member or other person with any authority in respect of us as described above.

The NAFM must be notified no later than the fifth business day following the relevant transaction date. Under certain circumstances, notification may be postponed until the date the value of the transactions performed for that person's own account, together with transactions carried out by the persons closely associated with that person, amounts to €5,000 or more in the calendar year in question.

Non-compliance with the notification obligations under the FMSA could lead to criminal fines, administrative fines, imprisonment or other sanctions. In addition, non-compliance with some of the notification obligations under the FMSA may lead to civil sanctions, including suspension of the voting rights relating to our shares held by the offender for a period of not more than three years and a prohibition to own shares or voting rights on our shares for a period of not more than five years.

The NAFM does not issue separate public announcements of notifications received by it. It does, however, keep a public register of all notifications under the FMSA on its website, <http://www.afm.nl>. Third parties can request to be notified automatically by e-mail of changes to the public register in relation to a particular company's shares or a particular notifying party.

The FMSA contains rules intended to prevent market abuse, such as insider trading, tipping and market manipulation.

Pursuant to the DCGC and in accordance with the rules intended to prevent market abuse, prior to the consummation of this offering we intend to adopt an insider trading policy in respect of the holding of and carrying out of transactions by management board members, supervisory board members and employees in our shares or in financial instruments the value of which is determined by the value of our shares. Furthermore, we have drawn up a list of those persons working for us who could have access to inside information on a regular or incidental basis and have informed such persons of the rules on insider trading and market manipulation, including the sanctions which can be imposed in the event of a violation of those rules.

## Comparison of Dutch Corporate Law and Our Articles of Association and U.S. corporate law

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

### **Corporate Governance**

#### *Duties of Management Board Members and Supervisory Board Members*

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

Under Dutch law, the management board is responsible for the management and the strategy, policy and operations of the company. The supervisory board is responsible for supervising the conduct of and providing advice to the management board and for supervising the business generally. Furthermore, each management board member and supervisory board member has a duty to act in the corporate interest of the company. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, whereby the circumstances generally dictate how such duty is to be applied. Any resolution of the management board regarding a significant change in the identity or character of the company requires shareholders' approval.

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

#### *Management Board Member and Supervisory Board Member Terms*

*The Netherlands.* In the Netherlands, management board members and supervisory board members of a listed company are generally appointed for an individual term of a maximum of four years. There is no limit in the number of consecutive terms management board members may serve. For supervisory board members, a limit of twelve years generally applies. Each of our management board members currently has an employment agreement for an indefinite period of time. Our supervisory board members are appointed by the general meeting of shareholders for a term of up to four years. A supervisory board member may be reappointed for a term of up to four years at a time. A supervisory board member may be a supervisory board member for a period not longer than twelve years, which period may or may not be interrupted, unless the general meeting of shareholders resolves otherwise.

The general meeting of shareholders shall at all times be entitled to suspend or dismiss a management board member or supervisory board member. The general meeting of shareholders may only adopt a resolution to suspend or dismiss such management board member or supervisory board member by at least a two thirds majority of the votes cast, if such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board, in which case a simple majority of the votes cast is sufficient. The supervisory board may at all times suspend (but not dismiss) a management board member.

## [Table of Contents](#)

*Delaware.* The Delaware General Corporation Law generally provides for a one-year term for directors, but permits directorships to be divided into up to three classes with up to three-year terms, with the years for each class expiring in different years, if permitted by the certificate of incorporation, an initial bylaw or a bylaw adopted by the stockholders. A director elected to serve a term on a “classified” board may not be removed by stockholders without cause. There is no limit in the number of terms a director may serve.

### *Management Board Member and Supervisory Board Member Vacancies*

*The Netherlands.* Under Dutch law, new management board members and supervisory board members are appointed by the general meeting of shareholders. Under our Articles of Association, management board members and supervisory board members are appointed by the general meeting of shareholders upon the binding nomination by our supervisory board. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of shareholders overrules the binding nomination, the supervisory board shall make a new nomination.

*Delaware.* The Delaware General Corporation Law provides that vacancies and newly created directorships may be filled by a majority of the directors then in office (even though less than a quorum) unless (i) otherwise provided in the certificate of incorporation or bylaws of the corporation or (ii) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case any other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.

### **Conflict-of-Interest Transactions**

*The Netherlands.* Under Dutch law and our Articles of Association, management board members and supervisory board members shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a conflict of interest with us. Our Articles of Association provide that if as a result thereof no resolution of the management board can be adopted, the resolution is adopted by the supervisory board. If as a result of the conflict of interest of supervisory board members no resolution of the supervisory board can be adopted, the resolution can nonetheless be adopted by the supervisory board. In that case, each supervisory board member is entitled to participate in the discussion and decision making process and to cast a vote.

*Delaware.* The Delaware General Corporation Law generally permits transactions involving a Delaware corporation and an interested director of that corporation if:

- the material facts as to the director’s relationship or interest are disclosed and a majority of disinterested directors consent;
- the material facts are disclosed as to the director’s relationship or interest and a majority of shares entitled to vote thereon consent; or
- the transaction is fair to the corporation at the time it is authorized by the board of directors, a committee of the board of directors or the stockholders.

### **Proxy Voting by Management Board Members and Supervisory Board Members**

*The Netherlands.* An absent management board member may issue a proxy for a specific management board meeting but only to another management board member in writing. An absent supervisory board member may issue a proxy for a specific supervisory board meeting but only to another supervisory board member in writing.

*Delaware.* A director of a Delaware corporation may not issue a proxy representing the director’s voting rights as a director.

## **Shareholder Rights**

### *Voting Rights*

*The Netherlands.* In accordance with Dutch law and our Articles of Association, each issued common share confers the right to cast one vote at the general meeting of shareholders. Each holder of common shares may cast as many votes as it holds shares. Shares that are held by us or our direct or indirect subsidiaries do not confer the right to vote.

For each general meeting of shareholders, a record date will be applied with respect to common shares in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders, which date is set by the management board. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

*Delaware.* Under the Delaware General Corporation Law, each stockholder is entitled to one vote per share of stock, unless the certificate of incorporation provides otherwise. In addition, the certificate of incorporation may provide for cumulative voting at all elections of directors of the corporation, or at elections held under specified circumstances. Either the certificate of incorporation or the bylaws may specify the number of shares and/or the amount of other securities that must be represented at a meeting in order to constitute a quorum, but in no event will a quorum consist of less than one third of the shares entitled to vote at a meeting.

Stockholders as of the record date for the meeting are entitled to vote at the meeting, and the board of directors may fix a record date that is no more than 60 nor less than 10 days before the date of the meeting, and if no record date is set then the record date is the close of business on the day next preceding the day on which notice is given, or if notice is waived then the record date is the close of business on the day next preceding the day on which the meeting is held. The determination of the stockholders of record entitled to notice or to vote at a meeting of stockholders shall apply to any adjournment of the meeting, but the board of directors may fix a new record date for the adjourned meeting.

### *Shareholder Proposals*

*The Netherlands.* Pursuant to our Articles of Association, extraordinary general meetings of shareholders will be held whenever our supervisory board or management board deems such to be necessary. Pursuant to Dutch law, one or more shareholders representing at least one-tenth of the issued share capital may request the Dutch courts to order that a general meeting of shareholders be held and may, on their application, be authorized by the court to convene a general meeting of shareholders if we refuse to convene a general meeting at their request. The court shall disallow the application if it does not appear that the applicants have previously requested the management board and the supervisory board to convene a general meeting of shareholders and neither the management nor the supervisory board has taken the necessary steps so that the general meeting of shareholders could be held within six weeks after the request.

Also, the agenda for a general meeting of shareholders shall include such items requested by one or more shareholders, and others entitled to attend general meetings of shareholders, representing at least 3% of the issued share capital, except where the articles of association state a lower percentage. Our Articles of Association do not state such lower percentage. Requests must be made in writing and received by the management board at least 60 days before the day of the convocation of the meeting. In accordance with the DCGC, a shareholder shall exercise the right of putting an item on the agenda only after consulting the management board in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in the company's strategy, the management board may invoke a response time of a maximum of 180 days until the day of the general meeting of shareholders.

*Delaware.* Delaware law does not specifically grant stockholders the right to bring business before an annual or special meeting. However, if a Delaware corporation is subject to the SEC's proxy rules, a stockholder who owns at least \$2,000 in market value, or 1% of the corporation's securities entitled to vote, may propose a matter for a vote at an annual or special meeting in accordance with those rules.

## [Table of Contents](#)

### *Action by Written Consent*

*The Netherlands.* Under our Articles of Association, shareholders' resolutions may be adopted in writing without holding a meeting of shareholders, provided that (i) all shareholders agree on this practice for decision making and, (ii) the resolution is adopted unanimously by all shareholders that are entitled to vote. For a listed company, this method of adopting resolutions is not feasible.

*Delaware.* Although permitted by Delaware law, publicly listed companies do not typically permit stockholders of a corporation to take action by written consent.

### *Appraisal Rights*

*The Netherlands.* The concept of appraisal rights is not known as such under Dutch law.

However, pursuant to Dutch law a shareholder who for his own account contributes at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. The proceedings are held before the Enterprise Chamber. The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the person acquiring the shares shall give written notice of the date and place of payment and the price to the holders of the shares to be acquired whose addresses are known to him. Unless the addresses of all of them are known to the acquiring person, such person is required to publish the same in a daily newspaper with a national circulation.

Furthermore, in accordance with the directive 2005/56/EC of the European Parliament and the Council of October 26, 2005 on cross-border mergers of limited liability companies, Dutch law provides that, to the extent that the acquiring company in a cross-border merger is organized under the laws of another EU member state, a shareholder of a Dutch disappearing company who has voted against the cross-border merger may file a claim with the Dutch company for compensation. Such compensation to be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the cross-border merger.

Payment by the acquiring company is only possible if the resolution to approve the cross-border merger by the corporate body of the other company or companies involved in the cross-border merger includes the acceptance of the rights of the shareholders of the Dutch company to oppose the cross-border merger.

*Delaware.* The Delaware General Corporation Law provides for stockholder appraisal rights, or the right to demand payment in cash of the judicially determined fair value of the stockholder's shares, in connection with certain mergers and consolidations.

### *Shareholder Suits*

*The Netherlands.* In the event a third party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the company. Only in the event that the cause for the liability of a third party to the company also constitutes a tortious act directly against a shareholder does that shareholder have an individual right of action against such third party in its own name. The Dutch Civil Code provides for the possibility to initiate such actions collectively. A foundation or an association whose objective is to protect the rights of a group of persons having similar interests can institute a collective action. The collective action itself cannot result in an order for payment of monetary damages but may only result in a declaratory judgment (*verklaring voor recht*). In order to obtain compensation for damages, the foundation or association and the defendant may reach—often on the basis of

## [Table of Contents](#)

such declaratory judgment—a settlement. A Dutch court may declare the settlement agreement binding upon all the injured parties with an opt-out choice for an individual injured party. An individual injured party may also itself institute a civil claim for damages.

*Delaware.* Under the Delaware General Corporation Law, a stockholder may bring a derivative action on behalf of the corporation to enforce the rights of the corporation. An individual also may commence a class action suit on behalf of himself and other similarly situated stockholders where the requirements for maintaining a class action under Delaware law have been met. A person may institute and maintain such a suit only if that person was a stockholder at the time of the transaction which is the subject of the suit. In addition, under Delaware case law, the plaintiff normally must be a stockholder at the time of the transaction that is the subject of the suit and throughout the duration of the derivative suit. Delaware law also requires that the derivative plaintiff make a demand on the directors of the corporation to assert the corporate claim before the suit may be prosecuted by the derivative plaintiff in court, unless such a demand would be futile.

### **Repurchase of Shares**

*The Netherlands.* Under Dutch law, a company such as ours may not subscribe for newly issued shares in its own capital. Such company may, however, subject to certain restrictions of Dutch law and its Articles of Association, acquire shares in its own capital. We may acquire fully paid shares in our own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and our Articles of Association, we may repurchase fully paid shares in our own capital if (i) such repurchase would not cause our shareholders' equity to fall below an amount equal to the sum of the paid-up and called-up part of the issued share capital and the reserves we are required to maintain pursuant to applicable law and (ii) we would not as a result of such repurchase hold more than 50% of our own issued share capital.

Other than shares acquired for no valuable consideration, common shares may only be acquired following a resolution of our management board, acting pursuant to an authorization for the repurchase of shares granted by the general meeting of shareholders. An authorization by the general meeting of shareholders for the repurchase of shares can be granted for a maximum period of 18 months. Such authorization must specify the number and class of shares that may be acquired, the manner in which these shares may be acquired and the price range within which the shares may be acquired. Our management board has been authorized, acting with the approval of our supervisory board, for a period of 18 months to cause the repurchase of common shares by us of up to 50% of our issued share capital, for a price per share not exceeding 110% of the average closing price of the common shares on the NASDAQ Global Market for the five trading days prior to the day of purchase.

No authorization of the general meeting of shareholders is required if common shares are acquired by us with the intention of transferring such common shares to our employees under an applicable employee stock purchase plan.

*Delaware.* Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

### **Anti-takeover Provisions**

*The Netherlands.* Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. We have adopted several provisions that may have the effect of making a takeover of our company more difficult or less attractive, including:

- the authorization of a class of cumulative preferred shares that may be issued by our management board to a friendly party, subject to the approval of our supervisory board, in such a manner as to dilute the interest of any potential acquirer;

## [Table of Contents](#)

- the staggered four-year terms of our supervisory board members, as a result of which only approximately one-fourth of our supervisory board members will be subject to election in any one year;
- a provision that our management board and supervisory board members may only be removed at the general meeting of shareholders by a two-thirds majority of votes cast representing more than half of our outstanding share capital if such removal is not proposed by our supervisory board; and
- requirements 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.

*Delaware.* In addition to other aspects of Delaware law governing fiduciary duties of directors during a potential takeover, the Delaware General Corporation Law also contains a business combination statute that protects Delaware companies from hostile takeovers and from actions following the takeover by prohibiting some transactions once an acquirer has gained a significant holding in the corporation.

Section 203 of the Delaware General Corporation Law prohibits “business combinations,” including mergers, sales and leases of assets, issuances of securities and similar transactions by a corporation or a subsidiary with an interested stockholder that beneficially owns 15% or more of a corporation’s voting stock, within three years after the person becomes an interested stockholder, unless:

- the transaction that will cause the person to become an interested stockholder is approved by the board of directors of the target prior to the transactions;
- after the completion of the transaction in which the person becomes an interested stockholder, the interested stockholder holds at least 85% of the voting stock of the corporation not including shares owned by persons who are directors and officers of interested stockholders and shares owned by specified employee benefit plans; or
- after the person becomes an interested stockholder, the business combination is approved by the board of directors of the corporation and holders of at least 66.67% of the outstanding voting stock, excluding shares held by the interested stockholder.

A Delaware corporation may elect not to be governed by Section 203 by a provision contained in the original certificate of incorporation of the corporation or an amendment to the original certificate of incorporation or to the bylaws of the company, which amendment must be approved by a majority of the shares entitled to vote and may not be further amended by the board of directors of the corporation. Such an amendment is not effective until twelve months following its adoption.

### ***Inspection of Books and Records***

*The Netherlands.* The management board and the supervisory board provide the general meeting of shareholders in good time with all information that the shareholders require for the exercise of their powers, unless this would be contrary to an overriding interest of us. If the management board or supervisory board invokes an overriding interest, it must give reasons.

*Delaware.* Under the Delaware General Corporation Law, any stockholder may inspect for any proper purpose certain of the corporation’s books and records during the corporation’s usual hours of business.

### ***Removal of Management Board Member and Supervisory Board Member***

*The Netherlands.* Under our Articles of Association, the general meeting of shareholders shall at all times be entitled to suspend or dismiss a management board member or supervisory board member. The general meeting of shareholders may only adopt a resolution to suspend or dismiss such a member by at least a two thirds majority of the votes cast, provided such majority represents more than half of the issued share capital, unless the proposal was made by the supervisory board in which case a simple majority of the votes cast is sufficient.



## [Table of Contents](#)

*Delaware.* Under the Delaware General Corporation Law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (i) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board is classified, stockholders may effect such removal only for cause, or (ii) in the case of a corporation having cumulative voting, if less than the entire board is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.

### **Preemptive Rights**

*The Netherlands.* Under Dutch law, in the event of an issuance of common shares, each shareholder will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to employees or common shares issued against a contribution other than in cash). Under our Articles of Association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting of shareholders upon proposal of the management board, subject to the approval of the supervisory board.

The management board, subject to approval of the supervisory board, may restrict or exclude the preemptive rights in respect of newly issued common shares if it has been designated as the authorized body to do so by the general meeting of shareholders. Such designation can be granted for a period not exceeding five years. A resolution of the general meeting of shareholders to restrict or exclude the preemptive rights or to designate the management board as the authorized body to do so requires a two-thirds majority of the votes cast, if less than one half of our issued share capital is represented at the meeting.

At our annual general meeting held on \_\_\_\_\_, 2015, our shareholders authorized our management board acting with the approval of our supervisory board for a period of \_\_\_\_\_ years from \_\_\_\_\_ to limit or exclude preemptive rights accruing to shareholders in connection with the issue of common shares or rights to subscribe for common shares.

No preemptive rights apply in respect of cumulative preferred shares.

*Delaware.* Under the Delaware General Corporation Law, stockholders have no preemptive rights to subscribe for additional issues of stock or to any security convertible into such stock unless, and to the extent that, such rights are expressly provided for in the certificate of incorporation.

### **Dividends**

*The Netherlands.* Dutch law provides that dividends may be distributed after adoption of the annual accounts by the general meeting of shareholders from which it appears that such dividend distribution is allowed. Moreover, dividends may be distributed only to the extent the shareholders' equity exceeds the amount of the paid-up and called-up part of the issued share capital and the reserves that must be maintained under Dutch law or the Articles of Association. Interim dividends may be declared as provided in the Articles of Association and may be distributed to the extent that the shareholders' equity exceeds the amount of the issued and paid-up and called-up part of the issued share capital and the required legal reserves as described above as apparent from our financial statements. Under Dutch law, the Articles of Association may prescribe that the management board decides what portion of the profits are to be held as reserves.

Under the Articles of Association, a dividend is first paid out of the profit, if available for distribution, on any preferred shares. After that, the management board shall determine which part of the remaining profit shall be added to our reserves. After reservation by the management board of any profit, the remaining profit will be at the disposal of the general meeting of shareholders. However, a distribution to the holders of common shares can

## [Table of Contents](#)

only be resolved upon by the general meeting at the proposal of the management board, subject to the approval of the supervisory board. We only make a distribution of dividends to our shareholders after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The management board is permitted, subject to certain requirements and subject to approval of the supervisory board, to declare interim dividends without the approval of the general meeting of shareholders.

Dividends and other distributions shall be made payable not later than the date determined by the management board. Claims to dividends and other distribution not made within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*).

*Delaware.* Under the Delaware General Corporation Law, a Delaware corporation may pay dividends out of its surplus (the excess of net assets over capital), or in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of the capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets). In determining the amount of surplus of a Delaware corporation, the assets of the corporation, including stock of subsidiaries owned by the corporation, must be valued at their fair market value as determined by the board of directors, without regard to their historical book value. Dividends may be paid in the form of common shares, property or cash.

### **Shareholder Vote on Certain Reorganizations**

*The Netherlands.* Under Dutch law, the general meeting of shareholders must approve resolutions of the management board relating to a significant change in the identity or the character of the company or the business of the company, which includes:

- a transfer of the business or virtually the entire business to a third party;
- the entry into or termination of a long-term cooperation of the company or a subsidiary with another legal entity or company or as a fully liable partner in a limited partnership or general partnership, if such cooperation or termination is of a far-reaching significance for the company; and
- the acquisition or divestment by the company or a subsidiary of a participating interest in the capital of a company having a value of at least one third of the amount of its assets according to its balance sheet and explanatory notes or, if the company prepares a consolidated balance sheet, according to its consolidated balance sheet and explanatory notes in the last adopted annual accounts of the company.

Under Dutch law, a shareholder who owns shares representing at least 95% of the nominal value of a company's issued share capital may institute proceedings against the company's other shareholders jointly for the transfer of their shares to that shareholder. The proceedings are held before the Enterprise Chamber (*Ondernemingskamer*), which may grant the claim for squeeze-out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of experts who will offer an opinion to the Enterprise Chamber on the value of the shares.

*Delaware.* Under the Delaware General Corporation Law, the vote of a majority of the outstanding shares of capital stock entitled to vote thereon generally is necessary to approve a merger or consolidation or the sale of all or substantially all of the assets of a corporation. The Delaware General Corporation Law permits a corporation to include in its certificate of incorporation a provision requiring for any corporate action the vote of a larger portion of the stock or of any class or series of stock than would otherwise be required.

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the

## [Table of Contents](#)

surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

### **Remuneration of Management Board Members and Supervisory Board Members**

*The Netherlands.* Under Dutch law and our Articles of Association, we must adopt a remuneration policy for management board members. Such remuneration policy shall be adopted by the general meeting of shareholders upon the proposal of the supervisory board. The supervisory board determines the remuneration of the management board members in accordance with the remuneration policy. A proposal by the supervisory board with respect to remuneration schemes in the form of shares or rights to shares is submitted by the supervisory board to the general meeting for its approval. This proposal must set out at least the maximum number of shares or rights to shares to be granted to the management board and the criteria for granting or amendment.

The general meeting may determine the remuneration of supervisory board members. The supervisory board members shall be reimbursed for their expenses.

*Delaware.* Under the Delaware General Corporation Law, the stockholders do not generally have the right to approve the compensation policy for directors or the senior management of the corporation, although certain aspects of executive compensation may be subject to stockholder vote due to the provisions of U.S. federal securities and tax law, as well as exchange requirements.

### **Dutch Corporate Governance Code**

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. A copy of the DCGC can be found on [www.corpgov.nl](http://www.corpgov.nl). 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 after the closing of the offering.

- *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),*

## [Table of Contents](#)

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.

- *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.)*

We are currently in the process of reviewing and implementing a share plan under which shares may be granted (including to the management board). 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).*

Our 2010 Option Plan, including the exercise price, is currently under review and may be amended prior to the closing of the offering.

- *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. We have the intention to increase the number of independent members on our supervisory board over time.

- *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).*

Our supervisory board members receive rights to acquire depositary receipts for shares in our capital as a part of their remuneration. Although the DCGC discourages such remuneration, we believe that such remuneration is appropriate due to our listing at Nasdaq and the anticipated recruitment of certain supervisory board members residing in the US.

- *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.

---

[Table of Contents](#)

**Listing**

We intend to apply to list the common shares on The NASDAQ Global Market under the symbol “MRUS.”

**Transfer Agent and Registrar**

The U.S. transfer agent and registrar for the common shares is

## SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no market for our common shares. Future sales of substantial amounts of our common shares in the public market could adversely affect market prices prevailing from time to time. Furthermore, because only a limited number of common shares will be available for sale shortly after this offering due to existing contractual and legal restrictions on resale as described below, there may be sales of substantial amounts of our common shares in the public market after such restrictions lapse. This may adversely affect the prevailing market price of our common shares and our ability to raise equity capital in the future.

Upon completion of this offering, we will have \_\_\_\_\_ common shares outstanding, or \_\_\_\_\_ common shares outstanding if the underwriters exercise their option in full to purchase additional common shares, and after giving effect to (i) the consummation of the Class C Financing; and (ii) the automatic conversion of all outstanding preferred shares, including the Class C preferred shares issued in the Class C Financing, into an aggregate of \_\_\_\_\_ common shares upon the closing of this offering. Of these shares, \_\_\_\_\_ common shares, or \_\_\_\_\_ common shares if the underwriters exercise their option in full to purchase additional common shares, sold in this offering will be freely transferable without restriction or registration under the Securities Act, except for any shares purchased by one of our existing “affiliates,” as that term is defined in Rule 144 under the Securities Act. The remaining common shares are “restricted shares” as defined in Rule 144. Restricted shares may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 of the Securities Act. As a result of the contractual 180-day lock-up period described below and the provisions of Rules 144 and 701, these shares will be available for sale in the public market as follows:

**Number of Shares**

**Date**

On the date of this prospectus.

After 90 days from the date of this prospectus (subject, in some cases, to volume limitations).

After 180 days from the date of this prospectus (subject, in some cases, to volume limitations).

### Rule 144

In general, a person who has beneficially owned our common shares that are restricted shares for at least six months would be entitled to sell such securities, provided that (i) such person is not deemed to have been one of our affiliates at the time of, or at any time during the 90 days preceding, a sale and (ii) we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Persons who have beneficially owned our common shares that are restricted shares for at least six months but who are our affiliates at the time of, or any time during the 90 days preceding, a sale, would be subject to additional restrictions, by which such person would be entitled to sell within any three month period only a number of securities that does not exceed the greater of either of the following:

- 1% of the number of our common shares then outstanding, which will equal approximately \_\_\_\_\_ common shares immediately after this offering, assuming no exercise of the underwriters’ option to purchase additional common shares; or
- the average weekly trading volume of our common shares on NASDAQ during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale;

provided, in each case, that we are subject to the Exchange Act periodic reporting requirements for at least 90 days before the sale. Such sales both by affiliates and by non-affiliates must also comply with the manner of sale, current public information and notice provisions of Rule 144 to the extent applicable.

### **Rule 701**

In general, under Rule 701, any of our employees, management board members, supervisory board members, officers, consultants or advisors who purchases shares from us in connection with a compensatory share or option plan or other written agreement before the effective date of this offering is entitled to resell such shares 90 days after the effective date of this offering in reliance on Rule 144, without having to comply with the holding period requirements or other restrictions contained in Rule 701.

The SEC has indicated that Rule 701 will apply to typical share options granted by an issuer before it becomes subject to the reporting requirements of the Exchange Act, along with the shares acquired upon exercise of such options, including exercises after the date of this prospectus. Securities issued in reliance on Rule 701 are restricted securities and, subject to the contractual restrictions described below, beginning 90 days after the date of this prospectus, may be sold by persons other than “affiliates,” as defined in Rule 144, subject only to the manner of sale provisions of Rule 144 and by “affiliates” under Rule 144 without compliance with its one-year minimum holding period requirement.

### **Regulation S**

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

### **Registration Rights**

We will enter into a registration rights agreement upon consummation of this offering pursuant to which we will agree 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. Registration of these shares under the Securities Act would result in these shares becoming freely tradable without restriction under the Securities Act immediately upon the effectiveness of the registration, except for shares purchased by affiliates. See “Related Party Transactions—Registration Rights Agreement.”

### **Lock-up Agreements**

All of our supervisory board members, management board members and the holders of all or substantially all of our common shares have agreed, subject to limited exceptions, not to offer, pledge, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase or otherwise dispose of, directly or indirectly, or enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the common shares or such other securities for a period of 180 days after the date of this prospectus, subject to certain exceptions, without the prior written consent of Citigroup Global Markets Inc. and Jefferies LLC. See “Underwriting.”

## MATERIAL TAX CONSIDERATIONS

The following summary contains a description of certain Dutch and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares. Please note that this summary should not be considered a comprehensive description of all the tax considerations that may be relevant to the decision to purchase common shares. The summary is based upon the tax laws of the Netherlands and regulations thereunder and on the tax laws of the United States and regulations thereunder as of the date hereof, which are subject to change.

### Material Dutch Tax Considerations

The following paragraphs summarize a number of material Dutch tax considerations relating to the purchase, ownership and disposition of our common shares. The following is intended as general information only, and is in no way a comprehensive or complete description of all aspects of Dutch tax law that may be relevant for a holder of common shares, shareholder.

Prospective shareholders should consult their tax advisor regarding the tax consequences of any purchase, ownership or disposal of common shares.

The following summary is based on the Dutch tax law as applied and interpreted by Dutch tax courts, and as published and effective on the date hereof, without prejudice to any amendments introduced at a later date and implemented with or without retroactive effect.

For the purpose of this paragraph, “Dutch Taxes” shall mean taxes of whatever nature levied by or on behalf of the Netherlands or any of its subdivisions or taxing authorities. The Netherlands means the part of the Kingdom of the Netherlands located in Europe.

Where in this Dutch taxation paragraph reference is made to “Shareholder,” that concept includes, but is not limited to:

- (1) an owner of one or more common shares who has both an economic interest in those common shares, as well as the title to those common shares;
- (2) a person who, or an entity that, holds the entire economic interest in one or more common shares;
- (3) a person who, or an entity that, holds an interest in an entity, that is transparent for Dutch tax purposes, such as a partnership or a mutual fund, the assets of which comprise of one or more common shares, within the meaning of items (1) or (2) above: or
- (4) a person who is deemed to hold an interest in common shares, as referred to under items (1) through (3), pursuant to the attribution rules of article 2.14a, of the Dutch Income Tax Act 2001 (*Wet inkomstenbelasting 2001*, or ITA), with respect to property that has been segregated, for instance in a trust or a foundation.

### Taxes on Income and Capital Gains

This section provides an overview of general Dutch tax consequences that may be relevant for Shareholders, but does not describe the possible Dutch tax considerations or consequences that may be relevant to a Shareholder who is:

- an individual for whom the income or capital gains derived from the common shares is attributable to employment activities, the income from which is taxable in the Netherlands;
- an entity that is not subject to Dutch corporate income tax or is in full or in part exempt from Dutch corporate income tax (such as pension funds);
- an investment institution (*beleggingsinstelling*) as defined in article 6a or 28 of the Dutch 1969 Corporate income tax act (*Wet op de vennootschapsbelasting 1969*, or CITA);
- is entitled to the participation exemption (*deelnemingsvrijstelling*) with respect to the common shares as defined in article 13, CITA. A participation generally exists in case of a shareholding of at least 5% of the company’s paid-in share capital;



## [Table of Contents](#)

- a holder of a lucrative interest (*lucratief belang* as defined in article 3.92b ITA), as we assume no employees of the company will purchase the common shares issued in this offering; or
- a holder of a substantial interest (*aanmerkelijk belang* as defined in chapter 4 ITA), which is generally the case when the Shareholder, alone, or where such shareholder is an individual, together with his or her partner (statutorily defined term), directly or indirectly, holds or is deemed to hold (a) an interest of at least 5% in either the capital or the voting rights of any class of shares in the Company, (b) rights or options to obtain such interest or (c) certain profit sharing rights in the Company.

### **Dutch Residents**

The description of certain Dutch tax consequences in this paragraph is only intended for Shareholders that are either individuals who are resident or deemed to be resident in the Netherlands for Dutch income tax purposes, or Dutch Individuals, or entities that are subject to the CITA and are resident or deemed to be resident in the Netherlands for corporate income tax purposes, or Dutch Corporate Entities.

#### *Dutch resident individuals*

Dutch Individuals that derive or are deemed to derive any benefits from common shares (including any capital gains realized on the disposal of such common shares) which benefits are attributable to an enterprise from which the Dutch Individual derives profits, whether as an entrepreneur (*ondernemer*) or pursuant to a co-entitlement to the net value of an enterprise, other than as a shareholder, are generally subject to Dutch income tax on those benefits at progressive rates with a maximum of 52%.

Dutch Individuals that derive or are deemed to derive any benefits from common shares, including any gains realized on the disposal of such common shares, that constitute benefits from miscellaneous activities (*resultaat uit overige werkzaamheden*), are generally subject to Dutch income tax at progressive rates on such benefits with a maximum of 52%.

Dutch Individuals may, among other things, derive, or be deemed to derive, benefits from common shares that are taxable as benefits from miscellaneous activities in case the investment activities go beyond the activities of an active portfolio investor, due to, for instance, the use of insider knowledge (*voorkennis*) or comparable forms of special knowledge.

Dutch Individuals, whose common shares are not attributable to an enterprise, and whose common shares do not qualify as generating income from miscellaneous activities will not be subject to Dutch income tax on the actual income (including capital gains) derived from the common shares. Instead, those Dutch Individuals will be taxed at a flat rate of 30% on the deemed income from savings and investments (*sparen en beleggen*). This deemed income is set at 4% of the yield basis (*rendementsgrondslag*) of the Dutch Individual. The yield basis would normally consist of the fair market value of the common shares generally to be determined at the beginning of the year to the extent that such yield basis exceeds the exempt net asset amount (*heffingsvrij vermogen*) for the relevant year.

#### *Dutch resident entities*

Dutch Corporate Entities may be subject to corporate income tax on income, including capital gains, derived from the common shares. The first €200,000 profits are taxable at a rate of 20%, while any profits in excess of €200,000 are taxable at a rate of 25%.

### **Non-Dutch residents**

#### *Non-Dutch resident individuals*

A Shareholder that is an individual and not a resident or deemed resident of the Netherlands, or Non-Resident Individuals, for Dutch tax purposes, will not be subject to any Dutch taxes on income (other than the

## [Table of Contents](#)

dividend withholding tax described below) or capital gains in respect of dividends distributed by the Company or in respect of any gains realized on the disposal of common shares unless:

- the Non-Resident Individual derives profits from an enterprise directly, or pursuant to a co-entitlement to the net value of such enterprise, other than as a holder of securities, which enterprise either is managed in the Netherlands or carried out, in whole or in part, through a permanent establishment or a permanent representative which is taxable in the Netherlands and the common shares are attributable to such enterprise; or
- the Non-Resident Individual derives benefits or is deemed to derive benefits from common shares that are taxable as benefits from miscellaneous activities in the Netherlands.

If either of the conditions above apply, income or capital gains in respect of dividends distributed by the Company or in respect of any gain realized on the disposal of common shares will in general be subject to Dutch income tax at the progressive rates with a maximum of 52%, on the understanding that such benefits derived as benefits from miscellaneous activities will only be taxable in the Netherlands if such activities are performed or deemed to be performed in the Netherlands.

### *Non-Dutch resident entities*

A Shareholder, other than an individual, that is not a resident or deemed resident of the Netherlands for Dutch tax purposes, will not be subject to any Dutch taxes on income or capital gains (other than the dividend withholding tax described below) in respect of dividends distributed by the Company or in respect of any gain realized on the disposal of common shares, unless that Shareholder derives profits from an enterprise directly, or pursuant to a co-entitlement to the net value of such enterprise other than as a holder of securities, which enterprise either is managed in the Netherlands or carried out, in whole or in part, through a permanent establishment or a permanent representative which is taxable in the Netherlands and the common shares are attributable to such enterprise.

If the condition above applies, income and capital gains derived from the common shares will, in general, be subject to regular Dutch corporate income tax. The first €200,000 profits are taxable at a rate of 20%, while any profits in excess of €200,000 are taxable at a rate of 25%.

### **Dividend withholding tax**

Dividends payments, or Dividend Payments, made by the Company are generally subject to 15% Dutch dividend withholding tax. The Company is responsible for withholding the Dutch dividend withholding tax, while the tax is ultimately for the account of the Shareholder. The term 'Dividend Payments' includes, but is not limited to:

- distributions in cash or in kind, as well as deemed or constructive distributions;
- liquidation proceeds, proceeds of redemption of common shares or, generally, considerations in excess of the average paid-in capital recognized for Dutch dividend withholding tax purposes, paid upon the repurchase of common shares by the company;
- the nominal value of common shares issued to a holder of common shares or an increase of the nominal value of common shares, to the extent that it does not appear that a contribution, recognized for Dutch dividend withholding tax purposes, has been made or will be made; and
- partial repayment of paid-in capital, recognized for Dutch dividend withholding tax purposes, if and to the extent that there are Net Profits (*zuivere winst*), unless
  - i the general meeting of the shareholders has resolved in advance to make such repayment; and
  - i the nominal value of the common shares concerned has been reduced by a corresponding amount by way of an amendment of the Company's articles of association.

The term Net Profits includes anticipated profits and losses that have yet to be realized but that are reasonably certain and determinable.

## [Table of Contents](#)

If a Shareholder is a resident for Dutch tax purposes of a country other than the Netherlands, and is considered to be a resident of Aruba, Curacao or St. Martin under the provisions of a Tax Convention for the Kingdom of the Netherlands (*Belastingregeling voor het Koninkrijk*), or is considered to be a resident of a country other than the Netherlands under the provisions of the double taxation convention between that country of residence and the Netherlands, that Shareholder may be eligible for a full or partial exemption from, or refund of Dutch dividend withholding tax, depending on the terms of the applicable double taxation convention. In addition, subject to certain conditions and based on Dutch legislation implementing the EU Parent Subsidiary Directive (Directive 90/435/EEG, as amended), an exemption from Dutch dividend withholding tax may exist for Dividend Payments to certain qualifying entities that are resident in another EU Member State or in a State of the EEA appointed by Ministerial Decree, if that entity holds at least 5% of the share capital of the Company.

A qualifying tax-exempt entity that is a resident of a Member State of the EU, or that is a resident of a State of the EEA that has been specifically designated in a Ministerial Regulation (e.g. Norway, Iceland and Liechtenstein), may be eligible for a refund of withheld Dutch dividend withholding taxes, if the entity is not subject to Dutch corporate income tax had it been a tax resident of the Netherlands. Such refund is not available to entities that are engaged in similar activities as investment institutions (*beleggingsinstellingen*) as referred to in Section 6a or 28 CITA.

Qualifying investors (such as pension funds, sovereign wealth funds and exempt government bodies) from outside the EU and the EEA (so-called third countries) may be eligible for a refund of Dutch dividend withholding tax. The refund only applies to portfolio investments when the following conditions are cumulatively met:

- the Shareholder is resident in a designated country with which the Netherlands has concluded adequate arrangements for the exchange of information; and
- the Shareholder is not subject to any profits tax or is exempt from any profits tax in the country of its residence and would not have been subject to Dutch corporate income tax, if the Shareholder had been resident in the Netherlands.

Dutch Individuals and Dutch Corporate Entities can generally credit Dutch dividend withholding tax against their personal income tax or corporate income tax liability. The same generally applies to Shareholders that are neither resident nor deemed resident of the Netherlands if the common shares are attributable to a Dutch permanent establishment of such a non-resident Shareholder to which the common shares are attributable.

Due to legislation introduced to counteract the practice of dividend stripping, a reduction, exemption, credit or refund of Dutch dividend withholding tax is denied if the recipient of the Dividend Payment does not qualify as the beneficial owner (*uiteindelijk gerechtigde*) of that Dividend Payment. The anti-dividend stripping legislation generally targets situations in which shareholders retain their economic interest in common shares but reduce the withholding tax due on the Dividend Payment by entering into a transaction with another party with (mainly) that intent. The Dutch Ministry of Finance takes the position that the definition of beneficial ownership introduced by this legislation will also be applied in the context of a double taxation convention.

### ***Gift tax and inheritance tax***

#### *Dutch Residents*

Gift or inheritance taxes will arise in the Netherlands with respect to a transfer of the common shares by way of a gift by, or, on the death of, a holder of common shares who is resident or deemed to be resident in the Netherlands at the time of the gift or his/her death.

## [Table of Contents](#)

No Netherlands gift tax will arise in case of a gift of the common shares under a condition precedent (*opschortende voorwaarde*) by an individual who at the date of the gift was resident or deemed to be resident, but at the date of the fulfillment of the condition was neither resident nor deemed to be resident in the Netherlands, unless such individual deceases within 180 days after the date of the fulfillment of the condition, while being resident or deemed to be resident in the Netherlands.

For purposes of Netherlands gift and inheritance taxes, amongst others, a person that holds the Dutch nationality will be deemed to be resident in the Netherlands if that person has been resident in the Netherlands at any time during the ten years preceding the date of the gift — in case of a gift under a condition precedent, the date of the fulfillment of the condition — or the date of the death of this person. Additionally, for purposes of Dutch gift tax, a person not holding the Dutch nationality will be deemed to be resident in the Netherlands if that person has been resident in the Netherlands at any time during the 12 months preceding the date of the gift or - in case of a gift under a condition precedent - the date of the fulfillment of the condition. Applicable tax treaties may override the tax implications of deemed residency.

### *Non-Dutch Residents*

No Dutch gift or inheritance tax will arise on the transfer of common shares by way of a gift by, or on the death of, a holder of common shares who is neither resident nor deemed to be resident in the Netherlands, unless:

- in case of a gift of the common shares under a condition precedent (*opschortende voorwaarde*) by an individual who at the date of the gift was neither resident nor deemed to be resident in the Netherlands, such individual is resident or deemed to be resident in the Netherlands at the date of the fulfillment of the condition; or
- in case of a gift of the common shares by an individual who at the date of the gift or, in case of a gift under a condition precedent, at the date of the fulfillment of the condition was neither resident nor deemed to be resident in the Netherlands, such individual is deceased within 180 days after the date of the gift or the fulfillment of the condition, while being resident or deemed to be resident in the Netherlands.

Furthermore, Dutch inheritance tax will arise in case of a gift under a condition precedent by an individual who, at the date of the gift, was neither resident nor deemed resident of the Netherlands, but at the date of his or her death was resident or deemed to be resident in the Netherlands, and the condition was fulfilled after the date of his or her death.

### **Value added tax**

No Dutch value added tax will be due in the Netherlands in respect of payments made in consideration for the issue of common shares, or in respect of the transfer of common shares.

### **Other taxes**

No Dutch registration tax, customs duty, stamp duty, real estate transfer tax or any other similar documentary tax or duty will be due in the Netherlands in respect of or in connection with the mere issue, transfer or delivery of the common shares.

### **Residency**

A Shareholder will not become, and will not be deemed to be, resident in the Netherlands merely by virtue of holding a common share or by virtue of the execution, performance and/or delivery of any relevant documents related thereto.

## Material U.S. Federal Income Tax Considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of common shares. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that holds common shares as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the provisions of the Code known as the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- tax exempt entities, including "individual retirement accounts" and "Roth IRAs";
- entities classified as partnerships for U.S. federal income tax purposes;
- regulated investment companies or real estate investment trusts;
- persons who acquired our common shares pursuant to the exercise of an employee stock option or otherwise as compensation;
- persons that own or are deemed to own ten percent or more of our voting shares; and
- persons holding common shares in connection with a trade or business conducted outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds common shares, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding common shares and partners in such partnerships are encouraged to consult their tax advisers as to the particular U.S. federal income tax consequences of holding and disposing of common shares.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the Netherlands and the United States (the "Treaty") all as of the date hereof, changes to any of which may affect the tax consequences described herein—possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of common shares who is eligible for the benefits of the Treaty and is:

- (1) a citizen or individual resident of the United States;
- (2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; or
- (3) an estate or trust the income of which is subject to U.S. federal income taxation regardless of its source.

U.S. Holders are encouraged to consult their tax advisers concerning the U.S. federal, state, local and foreign tax consequences of owning and disposing of common shares in their particular circumstances.

### ***Taxation of Distributions***

Subject to the discussion below under “Passive Foreign Investment Company Rules,” distributions paid on common shares, other than certain *pro rata* distributions of common shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to “qualified dividend income.” The amount of a dividend will include any amounts withheld by us in respect of Dutch income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder’s income on the date of the U.S. Holder’s receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain *pro rata* distributions of common shares or rights to acquire common shares) will be the fair market value of such property on the date of distribution.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder’s particular circumstances, Dutch income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder’s U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any Dutch income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

### ***Sale or Other Taxable Disposition of Common Shares***

Subject to the discussion below under “Passive Foreign Investment Company Rules,” gain or loss realized on the sale or other taxable disposition of common shares will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder’s tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

### ***Passive Foreign Investment Company Rules***

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not expect to be a PFIC for the current taxable year or the foreseeable future. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure you that the IRS will not take a contrary position. A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income; or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income.

## [Table of Contents](#)

We will be treated as owning our proportionate share of the assets and earning our proportionate share of the income of any other corporation in which we own, directly or indirectly, 25% or more (by value) of the equity.

A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change. In particular, the total value of our assets for purposes of the asset test generally will be calculated using the market price of our common shares, which may fluctuate considerably. Fluctuations in the market price of our common shares may result in our being a PFIC for any taxable year. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise in any offering, including this one. If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the common shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the common shares, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and (2) the U.S. Holder has made a “deemed sale” election under the PFIC rules.

If we are a PFIC for any taxable year during which you hold common shares, you will be subject to special tax rules with respect to any “excess distribution” that you receive and any gain you realize from a sale or other disposition (including a pledge) of common shares. Distributions you receive in a taxable year that are greater than 125% of the average annual distributions you received during the shorter of the three preceding taxable years or your holding period for the common shares will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over your holding period for the common shares;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or “excess distribution” cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the common shares cannot be treated as capital, even if you hold the common shares as capital assets.

Certain elections may be available that would result in alternative treatments (such as mark-to-market treatment of the common shares). The adverse consequences of owning stock in a PFIC could be mitigated if a U.S. Holder makes a valid “qualified electing fund” election, or QEF election, which, among other things, would require a U.S. Holder to include currently in income its pro rata share of the PFIC’s net capital gain and ordinary earnings, based on earnings and profits as determined for U.S. federal income tax purposes. We intend to provide the information necessary for U.S. Holders of our common shares to make qualified electing fund elections.

If we are considered a PFIC, a U.S. Holder will also be subject to information reporting requirements on an annual basis. If we are or become a PFIC, you should consult your tax advisor regarding any reporting requirements that may apply to you.

U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to the ownership and disposition of the common shares and the potential availability of a mark-to-market or QEF election

### ***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup

---

## [Table of Contents](#)

withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

### ***Information with Respect to Foreign Financial Assets***

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to the common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisers regarding their reporting obligations with respect to their ownership and disposition of the common shares.



## UNDERWRITING

Citigroup Global Markets Inc. and Jefferies LLC are acting as joint book-running managers of this offering and as representatives of the underwriters named below. Subject to the terms and conditions stated in the underwriting agreement dated the date of this prospectus, each underwriter named below has severally agreed to purchase, and we have agreed to sell to that underwriter, the number of common shares set forth opposite the underwriter's name.

<u>Underwriter</u>	<u>Number of Common Shares</u>
Citigroup Global Markets Inc.	
Jefferies LLC.	
Guggenheim Securities, LLC	
Wedbush Securities Inc.	
Total	

The underwriting agreement provides that the obligations of the underwriters to purchase the common shares included in this offering are subject to approval of legal matters by counsel and to other conditions. The underwriters are obligated to purchase all the common shares (other than those covered by the underwriters' option to purchase additional common shares described below) if they purchase any of the common shares.

Common shares sold by the underwriters to the public will initially be offered at the initial public offering price set forth on the cover page of this prospectus. Any common shares sold by the underwriters to securities dealers may be sold at a discount from the initial public offering price not to exceed \$ \_\_\_\_\_ per share. If all the common shares are not sold at the initial offering price, the underwriters may change the offering price and the other selling terms. The representatives have advised us that the underwriters do not intend to make sales to discretionary accounts.

If the underwriters sell more common shares than the total number set forth in the table above, we have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase up to \_\_\_\_\_ additional common shares at the initial public offering price less the underwriting discount. The underwriters may exercise the option solely for the purpose of covering over-allotments, if any, in connection with this offering. To the extent the option is exercised, each underwriter must purchase a number of additional common shares approximately proportionate to that underwriter's initial purchase commitment set forth in the table above. Any common shares issued or sold under the option will be issued and sold on the same terms and conditions as the other common shares that are the subject of this offering.

We, our management board members, our supervisory board members and all of our other shareholders and optionholders have agreed that, subject to specified limited exceptions, for a period of 180 days from the date of this prospectus, we and they will not, without the prior written consent of Citigroup Global Markets Inc. and Jefferies LLC, offer, sell, contract to sell, pledge or otherwise dispose of any common shares or any securities convertible into or exercisable or exchangeable for our common shares. Citigroup Global Markets Inc. and Jefferies LLC in their sole discretion may release any of the securities subject to these lock-up agreements at any time, which, in the case of our management board members and supervisory board members, shall be with notice.

Prior to this offering, there has been no public market for our common shares. Consequently, the initial public offering price for the common shares will be determined by negotiations between us and the representatives. Among the factors considered in determining the initial public offering price will be our results of operations, our current financial condition, our future prospects, our markets, the economic conditions in and future prospects for the industry in which we compete, our management board, and currently prevailing general

## [Table of Contents](#)

conditions in the equity securities markets, including current market valuations of publicly traded companies considered comparable to our Company. We cannot assure you, however, that the price at which the common shares will sell in the public market after this offering will not be lower than the initial public offering price or that an active trading market in our common shares will develop and continue after this offering.

We intend to apply to have our common shares listed on The NASDAQ Global Market under the symbol “MRUS.”

The following table shows the underwriting discounts and commissions that we are to pay to the underwriters in connection with this offering. These amounts are shown assuming both no exercise and full exercise of the underwriters’ option to purchase additional common shares.

	Paid by Merus	
	No Exercise	Full Exercise
Per common share	\$	\$
Total	\$	\$

We estimate that our portion of the total expenses of this offering, exclusive of underwriting discounts and commissions payable by us, will be approximately \$ . We have also agreed to reimburse the underwriters for expenses in an amount of up to \$ relating to the clearance of this offering with the Financial Industry Regulatory Authority, Inc.

In connection with the offering, the underwriters may purchase and sell common shares in the open market. Purchases and sales in the open market may include short sales, purchases to cover short positions, which may include purchases pursuant to the underwriters’ option to purchase additional common shares, and stabilizing purchases.

- Short sales involve secondary market sales by the underwriters of a greater number of common shares than they are required to purchase in the offering.
  - “Covered” short sales are sales of common shares in an amount up to the number of common shares represented by the underwriters’ option to purchase additional common shares.
  - “Naked” short sales are sales of common shares in an amount in excess of the number of common shares represented by the underwriters’ option to purchase additional common shares.
- Covering transactions involve purchases of common shares either pursuant to the underwriters’ option to purchase additional common shares or in the open market in order to cover short positions.
  - To close a naked short position, the underwriters must purchase common shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the common shares in the open market after pricing that could adversely affect investors who purchase in the offering.
  - To close a covered short position, the underwriters must purchase common shares in the open market or must exercise the option to purchase additional common shares. In determining the source of common shares to close the covered short position, the underwriters will consider, among other things, the price of common shares available for purchase in the open market as compared to the price at which they may purchase common shares through the underwriters’ option to purchase additional common shares.
- Stabilizing transactions involve bids to purchase common shares so long as the stabilizing bids do not exceed a specified maximum, to stabilize the price of the common shares.

Purchases to cover short positions and stabilizing purchases, as well as other purchases by the underwriters for their own accounts, may have the effect of preventing or retarding a decline in the market price of the

## [Table of Contents](#)

common shares. They may also cause the price of the common shares to be higher than the price that would otherwise exist in the open market in the absence of these transactions. The underwriters may conduct these transactions on The NASDAQ Global Market, in the over-the-counter market or otherwise. If the underwriters commence any of these transactions, they may discontinue them at any time.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make because of any of those liabilities.

A prospectus in electronic format may be made available on websites maintained by one or more of the underwriters or their respective affiliates. The representatives may agree with us to allocate a number of common shares to underwriters for sale to their online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' or their respective affiliates' websites and any information contained in any other website maintained by any of the underwriters or their respective affiliates is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors in this offering.

### **Conflicts of Interest**

The underwriters are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, principal investment, hedging, financing and brokerage activities. The underwriters and their respective affiliates may, from time to time, engage in transactions with and perform services for us in the ordinary course of their business for which they may receive customary fees and reimbursement of expenses. In the ordinary course of their various business activities, the underwriters and their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (which may include bank loans and/or credit default swaps) for their own account and for the accounts of their customers and may at any time hold long and short positions in such securities and instruments. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

The address of Citigroup Global Markets Inc. is 388 Greenwich Street, New York, New York 10013. The address of Jefferies LLC is 520 Madison Avenue, New York, New York 10022.

### **Notice to Prospective Investors in the European Economic Area**

In relation to each member state of the European Economic Area that has implemented the Prospectus Directive (each, a relevant member state), with effect from and including the date on which the Prospectus Directive is implemented in that relevant member state (the relevant implementation date), an offer of common shares described in this prospectus may not be made to the public in that relevant member state other than:

- to any legal entity which is a qualified investor as defined in the Prospectus Directive;
- to fewer than 100 or, if the relevant member state has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the relevant Dealer or Dealers nominated by us for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of common shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

## [Table of Contents](#)

For purposes of this provision, the expression an “offer of securities to the public” in any relevant member state means the communication in any form and by any means of sufficient information on the terms of the offer and the common shares to be offered so as to enable an investor to decide to purchase or subscribe for the common shares, as the expression may be varied in that member state by any measure implementing the Prospectus Directive in that member state, and the expression “Prospectus Directive” means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the relevant member state) and includes any relevant implementing measure in the relevant member state. The expression 2010 PD Amending Directive means Directive 2010/73/EU.

The sellers of the common shares have not authorized and do not authorize the making of any offer of common shares through any financial intermediary on their behalf, other than offers made by the underwriters with a view to the final placement of the common shares as contemplated in this prospectus. Accordingly, no purchaser of the common shares, other than the underwriters, is authorized to make any further offer of the common shares on behalf of the sellers or the underwriters.

### **Notice to Prospective Investors in the United Kingdom**

This prospectus is only being distributed to, and is only directed at, persons in the United Kingdom that are qualified investors within the meaning of Article 2(1)(e) of the Prospectus Directive that are also (i) investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the “Order”) or (ii) high net worth entities, and other persons to whom it may lawfully be communicated, falling within Article 49(2)(a) to (d) of the Order (each such person being referred to as a “relevant person”). This prospectus and its contents are confidential and should not be distributed, published or reproduced (in whole or in part) or disclosed by recipients to any other persons in the United Kingdom. Any person in the United Kingdom that is not a relevant person should not act or rely on this document or any of its contents.

### **Notice to Prospective Investors in Australia**

No prospectus or other disclosure document (as defined in the Corporations Act 2001 (Cth) of Australia, or Corporations Act) in relation to the common shares has been or will be lodged with the Australian Securities & Investments Commission (“ASIC”). This document has not been lodged with ASIC and is only directed to certain categories of exempt persons. Accordingly, if you receive this document in Australia:

- (a) you confirm and warrant that you are either:
  - (i) a “sophisticated investor” under section 708(8)(a) or (b) of the Corporations Act;
  - (ii) a “sophisticated investor” under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant’s certificate to us which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
  - (iii) a person associated with the company under section 708(12) of the Corporations Act; or
  - (iv) a “professional investor” within the meaning of section 708(11)(a) or (b) of the Corporations Act, and to the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this document is void and incapable of acceptance; and
- (b) you warrant and agree that you will not offer any of the common shares for resale in Australia within 12 months of that common shares being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

### **Notice to Prospective Investors in Chile**

The common shares are not registered in the Securities Registry (Registro de Valores) or subject to the control of the Chilean Securities and Exchange Commission (Superintendencia de Valores y Seguros de Chile). This prospectus and other offering materials relating to the offer of the common shares do not constitute a public offer of, or an invitation to subscribe for or purchase, the common shares in the Republic of Chile, other than to individually identified purchasers pursuant to a private offering within the meaning of Article 4 of the Chilean Securities Market Act (Ley de Mercado de Valores) (an offer that is not “addressed to the public at large or to a certain sector or specific group of the public”).

### **Notice to Prospective Investors in France**

Neither this prospectus nor any other offering material relating to the common shares described in this prospectus has been submitted to the clearance procedures of the *Autorité des Marchés Financiers* or of the competent authority of another member state of the European Economic Area and notified to the *Autorité des Marchés Financiers*. The common shares have not been offered or sold and will not be offered or sold, directly or indirectly, to the public in France. Neither this prospectus nor any other offering material relating to the common shares has been or will be:

- released, issued, distributed or caused to be released, issued or distributed to the public in France; or
- used in connection with any offer for subscription or sale of the common shares to the public in France.

Such offers, sales and distributions will be made in France only:

- to qualified investors (*investisseurs qualifiés*) and/or to a restricted circle of investors (*cercle restreint d’investisseurs*), in each case investing for their own account, all as defined in, and in accordance with articles L.411-2, D.411-1, D.411-2, D.734-1, D.744-1, D.754-1 and D.764-1 of the French *Code monétaire et financier*;
- to investment services providers authorized to engage in portfolio management on behalf of third parties; or
- in a transaction that, in accordance with article L.411-2-II-1°-or-2°-or-3° of the French *Code monétaire et financier* and article 211-2 of the General Regulations (*Règlement Général*) of the *Autorité des Marchés Financiers*, does not constitute a public offer (*appel public à l’épargne*).

The common shares may be resold directly or indirectly, only in compliance with articles L.411-1, L.411-2, L.412-1 and L.621-8 through L.621-8-3 of the French *Code monétaire et financier*.

### **Notice to Prospective Investors in Hong Kong**

The common shares may not be offered or sold in Hong Kong by means of any document other than (i) in circumstances which do not constitute an offer to the public within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong), or (ii) to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder, or (iii) in other circumstances which do not result in the document being a “prospectus” within the meaning of the Companies Ordinance (Cap. 32, Laws of Hong Kong) and no advertisement, invitation or document relating to the common shares may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public in Hong Kong (except if permitted to do so under the laws of Hong Kong) other than with respect to common shares which are or are intended to be disposed of only to persons outside Hong Kong or only to “professional investors” within the meaning of the Securities and Futures Ordinance (Cap. 571, Laws of Hong Kong) and any rules made thereunder.

### **Notice to Prospective Investors in Japan**

The common shares offered in this prospectus have not been and will not be registered under the Financial Instruments and Exchange Law of Japan. The common shares have not been offered or sold and will not be offered or sold, directly or indirectly, in Japan or to or for the account of any resident of Japan (including any corporation or other entity organized under the laws of Japan), except (i) pursuant to an exemption from the registration requirements of the Financial Instruments and Exchange Law and (ii) in compliance with any other applicable requirements of Japanese law.

### **Notice to Prospective Investors in Singapore**

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common shares may not be circulated or distributed, nor may the common shares be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275 of the SFA or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA, in each case subject to compliance with conditions set forth in the SFA.

Where the common shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

common shares, debentures and units of common shares and debentures of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the common shares pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor (for corporations, under Section 274 of the SFA) or to a relevant person defined in Section 275(2) of the SFA, or to any person pursuant to an offer that is made on terms that such common shares, debentures and units of common shares and debentures of that corporation or such rights and interest in that trust are acquired at a consideration of not less than S\$200,000 (or its equivalent in a foreign currency) for each transaction, whether such amount is to be paid for in cash or by exchange of securities or other assets, and further for corporations, in accordance with the conditions specified in Section 275 of the SFA;
- where no consideration is or will be given for the transfer; or
- where the transfer is by operation of law.

**EXPENSES OF THE OFFERING**

We estimate that our expenses in connection with this offering, other than underwriting discounts and commissions, will be as follows:

<u>Expenses</u>	<u>Amount</u>
Securities and Exchange Commission registration fee	\$ *
FINRA filing fee	*
The NASDAQ Global Market listing fee	*
Printing and engraving expenses	*
Legal fees and expenses	*
Accounting fees and expenses	*
Miscellaneous costs	*
Total	<u>*</u>

\* To be filed by amendment.

All amounts in the table are estimates except the SEC registration fee, The NASDAQ Global Market listing fee and the FINRA filing fee. We will pay all of the expenses of this offering.

**LEGAL MATTERS**

The validity of our common shares and certain other matters of Dutch law will be passed upon for us by Eversheds B.V. with the address of De Cuserstraat 85a, 1081 CN Amsterdam, P.O. Box 7902, 1008 AC Amsterdam, the Netherlands. Certain matters of U.S. federal law will be passed upon for us by Latham & Watkins LLP. Legal counsel to the underwriters in connection with this offering are Van Doorne N.V. with respect to Dutch law and Cooley LLP, New York, New York, with respect to U.S. federal law.

**EXPERTS**

The financial statements of Merus B.V. as of December 31, 2014 and 2013, and for each of the years then ended, have been included herein and in the registration statement in reliance upon the report of KPMG Accountants N.V., independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.



## ENFORCEMENT OF CIVIL LIABILITIES

We are a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) 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. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce against them or us in U.S. courts, including judgments predicated upon the civil liability provisions of the federal securities laws of 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. 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. 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 Civil Procedure Code.

Dutch civil procedure differs substantially from U.S. civil procedure in a number of respects. Insofar as the production of evidence is concerned, U.S. law and the laws of several other jurisdictions based on common law provide for pre-trial discovery, a process by which parties to the proceedings may prior to trial compel the production of documents by adverse or third parties and the deposition of witnesses. Evidence obtained in this manner may be decisive in the outcome of any proceeding. No such pre-trial discovery process exists under Dutch law.

## WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information set forth in the registration statement and the exhibits and schedules to the registration statement. For further information, we refer you to the registration statement and the exhibits and schedules filed as part of the registration statement. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Information on the operation of the Public Reference Room may be obtained by calling the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is [www.sec.gov](http://www.sec.gov).

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our management board members, supervisory board members and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We will send our transfer agent a copy of all notices of our general meetings of shareholders and other reports, communications and information that are made generally available to shareholders. The transfer agent has agreed to mail to all shareholders a notice containing the information (or a summary of the information) contained in any notice of a meeting of our shareholders received by the transfer agent and will make available to all shareholders such notices and all such other reports and communications received by the transfer agent.

[Table of Contents](#)

**INDEX TO FINANCIAL STATEMENTS**

**Financial Statements as of December 31, 2014 and 2013**

<a href="#">Independent Auditor's Report</a>	F-2
<a href="#">Statement of Financial Position</a>	F-3
<a href="#">Statement of Profit or Loss and Comprehensive Income</a>	F-4
<a href="#">Statement of Changes in Equity</a>	F-5
<a href="#">Statement of Cash Flows</a>	F-6
<a href="#">Notes to Financial Statements</a>	F-7

## INDEPENDENT AUDITOR'S REPORT

### Report of Independent Registered Public Accounting Firm

To: the Supervisory Board and Management Board of Merus B.V.

We have audited the accompanying statements of financial position of Merus B.V. as of 31 December 2014 and 2013, and the related statements of profit or loss and comprehensive income, statements of changes in equity and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Merus B.V. as of 31 December 2014 and 2013, and the results of its operations and its cash flows for the years then ended, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board (IASB).

Rotterdam, 4 September 2015

/s/ KPMG Accountants N.V.

**STATEMENT OF FINANCIAL POSITION AS AT DECEMBER 31, 2014**  
**(after appropriation of result for the year)**

	<u>Note</u>	<u>December 31, 2014</u>	<u>December 31, 2013</u>	<u>January 1, 2013</u>
		(euros in thousands)		
<b>Non-current assets</b>				
Property, plant and equipment	7	353	388	508
Intangible assets	8	497	558	619
		<u>850</u>	<u>946</u>	<u>1,127</u>
<b>Current assets</b>				
Trade and other receivables	10	849	831	938
Cash and cash equivalents	11	1,841	10,647	5,763
		<u>2,690</u>	<u>11,478</u>	<u>6,701</u>
<b>Total assets</b>		<u><u>3,540</u></u>	<u><u>12,424</u></u>	<u><u>7,828</u></u>
<b>Shareholders' equity</b>				
Issued and paid-in capital	15	282	241	159
Share premium account		36,924	30,931	19,005
Accumulated loss		<u>(40,765)</u>	<u>(23,510)</u>	<u>(13,784)</u>
Total equity (deficit)		<u>(3,559)</u>	<u>7,662</u>	<u>5,380</u>
<b>Non-current liabilities</b>				
Borrowings	13	652	819	986
Deferred revenue	14	613	—	—
<b>Current liabilities</b>				
Amounts owed to credit institutions	13	167	167	166
Trade payables		2,409	958	237
Taxes and social security liabilities		131	117	104
Deferred revenue	14	223	—	—
Other liabilities and accruals	12	2,904	2,701	955
		<u>5,834</u>	<u>3,943</u>	<u>1,462</u>
<b>Total liabilities</b>		<u><u>7,099</u></u>	<u><u>4,762</u></u>	<u><u>2,448</u></u>
<b>Total equity and liabilities</b>		<u><u>3,540</u></u>	<u><u>12,424</u></u>	<u><u>7,828</u></u>

**STATEMENT OF PROFIT OR LOSS AND COMPREHENSIVE INCOME FOR THE YEAR ENDED  
DECEMBER 31, 2014**

	<u>Note</u>	<u>2014</u>	<u>2013</u>
		(euros in thousands, except per share data)	
<b>Revenue</b>	<i>16</i>	<b>1,303</b>	558
		<b>1,303</b>	558
Costs of outsourced work and other external costs:			
Research and development expenditure	<i>17</i>	<b>(14,099)</b>	(6,054)
Other operating expenses	<i>17</i>	<b>(1,203)</b>	(1,294)
		<b>(15,302)</b>	(7,348)
Personnel expenses	<i>18</i>	<b>(3,168)</b>	(2,852)
Depreciation and amortization	<i>7,8</i>	<b>(253)</b>	(264)
<b>Total operating expenses</b>		<b>(18,723)</b>	(10,464)
<b>Operating result</b>		<b>(17,420)</b>	(9,906)
Finance income	<i>19</i>	<b>50</b>	53
Finance costs	<i>19</i>	<b>(39)</b>	(55)
<b>Total financial expenses</b>		<b>11</b>	(2)
<b>Result before tax</b>		<b>(17,409)</b>	(9,908)
Income tax expense	<i>20</i>	<b>—</b>	—
<b>Result after taxation</b>	<i>15</i>	<b>(17,409)</b>	(9,908)
<b>Other comprehensive income</b>		<b>—</b>	—
<b>Total comprehensive income for the year</b>		<b>(17,409)</b>	(9,908)
Basic (and diluted) loss per share	<i>21</i>	<b>(3.42)</b>	(2.75)

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

STATEMENT OF CHANGES IN EQUITY

(euros)	Note	Common share capital	Class A pref. share capital	Class B pref. share capital	Common share premium	Class A pref. share premium	Class B pref. share premium	Accumulated loss	Total equity
<b>Balance at January 1, 2013</b>		<b>28,230</b>	<b>20,615</b>	<b>110,558</b>	<b>1,450,857</b>	<b>1,334,386</b>	<b>16,219,660</b>	<b>(13,784,510)</b>	<b>5,379,796</b>
Result		—	—	—	—	—	—	(9,907,570)	(9,907,570)
Other comprehensive income		—	—	—	—	—	—	—	—
Total comprehensive income		—	—	—	—	—	—	(9,907,570)	(9,907,570)
Transactions with owners the Company:									
Issuance of shares	15	1,254	—	80,000	62,908	—	11,863,573	—	12,007,735
Equity settled shared-based payments	18	—	—	—	—	—	—	181,468	181,468
<b>Total contributions by and distributions to owners of the Company</b>		<b>1,254</b>	<b>—</b>	<b>80,000</b>	<b>62,908</b>	<b>—</b>	<b>11,863,573</b>	<b>181,468</b>	<b>12,189,203</b>
<b>Balance at December 31, 2013</b>		<b>29,484</b>	<b>20,615</b>	<b>190,558</b>	<b>1,513,765</b>	<b>1,334,386</b>	<b>28,083,233</b>	<b>(23,510,612)</b>	<b>7,661,429</b>
<b>Balance at January 1, 2014</b>		<b>29,484</b>	<b>20,615</b>	<b>190,558</b>	<b>1,513,765</b>	<b>1,334,386</b>	<b>28,083,233</b>	<b>(23,510,612)</b>	<b>7,661,429</b>
Result		—	—	—	—	—	—	(17,408,841)	(17,408,841)
Other comprehensive income		—	—	—	—	—	—	—	—
Total comprehensive income		—	—	—	—	—	—	(17,408,841)	(17,408,841)
Transactions with owners the Company:									
Issuance of shares	15	896	—	40,000	50,388	—	5,942,409	—	6,033,693
Equity settled shared-based payments	18	—	—	—	—	—	—	154,468	154,468
<b>Total contributions by and distributions to owners of the Company</b>		<b>896</b>	<b>—</b>	<b>40,000</b>	<b>50,388</b>	<b>—</b>	<b>5,942,409</b>	<b>154,468</b>	<b>6,188,161</b>
<b>Balance at December 31, 2014</b>		<b>30,380</b>	<b>20,615</b>	<b>230,558</b>	<b>1,564,153</b>	<b>1,334,386</b>	<b>34,025,642</b>	<b>(40,764,985)</b>	<b>(3,559,251)</b>

## STATEMENT OF CASH FLOWS FOR THE YEAR ENDED DECEMBER 31, 2014

	<u>Note</u>	<u>2014</u>	<u>2013</u>
		(euros in thousands)	
<b>Cash flows from operating activities</b>			
Total comprehensive income for the year		(17,409)	(9,908)
Adjustments for:			
Depreciation and amortisation	7, 8	253	264
Share option expenses	18	155	182
Net finance costs	19	(11)	2
		<u>(17,012)</u>	<u>(9,460)</u>
Changes in working capital:			
Trade and other receivables	10	(39)	72
Trade payables		1,451	721
Other liabilities and accruals	12	202	1,746
Deferred revenue	14	836	—
Tax and social security liabilities		14	13
<b>Cash used in operating activities</b>		<u>(14,548)</u>	<u>(6,908)</u>
Interest paid	19	(39)	(55)
Tax paid	9	—	—
<b>Net cash used in operating activities</b>		<u>(14,587)</u>	<u>(6,963)</u>
<b>Cash flow from investing activities</b>			
Acquisition of property, plant and equipment	7	(157)	(83)
Interest received	10, 19	71	88
<b>Net cash flow used in investing activities</b>		<u>(86)</u>	<u>5</u>
<b>Cash flow from financing activities</b>			
Proceeds from issuing shares	15	6,034	12,009
Repayment of borrowings	13	(167)	(167)
<b>Net cash from financing activities</b>		<u>5,867</u>	<u>11,842</u>
<b>Net (decrease)/increase in cash and cash equivalents</b>		<u>(8,806)</u>	4,884
Cash and cash equivalents as at January 1	11	<u>10,647</u>	<u>5,763</u>
<b>Cash and cash equivalents as at December 31</b>		<u>1,841</u>	<u>10,647</u>



## NOTES TO THE FINANCIAL STATEMENTS

### 1. General information

Merus B.V. (the Company), headquartered in Utrecht, the Netherlands, is a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. The Company has a pipeline of full-length human bispecific antibodies generated from its proprietary technology platform.

The Company is a limited liability company incorporated in the Netherlands, with its statutory seat in Utrecht. The address of the registered office is Padualaan 8, 3584CH Utrecht, the Netherlands.

### 2. Basis of preparation

#### *Statement of compliance*

The financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards (IAS) Board. These financial statements are the first financial statements of the Company prepared in accordance with IFRS and IFRS 1 *First time adoption of IFRS* has been applied.

The disclosures required by IFRS 1 concerning the transition from the previous accounting principles to IFRSs are given in note 27.

The financial statements were authorised for issuance by the management board and the supervisory board on 4 September 2015.

#### *Basis of preparation*

The financial statements have been prepared under the historical cost convention unless otherwise stated in 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 euro, except otherwise indicated.

#### *Going concern*

During 2014, the Company suffered losses from its operations, which further weakened the shareholders' equity. In view of its financial position at the end of 2014, the Company exercised its right to request the issuance of new Class B preferred shares in January 2015, which increased the Company's shareholders' equity and cash position by €5 million.

Based on the then existing agreement with Class B preferred shareholders, the Company had the right to request the issuance of new Class B preferred shares up to an amount of €8.0 million, with €4.0 million between 1 September 2015 and 31 December 2016 (Tranche 6) and €4.0 million between 1 March 2016 and 31 December 2016 (Tranche 7).

On 11 June 2015, the Company reached an agreement with the Class B preferred shareholders to provide the Company with a convertible bridge loan of €8 million in lieu of Tranches 6 and 7, and to cancel these two tranches.

On 16 June 2015, the Company reached an agreement with existing and new shareholders to provide the Company with additional funding up to an amount of approximately €73 million of which approximately

## [Table of Contents](#)

€50 million would be contributed in August 2015 in connection with the issuance of new Class C preferred shares. In connection with this Class C preferred share financing, the convertible bridge loan was repaid in August 2015 by converting the principal and interest thereon into Class C preferred shares.

The Company expects to incur significant expenses and operating losses for the foreseeable future as its bispecific antibody candidates 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 in-license or acquisition of additional bispecific antibody candidates.

As a result, the Company will need additional financing to support its continuing operations. Until such time as it can generate significant revenue from product sales, if ever, the Company expects to finance its 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 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 its 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.

The Company expects that its existing cash and cash equivalents, together with the net proceeds from the issuance of Class C preferred shares in August 2015, will enable the Company to fund its operating expenses and capital expenditure requirements for at least the next 12 months.

Based on the assumption that the Company will be able to continue as a going concern, the accounting principles as disclosed in note 4 have been applied in these financial statements.

### **3. Use of estimates, judgements and assumptions**

In preparing these financial statements, management has made judgements, estimates and assumptions that affect the application of accounting policies and the reported amounts of assets, liabilities, income and expenses. Actual results may differ from these estimates.

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

The following are the critical judgments and assumptions, apart from those involving estimations (see below), that management has made in the process of applying the Company's accounting policies and that have the most significant effect on the amounts recognised in the financial statements.

#### ***Capitalization of development costs***

Determination whether the capitalization criteria for development costs are met or not.

The criteria for capitalization of development costs are disclosed in note 4 "Significant accounting policies" and were not met in 2014. Therefore, all development expenditures relating to internally generated intangible assets in 2014 were expensed when incurred.

#### ***Income tax***

Determination whether the criteria for the recognition of unused tax losses are met or not.

The criteria for the recognition of unused tax losses are disclosed in note 4 "Significant accounting policies". As at 31 December 2014, deferred tax assets have not been recognised 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 utilised. 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 a customer 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

## [Table of Contents](#)

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 performs its integrated service activities to the third-party.

### ***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 formula 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 behaviour. Since the Company is a private company, there is no published share price information available. Consequently, the Company needs to estimate the fair value of its share and the expected volatility of that share value. These assumptions and estimates are further discussed in note 15 to the financial statements.

The result of the share option valuations and the related compensation expense that is recognised 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.

## **4. 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 the accruals basis. Profit is only included when realized at balance sheet 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.

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

Transactions in foreign currencies are translated to the respective functional currency of the Company at exchange rates at the dates of the transactions.

Monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rate at the reporting date. Foreign currency differences are generally recognised in profit or loss.

### ***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 to the income statement on a straight-line basis over estimated useful lives of generally five years. If significant parts of an item of property, plant and equipment have different useful lives, then they are accounted for as separate items (major components) of property, plant and equipment.

## [Table of Contents](#)

Subsequent expenditure is capitalised only when it is probable that the future economic benefits associated with the expenditure will flow to the Company.

### ***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.

#### *Patents*

Patents acquired separately by the Company are reported at cost less accumulated amortisation and accumulated impairment losses. Amortisation is charged on a straight-line basis over the estimated useful lives of the patents. The estimated useful life and amortisation 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.

The useful lives of intangible assets are assessed to be finite and amortised over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired.

Patents are amortised on a straight-line basis over the shorter of their estimated economic or legal lives. Amortisation begins when the asset is available for use.

#### *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 recognised as an expense in the period in which it is incurred.

Development is recognised 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.

### ***Financial instruments***

The Company classifies non-derivative financial assets into the following categories: loans and receivables. The Company classifies non-derivative financial liabilities into the other financial liabilities category.

#### *Non-derivative financial assets and financial liabilities*

The Company initially recognises loans and receivables issued on the date when they are originated. All other financial assets and financial liabilities are initially recognised on the trade date.

## [Table of Contents](#)

The Company derecognises 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 derecognised financial assets that is created or retained by the Company is recognised as a separate asset or liability.

The Company derecognises a financial liability when its contractual obligations are discharged 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 realise the asset and settle the liability simultaneously.

### *Loans and receivables*

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

### *Non-derivative financial liabilities*

Non-derivative financial liabilities are initially recognised at fair value less any directly attributable transaction costs. Subsequent to initial recognition, these liabilities are measured at amortised cost using the effective interest method.

## **Share capital**

### *Common shares*

Incremental costs directly attributable to the issue of common shares, net of any tax effects, are recognised as a deduction from equity.

### *Preferred shares*

Non-redeemable preferred shares are classified as equity, because they bear discretionary dividends, do not contain any obligations to deliver cash or other financial assets and do not require settlement in a variable number of the Company's equity instruments. Discretionary dividends thereon are recognised as equity distributions on approval by the Company's shareholders.

## **Provisions**

A provision is recognised if the following applies:

- the company has a legal or constructive obligation, arising from a past event; and
- the amount can be estimated reliably;
- 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 likely 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 recognised as finance cost.

## **Impairment**

### *Financial assets measured at amortised 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 recognised 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 recognised, then the previously recognised 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 recognised if the carrying amount of an asset or CGU exceeds its recoverable amount.

Impairment losses are recognised 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 amortisation, if no impairment loss had been recognised.

## **Revenue**

### *Fees and royalties*

Fees and royalties paid for the use of the Company's assets (such as patents) are normally recognised 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.

## [Table of Contents](#)

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 recognised in the profit and loss account in proportion to the stage of completion of the transaction as at reporting date. The stage of completion is assessed by reference to assessments of the work performed.

### *Government grants*

Government grants are initially recognised in the balance sheet as deferred income at fair value when there is reasonable assurance that they will be received and the Company will comply with the conditions associated with the grant. Grants that compensate the Company for expenses incurred are recognised in the profit and loss on a systematic basis in the same period in which the expenses are recognised. Grants that compensate the Company for the cost of an asset are recognised in the profit and loss account on a systematic basis over the useful life of the asset.

### **Employee benefits**

#### *Short-term employee benefits*

Short-term employee benefits are expensed as the related service is provided. A liability is recognised 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 recognised as an expense, with a corresponding increase in equity, over the vesting period of the awards. Service provisions and non-market related conditions are not taken into account in determining the fair value. The amount recognised 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 recognised 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 defined 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.

## [Table of Contents](#)

Obligations for contributions to defined contribution plans are expensed as the related service is provided. Prepaid contributions are recognised as an asset to the extent that a cash refund or a reduction in future payments is available.

### **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 recognised 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 recognised using the Group'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 recognised in the Group's statement of financial position.

#### *Lease payments*

Payments made under operating leases are recognised in profit or loss on a straight-line basis over the term of the lease. Lease incentives received are recognised 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 costs**

The Company's finance income and finance costs include:

- interest income;
- interest expense; and
- the foreign currency gain or loss on financial assets and financial liabilities.

Interest income or expense is recognised using the effective interest method.

### **Income tax**

Income tax expense comprises current and deferred tax. It is recognised in profit or loss except to the extent that it relates to a business combination, or items recognised directly in equity or in other comprehensive



income (OCI). 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 recognised 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 recognised 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 recognised 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 realised; such reductions are reversed when the probability of future taxable profits improves.

Unrecognised deferred tax assets are reassessed at each reporting date and recognised to the extent that it has become probable that future taxable profits will be available against which they can be utilised.

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.

## **5. New standards and interpretations not yet adopted**

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning on or after 1 January 2015, 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 1 January 2018, with early adoption permitted.

The Company is assessing the potential impact on its financial statements resulting from the application of IFRS 9.

## [Table of Contents](#)

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

IFRS 15 establishes a comprehensive framework for determining whether, how much and when revenue is recognised. 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 1 January 2017, with early adoption permitted.

The Company is assessing the potential impact on its financial statements resulting from the application of IFRS 15.

### **6. Segment reporting**

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

### **Notes to the statement of financial position as at 31 December 2014**

#### **7. Property, plant and equipment**

Movements in property, plant and equipment were as follows:

	Plant and equipment	Other fixed assets	Total
	(euros in thousands)		
<b>Balance as at 1 January 2014</b>			
Costs	134	1,169	1,303
Accumulated depreciation	(121)	(794)	(915)
Book value	<u>13</u>	<u>375</u>	<u>388</u>
<b>Changes in book value</b>			
Additions	125	32	157
Depreciation	(24)	(168)	(192)
Balance	<u>101</u>	<u>(136)</u>	<u>(35)</u>
<b>Balance as at 31 December 2014</b>			
Costs	259	1,201	1,460
Accumulated depreciation	(145)	(962)	(1,107)
Book value	<u>114</u>	<u>239</u>	<u>353</u>
	Plant and equipment	Other fixed assets	Total
	(euros in thousands)		
<b>Balance as at 1 January 2013</b>			
Costs	134	1,086	1,220
Accumulated depreciation	(106)	(606)	(712)
Book value	<u>28</u>	<u>480</u>	<u>508</u>
<b>Changes in book value</b>			
Additions	—	83	83
Depreciation	(15)	(188)	(203)
Balance	<u>(15)</u>	<u>(105)</u>	<u>(120)</u>
<b>Balance as at 31 December 2013</b>			
Costs	134	1,169	1,303
Accumulated depreciation	(121)	(794)	(915)
Book value	<u>13</u>	<u>375</u>	<u>388</u>

## [Table of Contents](#)

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

### 8. Intangible assets

The intangible assets related to acquired intellectual property rights.

The movements are as follows:

	<u>2014</u>	<u>2013</u>
	(euros in thousands)	
<b>Balance as at 1 January</b>		
Historical cost	860	860
Accumulated amortization	<u>(302)</u>	<u>(241)</u>
Book value	558	619
Capital expenditures	—	—
Amortization charge for the year	<u>(61)</u>	<u>(61)</u>
Book value as at 31 December	<u>497</u>	<u>558</u>
<b>Balance as at 31 December</b>		
Historical cost	860	860
Accumulated amortization	<u>(363)</u>	<u>(302)</u>
Book value	<u>497</u>	<u>558</u>

The Company purchased at 23 January 2009 the patents regarding the recombinant production of mixtures of antibodies from Crucell Holland B.V. The majority of the patents were filed by Crucell Holland B.V. at 15 July 2003 and have an economic life of 20 years. Therefore, the Company decided to amortise over the remaining economic life of 14 years.

### 9. Taxation

Deferred tax assets have not been recognised 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 utilised. As at 31 December 2014, the tax losses carried forward amount to €43.5 million as compared to €28.2 million in 2013.

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, 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%. The agreement with the tax authorities is currently signed for the years 2011 to 2015 but is expected to be extended. Taxable profits will only qualify for the Innovations Box once the tax losses carried forward are completely utilised.

## [Table of Contents](#)

### 10. Trade and other receivables

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

	2014	2013
	(euros in thousands)	
Trade receivables	172	150
Taxation and social security premiums	269	142
Prepaid general expenses	292	89
Interest bank	19	40
Subsidy	86	390
Other receivables	11	20
	<u>849</u>	<u>831</u>

### 11. Cash and cash equivalents

The cash and cash equivalents balance includes an amount of €273,000 (2013: €453,000) that is not immediately accessible as it is pledged to the bank as a security for a loan received. See also note 13.

### 12. Trade and other payables

All trade and other payables are short-term and payable within 1 year.

	2014	2013
	(euros thousands)	
Accrued auditor's fee	34	30
Accrual for holiday expenses	117	107
Personnel	43	27
R&D studies	388	525
IP – Legal fee	858	—
Bonuses	276	225
Subsidy advance received	1,057	1,583
Other accruals	131	204
	<u>2,904</u>	<u>2,701</u>

### 13. Borrowings

Movements in borrowings were as follows:

	<u>Rabobank</u> (euros in thousands)
Balance January 1, 2013	1,152
Repayments	(166)
Balance portion December 31, 2013	986
Short term portion December 31, 2013	(167)
Long term portion December 31, 2013	819
	(euros in thousands)
Balance January 1, 2014	986
Repayments	(167)
Balance December 31, 2014	819
Short term portion December 31, 2014	(167)
Long term portion December 31, 2014	652

**Rabobank**

The Company entered into a financing agreement with Rabobank Utrechtse Heuvelrug U.A. (Rabobank) on 29 December 2009, which provided 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 are to be repaid in monthly instalments of €14,000, beginning on 31 January 2009. Repayments were deferred in January 2010 for a period of two years. Repayment recommenced in January 2012. The loans bear interest at an annual rate equal to 4.45% and is fixed until 1 April 2016 and thereafter, at our option, at a fixed or variable rate to be agreed.

In connection with the financing agreement, the Company provided security in the form of:

- a right of pledge on the account of €500,000, 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."

See also note 11.

**14. Deferred revenue**

On 8 April 2014, the Company entered into a research and license agreement with ONO Pharmaceutical Co., Ltd. (ONO). As part of this agreement, the Company received a non-refundable upfront payment of €1.0 million. This upfront payment is amortised on a straight-line basis, and presented as revenue, over a period from 8 April 2014 through 30 September 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.

	<u>2014</u>	<u>2013</u>
	(euros in thousands)	
Deferred revenue – current portion	223	—
Deferred revenue	<u>613</u>	<u>—</u>
	<u>836</u>	<u>—</u>

## 15. Shareholders' equity

Changes in shareholders' equity were as follows:

	Common share capital	Class A pref. share capital	Class B pref. share capital	Common share premium	Class A pref. share premium	Class B pref. share premium	Accumulated loss	Total equity
<b>Balance at 1 January 2013</b>	28,230	20,615	110,558	1,450,857	1,334,386	16,219,660	(13,784,510)	5,379,796
Issuance of shares	1,254	—	80,000	62,908	—	11,863,573	—	12,007,735
Result for the year	—	—	—	—	—	—	(9,907,570)	(9,907,570)
Options	—	—	—	—	—	—	181,468	181,468
<b>Balance at 31 December 2013</b>	<u>29,484</u>	<u>20,615</u>	<u>190,558</u>	<u>1,513,765</u>	<u>1,334,386</u>	<u>28,083,233</u>	<u>(23,510,612)</u>	<u>7,661,429</u>
Balance at 1 January 2014	29,484	20,615	190,558	1,513,765	1,334,386	28,083,233	(23,510,612)	7,661,429
Issuance of shares	896	—	40,000	50,388	—	5,942,409	—	6,033,693
Result for the year	—	—	—	—	—	—	(17,408,841)	(17,408,841)
Options	—	—	—	—	—	—	154,468	154,468
<b>Balance at 31 December 2014</b>	<u>30,380</u>	<u>20,615</u>	<u>230,558</u>	<u>1,564,153</u>	<u>1,334,386</u>	<u>34,025,642</u>	<u>(40,764,985)</u>	<u>(3,559,251)</u>

### *Issued and paid-in share capital*

#### *Common shares*

In 2013, 25,082 options were exercised at an average price of €2.56 per share; accordingly, 25,082 common shares were issued, share capital increased by €1,254 and share premium increased by €62,908.

In 2014, 17,915 options were exercised at an average price of €2.86 per share; accordingly, 17,915 common shares were issued, share capital increased by €896 and share premium increased by €50,388.

#### *Class A preferred shares*

There were no changes in 2013 and 2014. The Class A preferred shares are convertible into common shares only.

#### *Class B preferred shares*

In January 2010, the Company closed a €21.7 million (\$30.7 million) Class B preferred share financing led by new investors Novartis Bioventures Ltd, Pfizer Inc., Bay City Capital, and Life Sciences Partners. Merus' seed investor Aglaia Oncology Fund also participated in this financing. The first tranche of the Class B preferred share financing (€8.5 million) was drawn down in January 2010. The second tranche of the Class B preferred share financing (€8.1 million) was drawn down in April 2012.

The initial Class B preferred share financing commitment was reduced in 2013 by cancellation of the third tranche in relation with the closing of the Class B preferred share extension on 30 September 2013. Johnson & Johnson Development Corporation joined the existing investor group and a total of €31.0 million was committed in addition to the €16.6 million already drawn down from the original Class B preferred share financing. The Class B preferred share extension consists of up to a further 5 tranches (tranches 3 to 7) over and above the initial Class B preferred share tranches 1 and 2 already drawn down.

## [Table of Contents](#)

Tranche 3 of €12.0 million was drawn down at the time of closing of the Class B preferred share extension (30 September 2013) and a total of 1,600,000 Class B preferred shares were issued.

Tranche 4 of €6.0 million was drawn down on 29 August 2014 and a total of 800,000 Class B preferred shares were issued.

The Class B preferred shares are convertible into common shares only and carry an annual cumulative profit entitlement of 8% of the amount paid on such shares. The dividend entitlement rights are at all times senior to the dividend entitlement rights of the Class A preferred shares and the common shares.

### **Conversion**

Shares of Class A and Class B preferred (together with any accrued and unpaid dividends) are convertible into common shares only. Conversion is at the option of the holders of the Class A and Class B preferred shares, although conversion is mandatory and automatic in any of the following events: (i) the affirmative vote of specified Class B preferred shareholders to convert all (and not less than all) of the issued and outstanding Class A and Class B preferred shares or (ii) the consummation of an initial public offering resulting in gross proceeds to the Company of €30.0 million or more and a price per share to the public of not less than four times the original issue price of the Class B preferred shares.

### *Situation as at 31 December 2014*

At 31 December 2014, a total of 4,611,156 Class B preferred shares, 412,296 Class A preferred shares and 607,596 common shares with a nominal value of €0.05 each were issued and paid up.

### **Share premium reserves**

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.

### **Foundation**

The Company established a foundation “Stichting Administratiekantoor Merus” (Foundation). The Foundation has an agreement with the Company to facilitate the administration of share-based compensation awards.

Options granted under the Company’s share option programs entitle the eligible participant to purchase depositary receipts for common shares in the Company, subject to meeting the vesting conditions. The ownership of such depositary receipts is conditional to the terms and conditions of the foundation’s Conditions of Administration. Under defined circumstances, the participants are obliged to offer the acquired depositary receipts to the Foundation.

### **Share-based payment arrangements**

At 31 December 2014, the Company operated the following share-based payment arrangements.

#### *Share option program (equity-settled)*

In 2010, the Company established share option programs that entitle key management personnel, staff and consultants providing similar services to purchase depositary receipts for common shares in the Company. Under these programs, holders of vested options are entitled to purchase depositary receipts for common shares at the exercise price determined at the date of grant.

## [Table of Contents](#)

Upon exercise of options, the Foundation issues to such individuals non-voting depositary receipts representing the underlying common shares, against payment of the option exercise price. The voting rights associated with the common shares remain with the Foundation. The Options granted under the share option programs vest in installments over a four-year period from the grant date. 25% of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. The options granted are exercisable once vested. Options will lapse on the eighth anniversary of the date of grant.

For participants who are not members of the supervisory board, a participant who voluntarily leaves employment with the Company is 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. Up to the first anniversary of the date of exercise, the participant has an obligation to offer 100% of his depositary receipts to the Foundation. This obligation for a participant to offer depositary receipts to the Foundation upon resignation is reduced by 25% per year, which means that there is no such obligation if a participant leaves after the fourth anniversary of the date of exercise, and is treated as a vesting condition.

The following number of options are outstanding as per year-end:

<u>Group of employees entitled</u>	<u>December 31, 2014</u>	<u>December 31, 2013</u>	<u>January 1, 2013</u>
Executives	<b>226,996</b>	210,020	218,082
Other employees	<b>46,537</b>	32,380	31,790
Supervisory board members	<b>72,563</b>	45,000	45,000
Total	<b>346,096</b>	287,400	294,872

### *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 Black-Scholes formula (members of the executive management team, which includes our management board and other key personnel) or a binomial option pricing model (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. In addition to the vesting period of the options, the vesting period for the depositary receipts were also taken into account when allocating the fair values of the options granted over the required service period.

The inputs used in the measurement of the fair values and the related fair values at the grant dates were as follows for respectively options granted to members of the executive management team (Black-Scholes formula) and other participants (binomial option pricing model):

	<u>2014</u>		<u>2013</u>	
	<u>Executives</u>	<u>Other</u>	<u>Executives</u>	<u>Other</u>
	€	€	€	€
Fair value at grant date	<b>2.39</b>	<b>2.45-2.71</b>	2.61	2.92
Share price at grant date	<b>3.70</b>	<b>3.40-3.70</b>	3.80	3.80
Exercise price	<b>2.58</b>	<b>2.58</b>	2.58	2.58
Expected volatility (weighted-average)	<b>101.1%</b>	<b>101.1%</b>	111.7%	111.7%
Expected life (weighted-average)	<b>4 year</b>	<b>8 year</b>	4 year	8 year
Expected dividends	<b>0%</b>	<b>0%</b>	0%	0%
Risk-free interest rate (based on government bonds)	<b>1.2%</b>	<b>1.0%-1.2%</b>	1.5%	1.5%

Since the Company is a private company, company-specific historical and implied volatility information is not available. Expected volatility is therefore estimated based on the observed daily share price returns of



## [Table of Contents](#)

publicly traded peer companies over a historic period equal to the period for which expected volatility is estimated. The group of comparable listed companies are publicly traded entities active in the business of developing antibody-based therapeutics, treatments and drugs and are selected by taking into consideration the availability of meaningful trading data history and market capitalization.

Since the options are not transferable, the participants will tend to exercise the options prior to the maturity date. For participants, not being members of the executive management team, 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. The members of the executive management team are expected to exercise their options immediately after vesting of the final vesting instalment.

Since the Company is a private company, the share price is not readily available at the valuation date of the share option. In determining the fair values of the Company's 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 (AICPA) Audit and Accounting Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation has been considered.

The "prior sale of company stock" method, a form of the market approach, has been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm's length sales of the Company's equity securities. Considerations factored into the analysis include: the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the relationship of the parties involved, the risk-free rate, the timing compared to the common shares valuation date and the financial condition and structure of the Company at the time of the sale. As such, the value per share has been benchmarked to the external transactions of company stock and external financing rounds. For determining the value of the Company's shares for 2010 through 2014, the prior sale of company stock method has been relied on to estimate the total value of the company's equity. 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 is considered a strong indication of fair value.

Given that there are multiple classes of equity, the hybrid method has been applied in order to allocate equity to the various equity classes. The Hybrid method is a hybrid between the probability-weighted expected return method (PWERM) and the Option Pricing Method (OPM), which estimates the probability weighted value across certain exit scenarios, but uses the OPM to estimate the remaining unknown potential exit scenarios. A discount for lack of marketability (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.

## [Table of Contents](#)

### *Reconciliation of outstanding share options*

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

	2014		2013	
	Weighted average exercise price (in euros)	Number of options	Weighted average exercise price (in euros)	Number of options
Outstanding at 1 January	2.93	287,400	2.92	294,872
Forfeited during the year	2.58	(13,562)	2.58	(1,280)
Exercised during the year	2.86	(17,915)	2.56	(25,082)
Granted during the year	2.58	90,173	2.58	18,890
Outstanding at 31 December	2.86	346,096	2.93	287,400
Exercisable at 31 December		249,247		189,683

The options outstanding at 31 December 2014 had an exercise price in the range of €2.13 to €7.50 (2013: €2.13 to €7.50) and a weighted-average remaining contractual life of 4.4 years (2013: 4.6 years).

The weighted-average share price at the date of exercise for share options exercised in 2014 was €3.40 (2013: €3.80).

### *Expense recognised in profit or loss*

For details on the related option expenses recognised as employee benefit expenses, see note 18.

## 16. 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.

	2014	2013
	(euros in thousands)	
Amgen evaluation	0	39
GSK evaluation	0	150
ONO Pharmaceutical Co., Ltd.—research funding	677	0
Smithkline Beecham—exclusivity fee	100	0
Subsidy income on research projects	526	369
	<u>1,303</u>	<u>558</u>

## 17. Costs of outsourced work and other external costs

	2014	2013
	(euros in thousands)	
Manufacturing costs	3,646	2,730
IP and litigation costs	5,404	845
Research and development costs	5,049	2,479
Total research and development expenditure	14,099	6,054
Other operating expenses	1,203	1,294
	<u>15,302</u>	<u>7,348</u>

## [Table of Contents](#)

In March 2014 Regeneron Pharmaceuticals Inc. (Regeneron) filed a complaint in the United States District Court for the Southern District of New York, alleging that the Company was infringing one or more claims in their U.S. Patent No. 8,502,018, entitled “Methods of Modifying Eukaryotic Cells.” On 3 July 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 21 November 2014, the District 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 11 March 2014, Regeneron served a writ in the Netherlands alleging that we were infringing one or more claims in their European patent EP 1 360 287 B1. The Company had opposed that patent in June 2014 and the Dutch litigation is currently stayed. On 17 September 2014, Regeneron’s patent EP 1 360 287 B1 was revoked in its entirety by the European Opposition Division of the European Patent Office (EPO). An appeal has been set for October 2015 at the Technical Board of Appeal for the EPO.

The costs incurred in the above litigation and opposition (€5.4 million) are included in the profit and loss statement for the year. No litigation costs were incurred in 2013.

### 18. Employee benefits

The average number of personnel during the year was approximately 32 (2013: 27), all employed in the Netherlands in the area of research and development.

Details of the employee benefits read as follows:

	2014	2013
	(euros in thousands)	
Salaries and wages	2,645	2,370
WBSO subsidy	(276)	(241)
Social security premiums	318	235
Health insurance	40	67
Pension costs	286	239
Option expense	155	182
	<u>3,168</u>	<u>2,852</u>

### 19. Finance income and expense

	2014	2013
	(euros in thousands)	
Interest income and similar income	50	53
Interest expenses and similar expenses	(39)	(55)
	<u>11</u>	<u>(2)</u>

## [Table of Contents](#)

### 20. Income taxes

As disclosed in note 9, the Company has tax losses available which have not been recognised. As a result 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 2014 amounts to €4.1 million (2013: €2.4 million).

### 21. Loss per share

#### *(a) Basic and diluted loss per share*

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

	January 1- December 31, 2014	January 1- December 31, 2013
	(euros)	
Loss attributable to equity holders of the Company	(17,409)	(9,908)
Weighted average number of shares	5,093,258	3,603,827
Basic (and diluted) loss per share (€ per share)	<u>(3.42)</u>	<u>(2.75)</u>

#### *(b) 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 are equal.

#### *(c) Dividends per share*

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

### 22. 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.

	2014	2013
	(euros in thousands)	
Trade receivables	172	150
Cash and cash equivalents	1,841	10,647
	<u>2,013</u>	<u>10,797</u>

## [Table of Contents](#)

At year-end, there is no significant concentration of credit risk at any of the counterparties regarding financial instruments and cash and cash equivalents.

At 31 December 2014, the ageing of trade and other receivables that were not impaired was as follows:

	2014	2013
	(euros in thousands)	
Neither past due nor impaired	172	150
Past due	—	—
	<u>172</u>	<u>150</u>

There is no allowance for impairment.

### **Liquidity risk**

Prudent liquidity risk management implies maintaining sufficient funds and marketable securities. Management considers the existing funding per 31 December 2014 to provide sufficient time to create shareholder value before a next funding round is carried out.

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:

<u>31 December 2014</u>	Carrying amount	Total	< 12 months	1 - 2 years	2 - 5 years	More than 5 years
	(euros in thousands)					
<b>Non-derivative financial liabilities</b>						
Secured bank loans	819	912	200	193	519	—
Trade and other payables	5,444	5,444	5,444	—	—	—
	<u>6,263</u>	<u>6,356</u>	<u>5,644</u>	<u>193</u>	<u>519</u>	<u>—</u>
<u>31 December 2013</u>	Carrying amount	Total	< 12 months	1 - 2 years	2 - 5 years	More than 5 years
	(euros in thousands)					
<b>Non-derivative financial liabilities</b>						
Secured bank loans	986	1,120	208	200	556	156
Trade and other payables	3,776	3,776	3,776	—	—	—
	<u>4,762</u>	<u>4,896</u>	<u>3,984</u>	<u>200</u>	<u>556</u>	<u>156</u>

The secured bank loans have an interest rate that is fixed until 2016. 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**

Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies.

The Company is not exposed to equity securities price risk, since it does not hold any such investments, or commodity price risk.

## [Table of Contents](#)

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 optimising the return.

The Company’s market risk is limited and originates mainly from currency risk and interest risks. Due to the limited impact of currency risk on the Company no summary quantitative data is provided. Furthermore, the sensitivity analysis resulting from a change in foreign exchange rates is not material and therefore omitted.

### *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>2014</u>	<u>2013</u>
	<u>(euros in thousands)</u>	
<b>Fixed-rate instruments</b>		
Financial liabilities	(819)	(986)
	<u>(819)</u>	<u>(986)</u>
<b>Variable rate instruments</b>		
Cash and cash equivalents	1,841	10,647
	<u>1,841</u>	<u>10,647</u>

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. 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.

## **23. Compensation of Management Board and Supervisory Board**

### *Management Board*

In 2014, the following amounts were charged to the profit and loss statement for the remuneration of the statutory directors:

<u>Name</u>	<u>Gross Salary</u>	<u>Bonus</u>	<u>Pension</u>	<u>Crisis tax</u>	<u>Option cost</u>	<u>Total</u>
Ton Logtenberg, CEO	<b>199,997</b>	50,000	34,010	14,676	46,816	345,499
Shelley Margetson, CFO	<b>149,322</b>	27,500	17,732	—	14,024	208,578
<b>Total</b>						<b>554,077</b>

In June 2014, Ton Logtenberg was granted 11,250 options to purchase common shares and Shelley Margetson was granted 9,000 options to purchase common shares. The exercise price of each option is €2.58.

## [Table of Contents](#)

In 2013, the following amounts were charged to the statement of profit or loss for the remuneration of the statutory directors:

<u>Name</u>	<u>Gross Salary</u>	<u>Bonus</u>	<u>Pension</u>	<u>Crisis tax</u>	<u>Option cost</u>	<u>Total</u>
Ton Logtenberg, CEO	<b>191,250</b>	35,000	31,613	9,824	55,700	323,387
Shelley Margetson, CFO	<b>122,304</b>	25,000	14,936	—	9,454	171,694
<b>Total</b>						<b>495,081</b>

In 2013, no options were granted to the statutory directors.

At 31 December 2014, Ton Logtenberg holds 98,758 options (2013: 102,720) with an average exercise price of €2.58 (2013: €2.58) and Shelley Margetson holds 19,000 options (2013: 10,000) with an average exercise price of €2.56 (2013: €2.54).

### **Supervisory Board**

In July 2014, the Company granted options to the following members of the supervisory board as remuneration for their work in 2013 and 2014:

<u>Name</u>	<u>2013</u>	<u>2014</u>	<u>Total</u>
Wolfgang Berthold	5,000	5,500	10,500
Gabriele Dallmann	1,875	2,063	3,938
Gerard van Odijk	6,250	6,875	13,125

The exercise price of each option is €2.58.

In 2014, the following amounts were charged to the profit and loss statement for the remuneration of the members of the Supervisory Board:

<u>Name</u>	<u>Cash compensation</u>	<u>Option cost</u>	<u>Total</u>
Wolfgang Berthold	—	16,633	16,633
Gabriele Dallmann	11,000	6,579	17,579
Gerard van Odijk	—	25,258	25,258
<b>Total</b>			<b>59,470</b>

In 2013, the following amounts were charged to the profit and loss statement for the remuneration of the members of the Supervisory Board:

<u>Name</u>	<u>Cash compensation</u>	<u>Option cost</u>	<u>Total</u>
Wolfgang Berthold	—	10,116	10,116
Gabriele Dallmann	10,000	3,458	13,458
Gerard van Odijk	—	7,720	7,720
<b>Total</b>			<b>31,294</b>

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

## [Table of Contents](#)

As at 31 December 2014 and 2013, members of the Supervisory Board hold the following number of options:

<u>Name</u>	<u>31 December 2014</u>		<u>31 December 2013</u>	
	<u>Number</u>	<u>Average exercise price</u>	<u>Number</u>	<u>Average exercise price</u>
Wolfgang Berthold	25,500	2.54	15,000	2.52
Gabriele Dallmann	7,688	2.49	3,750	2.39
Gerard van Odijk	39,375	3.47	26,250	3.92
Total	<u>72,563</u>	<u>3.04</u>	<u>45,000</u>	<u>3.33</u>

### 24. Related party disclosures

Transactions with the management board and the supervisory board are set out in note 23.

In 2010, the Company entered into an option agreement with the Novartis Bioventures Ltd for an exclusive license to one of the Company's oncology programs. The agreement includes upfront and potential milestones payments totalling over \$200 million plus royalties. In the current year nothing was received under this agreement. In January 2015, the option expired without Novartis Bioventures Ltd having exercised it.

On 30 September 2013, the Company entered into a right of first negotiation agreement under which the Company granted Johnson & Johnson Development Corporation (JJDC), or an affiliate nominated by JJDC, rights of first negotiation to acquire or license two undisclosed bispecific antibody candidates in pre-clinical development. Pursuant to this agreement, prior to soliciting an offer from, or negotiating terms with, any third party, with respect to a sale or license for such bispecific antibody candidates, the Company must first notify JJDC of such opportunity and negotiate in good faith with JJDC the terms of a purchase or license agreement for such bispecific antibody candidates. This agreement is effective until 30 September 2017.

The Company has agreed to reimburse investors' external expenses which are directly related to the legal proceedings of Regeneron against the Company, subject to agreed terms and conditions. An amount of €76,000 was included in the trade payables at 31 December 2014 to the Company's investor, Bay City Capital.

### 25. Operating leases

#### *Rent*

Merus B.V. has a contract for the rent of housing facilities with Utrecht University, seated in Utrecht. The duration of this contract is 2 years, until 31 December 2015. The total annual obligation is €256,000.



## [Table of Contents](#)

### 26. Auditor's fees

With reference to Section 2:382a(1) and (2) of the Netherlands Civil Code, the following fees for the financial year have been charged by KPMG Accountants N.V. to the Company:

	<u>KPMG Accountants N.V. 2014</u>	<u>Other KPMG network 2014</u>	<u>Total KPMG 2014</u>
	(euros in thousands)		
Audit of the financial statements	30	—	30
Other audit engagements	2	—	2
Tax-related advisory services	—	19	19
	<u>32</u>	<u>19</u>	<u>51</u>
	(euros in thousands)		
	<u>KPMG Accountants N.V. 2013</u>	<u>Other KPMG network 2013</u>	<u>Total KPMG 2013</u>
	(euros in thousands)		
Audit of the financial statements	18	—	18
Other audit engagements	—	—	—
Tax-related advisory services	—	4	4
	<u>18</u>	<u>4</u>	<u>22</u>

### 27. Adoption of IFRS

The Company has adopted IFRS as issued by the International Accounting Standards Board, including IAS as its primary accounting basis for the financial statements from 1 January 2014.

Until 2013, the Company prepared financial statements in accordance with Generally Accepted Accounting Principles in the Netherlands Dutch GAAP. Adoption of IFRS resulted in an increase in the share option expense by an amount of €128,000, which affected the Statement of profit or loss:

	<u>2013 (euros in thousands)</u>
Net result reported under previous GAAP	(9,780)
Increase of share option expense	(128)
Net result reported under IFRS	<u>(9,908)</u>

### 28. Subsequent events

On 26 January 2015 the Company drew down tranche 5 of the existing Class B preferred share financing. Shareholders contributed €5.0 million and a total of 2,407,224 Class B preferred shares were issued.

On 16 March 2015, the Company granted 301,018 options over common shares to its executives and other staff members with an exercise price of €1.07 per share.

On 11 June 2015, the Company entered into a convertible bridge loan in the amount of €8.0 million with its Class B preferred shareholders in lieu of closing Tranche 6 and 7 of the extended Class B preferred share financing.

## [Table of Contents](#)

On 16 June 2015, the Company reached an agreement with existing and new shareholders that additional funding up to an amount of approximately €73 million will be provided to the Company on terms to be agreed upon.

On 21 August 2015, closed a €73 million (\$80.5 million) Class C preferred share financing led by new investors Sofinnova Ventures and Novo A/S. Existing investors Novartis Bioventures Ltd, Pfizer Inc., Bay City Capital, Life Sciences Partners and Aglaia Oncology Fund also participated in this financing. Other new investors joining this round are Tekla, Rocksprings, RA Capital and a U.S.-based life sciences-focused investor.

The first tranche of the Class C preferred share financing of €49.7 million (\$55 million) was drawn down on 21 August 2015 and 7,469,780 Class C preferred shares were issued. The convertible bridge loan entered into on 11 June 2015 was repaid by converting the outstanding principal and interest thereon into Class C preferred shares under the terms of the agreement, bringing the net cash inflow to the Company to €41.6 million.

Shares

**Merus B.V.**

Common Shares

**Merus**

---

PRELIMINARY PROSPECTUS

, 2015

---

**Citigroup**

**Jefferies**

**Guggenheim Securities**

**Wedbush PacGrow**

Through and including \_\_\_\_\_, 2015 (25 days after the commencement of this offering), all dealers that buy, sell or trade our common shares, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

---

---

**PART II—INFORMATION NOT REQUIRED IN THE PROSPECTUS**

**Item 6. Indemnification of directors and officers**

Members of our management board and supervisory board have the benefit of the following indemnification provisions in our Articles of Association:

Current and former management board members and supervisory board members shall be reimbursed for:

- (a) any financial losses or damages incurred by such indemnified officer; and
- (b) any expense reasonably paid or incurred by such indemnified officer in connection with any threatened, pending or completed suit, claim, action or legal proceedings, whether civil, criminal, administrative or investigative and whether formal or informal, in which he or she becomes involved, to the extent this relates to his or her position or former position with the Company, in each case to the fullest extent permitted by applicable law.

There shall be no entitlement to reimbursement as referred to above if and to the extent that:

- (a) if a Dutch court has established, without possibility for appeal, that the acts or omissions of such indemnified officer that led to the financial losses, damages, suit, claim, action or legal proceedings as described above results from either an improper performance of his or her duties as an officer of the Company or an unlawful or illegal act; and
- (b) his or her financial losses, damages and expenses are covered by an insurance and the insurer has settled these financial losses, damages and expenses (or has indicated that it would do so).

The underwriting agreement we will enter into in connection with the offering of common shares being registered hereby provides that the underwriters will indemnify, under certain conditions, our management board members and supervisory board members (as well as certain other persons) against certain liabilities arising in connection with this offering.

**Item 7. Recent sales of unregistered securities**

***Class B Investment Agreement***

- On April 27, 2012, the registrant issued 1,082,666 Class B preferred shares to certain investors for aggregate consideration of €8.1 million in cash.
- On September 30, 2013, the registrant issued 1,600,000 Class B preferred shares to certain investors for aggregate consideration of €12.0 million in cash.
- On August 29, 2014, the registrant issued 800,000 Class B preferred shares to certain investors for aggregate consideration of €6.0 million in cash.
- On January 26, 2015, the registrant issued 2,407,224 Class B preferred shares to certain investors for aggregate consideration of €5.0 million in cash.

All of the foregoing issuances were made outside of the United States pursuant to Regulation S or to U.S. entities pursuant to Section 4(a)(2) of the Securities Act.

***Class C Investment Agreement***

On August 21, 2015, the registrant issued 7,469,780 Class C preferred shares to certain investors in exchange for an aggregate consideration of €49.7 million, which includes the conversion of the registrant's existing €8.0 million convertible bridge loan and interest thereon into Class C preferred shares. The foregoing issuance was made outside of the United States pursuant to Regulation S or to U.S. entities pursuant to Section 4(a)(2) of the Securities Act.

## [Table of Contents](#)

### **Option Grants**

The table below summarizes the share options we granted to our management board members, supervisory board members and our employees within the past three years. The grant of the options and the issuance of common shares upon the exercise of options described in the table below were or will be made pursuant to Regulation S under the Securities Act or Section 4(a)(2) of the Securities Act.

<u>Grant Date</u>	<u>Number of underlying options</u>	<u>Exercise price per share</u>
September 4, 2012 (management board members)	25,700	€ 2.58
September 4, 2012 (employees)	52,870	€ 2.58
October 18, 2012 (supervisory board members)	13,125	€ 2.58
June 17, 2013 (employees)	18,890	€ 2.58
June 17, 2014 (management board members)	20,250	€ 2.58
June 17, 2014 (employees)	42,360	€ 2.58
July 17, 2014 (supervisory board members)	27,563	€ 2.58
March 16, 2015 (management board members)	175,688	€ 1.07
March 16, 2015 (employees)	125,330	€ 1.07

### **Item 8. Exhibits**

(a) The following documents are filed as part of this registration statement:

- 1.1\* Form of Underwriting Agreement.
- 3.1\* Articles of Association of the Registrant.
- 3.2\* Form of Deed of Amendment to Articles of Association of the Registrant to be effective prior to the effectiveness of this registration statement.
- 3.3\* Form of Articles of Association of Merus N.V.
- 4.1\* Form of Registration Rights Agreement.
- 5.1\* Opinion of Eversheds B.V., counsel of the Registrant, as to the validity of the common shares.
- 10.1#\* Merus B.V. 2010 Employee Option Plan.
- 10.2#\* Non-Employee Director Compensation Program.
- 10.3#\* Form of Supervisory Board Member and Management Board Member Indemnification Agreement.
- 10.4#\* Employment Agreement between the Registrant and Ton Logtenberg, Chief Executive Officer, dated January 21, 2010.
- 10.5#\* Employment Agreement between the Registrant and Shelley Margetson, Chief Financial Officer, dated October 1, 2010.
- 10.6\* Lease Agreement between the Registrant and The University of Utrecht, dated July 30, 2014.
- 10.7\* Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A., dated December 29, 2005.
- 10.8†\* Contract Research and License Agreement and Addendum between the Registrant and ONO Pharmaceutical Co., Ltd., dated April 8, 2014.
- 21.1\* List of subsidiaries.
- 23.1\* Consent of KPMG Accountants N.V.

## Table of Contents

23.2\* Consent of Eversheds B.V., counsel of the Registrant (included in Exhibit 5.1).

24.1\* Powers of attorney (included on signature page to the registration statement).

---

\* To be filed by amendment.

# Indicates management contract or compensatory plan.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

(b) Financial Statement Schedules

None.

### **Item 9. Undertakings**

- a. The undersigned registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.
- b. Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the U.S. Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer, or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.
- c. The undersigned registrant hereby undertakes that:
  - 1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
  - 2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Utrecht, the Netherlands on \_\_\_\_\_, 2015.

MERUS B.V.

By: \_\_\_\_\_

Name: Ton Logtenberg  
Title: Chief Executive Officer

By: \_\_\_\_\_

Name: Shelley Margetson  
Title: Chief Financial Officer

[Table of Contents](#)

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Ton Logtenberg and Shelley Margetson and each of them, individually, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on \_\_\_\_\_, 2015 in the capacities indicated:

<u>Name</u>	<u>Title</u>
_____ Ton Logtenberg	Chief Executive Officer and Management Board Member (Principal Executive Officer)
_____ Shelley Margetson	Chief Financial Officer and Management Board Member (Principal Financial Officer and Principal Accounting Officer)
_____ Mark Iwicki	Chairman of the Supervisory Board
_____ Wolfgang Berthold	Member of the Supervisory Board
_____ Lionel Carnot	Member of the Supervisory Board
_____ Gabrielle Dallman	Member of the Supervisory Board
_____ John de Koning	Member of the Supervisory Board
_____ Florent Gros	Member of the Supervisory Board
_____ Anand Mehra	Member of the Supervisory Board
_____ Jack Nielsen	Member of the Supervisory Board



**Signature of Authorized U.S. Representative of Registrant**

Pursuant to the requirements of the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Merus B.V. has signed this registration statement on \_\_\_\_\_, 2015.

By: \_\_\_\_\_  
Name:  
Title:

**EXHIBIT INDEX**

The following documents are filed as part of this registration statement:

- 1.1\* Form of Underwriting Agreement.
- 3.1\* Articles of Association of the Registrant.
- 3.2\* Form of Deed of Amendment to Articles of Association of the Registrant to be effective prior to the effectiveness of this registration statement.
- 3.3\* Form of Articles of Association of Merus N.V.
- 4.1\* Form of Registration Rights Agreement.
- 5.1\* Opinion of Eversheds B.V., counsel of the Registrant, as to the validity of the common shares.
- 10.1#\* Merus B.V. 2010 Employee Option Plan.
- 10.2#\* Non-Employee Director Compensation Program.
- 10.3#\* Form of Supervisory Board Member and Management Board Member Indemnification Agreement.
- 10.4#\* Employment Agreement between the Registrant and Ton Logtenberg, Chief Executive Officer, dated January 21, 2010.
- 10.5#\* Employment Agreement between the Registrant and Shelley Margetson, Chief Financial Officer, dated October 1, 2010.
- 10.6\* Lease Agreement between the Registrant and The University of Utrecht, dated July 30, 2014.
- 10.7\* Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A., dated December 29, 2005.
- 10.8†\* Contract Research and License Agreement and Addendum between the Registrant and ONO Pharmaceutical Co., Ltd., dated April 8, 2014.
- 21.1\* List of subsidiaries.
- 23.1\* Consent of KPMG Accountants N.V.
- 23.2\* Consent of Eversheds B.V., counsel of Merus B.V. (included in Exhibit 5.1).
- 24.1\* Powers of attorney (included on signature page to the registration statement).

\* To be filed by amendment.

# Indicates management contract or compensatory plan.

† Confidential treatment requested as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.