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

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**Amendment No. 1**

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

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**Merus N.V.**

(Exact Name of Registrant as Specified in its Charter)

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Not Applicable  
(Translation of Registrant's Name into English)

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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)

Yalelaan 62  
3584 CM Utrecht  
The Netherlands  
+31 30 253 8800

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

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Merus US, Inc.  
One Broadway  
Cambridge, Massachusetts 02142  
+1 781 760 0013

(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. Handrinios  
Latham & Watkins LLP  
200 Clarendon Street  
Boston, Massachusetts 02116  
+1 617 948 6000

Paul van der Bijl  
NautaDutilh N.V.  
Beethovenstraat 400  
1082 PR Amsterdam  
The Netherlands  
+31 20 717 1000

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**Approximate date of commencement of proposed sale to the public:** From time to time after the effective date of this Registration Statement

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.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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**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.**

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**The information in this preliminary prospectus is not complete and may be changed. The selling shareholders 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 APRIL 3, 2019**

**PROSPECTUS**

**Merus** *closing in on cancer*

**6,299,997 Shares**

**Merus N.V.**

**Common Shares**

This prospectus relates to the resale from time to time in one or more offerings by the selling shareholders named herein of up to an aggregate of 6,299,997 of our common shares, nominal value €0.09 per share.

The common shares registered hereby may be offered and sold by the selling shareholders through one or more underwriters, broker-dealers or agents. If the common shares are sold through underwriters or broker-dealers, the selling shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The common shares may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. See "Plan of Distribution."

We are not selling any common shares under this prospectus, and we will not receive any of the proceeds from the offer and sale of common shares by the selling shareholders.

This prospectus describes the general manner in which our common shares may be offered and sold by any selling shareholder. When the selling shareholders sell common shares under this prospectus, we may, if necessary and required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. Any prospectus supplement may also add to, update, modify or replace information contained in this prospectus. We urge you to read carefully this prospectus, and any accompanying prospectus supplement before you make your investment decision.

Our common shares are listed on The Nasdaq Global Market under the symbol "MRUS." On April 2, 2019, the last reported sale price of our common shares on The Nasdaq Global Market was \$13.06 per share.

**Investing in our common shares involves risks. See "[Risk Factors](#)" beginning on page 11 and the documents incorporated by reference into this prospectus concerning factors you should consider before investing in our common shares.**

We are an "emerging growth company" under applicable Securities and Exchange Commission rules and are 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.**

**The date of this prospectus is \_\_\_\_\_, 2019**

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You should rely only on the information contained or incorporated by reference in this prospectus, any prospectus supplement or in any free writing prospectus we may authorize to be delivered or made available to you. We have not and the selling shareholders have not authorized anyone to provide you with different information. The selling shareholders are offering to sell, and seeking offers to buy, our common shares only in jurisdictions where offers and sales are permitted. The information contained in this prospectus is accurate only as of the date of this prospectus and any information incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of common shares.

**For investors outside the United States: Neither we nor the selling shareholders 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.**

This prospectus is a part of a registration statement on Form F-1 that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration or continuous offering process. Under this shelf process, the selling shareholders may from time to time sell the common shares covered by this prospectus. Additionally, under the shelf process, in certain circumstances, we may provide a prospectus supplement that will contain certain specific information about the terms of a particular offering by one or more of the selling shareholders. We may also provide a prospectus supplement to add information to, or update or change information contained in this prospectus. You should read this prospectus before deciding to invest in our common shares. You may obtain this information without charge by following the instructions under “Where You Can Find More Information; Incorporation by Reference” appearing elsewhere in this prospectus.

Under the rules of the SEC, we are currently eligible for treatment as a “foreign private issuer.” As a foreign private issuer, we are not 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.

## PRESENTATION OF FINANCIAL INFORMATION AND CERTAIN DEFINED TERMS

We report under International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or the IASB. None of the financial statements presented or incorporated by reference in this prospectus 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 as issued by the IASB. 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 “€” mean euros, unless otherwise noted. In addition, throughout this prospectus, the U.S. Securities and Exchange Commission is referred to as the “SEC”, the Securities Act of 1933, as amended, is referred to as the “Securities Act” and the Securities Exchange Act of 1934, as amended, is referred to as the “Exchange Act.”

## CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

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

In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions. The forward-looking statements in this prospectus are only predictions. We have based these forward-looking statements largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this prospectus and are subject to a number of risks, uncertainties and assumptions described under the sections in this prospectus titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this prospectus. These forward-looking statements are subject to numerous risks, including, without limitation, the following:

- our operations as a clinical-stage company with a limited operating history and a history of operating losses;
- uncertainty about the initiation, timing, progress and results of clinical trials of our bispecific antibody candidates, including regarding when results of such trials will be made public;
- our expectations related to payments and clinical development under our collaboration agreement with Incyte Corporation, or Incyte;
- our clinical development plans for MCLA-128, MCLA-117, MCLA-158, and MCLA-145 for the treatment of patients with solid tumors with an initial focus on metastatic colorectal cancer;
- research and/or development of preclinical programs being co-developed with Incyte, Simcere Pharmaceutical Group and Betta Pharmaceuticals Co. Ltd., and for other bispecific antibody candidates;
- the timing or likelihood of regulatory filings and approvals for any of our bispecific antibody candidates;

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- our ability to establish sales, marketing and distribution capabilities for any of our bispecific antibody candidates for which we may obtain regulatory approval;
- our ability to establish and maintain manufacturing arrangements for our bispecific antibody candidates;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our bispecific antibody candidates and related technology;
- our ability to defend against any claims by third parties that we are infringing upon their intellectual property rights;
- our estimates regarding expenses, future revenues, capital requirements and our need for additional financing;
- the rate and degree of market acceptance of our bispecific antibody candidates;
- the impact of government laws and regulations on our business;
- our competitive position; and
- other risk factors discussed in this prospectus.

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

## 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 and the documents incorporated by reference in this prospectus carefully, including the “Risk Factors” section and our audited financial statements, including the notes thereto, before deciding to invest in our common shares.*

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. Our pipeline of full-length human bispecific antibody candidates, which we refer to as Biclonics®, are generated from our Biclonics® technology platform, which is able to generate a diverse array of antibody-heavy chains against virtually any target, paired with a common light chain. Two heavy chains paired with a common light chain can be combined to produce novel bispecific antibodies that bind a diverse array of targets and display differentiated biology. By binding to two different targets, Biclonics® can provide a variety of mechanisms of action. For example, Merus Biclonics® can be designed to simultaneously block receptors that drive tumor cell growth and survival and to mobilize the patient’s immune response by engaging T-cells and/or activating various killer cells to eradicate tumors. In our pre-clinical studies, our bispecific antibody candidates killed tumor cells, a result that we believe supports their potential development for the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our most advanced bispecific antibody candidate, MCLA-128, for the treatment of HER2-expressing solid tumors. In January 2018, we dosed the first patient in a Phase 2, open-label, multi-center international clinical trial to evaluate MCLA-128 in two metastatic breast cancer, or MBC, populations including HER2-positive MBC patients and hormone receptor positive/HER2-low MBC patients. MCLA-128 is a full-length IgG bispecific antibody candidate with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 is designed to block the HER3 signaling pathway by employing a DOCK & BLOCK® mechanism. MCLA-128 is designed to “dock” onto a specific region of the HER2 receptor to orientate MCLA-128’s HER3 binding arm to “block” HER2:HER3 heterodimerization. Oncogenic signaling through the HER3 pathway, even in the presence of high heregulin concentrations, may thus be blocked. The Phase 2 clinical trial is designed to observe the activity of this HER2/HER3-targeted candidate in combination with current standards of care in areas of unmet need. The trial is ongoing and is enrolling patients at sites in the United States and Europe. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and non-small cell lung cancer, or NSCLC, is ongoing. We reported interim data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress, or ESMO, in October 2018. As of February 15, 2018, the data showed a clinical benefit rate of 24% (6 of 25 patients), and that MCLA-128 was well tolerated with mainly grade 1/2 adverse events observed in patients treated with MCLA-128 across all indications explored. Single agent antitumor activity was seen in heavily pretreated gastric/gastro-oesophageal junction, or G/GEJ, cancer patients progressing on anti-HER2 therapy.

In May 2016, we commenced a single-arm, open-label, global Phase 1 clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML, and we announced the filing of the Investigational New Drug application, or IND, in the United States for MCLA-117 in 2018 and the subsequent authorization to proceed with clinical studies by the U.S. Food and Drug Administration, or the FDA. AML generally has a poor prognosis and limited progress has been made in disease outcomes despite a growing AML patient population. Clinical and pre-clinical studies suggest that treatment-resistant leukemic stem cells are a potential cause of disease relapse. MCLA-117 is designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of AML tumor cells and stem cells in newly diagnosed and relapsed patients. MCLA-117 is designed to recruit and activate T-cells to kill AML tumor cells and stem cells. In our pre-clinical studies, MCLA-117 killed tumor cells in blood samples

of AML patients. If the results of our Phase 1 clinical trial are favorable, we plan to seek orphan drug designation for MCLA-117 for the treatment of AML from the FDA and the European Medicines Agency, or EMA. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. We also intend to evaluate MCLA-117 for the treatment of myelodysplastic syndrome, or MDS.

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

We also plan to commence a clinical trial for MCLA-145, which is the first product candidate being co-developed under our global research collaboration with Incyte Corporation, or Incyte. Developed through an unbiased functional screening of multiple immunomodulatory target combinations, MCLA-145 is a Biclonics® T-cell agonist that has been observed to bind with high affinity and specificity to human PD-L1 and CD137 in preclinical models. In December 2018, we filed an IND for MCLA-145 with the FDA and in January 2019, we received authorization to proceed from the FDA. In addition, we are developing MCLA-129, which is designed to bind to EGFR and the protein c-MET, for the treatment of solid tumors in collaboration with Betta Pharmaceuticals Co. Ltd., or Betta. EGFR is an important oncogenic driver in many cancers, and the upregulation of c-MET signaling has been associated with resistance to EGFR inhibition.

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

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

## Our Strategy

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

- **Successfully develop our most advanced bispecific antibody candidate, MCLA-128, for the treatment of solid tumors.** We are developing MCLA-128 for the treatment of patients with HER2-expressing and other solid tumors including NSCLC and breast and gastric cancer. We commenced a Phase 1/2 clinical trial of MCLA-128 in Europe in February 2015. In the dose escalation phase of the trial, the recommended dose of MCLA-128 was established. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated MBC patients progressing on HER2 therapies. In January 2018, we commenced a combination Phase 2 clinical trial in the United States for MCLA-128 and we plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and NSCLC is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at ESMO in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients), and that MCLA-128 was well tolerated with mainly grade 1/2 adverse events observed in patients treated with MCLA-128 across all indications explored. Single-agent antitumor activity was seen in heavily pretreated G/GEJ cancer patients progressing on anti-HER2 therapy. We believe that if MCLA-128 is successfully developed and obtains regulatory approval, it has the potential to address disease-specific challenges that are not currently being met by existing therapies.
- **Successfully develop our second most advanced bispecific antibody candidate, MCLA-117, for the treatment of AML.** We are developing MCLA-117 for the treatment of patients with AML. We commenced a Phase 1 clinical trial of MCLA-117 in Europe in May 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity. We filed an IND in the United States in January 2018, for which we obtained authorization to proceed from the FDA in February 2018. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. If the results of this clinical trial are favorable, we plan to seek orphan drug designation from the FDA and the EMA for MCLA-117 for the treatment of AML. We believe that if MCLA-117 is successfully developed and obtains regulatory approval, it has the potential to transform the treatment of AML. We also intend to evaluate MCLA-117 for the treatment of MDS.
- **Successfully develop our third bispecific antibody candidate, MCLA-158, for the treatment of metastatic colorectal cancer and other solid tumors.** We are developing MCLA-158 for the treatment of solid tumors with an initial focus on the treatment of metastatic colorectal cancer. MCLA-158 has received approval of a CTA in several European countries for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018, for which we received authorization to proceed from the FDA in April 2018. In May 2018, we commenced an open-label, multicenter, Phase 1 clinical trial of MCLA-158. Emerging data for our Phase 1 trial is expected at the end of 2019. MCLA-158 is an investigational, ADCC-enhanced Biclomics® designed to bind to cancer stem cells expressing Lgr5 and EGFR. We believe that if MCLA-158 is successfully developed and obtains regulatory approval, it has the potential to address and transform the treatment of metastatic colorectal cancer and other solid tumors.
- **Successfully develop our fourth bispecific antibody candidate, MCLA-145, for the treatment of solid tumors.** We plan to commence a clinical trial for MCLA-145 for the treatment of solid tumors in the first half of 2019. We filed an IND for MCLA-145 with the FDA in December 2018, which received authorization to proceed from the FDA in January 2019. MCLA-145, which is being developed in

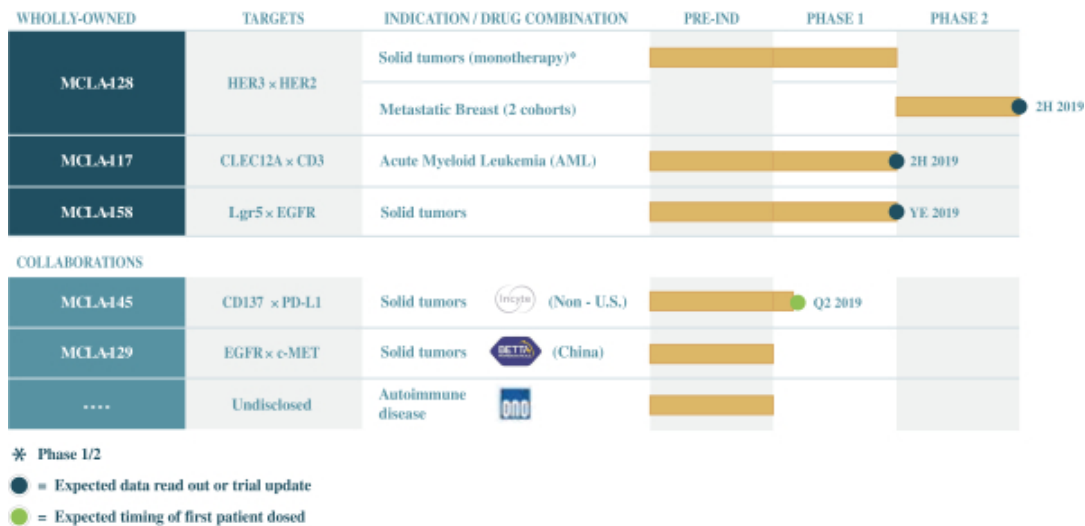


collaboration with Incyte and is designed to bind to PD-L1 and CD137, was developed through an unbiased functional screening of multiple immunomodulatory target combinations and is a Biclomics® T-cell agonist that has been observed to bind with high affinity and specificity to human PD-L1 and CD137 in preclinical models. We believe that the unique immunostimulatory profile of MCLA-145 derives from its ability to potently activate immune effector cells in the context of the tumor microenvironment while simultaneously blocking inhibitory signals in the same immune cell population.

- **Accelerate the internal discovery and development of additional immunotherapeutic antibody candidates.** We believe we are well positioned to expand our pipeline of Biclomics® for the treatment of other forms of cancer. Our platform employs our proprietary common light chain transgenic MeMo® for the production of diverse human heavy chains that can be paired to generate bispecific antibodies, coupled with our Spleen to Screen™ technology that is designed to allow us to rapidly identify and generate Biclomics® therapeutic candidates with differentiated modes of action that have the potential to kill tumor cells with high potency. We are conducting preclinical studies of an array of candidates for our internal proprietary pipeline as well as in collaboration with Incyte.
- **Seek strategic collaborative relationships.** We intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Biclomics® technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We have entered into collaborations with Incyte, ONO Pharmaceutical Co., Ltd., Sincere Pharmaceutical Group and Betta to develop bispecific antibody candidates based on our Biclomics® technology platform and plan to work with other collaborators to validate and expand the use of our Biclomics® platform and the development of bispecific antibody candidates. We believe these collaborations could potentially provide significant funding to advance our bispecific antibody candidate pipeline while allowing us to benefit from the development expertise of our collaborators.

**Our Product Pipeline**

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



### **Corporate Information**

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

### **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, any prospectus supplement and any documents incorporated by reference into 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 common shares. 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 early in our development efforts and our bispecific antibody candidates 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 rely on our collaboration agreements with third parties for the development of certain of our bispecific antibody candidates, and if those third parties fail to perform or if those agreements are terminated, the development and commercialization of such bispecific antibody candidates would be delayed or terminated.
- 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 ability to compete may be adversely affected if we are unsuccessful in defending against claims that we are infringing on our competitors' intellectual property rights.

- 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, like us, 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:

- we are not 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, 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 shareholder 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 closing of the initial public offering of our common shares or such earlier time that we no longer qualify as 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 have chosen to irrevocably opt out of this extended transition period and as a result, we 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 \$1.07 billion; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of the initial public offering of our common shares; (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.

We 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 the selling shareholders	6,299,997 common shares
Common shares issued and outstanding	23,358,977 common shares
Use of proceeds	The selling shareholders will receive the proceeds from the sale of common shares in this offering. We will not receive any proceeds from the sale of the common shares but will pay the expenses (other than any underwriting discounts and broker's commissions and similar expense) of this offering.
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	Our common shares are listed on The Nasdaq Global Market under the symbol "MRUS."

The number of our common shares issued and outstanding is based on 23,358,977 common shares outstanding as of December 31, 2018 and excludes the following:

- 2,633,039 common shares issuable upon the exercise of share options outstanding as of December 31, 2018 at a weighted average exercise price of €14.62 per share;
- 101,302 common shares issuable upon the vesting of restricted share units outstanding as of December 31, 2018; and
- 535,426 common shares reserved for future issuance under our 2016 Incentive Award Plan.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise of the outstanding options and no vesting of the restricted share units described above after December 31, 2018.

## 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 €24.2 million, €64.7 million, and €47.4 million for the years ended December 31, 2018, 2017 and 2016, respectively.

As of December 31, 2018, we had an accumulated loss of €175.1 million. Our losses have resulted principally from expenses incurred in research and development of our bispecific antibody candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our bispecific antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing Phase 2 clinical trial of MCLA-128, our most advanced bispecific antibody candidate, for the treatment of metastatic breast cancer in combination with other therapies and our ongoing, single agent, Phase 1/2 clinical trial for the treatment of gastric and non-small cell lung cancers;
- conduct our ongoing Phase 1 clinical trial of MCLA-117, our second most advanced bispecific antibody candidate, for the treatment of acute myeloid leukemia;
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors with an initial focus on colorectal cancer;
- commence clinical trials for MCLA-145 for the treatment of solid tumors, which is being co-developed with Incyte Corporation, or Incyte;
- continue the research and development of our other bispecific antibody candidates, including the development of MCLA-129 in collaboration with Betta Pharmaceuticals Co. Ltd.;
- expand the clinical programs to explore new potential combination therapies or indications;
- seek to enhance our technology platform, which generates our pipeline of product candidates, and discover and develop additional antibody candidates;
- seek regulatory approvals for any antibody candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approvals;
- maintain, expand and protect our intellectual property portfolio;
- secure, maintain and/or obtain freedom to operate for our technologies and products;
- add clinical, scientific, operational, financial, information technology and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operation as a public company; and

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- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

We have financed our operations primarily through public offerings and private placements of our common shares and our collaboration and license agreement with Incyte. We have devoted a significant portion of our financial resources and efforts to developing our full-length human bispecific antibody therapeutics, which we refer to as Biclomics<sup>®</sup>, our technology platform, identifying potential bispecific antibody candidates, conducting pre-clinical studies of a variety of candidates, conducting our clinical trials of MCLA-128, MCLA-117 and MCLA-158, and preparing to commence clinical study of MCLA-145. We are in the early stages of development of our bispecific antibody candidates, and we have not completed development of any Biclomics<sup>®</sup> or any other drugs or biologics.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our bispecific antibody candidates, discovering and developing additional antibody candidates, obtaining regulatory approval for any bispecific antibody candidates that successfully complete clinical trials, establishing manufacturing and marketing capabilities and ultimately selling any products for which we may obtain regulatory approval. We are only in the preliminary stages of most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of MCLA-128, MCLA-117, and MCLA-158 and commence the clinical study of MCLA-145 and continue to research, develop and conduct pre-clinical studies of our other antibody candidates. In addition, if we obtain regulatory approval for any of our bispecific antibody candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. Furthermore, we continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our research and development programs or any future commercialization efforts.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2018 will be sufficient to fund our operations into the second quarter of 2021. We have based this

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estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost, progress and results of our ongoing clinical trials of MCLA-128 and the Phase 1 clinical trials of MCLA-117 and MCLA-158;
- the success of our collaboration with Incyte to develop bispecific antibodies candidates, including the expected commencement of a clinical trial for MCLA-145;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our antibody candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any potential future claims by third parties that we are infringing upon their intellectual property rights;
- the costs and timing of securing, maintaining and/or obtaining freedom to operate for our technologies and products;
- the revenue, if any, received from commercial sales of our bispecific antibody candidates for which we receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including our collaboration with Incyte and any other licensing or collaboration arrangements for any of our bispecific antibody candidates.

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

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

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



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- for the bispecific antibody candidates to which we retain rights, completion of pre-clinical studies and clinical trials of, receipt of marketing approvals for, establishment of commercial manufacturing supplies of and successful commercialization of such bispecific antibody candidates; and
- for all of our bispecific antibody candidates, if and when approved, acceptance of our bispecific antibody candidates by patients, the medical community and third-party payors, effectively competing with other therapies, a continued acceptable safety profile following approval and qualifying for, maintaining, enforcing and defending our intellectual property rights and claims.

If we or our collaborators, as applicable, do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our bispecific antibody candidates, which would materially adversely affect our business, financial condition and results of operations.

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

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

### ***The Biclonics® technology platform is an unproven, novel approach to the production of molecules for therapeutic intervention.***

We have not received regulatory approval for a therapeutic based on a full-length human bispecific IgG approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Biclonics® may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA, the EMA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on Biclonics® 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 Biclonics® technology platform relies on third parties for biological materials. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or product candidates.

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

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the bispecific antibody candidates we are developing. Through collaborations, we may develop

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

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

Since our inception in 2003, we have devoted a significant portion of our resources to developing MCLA-128, MCLA-117, MCLA-158, MCLA-145 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for MCLA-128, MCLA-117 and MCLA-158, and expect to commence a clinical trial for MCLA-145 in the first half of 2019, we have not completed any clinical trials for any bispecific antibody candidate. We have not yet demonstrated our ability to successfully complete any Phase 2 clinical trial or any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through equity or debt financings and upfront and milestone payments, if any, received under our collaboration with Incyte and any other future licenses or collaborations, together with our existing cash and cash equivalents. In order to accomplish our business objectives and further develop our product pipeline, we will, however, need to seek additional funds. If we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common shares. In addition, the possibility of such issuance may cause the market price of our common shares to decline. Debt financing, if available, may result in increased fixed payment obligations and involve agreements that include covenants limiting or restricting our ability to take specific

actions, such as incurring additional debt, making capital expenditures, declaring dividends, or acquiring, selling or licensing intellectual property rights, which could adversely impact our ability to conduct our business.

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

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our bispecific antibody candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our bispecific antibody candidates, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

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

- economic weakness, including inflation, or political instability, in particular, in non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining and/or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with international privacy regulations, including the General Data Protection Regulation, or the GDPR, that went into effect in 2018;
- negative consequences from Brexit, and its potential impact on supply-chain and our personnel;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

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- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators that would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, health care, employment, foreign corrupt practices, trade restrictions and sanctions, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our ability to conduct business, operating results, and reputation.

We are subject to a number of anti-corruption laws, including the Foreign Corrupt Practices Act, or FCPA, in the United States, the Bribery Act in the United Kingdom and the anti-corruption provisions of the Dutch Criminal Code in the Netherlands. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of improperly or corruptly obtaining or keeping business, obtaining preferential treatment and/or other undue benefits or advantages. The FCPA also requires public companies to maintain accurate books and records and devise a system of sufficient internal accounting controls. We regularly review and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, distributors and other intermediaries comply with the anti-corruption laws to which we are subject. However, there are inherent limitations to the effectiveness of any policies, procedures and internal controls, including the possibility of human error and the circumvention or overriding of the policies, procedures

and internal controls. There can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, distributors and other intermediaries with respect to our business.

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

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

*All of our bispecific antibody candidates are in pre-clinical or early-stage clinical development. Clinical drug development is a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical trials of our bispecific antibody candidates, particularly MCLA-128, MCLA-117 or MCLA-158, and the commencement of our clinical trial for MCLA-145, which we are developing with Incyte, are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our bispecific antibody candidates on a timely basis or at all.*

To obtain the requisite regulatory approvals to market and sell any of our bispecific antibody candidates, we or any collaborator for such candidates must demonstrate through extensive pre-clinical studies and clinical trials that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early-stage clinical trials of our bispecific antibody candidates may not be predictive of the results of later-stage clinical trials. Bispecific antibody candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

To date, we have not completed any clinical trials required for the approval of any of our bispecific antibody candidates. Although we are conducting ongoing clinical trials for MCLA-128, MCLA-117 and MCLA-158, plan to commence a clinical trial for MCLA-145 in the first half of 2019, and are conducting pre-clinical studies for other bispecific antibody candidates, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to reach agreement on acceptable terms with prospective 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 recruit suitable patients to participate in a trial;
- 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;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;

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- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or Health Authorities, as applicable, to suspend or terminate a trial if we or our collaborators or Health Authorities, find that the participants are being exposed to unacceptable health risks;
- delays in or failure to obtain regulatory approval to commence a trial;
- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or applicable law, or to meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of bispecific antibody candidate for use in clinical trials;
- the quality or stability of a bispecific antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our bispecific antibody candidates no longer relevant;
- third party actions claiming infringement by our bispecific antibody candidates in clinical trials outside of the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, the Competent Authorities of the EEA Member States (the 28 EU Member States plus Iceland, Liechtenstein and Norway) or other regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EEA Competent Authorities or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience delays in the completion of, or termination of, any clinical trial of our bispecific antibody candidates, the commercial prospects of our bispecific antibody candidates will be harmed, and our ability to generate product revenues from any of these bispecific antibody candidates will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our bispecific antibody candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Significant clinical trial delays could also allow our competitors to bring products to market before we do or shorten any periods during which we have the exclusive right to commercialize our bispecific antibody candidates and impair our ability to commercialize our bispecific antibody candidates and may harm our business and results of operations.

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

Clinical trials must be conducted in accordance with the FDA, the EU and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our bispecific antibody candidates produced under current good

manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the EU and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

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

Undesirable side effects that may be caused by our bispecific antibody candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign authorities. In February 2015, we commenced a Phase 1/2 clinical trial in Europe of our most advanced bispecific antibody candidate, MCLA-128, for the treatment of various solid tumors. Additionally, in January 2018 we commenced a Phase 2 clinical trial in Europe and the United States exploring MCLA-128, in combination with other agents, in patients with metastatic breast cancer. To date, patients treated with MCLA-128 have experienced adverse reactions that may be related to the treatment, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. In May 2016, we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-117. To date, patients treated with MCLA-117 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors with an initial focus on colorectal cancer. To date, patients treated with MCLA-158 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA, the EMA, EEA Competent Authorities, or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our bispecific antibody candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if any of our bispecific antibody candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

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

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- we may be subject to limitations on how we may promote the product;
- sales of the product may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

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

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

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

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

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For the MCLA-128 Phase 2 clinical trial, we plan to enroll approximately 120 patients with metastatic breast cancer in the United States and Europe. In the Phase 1 clinical trial of MCLA-117, we plan to enroll approximately 50 adult patients with AML. In the Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with colorectal cancer and possibly other solid tumors. In the planned Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

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

Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to



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complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our bispecific antibody candidates will increase our costs, slow down our bispecific antibody candidate development and approval process, delay or potentially jeopardize our ability to commence product sales and generate revenue and harm our reputation and ability to obtain financing. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our bispecific antibody candidates.

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

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

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

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

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

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

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

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

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a bispecific antibody candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that a bispecific antibody candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our bispecific antibody candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA, the EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, the EMA or comparable foreign regulatory authorities may fail to approve the companion diagnostics we contemplate developing with collaborators; and
- the approval policies or regulations of the FDA, the EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process as well as the unpredictability of future clinical trial results may result in our failing to obtain regulatory approval to market any of our bispecific antibody candidates, which would significantly harm our business, results of operations and prospects. The FDA, the EMA and other regulatory authorities have substantial discretion in the approval process, and determining when or whether regulatory approval will be obtained for any of our bispecific antibody candidates. Even if we believe the data collected from clinical trials of our bispecific antibody candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

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

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

If the FDA, the EMA or a comparable foreign regulatory authority approves any of our bispecific antibody candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs for any clinical trials that we

conduct post-approval, all of which may result in significant expense and limit our ability to commercialize such products. In addition, any regulatory approvals that we receive for our bispecific antibody candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the bispecific antibody candidate.

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

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

A key element of our strategy is to use and expand our Bionics® technology platform to build a pipeline of antibody candidates and progress these antibody candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of bispecific antibody candidates directed at various cancers, we may not be able to develop bispecific antibody candidates that are safe and effective. Even if we are successful in continuing to build our pipeline, the potential antibody candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize antibody candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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

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

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

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

***Because we are subject to environmental, health and safety laws and regulations, we may become exposed to liability and substantial expenses in connection with environmental compliance or remediation activities which may adversely affect our business and financial condition.***

Our operations, including our research, development, testing and manufacturing activities, are subject to numerous environmental, health and safety laws and regulations. These laws and regulations govern, among other things, the controlled use, handling, release and disposal of, and the maintenance of a registry for, hazardous materials and biological materials, such as chemical solvents, human cells, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

As with other companies engaged in activities similar to ours, we face a risk of environmental liability inherent in our current and historical activities, including liability relating to releases of or exposure to hazardous or biological materials. Environmental, health and safety laws and regulations are becoming more stringent. We may be required to incur substantial expenses in connection with future environmental compliance or remediation activities, in which case, our production and development efforts may be interrupted or delayed and our financial condition and results of operations may be materially adversely affected.

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaborators may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, the EMA and other regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could

result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, other sanctions, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

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

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

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

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

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

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- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

We expect that the current presidential administration and U.S. Congress may continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. There have also been judicial challenges to certain aspects of the ACA. For example, on December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. While the current presidential administration and the Centers for Medicare & Medicaid Services, or CMS, have both stated that the ruling will have no immediate effect, it is unclear how this decision and subsequent appeals, if any, will impact the law. We cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our customers and accordingly, our financial operations.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS began paying for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act, or Cures Act, changed the reimbursement methodology for infusion drugs and biologics furnished through durable medical equipment in an attempt to remedy over- and underpayment of certain products. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our bispecific antibody candidates or additional pricing pressures.

Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or

patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our products or put pressure on our product pricing, which could negatively affect our business, results of operations, financial condition and prospects.

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

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

Finally, policies of the individual government agencies, including the FDA or similar regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. For example, in December 2016, the Cures Act was signed into law and, among other things, is intended to modernize the regulation of drugs and biologics and spur innovation. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our bispecific antibody candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

The ability of the FDA to review and approve or clear new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs, biologics and medical devices to be reviewed and/or approved or cleared by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, and as amended again by the Final HIPAA



Omnibus Rule, Modifications to the HIPAA Privacy, Security, Enforcement and Breach Notification Rules Under HITECH and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules, published in January 2013, which imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities subject to the rule, such as health plans, healthcare clearinghouses and healthcare providers as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;

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

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

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

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act. Any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

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

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer "adequate" protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU model clauses. In addition, the U.S. Privacy Shield is under review by the European Commission. As such, it is uncertain whether the Privacy Shield framework and/or model clauses will be invalidated in the near future. Further, the United Kingdom's decision to leave the EU has created uncertainty with regard to the status of the UK as an "adequate country" for the purposes of data transfers outside the European Economic Area. In particular, it is unclear how data transfers to and from the UK will be regulated. These changes could require us to make operational changes and could increase costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business. See "Business—Privacy and Data Protection Laws in Europe."

We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

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

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

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

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

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

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

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

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

***If we fail to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our products, our competitors may sell products to treat the same conditions and our revenue will be reduced.***

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient

population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the EU, the EMA's Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the EU would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

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

We plan to seek orphan drug designation from the FDA and the EMA for our assets in clinical development, including MCLA-128, MCLA-117 and other clinical assets, where supported by data in the appropriate indications that meet the criteria for orphan status. Even if we are able to obtain orphan designation in the United States and/or the EU, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA or the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation, when appropriate, we may not receive such designation.

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

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our bispecific antibody candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaborators to invest in the development of our bispecific antibody candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be

adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our bispecific antibody candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our bispecific antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our bispecific antibody candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our bispecific antibody candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our bispecific antibody candidates.

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

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

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

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

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

- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- availability of adequate coverage, reimbursement and adequate payment from health maintenance organizations and other insurers, both public and private; and
- other potential advantages over alternative treatment methods.

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

***We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, or if we fail to achieve adequate pricing and/or reimbursement we will not be successful in commercializing our bispecific antibody candidates.***

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

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

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

We have never commercialized a bispecific antibody candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for the bispecific antibody candidates, which we may license to others, we will rely on the assistance and guidance of those collaborators. For bispecific antibody candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party.

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

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

The Patient Protection and Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our bispecific antibody candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2005.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our clinical candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It

is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

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

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our pre-clinical studies and clinical trials and to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with good clinical practice, or GCP, requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign regulatory authorities for all of our products in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our bispecific antibody candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our bispecific antibody candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any bispecific antibody candidates that we develop. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

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

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

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which



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

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

The Collaboration Agreement may be terminated:

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

If the Collaboration Agreement is terminated with respect to one or more programs, all rights in the terminated programs revert to us, subject to payment to Incyte of a reverse royalty of between 0% and 4% on sales of future products, depending on the stage of development as of the date of termination, if we elect to pursue development and commercialization of bispecific antibody products arising from the terminated programs.

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

Under the Collaboration Agreement, with the exception of MCLA-145 where we retain full US rights, we are dependent upon Incyte to successfully develop and commercialize bispecific antibody candidates that are identified for further development under the Collaboration Agreement. With the exception of those programs where we retain certain co-development rights, we have limited ability to influence or control Incyte's development and commercialization activities or the resources it allocates to development of bispecific antibody product candidates identified under the Collaboration Agreement. Our interests and Incyte's interests may differ or conflict from time to time, or we may disagree with Incyte's level of effort or resource allocation. Incyte may internally prioritize programs under development within the collaboration differently than we would, or it may not allocate sufficient resources to effectively or optimally develop or commercialize bispecific antibody candidates arising from such programs. If these events were to occur, our ability to receive revenue from the commercialization of products arising from such programs would be reduced, and our business would be adversely affected.

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

Our product development programs and the potential commercialization of our bispecific antibody candidates will require substantial additional cash to fund expenses. Therefore, for some of our bispecific antibody candidates, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those bispecific antibody candidates. For instance, we have license and collaboration agreements with ONO, Incyte, Simcere Pharmaceutical Group and Betta Pharmaceuticals Co. Ltd. which we have licensed the development and commercialization of certain of our bispecific antibody candidates.

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

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

***We currently rely on third-party suppliers and other third parties for production of our bispecific antibody candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our bispecific antibody candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved bispecific antibody candidate and our commercialization of any of our bispecific antibody candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable regulatory authorities, fail to provide us with sufficient quantities of bispecific antibody product or fail to do so at acceptable quality levels or prices or fail to otherwise complete their duties in compliance with their obligations to us or other parties.***

We rely on and expect to continue to rely on third-party contract manufacturing organizations, or CMOs, for the supply of current good manufacturing practice-grade, or cGMP-grade, clinical trial materials and commercial quantities of our bispecific antibody candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture bispecific antibody candidates ourselves. The facilities used by our contract manufacturers to manufacture our bispecific antibody candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our

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CMOs for compliance with cGMP for the manufacture of our bispecific antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our bispecific antibody candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our bispecific antibody candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our bispecific antibody candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our bispecific antibody candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, there is no guarantee that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

We rely on our CMOs to purchase from third-party suppliers the materials necessary to produce our bispecific antibody candidates for our clinical trials, and will rely on our existing and future collaborators to purchase from third-party suppliers the materials necessary to develop and produce our bispecific antibody candidates for future clinical trials. There are a limited number of suppliers for raw materials that we use to manufacture our drugs and there may be a need to assess alternate suppliers to prevent a possible disruption of the manufacture of the materials necessary to produce our bispecific antibody candidates for our clinical trials, and if approved, ultimately for commercial sale. We do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers or manufacturers paid by our collaborators. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of a bispecific antibody candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of a bispecific antibody candidate, or the raw material components thereof, for a planned or an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our bispecific antibody candidates. If our manufacturers, collaborators or we are unable to purchase these raw materials after regulatory approval has been obtained for our bispecific antibody candidates, the commercial launch of our bispecific antibody candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of our bispecific antibody candidates.

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

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

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

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our Biclomics® technology platform, our bispecific antibody and antibody candidates, products, their format and methods used to produce, screen, manufacture and purify those antibody and antibody candidates, the methods for treating patients using those candidates, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and bispecific antibody candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue and even if such patents cover our Biclomics® technology platform, bispecific antibody candidates, and other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, interpartes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our technology, including a bispecific antibody candidate. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs.

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

To protect our competitive position, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being enjoined, required to pay us any license fees,

or compensate us for lost profits. In addition, litigation involving our patents carries the risk that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize our product candidates or methods, or our Biclomics® technology platform, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering our Biclomics® technology platform, one of our products or methods, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of utility, novelty, obviousness, non-enablement or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the U.S. Patent and Trademark Office or Patent Office, or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the Patent Office. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our technologies, products, methods or certain aspects of our Biclomics® technology platform. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our technology, methods or product candidates or elements thereof, our manufacture or uses relevant to our development plans, our bispecific antibody candidates, or other attributes of our bispecific antibody candidates or our Biclomics® technology platform. In such cases, we may not be in a position to develop or commercialize products or bispecific antibody candidates unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. In addition, we are aware of issued patents and/or pending patent applications held by third parties that may be alleged as covering some of our bispecific antibody candidates. We believe that if such patents or patent applications (if issued as currently pending) were asserted against us, we would have counterclaims and defenses against such claims, including non-infringement, the affirmative defense of safe harbor designed to protect activity undertaken to obtain federal regulatory approval of a drug, including under 35 U.S.C. § 271(e) and similar foreign exceptions to infringement, patent invalidity and/or unenforceability. However, if such counterclaims and defenses were not successful and such patents were successfully asserted against us such that they are found to be valid and enforceable, and infringed by our bispecific antibody candidates, unless we obtain a license to such patents, which may not be available on commercially reasonable terms or at all, we could be prevented from continuing to develop or commercialize our products. We could also be required to pay substantial damages. Similarly, the targets of our bispecific antibody candidates have also been the subject of research by many companies, which have filed patent applications or have patents related to such targets and their uses. There can be no assurance any such patents will not be asserted against us or that we will not need to seek licenses from such third parties. We may not be able to secure such licenses on acceptable terms, if at all, and any such litigation would be costly and time-consuming.

It is also possible that we failed to identify relevant patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the

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United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, product candidates or the use of our product candidates.

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

If we fail in any such dispute, in addition to being forced to pay damages, we or our licensees may be temporarily or permanently prohibited from commercializing any of our bispecific antibody candidates that are held to be infringing. We might, if possible, also be forced to redesign bispecific antibody candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

In addition, if the breadth or strength of protection provided by our or our present or future licensors', collaborators' or partners' patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future bispecific antibody candidates. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

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

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

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

- stop selling, incorporating, manufacturing or using our products in the United States and/or other jurisdictions that are covered by the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;

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- redesign those technologies, products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

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

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

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

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings and the legal costs associated with them, could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

We currently have rights to the intellectual property, including patent applications relating to our bispecific antibody candidates. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our bispecific antibody candidates may require specific formulations to work effectively and efficiently and the rights to these formulations may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we identify as necessary for our bispecific antibody candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

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

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to

make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a bispecific antibody candidate or program, we may have to abandon development of that bispecific antibody candidate or program and our business and financial condition could suffer.

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

Our registered or unregistered trademarks, trade names or service marks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks, trade names, and service marks, which we need to build name recognition by potential collaborators, partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names and service marks then we may not be able to compete effectively and our business may be adversely affected. If other entities use trademarks, trade names or service marks similar to ours in different jurisdictions, or have senior rights to ours, it could interfere with our use of our current trademarks, trade names or service marks throughout the world.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our bispecific antibody candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications. Given the amount of time required for the development, testing and regulatory review of new bispecific antibody candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, causing our revenue from applicable products to be reduced, possibly materially, and potentially harming our ability to recover our investment in such product or obtain a reasonable return on that investment.

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

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

We generally file our first patent application (*i.e.*, priority filing) at the EPO or the United States Patent and Trademark Office. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may



be filed in additional jurisdictions where we believe our bispecific antibody candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same bispecific antibody candidate and/or technology.

Competitors may use our and our existing or future licensors', collaborators' or partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we and our existing or future licensors, collaborators or partners have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our bispecific antibody candidates, and our and our existing or future licensors', collaborators' or partners' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

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

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business, or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make compounds that are the same as or similar to our bispecific antibody candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.
- the patents of third parties may have an adverse effect on our business.
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions.
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- it is possible that our pending patent applications will not lead to issued patents.
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.

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- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license.
- we may not develop additional technologies that are patentable.

### ***Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our products.***

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

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

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

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

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

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

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, collaborators and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors, collaborators and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information or we may be unaware of such disclosure to enforce our confidentiality agreements. Enforcing a claim that a third party obtained illegally and is using trade secrets and/or confidential know-how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Furthermore, if a competitor lawfully obtained or independently developed any of our trade secrets, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating the trade secret.

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

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

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

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

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

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly

legalize and submit formal documents. If we or our existing or future licensors or collaborators fail to maintain the patents and patent applications covering our bispecific antibody candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

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

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

Despite the implementation of security measures, our computer systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, including in the hiring of information technology personnel, and improvements to IT infrastructure and controls, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to regulatory actions taken by governmental authorities, litigation under laws that protect the privacy of personal information, or other forms of legal proceedings, which could result in significant liabilities or penalties. Further, a cybersecurity incident may disrupt our business or damage our reputation, which could have a material adverse effect on our business, prospects, operating results, share price and shareholder value, and financial condition. We could also incur substantial remediation costs, including the costs of investigating the incident, repairing or replacing damaged systems, restoring normal business operations, implementing increased cybersecurity protections, and paying increased insurance premiums.

**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

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related technologies. These key management individuals include the members of our board of directors. For example, our founder and President, Chief Executive Officer and Principal Financial Officer, Ton Logtenberg, holds a Ph.D. in medical biology, was a professor in the Department of Immunology at Utrecht University and co-founded the Dutch biotechnology company, Crucell N.V.

The loss of key managers and senior scientists could delay our research and development activities. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement business strategy, which could have a material adverse effect on our business.

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

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

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

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

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

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

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from

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readily selling their common shares and may otherwise negatively affect the liquidity of our common shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

As a public company, and particularly after we no longer qualify as an emerging growth company, we will continue to incur significant legal, accounting and other expenses related to our operation as a public company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of 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 Board of Directors and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 20-F. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources and have engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to maintain effective internal control over financial reporting as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

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

In its review of our internal control over financial reporting in connection with the annual audit for 2017, management identified a material weakness associated with a lack of adequate cut-off procedures to ensure the timely recognition, measurement and classification of operating expenses and recording of certain period-end accruals. Specifically, we did not design and maintain effective internal control over the assessment of the

accounting for significant contractual arrangements related to our clinical research and manufacturing agreements and the classification of operating expenses. Management also concluded that two material weaknesses identified for the year ended December 31, 2016 were unremediated as of December 31, 2017. Specifically, we had insufficient accounting resources to fulfill IFRS and SEC reporting requirements and an absence of comprehensive IFRS accounting policies and financial reporting procedures. To remediate these material weaknesses, we (i) redesigned specific processes and controls associated with review of contractual agreements, including to assure proper clinical research and manufacturing expense cut-off, including a quarterly identification and review of significant agreements with our management team to ensure that the relevant accounting implications are identified and considered, (ii) redesigned our controls over proper classification and recognition of operating expenses, including the related balance sheet accounts, (iii) hired several new, experienced personnel in our financial reporting organization and engaged several experienced consultants to further assist our financial reporting organization, (iv) enhanced our documentation of IFRS accounting policies and SEC financial reporting procedures and (v) increased the oversight and review procedures related to our financial close and reporting processes. As of December 31, 2018, our management concluded that these material weaknesses had been remediated and that our internal control over financial reporting was effective as of December 31, 2018.

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

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

As of December 31, 2018, members of our senior management, our board of directors and shareholders affiliated with members of our board of directors, in the aggregate, beneficially owned approximately 19% of our common shares. Depending on the level of attendance at our general meetings of shareholders, these shareholders may be in a position to determine the outcome of decisions taken at any such general meeting. Any shareholder or group of shareholders controlling more than 50% of the share capital present and voting at our general meetings of shareholders may control any shareholder resolution requiring a simple majority, including the appointment of board members, certain decisions relating to our capital structure, the approval of certain significant corporate transactions and amendments to our articles of association. Among other consequences, this concentration of ownership may have the effect of delaying or preventing a change in control and might therefore negatively affect the market price of our common shares.

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

We have entered into a registration rights agreement pursuant to which we agreed, under certain circumstances, to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. In addition, we have registered and intend to continue to register all common shares that we may issue under our equity compensation plans. Once registered,

these common shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates who hold such shares. In addition, in connection with entering into the Collaboration Agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which we issued and sold to Incyte 3,200,000 of our common shares. Incyte's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. In addition, in connection with entering into a settlement agreement with Regeneron Pharmaceuticals, we entered into a Share Subscription Agreement with Regeneron, pursuant to which we issued and sold to Regeneron 600,000 of our common shares. Regeneron's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. However, future sales of a substantial number of our common shares, or the perception that such sales will occur, could cause a decline in the market price of our common shares.

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

Provisions of our articles of association may make it more difficult for a third party to acquire control of us or effect a change in our board of directors. These provisions include:

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

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

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

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



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

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

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

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

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

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

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

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

the rights of our shareholders may be affected and our shareholders may not have the same level of protection as a shareholder in another Dutch public company with limited liability (*naamloze vennootschap*) listed in the Netherlands that fully complies with the DCGC.

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

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

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

We report under the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers. However, we are subject to Dutch laws and regulations with regard to such matters and voluntarily furnish quarterly unaudited financial information to the SEC on Form 6-K.

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

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

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

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

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

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an "emerging growth company," we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "emerging growth companies," including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a

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nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an “emerging growth company,” we are not required to report selected financial data for periods prior to the earliest audited financial statements presented in the registration statement for the initial public offering of our common shares. As a result, we only have to present selected financial data for periods starting with the year ended December 31, 2014. Public companies that are not emerging growth companies must present selected financial data for a five-year period. We may take advantage of these exemptions until we are no longer an “emerging growth company.” We could be an “emerging growth company” for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds \$700 million as of the end of our second fiscal quarter, in which case we would no longer be an “emerging growth company” as of the fiscal year-end. We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

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

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

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

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not believe we were a “passive foreign investment company,” or PFIC, for our taxable year ended December 31, 2018. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise. It is possible the Internal Revenue Service could disagree with our position that we were not a PFIC in 2018. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined in the section of this prospectus entitled “Material Tax Considerations”) holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See “Certain Material Tax Considerations for U.S. Holders—Passive Foreign Investment Company Rules.”

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

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such U.S. Holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any). If our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations (regardless of whether we are treated as a controlled foreign corporation). A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income its pro rata share of “Subpart F income,” “global intangible low-taxed income” and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign

tax credits that would be allowed to a United States shareholder that is a U.S. corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may prevent the statute of limitations from starting with respect to such United States shareholder's U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether any of our non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares.

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

On December 22, 2017, the U.S. government enacted comprehensive tax legislation that includes significant changes to the taxation of business entities, known as the Tax Cuts and Jobs Act, or TCJA. These changes include, among others, a permanent reduction to the corporate income tax rate, limiting interest deductions and the use of net operating losses, adopting elements of a territorial tax system and introducing certain anti-base erosion provisions. We continue to examine the impact the TCJA may have on our business. The effect of the TCJA on our business, whether adverse or favorable, is uncertain, and may not become evident for some period of time. U.S. Holders should consult their legal and tax advisors regarding the TCJA and the potential tax consequences of investing in our common shares.

## **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, Biclomics 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.

## USE OF PROCEEDS

We will not receive any of the proceeds from the sale of our common shares in this offering. The selling shareholders will receive all of the proceeds from this offering.

The selling shareholders will pay any underwriting discounts, selling commissions and share transfer taxes or any other expenses incurred by the selling shareholders in connection with the sale of the shares. We will bear all other costs, fees and expenses incurred in effecting the registration of the shares covered by this prospectus, including, without limitation, all registration and filing fees, fees and expenses of our counsel and our independent registered public accountants.

## 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, as a Dutch public company with limited liability (*naamloze vennootschap*), we may only pay dividends to the extent that our shareholders' equity (*eigen vermogen*) exceeds the sum of our 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 our board of directors. Any future approval will depend upon our board of directors' 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 our board of directors deems relevant.



## CAPITALIZATION

The table below sets forth our cash and cash equivalents and capitalization as of December 31, 2018 derived from our audited financial statements incorporated by reference in this prospectus:

Investors should read this table in conjunction with our audited financial statements incorporated by reference in this prospectus, as well as “Use of Proceeds” and the documents incorporated by reference in this prospectus.

<u>(euro in thousands)</u>	<u>As of</u> <u>December 31, 2018</u>
Cash and cash equivalents	€ 143,747
Borrowings (including current portion)	—
Shareholders' equity:	
Issued capital:	
Common shares	2,102
Share premium	264,854
Accumulated loss	(175,085)
Total equity	91,871
Total capitalization	<u>€ 91,871</u>

The table above excludes:

- 2,633,039 common shares issuable upon the exercise of share options outstanding as of December 31, 2018 at a weighted average exercise price of €14.62 per share;
- 101,302 common shares issuable upon the vesting of restricted share units outstanding as of December 31, 2018; and
- 535,426 common shares reserved for future issuance under our 2016 Incentive Award Plan as of December 31, 2018.

## PRINCIPAL AND SELLING SHAREHOLDERS

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

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

The number of common shares beneficially owned by each entity, person, director or member of senior management 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 entity or individual has sole or shared voting power or investment power as well as any shares that the entity or individual has the right to acquire within 60 days following December 31, 2018 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all common shares held by that person, as applicable. Common shares that a person has the right to acquire within 60 days following December 31, 2018 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. The percentage of shares beneficially owned before the offering is computed on the basis of 23,358,977 common shares as of December 31, 2018. The percentage of shares beneficially owned after the offering assumes the sale by the selling shareholders of all common shares registered pursuant to this prospectus.

The selling shareholders named below may offer or sell from time to time pursuant to this prospectus up to an aggregate of 6,299,997 common shares. Because the selling shareholders may sell, transfer or otherwise dispose of all, some or none of the common shares covered by this prospectus, we cannot determine the number of such shares that will be sold, transferred or otherwise disposed of by the selling shareholders, or the amount or percentage of common shares that will be held by the selling shareholders upon termination of any particular offering or sale. See “Plan of Distribution.” For the purposes of the table below, we assume that each selling shareholder will sell all of its common shares covered by this prospectus. When we refer to the selling shareholders in this prospectus, we mean the entities listed in the table below, as well as their pledgees, donees, assignees, transferees and successors in interest.

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Unless otherwise indicated below, the address for each beneficial owner listed is c/o Merus N.V., at Yalelaan 62, 3584 CM Utrecht, The Netherlands.

Name of beneficial owner	Shares Beneficially Owned Prior to Offering		Number of Shares Being Offered	Shares Beneficially Owned After Offering	
	Number	Percent		Number	Percent
<b>5% or greater shareholders and selling shareholders:</b>					
BVF(1)	4,514,913	19.3%	2,124,443	2,390,470	10.2%
Incyte Corporation(2)	3,200,000	13.7%	3,200,000	—	—
Bay City Capital Coöperatief U.A.(3)	2,113,574	9.1%	—	2,113,574	9.1%
Sofinnova Venture Partners IX, L.P.(4)	1,961,039	8.4%	222,222	1,738,817	7.4%
Aquilo Capital Management, LLC(5)	1,480,855	6.3%	531,110	949,745	4.1%
Cooperatief LSP IV UA(6)	1,225,661	5.3%	—	1,225,661	5.3%
Baker Brothers Life Sciences L.P.(7)	1,160,014	5.0%	—	1,160,014	5.0%
LSP Life Sciences Fund N.V.(8)	222,222	*	222,222	—	—
<b>Senior management and Board of Directors:</b>					
Ton Logtenberg, Ph.D.(9)	762,263	3.2%	—	762,263	3.2%
Hui Liu, Ph.D.(10)	178,553	*	—	178,553	*
L. Andres Sirulnik(11)	141,394	*	—	141,394	*
Mark Throsby, Ph.D.(12)	165,751	*	—	165,751	*
Lex B.H. Bakker, Ph.D.(13)	49,110	*	—	49,110	*
Peter B. Silverman(14)	31,414	*	—	31,414	*
John de Kruif(15)	37,444	*	—	37,444	*
Russell G. Greig, Ph.D.	—	—	—	—	—
Mark Iwicki(16)	74,475	*	—	74,475	*
Len Kanavy(17)	8,166	*	—	8,166	*
John de Koning, Ph.D.(18)	24,132	*	—	24,132	*
Anand Mehra(4)(19)	1,985,171	8.5%	222,222	1,762,949	7.5%
Gregory Perry(20)	24,132	*	—	24,132	*

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

- (1) Consists of (a) 2,179,666 shares held directly by Biotechnology Value Fund, L.P. (“BVF”), (b) 1,659,586 shares held directly by Biotechnology Value Fund II, L.P. (“BVF2”), (c) 315,275 shares held by Biotechnology Value Trading Fund OS LP (“Trading Fund OS”) (d) 100,751 shares held directly by Investment 10, L.L.C. (“Investment 10”), and (e) 259,635 shares held directly by MSI BVF SPV LLC (“MSI”). BVF Partners OS Ltd. (“Partners OS”), as the general partner of Trading Fund OS, may be deemed to beneficially own the shares held by Trading Fund OS. BVF Partners L.P. (“Partners”), as the general partner of BVF and BVF2, the investment manager of Trading Fund OS, Investment 10, and MSI and the sole member of Partners OS, may be deemed to beneficially own the shares beneficially owned in the aggregate by BVF, BVF2, Trading Fund OS, Investment 10, and MSI. BVF Inc., as the general partner of Partners, may be deemed to beneficially own the shares beneficially owned by Partners Investment 10, and MSI. Mark N. Lampert, as a director and officer of BVF Inc., may be deemed to beneficially own the shares beneficially owned by BVF Inc. The beneficial ownership information is based on a Schedule 13G/A filed with the SEC on February 14, 2019 and information known to us. The address for each of these entities is 44 Montgomery Street, 40th Floor, San Francisco, CA 94104.
- (2) Consists of 3,200,000 common shares held directly by Incyte Corporation (“Incyte”).
- (3) Consists of (a) 2,062,025 common shares held directly by Bay City Capital Fund V, L.P. (“Fund V”), (b) 39,295 common shares held by Bay City Capital Fund V Co-Investment Fund, L.P. (“Fund V-SBS”) are the two sole investors of COOP. Bay City Capital Management V LLC (“BCCM V”) is the general partner of Fund V and Fund V-SBS, and (c) 12,254 common shares held directly by Bay City Capital LLC (“BCC”). BCC is the adviser and manager of BCCM V. BCCM V and BCC represent Fund V and Fund V-SBS, respectively. Thus, BCCM V and BCC share voting and investment power over the shares held by each of

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Fund V and Fund V-SBS. Lionel Carnot is a member of BCCM V and is employed as a managing director of BCC together with Fred Craves, Carl Goldfischer, Dayton Misfeldt and Rob Hopfner. As such, each of these individuals may be deemed to share voting and investment power over these entities, and they disclaim beneficial ownership of all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on a Schedule 13D filed with the SEC on November 28, 2018. The mailing address for BCC, Fund V, Fund V-SBS and BCCM V is De Boelelaan 7, 1083 HJ Amsterdam, Netherlands.

- (4) Consists of 1,961,039 common shares held directly by Sofinnova Venture Partners IX, L.P. (“Sofinnova VP”). Sofinnova Management IX, L.L.C. (“Sofinnova Management”) is the general partner of Sofinnova VP and Anand Mehra, Michael Powell and James Healy are the managing members of Sofinnova Management. Sofinnova Management, Anand Mehra (a member of our board), Michael Powell and James Healy may be deemed to have shared voting and dispositive power over the shares owned by Sofinnova VP. Such entities and individuals disclaim beneficial ownership over all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on information known to us and a Schedule 13D filed with the SEC on September 27, 2017. The address for Sofinnova VP and Sofinnova Management is 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, California 94025.
- (5) Consists of (a) 1,194,112 common shares held directly by Aquilo Capital, L.P. (“Aquilo”) and (b) 286,743 common shares held directly by Aquilo Capital II, L.P. (“Aquilo II”). Aquilo Capital Management LLC (“Aquilo Management”) is the general partner of Aquilo and Aquilo II and Marc Schneidman is the managing member of Aquilo Management. Aquilo Management and Mr. Schneidman may be deemed to be beneficial owners of the shares held by Aquilo and Aquilo II, and Aquilo and Aquilo II may be deemed to beneficially own the shares held by the other entity. The beneficial ownership information presented is based on a Schedule 13G/A filed with the SEC on February 14, 2019 and information known to us. The address for Aquilo and Aquilo II is One Letterman Drive, Suite D4900, San Francisco, California, 94129.
- (6) Consists of 1,225,661 common shares held directly by Coöperatief LSP IV U.A. (“LSP”). LSP IV Management BV (“LSP Management”) is the sole director of LSP. The managing directors of LSP Management are Martijn Kleijwegt, Rene Kuijten and Joachim Rothe. As such, LSP Management, Martijn Kleijwegt, Rene Kuijten and Joachim Rothe may be deemed to beneficially own and share voting power over these shares. LSP Management, Martijn Kleijwegt, Rene Kuijten and Joachim Rothe disclaim beneficial ownership of the shares. John de Koning, a member of our board, is employed as a partner at LSP. Mr. de Koning has no beneficial ownership of these shares, but he has a pecuniary interest in these shares pursuant to his employment at LSP. Beneficial ownership information is based on a Schedule 13D/A filed with the SEC on June 3, 2016. LSP’s mailing address is c/o LSP, Johannes Vermeerplein 9, 1071 DV Amsterdam, Netherlands.
- (7) Consists of (a) 1,054,257 common shares held directly by Baker Brothers Life Sciences, L.P. (“Life Sciences”) and (b) 105,757 common shares held directly by 667, L.P. (“667”), and together with Life Sciences, the “Baker Funds”). Baker Bros. Advisors LP (“Advisors”) is the Investment Adviser for the Baker Funds and has sole voting and investment power with respect to the shares held by the Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Advisors. Baker Bros. Advisors (GP) LLC, Julian C. Baker and Felix J. Baker as principals of the Baker Bros. Advisors (GP) LLC, and Advisors disclaim beneficial ownership of all shares. Beneficial ownership information is based on a Schedule 13G filed with the SEC on February 14, 2017. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.
- (8) LSP Advisory B.V. (“LSP Advisory”) is the sole director of LSP Life Sciences Fund N.V. (“LSP”). The directors of LSP Advisory are Mark Wegter and Geraldine O’Keeffe. As such, LSP Advisory, Mark Wegter and Geraldine O’Keeffe may be deemed to beneficially own and share voting power over the shares held by LSP. LSP Advisory, Mark Wegter and Geraldine O’Keeffe disclaim beneficial ownership of the shares. LSP’s mailing address is Johannes Vermeerplein 9, 1071 DV Amsterdam, Netherlands.
- (9) Consists of (a) 160,814 common shares held by BioPhrase, B.V. (“BioPhrase”), Dr. Logtenberg’s personal holding company, (b) 129,647 common shares held by Dr. Logtenberg, (c) 464,068 options to purchase common shares held by Dr. Logtenberg, including options that vest within 60 days following December 31, 2018 and (d) 7,734 restricted stock units (“RSUs”) held by Dr. Logtenberg, including RSUs that vest within 60 days following December 31, 2018.

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- (10) Consists of (a) 40,490 common shares, (b) 136,317 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 1,746 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (11) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (12) Consists of (a) 11,038 common shares, (b) 152,589 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 2,124 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (13) Consists of (a) 9,010 common shares, (b) 39,776 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 324 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (14) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (15) Consists of (a) 1,811 common shares, (b) 35,396 options to purchase common shares including options that vest within 60 days following December 31, 2018 and (c) 237 restricted stock units (“RSUs”), including RSUs that vest within 60 days following December 31, 2018.
- (16) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (17) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (18) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (19) Consists of (a) 1,961,039 shares held by Sofinnova Venture Partners IX LP prior to this offering and (b) 24,132 options to purchase common shares, including options that vest within 60 days following December 31, 2018.
- (20) Consists of options to purchase common shares, including options that vest within 60 days following December 31, 2018.

To our knowledge other than as provided in the table above, our other filings with the SEC and this prospectus, there has been no significant change in the percentage ownership held by any major shareholder listed above since January 1, 2016.

## DESCRIPTION OF SHARE CAPITAL

Set forth below is a summary of certain information concerning our share capital. Because the following is only a summary, it does not purport to be complete or contain all of the information that may be important to you.

### Share Capital

#### Common Shares

As of December 31, 2018, our issued share capital was €2.1 million, comprised of 23,358,977 common shares, nominal value €0.09 per share. As of December 31, 2018, our authorized share capital comprised 45,000,000 common shares and 45,000,000 preferred shares.

#### Preferred Shares

On May 24, 2016, we entered into a call option agreement with an independent foundation (*stichting*) under Dutch law called Stichting Continuïteit Merus, or the Protective Foundation, pursuant to which the Protective Foundation would be allowed to acquire preferred shares up to 100% of our issued capital held by third parties immediately prior to the issuance of such preferred shares without approval by our general meeting of shareholders or our board of directors. As of December 31, 2018, there were no preferred shares outstanding, and we have no present plans to issue any preferred shares other than pursuant to an exercise by the Protective Foundation of its rights under the call option agreement.

#### History of Share Capital

Since January 1, 2016, our issued share capital has changed as provided below.

On March 16, 2016, we issued 12,107 common shares upon the exercise of options by the former Chairman of our board of directors (through the STAK) for aggregate consideration of €23,317 in cash.

On May 6, 2016, we effected a 1-for-1.80 reverse share split of our common shares and all classes of our preferred shares issued at that time.

On May 19, 2016, in connection with the listing of our common shares on The Nasdaq Global Market, or Nasdaq, we effected a conversion of all issued and outstanding preferred shares into 8,627,712 common shares, and we issued a total of 1,312,718 common shares to holders of our preferred shares in satisfaction of accrued and unpaid dividends.

On May 24, 2016, we issued 5,500,000 common shares upon the closing of the initial public offering of our common shares, or IPO, at a price per share of \$10.00. On May 26, 2016, we issued 639,926 common shares upon the exercise in part of the underwriters' option to purchase additional shares. We received aggregate net proceeds of \$53.3 million, after deducting underwriting discounts and commissions and offering expenses payable by us, from our IPO and the exercise of the underwriters' option to purchase additional shares.

On January 23, 2017, we issued 3,200,000 common shares to Incyte Corporation at price per share of \$25.00, for an aggregate purchase price of \$80.0 million.

In January 2017, we issued 96,816 common shares upon the exercise of options by directors, officers, and employees for aggregate consideration of €189,574 in cash and granted 214,096 restricted share units, or RSUs.

In February 2017, we issued 8,846 common shares upon the exercise of options by directors, officers, and employees for aggregate consideration of €18,865 in cash.

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In May 2017, we issued 783 common shares upon the exercise of options by employees for aggregate consideration of €1,511 in cash.

In June 2017, we issued 4,424 common shares upon the exercise of options by employees for aggregate consideration of €16,858 in cash.

In July 2017, we issued 7,331 common shares upon the vesting of RSUs.

In September 2017, we issued 5,556 common shares upon the exercise of options by an employee for aggregate consideration of €10,723 in cash.

In October 2017, we issued 20,241 common shares upon the exercise of options by an employee for aggregate consideration of €69,088 in cash.

In January 2018, we issued 6,876 common shares upon the exercise of options by employees for aggregate consideration of €13,271 in cash and we issued 48,639 common shares upon the vesting of RSUs.

In February 2018, we issued 27,165 common shares upon the exercise of options by employees for aggregate consideration of €52,428 in cash.

On February 15, 2018, we issued 3,099,997 common shares to certain new and existing investors at price per share of \$18.00, for an aggregate purchase price of \$55.8 million.

In July 2018, we issued 47,279 common shares upon the exercise of options by employees for aggregate consideration of €583,111 in cash.

In August 2018, we issued 1,750 common shares upon the exercise of options by employees for aggregate consideration of €23,865 in cash.

In September 2018, we issued 40,564 common shares upon the exercise of options by employees for aggregate consideration of €97,598 in cash.

In October 2018, we issued 12,254 common shares upon the exercise of options by employees for aggregate consideration of €106,179 in cash.

In December 2018, we issued 600,000 common shares to Regeneron Pharmaceuticals, Inc. for aggregate consideration of \$15.0 million.

In January 2019, we issued 7,134 common shares upon the exercise of options by employees for aggregate consideration of €22,406.

In February 2019, we issued 1,379 common shares upon the exercise of options by employees for aggregate consideration of €2,661.

From February 2018 through March 2019, we issued 4,055 common shares upon the vesting of RSUs each month.

### **Options**

We have established equity incentive plans pursuant to which we have issued options to purchase common shares and RSUs to employees and directors. As of December 31, 2018, there were 2,734,431 common shares subject to outstanding options and RSUs.

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The tables below summarize the share options and RSUs that we have granted to our directors and our employees pursuant to our equity incentive plans. Share options granted under the Merus B.V. 2010 Employee Option Plan, or the 2010 Plan, have a term of eight years from grant date and share options granted under the 2016 Plan have a term of ten years from grant date.

<b>Share Options Granted Under the Merus B.V. 2010 Employee Option Plan</b>		
<b>Grant Date</b>	<b>Number of Share Options</b>	<b>Exercise Price Per Share Option</b>
July 1, 2009 (employee)	556	€ 13.50
October 1, 2009 (employee)	444	€ 13.50
June 4, 2010 (officers and employees)	75,600	€ 1.93
August 17, 2010 (officer)	7,556	€ 1.93
September 15, 2010 (director and employee)	3,223	€ 1.93
May 1, 2011 (employee)	333	€ 1.93
September 9, 2011 (director)	1,042	€ 1.93
November 3, 2011 (employees)	1,399	€ 1.93
November 4, 2011 (director)	2,778	€ 1.93
September 4, 2012 (officers and employees)	29,050	€ 1.93
October 18, 2012 (directors)	3,820	€ 1.93
June 17, 2013 (employees)	10,493	€ 1.93
June 17, 2014 (officers and employees)	34,008	€ 1.93
July 17, 2014 (directors)	8,022	€ 1.93
March 16, 2015 (officers and employees)	167,233	€ 1.93
June 4, 2015 (directors)	36,944	€ 5.94
August 21, 2015 (directors)	36,632	€ 7.20
October 30, 2015 (officers and employees)	432,766	€ 7.20
December 16, 2015 (officer)	98,085	€ 7.20
March 21, 2016 (directors)	25,112	€ 8.46



**Share Options Granted Under the  
Merus N.V. 2016 Incentive Award Plan, as amended**

<u>Grant Date</u>	<u>Number of Share Options</u>	<u>Exercise Price Per Share Option</u>
May 18, 2016 (directors)	68,000	€ 8.87
October 29, 2016 (officer)	219,890	\$ 18.41
November 1, 2016 (officer)	183,241	\$ 16.80
January 1, 2017 (officers)	707,734	\$ 21.11
January 17, 2017 (employees)	74,450	\$ 24.00
February 15, 2017 (employee)	50,000	\$ 25.90
March 13, 2017 (employee)	20,000	\$ 29.29
March 27, 2017 (employee)	1,300	\$ 25.00
April 13, 2017 (employee)	7,000	\$ 19.38
May 24, 2017 (directors)	33,900	\$ 18.23
May 29, 2017 (employees)	31,700	\$ 19.17
July 1, 2017 (employee)	20,000	\$ 15.85
October 4, 2017 (employee)	14,149	\$ 20.80
November 9, 2017 (employees)	54,500	\$ 15.95
February 21, 2018 (employees and officers)	442,568	\$ 17.94
April 4, 2018 (officer)	14,000	\$ 18.25
June 25, 2018 (employee)	5,040	\$ 20.30
June 28, 2018 (employee)	12,500	\$ 21.13
July 4, 2018 (employee)	5,040	\$ 24.48
July 20, 2018 (employee)	29,898	\$ 23.30
August 1, 2018 (employee)	10,080	\$ 22.30
August 19, 2018 (employee)	39,450	\$ 19.10
October 24, 2018 (employee)	55,000	\$ 14.01
November 5, 2018 (officer)	7,669	\$ 14.83
November 16, 2018 (employee)	4,200	\$ 14.06
January 10, 2019 (director)	17,000	\$ 14.39
February 20, 2019 (employee & officers)	842,071	\$ 11.20
March 19, 2019 (director)	17,000	\$ 12.54
March 21, 2019 (employees)	5,600	\$ 12.89

**Restricted Share Units Granted Under the  
Merus N.V. 2016 Incentive Award Plan, as amended**

<u>Grant Date</u>	<u>Number of Share Subject to Vesting</u>
January 1, 2017 (officers)	214,096

**Listing**

Our common shares are listed on The Nasdaq Global Market under the symbol “MRUS.”

**Transfer Agent and Registrar**

The U.S. transfer agent and registrar for our common shares is American Stock Transfer & Trust Company, LLC.

## CERTAIN MATERIAL 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 our 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 United States Internal Revenue Code of 1986, as amended, or 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;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- persons holding our 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 our 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", or government organizations;
- S corporations or 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 subject to special tax accounting rules as a result of any item of gross income with respect to our common shares being taken into account in an applicable financial statement;
- persons that own or are deemed to own ten percent or more of our shares by vote or value; and
- persons holding our 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 our 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 our 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.” However, the qualified dividend income treatment may not apply if we are treated as a PFIC with respect to the U.S. Holder. 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 our common shares or rights to acquire our 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 our 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 Our 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 our 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.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if our common shares are treated as traded on an “established securities market” and the U.S. Holder is either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), such holder will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If a U.S. Holder is

an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, such holder will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

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

Based on the value of our assets, including goodwill, and the composition of our income, assets and operations during the year ended December 31, 2018, we do not believe we were a PFIC for our taxable year ended December 31, 2018. However, the application of the PFIC rules is subject to uncertainty in several respects, and we cannot assure holders of our common shares 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.

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.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns our 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 such common shares, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and the U.S. Holder has made a “deemed sale” election under the PFIC rules, or (2) the U.S. Holder makes a QEF Election (defined below) with respect to taxable years in which we are a PFIC.

If we are a PFIC for any taxable year, U.S. Holders will be subject to special tax rules with respect to any “excess distribution” that they receive and any gain they realize from a sale or other disposition (including a pledge) of our common shares. Distributions U.S. Holders of our common shares receive in a taxable year that are greater than 125% of the average annual distributions they received during the shorter of the three preceding taxable years or their 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 their 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 U.S. Holders hold the common shares as capital assets.

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Certain elections may be available that would result in alternative treatments. U.S. Holders can avoid the interest charge on excess distributions or gain relating to our common shares by making a mark-to-market election with respect to our common shares, provided that our common shares are “marketable.” Our common shares will be marketable if they are “regularly traded” on certain U.S. stock exchanges or on a foreign stock exchange that meets certain conditions. The adverse consequences of owning stock in a PFIC could also 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.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder’s failure to file the annual report will cause the statute of limitations for such U.S. Holder’s U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder’s entire U.S. federal income tax return will remain open during such period.

If we are or become a PFIC, U.S. Holders should consult their tax advisors regarding any reporting requirements that may apply to them. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to the ownership and disposition of our 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 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 our common shares, subject to certain exceptions (including an exception for our 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 our common shares.

## PLAN OF DISTRIBUTION

We are registering the common shares issued to the selling shareholders to permit the resale of these shares by the holders of the common shares from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling shareholders of the common shares. We will bear all fees and expenses incident to our obligation to register the common shares.

The selling shareholders and any of their transferees, donees, pledgees or other successors in interest may, from time to time, sell all or a portion of the common shares beneficially owned by the selling shareholders and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the common shares are sold through underwriters or broker-dealers, the selling shareholders will be responsible for underwriting discounts or commissions or agent's commissions. The common shares may be sold on any national securities exchange or quotation service on which the common shares may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions. The selling shareholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales entered into after the effective date of the registration statement of which this prospectus is a part;
- in transactions through broker-dealers that agree with the selling shareholder to sell a specified number of such shares at a stipulated price per share;
- through the writing or settlement of options or other hedging transactions, whether such options are listed on an options exchange or otherwise;
- through one or more underwritten offerings on a firm commitment or best efforts basis;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

A selling shareholder also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, as permitted by that rule, or Section 4(a)(1) under the Securities Act, if available, rather than under this prospectus, provided that the selling shareholder meets the criteria and conforms to the requirements of those provisions.

Broker-dealers engaged by the selling shareholders may arrange for other broker-dealers to participate in sales. If the selling shareholders effect such transactions by selling common shares to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling shareholders or commissions from purchasers of the common shares for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with FINRA Rule 2121 (and any successor); and in the case of a principal transaction a markup or markdown in compliance with FINRA 2121.

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In connection with sales of common shares or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common shares in the course of hedging in positions they assume. The selling shareholders may also sell common shares short and if such short sale shall take place after the date that the registration statement of which this prospectus is a part is declared effective by the SEC, the selling shareholders may deliver common shares covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling shareholders may also loan or pledge common shares to broker-dealers that in turn may sell such shares, to the extent permitted by applicable law. The selling shareholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction). Notwithstanding the foregoing, the selling shareholders have been advised that the selling shareholders may not use shares registered on the registration statement of which this prospectus forms a part to cover short sales of our common shares made prior to the date the registration statement, of which this prospectus forms a part, has been declared effective by the SEC.

The selling shareholders may, from time to time, pledge or grant a security interest in some or all of the common shares owned by the selling shareholders and, if the selling shareholders default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the common shares from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act, amending, if necessary, the list of selling shareholders to include the pledgee, transferee or other successors in interest as a selling shareholder under this prospectus. The selling shareholders also may transfer and donate the common shares in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders and any broker-dealer or agents participating in the distribution of the common shares may be deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act in connection with such sales. In such event, any commissions paid, or any discounts or concessions allowed to, any such broker-dealer or agent and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. If the selling shareholders are deemed to be an “underwriter” within the meaning of Section 2(11) of the Securities Act, they will be subject to the applicable prospectus delivery requirements of the Securities Act and may be subject to certain statutory liabilities of, including but not limited to, Sections 11, 12 and 17 of the Securities Act and Rule 10b-5 under the Exchange Act.

The selling shareholders have informed us that they are not registered broker-dealers and do not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the common shares. Upon our being notified in writing by the selling shareholders that any material arrangement has been entered into with a broker-dealer for the sale of common shares through a block trade, special offering, exchange distribution or secondary distribution or a purchase by a broker-dealer, a supplement to this prospectus will be filed, if required, pursuant to Rule 424(b) under the Securities Act, disclosing:

- the name of the selling shareholder and of the participating broker-dealer(s),
- the number of shares involved,
- the price at which such the shares were sold,
- the commissions paid or discounts or concessions allowed to such broker-dealer(s), where applicable,
- that such broker-dealer(s) did not conduct any investigation to verify the information set out or incorporated by reference in this prospectus, and
- other facts material to the transaction.

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In no event shall any broker-dealer receive fees, commissions and markups, which, in the aggregate, would exceed eight percent (8%).

Under the securities laws of some states, the common shares may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states the common shares may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that the selling shareholders will sell any or all of the common shares registered pursuant to the registration statement, of which this prospectus forms a part.

The selling shareholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the common shares by the selling shareholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of the common shares to engage in market-making activities with respect to the common shares. All of the foregoing may affect the marketability of the common shares and the ability of any person or entity to engage in market-making activities with respect to the common shares.

We will pay all expenses of the registration of the common shares, including, without limitation, SEC filing fees and expenses of compliance with state securities or "blue sky" laws; *provided, however*, that the selling shareholders will pay all underwriting discounts and selling commissions, if any. We will indemnify the selling shareholders against certain liabilities, including some liabilities under the Securities Act or the selling shareholders will be entitled to contribution. We may be indemnified by the selling shareholders against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by the selling shareholders specifically for use in this prospectus or we may be entitled to contribution.

To the extent required, this prospectus may be amended and/or supplemented from time to time to describe a specific plan of distribution.



## EXPENSES

The following is an estimate of the expenses (all of which are to be paid by us) that we may incur in connection with the common shares being registered hereby, other than the SEC registration fee.

SEC registration fee	\$ 9,193
Legal fees and expenses	125,067
Accounting fees and expenses	84,000
Printing and miscellaneous expenses	126,740
Total	<u>\$ 345,000</u>

## LEGAL MATTERS

The validity of the common shares held by the selling shareholders will be passed upon for us by NautaDutilh N.V. with its address at Beethovenstraat 400, 1082 PR Amsterdam, the Netherlands.

## EXPERTS

The consolidated financial statements of Merus N.V. as of December 31, 2018 and 2017, and for each of the years in the three-year period ended December 31, 2018, included in the Annual Report on Form 20-F filed by Merus N.V. on April 3, 2019 have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG Accountants N.V., independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report refers to the adoption of International Financial Reporting Standard 15 *Revenue from Contracts with Customers*. The registered offices of KPMG Accountants N.V. are located at Laan van Langerhuize 1, 1186 DS Amstelveen, the Netherlands.

## ENFORCEMENT OF CIVIL LIABILITIES

We are incorporated under the laws of the Netherlands. A majority of our assets are located 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. Under current practice, the courts of the Netherlands may be expected to render a judgment in accordance with the judgment of the relevant foreign court, provided that such judgment (i) is a final judgment and has been rendered by a court which has established its jurisdiction over the Dutch company on the basis of internationally accepted grounds of jurisdiction, (ii) has not been rendered in violation of elementary principles of fair trial, (iii) is not contrary to the public policy of the Netherlands and (iv) is not incompatible with (a) a prior judgment of a Netherlands court rendered in a dispute between the same parties, or (b) a prior judgment of a foreign court rendered in a dispute between the same parties, concerning the same subject matter and based on the same cause of action, provided that such prior judgment is capable of being recognized in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Civil Procedure Code. If no leave to enforce is granted, claimants must litigate the claim again before a competent Dutch court.

Despite any generally recognized choice of law clause for a jurisdiction other than the Netherlands contained in an agreement, a court in the Netherlands (a) may apply overriding mandatory provisions of (i) Netherlands law and (ii) the law of the country where the obligations arising out of such agreement have to be or have been performed, in so far as those overriding mandatory provisions render the performance of such agreement unlawful, (b) may refuse application of a provision of the chosen law if application thereof is manifestly incompatible with the public policy (*ordre public*) of the Netherlands or the European Union, (c) may, in relation to the manner of performance of such agreement and the steps to be taken in the event of defective performance, have regard to the law of the country where performance of such agreement takes place and (d) will ignore the choice of law clause to the extent it relates to (i) an act of unfair competition or an act restricting free competition, (ii) infringement of an intellectual property right, or (iii) the proprietary aspects of a transfer of title or the granting of security and other proprietary rights.

## WHERE YOU CAN FIND MORE INFORMATION; INCORPORATION BY REFERENCE

### Available Information

We have filed with the SEC a registration statement on Form F-1 under the Securities Act with respect to the common shares offered by this prospectus. This prospectus is a part of the registration statement and does not contain all of the information set forth in the registration statement and its exhibits and schedules, portions of which have been omitted as permitted by the rules and regulations of the SEC. For further information about us and our common shares, you should refer to the registration statement and its exhibits and schedules. Statements contained in this prospectus about the contents of any contract or any other document filed as an exhibit are not complete and in each instance we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference. The agreements and other documents filed as exhibits to this registration statement are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by the registrant in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we file annual reports and other information with the SEC. As a foreign private issuer, we are exempt from, among other things, the rules under the Exchange Act prescribing the filing of proxy statements and quarterly and current reports. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as we, that file electronically with the SEC at <http://www.sec.gov>.

### Incorporation by Reference

The SEC's rules allow us to "incorporate by reference" information into this prospectus, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is deemed to be part of this prospectus. Any statement contained in a previously filed document incorporated by reference will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus modifies or replaces that statement.

This prospectus incorporates by reference the document set forth below that has previously been filed with the SEC:

- Our Annual Report on Form 20-F for the year ended December 31, 2018, filed with the SEC on April 3, 2019.

Unless expressly incorporated by reference, nothing in this prospectus shall be deemed to incorporate by reference information furnished to, but not filed with, the SEC. Copies of all documents incorporated by reference in this prospectus, other than exhibits to those documents unless such exhibits are specifically incorporated by reference in this prospectus, will be provided at no cost to each person, including any beneficial owner, who receives a copy of this prospectus on the written or oral request of that person made to:

Merus N.V.  
Yalelaan 62  
3584 CM Utrecht  
The Netherlands  
+31 30 253 8800

The documents incorporated by reference in this prospectus and certain other information filed by us with the SEC are also available on our website at [www.merus.nl](http://www.merus.nl). Our website is not a part of this prospectus and is not incorporated by reference in this prospectus.

**6,299,997 Shares**

**Merus N.V.**

**Common Shares**

**Merus** *closing in on cancer*

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**PROSPECTUS**

**, 2019**

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**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 6. Indemnification of Directors and Officers.**

Our current and former directors and such other current or former officer or employee of the Company or its group companies as designated by the board of directors have the benefit of the following indemnification provisions in our articles of association:

Indemnified officers shall be indemnified and held harmless for (in each case to the extent this relates to his or her position or former position with us, and in each case to the fullest extent permitted by applicable law):

- (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.

There shall be no entitlement to indemnification as referred to above:

- (a) if a competent court or arbitral tribunal 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;
- (b) to the extent that his or her financial losses, damages and expenses are covered by an insurance and the insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so); or
- (c) in relation to proceedings brought by such indemnified officer against us, except for proceedings brought to enforce indemnification to which he or she is entitled pursuant to our articles of association or an agreement between such indemnified officer and us that has been approved by our board of directors

We have entered into indemnification agreements with each of our directors and members of senior management. These indemnification agreements may require us, among other things, to indemnify our directors and members of senior management for judgments, settlements, fines, and some expenses, including attorneys' fees, incurred by a director or a member of senior management in any action or proceeding arising out of his or her service as a director or a member of senior management, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request.

**Item 7. Recent sales of unregistered securities**

On March 16, 2016, we issued 12,107 common shares to Stichting Administratiekantoor Merus (or "STAK") upon the exercise of options to purchase depositary receipts by the former Chairman of our Board for aggregate consideration of €23,317 in cash. Such issuance was made outside of the United States pursuant to Regulation S.

On January 23, 2017, we issued 3,200,000 common shares to Incyte Corporation for aggregate gross proceeds of \$80.0 million. Such issuance was made pursuant to Section 4(a)(2) of the Securities Act.

On February 15, 2018, we issued 3,099,997 common shares to certain new and existing investors for aggregate gross proceeds of \$55.8 million. Such issuance was made pursuant to Section 4(a)(2) of the Securities Act.

On December 20, 2018, we issued 600,000 common shares to Regeneron Pharmaceuticals, Inc. for aggregate gross proceeds of \$15.0 million. Such issuance was made pursuant to Section 4(a)(2) of the Securities Act.

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### **Item 8. Exhibits.**

(a)

<u>Exhibit Number</u>	<u>Exhibit Description</u>	<u>Form</u>	<u>Incorporated by Reference to Filings Indicated</u>		
			<u>File No.</u>	<u>Exhibit No.</u>	<u>Filing Date</u>
3.1	<a href="#">Articles of Association (English Translation)</a>	20-F	001-37773	1.1	4/30/18
5.1	<a href="#">Opinion of NautaDutilh, counsel of the Registrant</a>				*
10.1#	<a href="#">Merus N.V. 2010 Employee Option Plan, as amended</a>	20-F	001-37773	4.1	4/30/18
10.2#	<a href="#">Merus N.V. 2016 Incentive Award Plan and forms of award agreements thereunder, as amended</a>	20-F	001-37773	4.2	4/30/18
10.3#	<a href="#">Non-Executive Director Compensation Program</a>	F-1	333-229044	10.3	12/27/18
10.4#	<a href="#">Form of Board of Directors Indemnification Agreement</a>	F-1/A	333-207490	10.4	5/9/16
10.5#	<a href="#">Employment Contract between the Registrant and Ton Logtenberg, dated January 21, 2010.</a>	F-1	333-207490	10.5	10/19/15
10.6#	<a href="#">Employment Agreement, dated December 16, 2015, by and among Merus US, Inc., the Registrant and Hui Liu, as amended on March 2, 2016</a>	20-F	001-37773	4.7	4/30/18
10.7#	<a href="#">Employment Agreement, dated November 1, 2016, by and among Merus US, Inc., the Registrant and L. Andres Sirulnik</a>	20-F	001-37773	4.8	4/30/18
10.8#	<a href="#">English language translation of Employment Agreement, dated as of July 19, 2008, by and between the Registrant and Mark Throsby, as amended on March 10, 2010</a>	20-F	001-37773	4.9	4/30/18
10.9#	<a href="#">English language translation of Employment Agreement, dated as of August 5, 2010, by and between the Registrant and Alexander Bakker</a>	20-F	001-37773	4.10	4/30/18
10.10#	<a href="#">English language translation of Employment Agreement, dated as of April 2, 2007, by and between the Registrant and John de Kruif, as amended on March 10, 2010</a>	20-F	001-37773	4.11	4/30/18
10.11#	<a href="#">Employment Agreement, dated as of December 24, 2016, by and between the Registrant and Peter Silverman, as amended February 1, 2017</a>	20-F	001-37773	4.12	4/30/18
10.12	<a href="#">English language translation of Lease Agreement, dated April 22, 2016, by and between the Registrant and Stichting Incubator Utrecht.</a>	F-1/A	333-207490	10.12	5/9/16
10.13	<a href="#">English language translation of Amendment to Lease Agreement, dated as of November 1, 2016 by and between the Registrant and Stichting Incubator Utrecht</a>	20-F	001-37773	4.15.1	4/30/18
10.14	<a href="#">English language translation of Lease Agreement, dated as of May 1, 2018, by and between the Registrant and Stichting Incubator Utrecht</a>	6-K	001-37773	3	8/10/18

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Exhibit Number	Exhibit Description	Form	Incorporated by Reference to Filings Indicated		
			File No.	Exhibit No.	Filing Date
10.15†	<a href="#">Collaboration and License Agreement, dated December 20, 2016, by and between the Registrant and Incyte Corporation</a>	20-F	001-37773	4.12	4/28/17
10.16†	<a href="#">Share Subscription Agreement, dated December 20, 2016, by and between the Registrant and Incyte Corporation</a>	20-F	001-37773	4.13	4/28/17
10.17	<a href="#">Contract Research and License Agreement and Addendum between the Registrant and ONO Pharmaceutical Co., Ltd., dated April 8, 2014.</a>	F-1	333-207490	10.9	10/19/15
10.18†	<a href="#">Contract Research and License Agreement by and between the Registrant and Ono Pharmaceuticals Co., Ltd., dated March 14, 2018</a>	20-F	001-37773	4.19	4/30/18
10.19	<a href="#">Securities Purchase Agreement, dated February 13, 2018, by an among the registrant and the Investors identified on Exhibit A attached thereto</a>	6-K	001-37773	99.1	2/16/18
10.20	<a href="#">Registration Rights Agreement, dated February 13, 2018, by and among the registrant and the Investors identified on Exhibit A attached thereto</a>	6-K	001-37773	99.2	2/16/18
10.21	<a href="#">Registration Rights Agreement, dated May 24, 2016, by and among the Registrant and the shareholders party thereto</a>	6-K	001-37773	4.1	5/27/16
10.22	<a href="#">English language translation of the Lease, dated May 1, 2018, by and between the Registrant and Stichting Incubator Utrecht</a>	6-K	001-37773	99.3	8/10/18
21.1	<a href="#">List of Subsidiaries</a>	F-1/A	333-207490	21.1	4/8/16
23.1	<a href="#">Consent of KPMG Accountants N.V.</a>				*
23.2	<a href="#">Consent of NautaDutilh, counsel to the Registration (included in Exhibit 5.1)</a>				*
24.1	<a href="#">Powers of attorney (included on signature page to the registration statement)</a>	F-1	333-229044	24.1	12/27/18

\* Filed herewith.

# Indicates management contract or compensatory plan.

† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.

### **Item 9. Undertakings.**

(a) The undersigned hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate,

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represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment 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.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A. of Form 20-F at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Securities Act of 1933 need not be furnished, provided, that the registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (a)(4) and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

(A) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(B) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(6) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of securities:

The undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following



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communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

- (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
- (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
- (iii) The portion of any other free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
- (iv) Any other communications that is an offer in the offering made by the undersigned registrant to the 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 the City of Utrecht, the Netherlands on April 3, 2019.

**MERUS N.V.**

By: /s/ Ton Logtenberg

Name: Ton Logtenberg

Title: President, Chief Executive Officer and Principal Financial Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on April 3, 2019 in the capacities indicated:

<u>Name</u>	<u>Title</u>
<u>/s/ Ton Logtenberg</u> Ton Logtenberg	President, Chief Executive Officer, Principal Financial Officer and Executive Director (Principal Executive Officer and Principal Accounting Officer)
<u>*</u> Russell G. Greig	Chairman of the Board of Directors
<u>*</u> Mark Iwicki	Non-Executive Director
<u>*</u> Len Kanavy	Non-Executive Director
<u>*</u> John de Koning	Non-Executive Director
<u>*</u> Anand Mehra	Non-Executive Director
<u>*</u> Gregory Perry	Non-Executive Director

\*By: /s/ Ton Logtenberg

Ton Logtenberg  
Attorney-in-fact

**SIGNATURE OF AUTHORIZED UNITED STATES REPRESENTATIVE**

Pursuant to the Securities Act, the undersigned, the duly authorized representative in the United States of MERUS N.V. has signed this registration statement in the City of Utrecht, the Netherlands on April 3, 2019.

Authorized U.S. Representative

Merus US, Inc.

By: /s/ Ton Logtenberg

Name: Ton Logtenberg

Title: President

P.O. Box 7113  
1007 JC Amsterdam  
Beethovenstraat 400  
1082 PR Amsterdam  
T +31 20 71 71 000  
F +31 20 71 71 111

Amsterdam, April 3, 2019

To the Company

Ladies and Gentlemen,

We have acted as legal counsel as to Netherlands law to the Company in connection with the Registration Statement. This opinion letter is rendered to you in order to be filed with the SEC as an exhibit to the Registration Statement.

Capitalised terms used in this opinion letter have the meanings set forth in Exhibit A to this opinion letter. The section headings used in this opinion letter are for convenience of reference only and are not to affect its construction or to be taken into consideration in its interpretation.

This opinion letter is addressed solely to you. This opinion letter is strictly limited to the matters stated in it and may not be read as extending by implication to any matters not specifically referred to in it. Nothing in this opinion letter should be taken as expressing an opinion in respect of any representations or warranties, or other information, contained in any document.

In rendering the opinions expressed in this opinion letter, we have exclusively reviewed and relied upon pdf copies of the Deeds of Issue and the Corporate Documents and we have assumed that the Deeds of Issue have been entered into for bona fide commercial reasons. We have not investigated or verified any factual matter disclosed to us in the course of our review.

This opinion letter sets out our opinion on certain matters of the laws with general applicability of the Netherlands, and, insofar as they are directly applicable in the Netherlands, of the European Union, as at today's date and as presently interpreted under published authoritative case law of the Netherlands courts, the General Court and the Court of Justice of the European Union. We do not express any opinion on Netherlands or European competition law, tax law or regulatory law. No undertaking is assumed on our part to revise, update or amend this opinion letter in connection with or to notify or inform you of, any developments and/or changes of Netherlands law subsequent to today's date. We do not purport to opine on the consequences of amendments to the Deeds of Issue or the Corporate Documents subsequent to the date of this opinion letter.

Amsterdam

Brussels

London

Luxemburg

New York

Rotterdam

This communication is confidential and may be subject to professional privilege. All legal relationships are subject to NautaDutilh N.V.'s general terms and conditions (see <https://www.nautadutilh.com/terms>), which apply mutatis mutandis to our relationship with third parties relying on statements of NautaDutilh N.V., include a limitation of liability clause, have been filed with the Rotterdam District Court and will be provided free of charge upon request. NautaDutilh N.V.; corporate seat Rotterdam; trade register no. 24338323.

The opinions expressed in this opinion letter are to be construed and interpreted in accordance with Netherlands law. The competent courts at Amsterdam, the Netherlands, have exclusive jurisdiction to settle any issues of interpretation or liability arising out of or in connection with this opinion letter. Any legal relationship arising out of or in connection with this opinion letter (whether contractual or non-contractual), including the above submission to jurisdiction, is governed by Netherlands law and shall be subject to the general terms and conditions of NautaDutilh. No person other than NautaDutilh may be held liable in connection with this opinion letter.

In this opinion letter, legal concepts are expressed in English terms. The Netherlands legal concepts concerned may not be identical in meaning to the concepts described by the English terms as they exist under the law of other jurisdictions. In the event of a conflict or inconsistency, the relevant expression shall be deemed to refer only to the Netherlands legal concepts described by the English terms.

For the purposes of this opinion letter, we have assumed that:

- a. each copy of a document conforms to the original, each original is authentic, and each signature is the genuine signature of the individual purported to have placed that signature;
- b. the Deed of Incorporation and the Deed of Conversion are valid notarial deeds and the Deed of Incorporation has been executed on the basis of a valid declaration of no objection (*verklaring van geen bezwaar*);
- c. (i) no internal regulations (*reglementen*) were adopted by any corporate body of the Company at the time of passing the resolutions recorded in the Resolutions which would affect the validity of such resolutions, (ii) the Prior Articles were the Articles of Association in force at the Relevant Moment when Registered Shares were issued to Incyte, and (iii) the Current Articles were the Articles of Association in force at the Relevant Moment when Registered Shares were issued to the respective Investors;
- d. at each Relevant Moment, the Company had not (i) been dissolved (*ontbonden*), (ii) ceased to exist pursuant to a merger (*fusie*) or a division (*splitsing*), (iii) been converted (*omgezet*) into another legal form, either national or foreign, (iv) had its assets placed under administration (*onder bewind gesteld*), (v) been declared bankrupt (*failliet verklaard*), (vi) been granted a suspension of payments (*surseance van betaling verleend*), or (vii) been made subject to similar proceedings in any jurisdiction or otherwise been limited in its power to dispose of its assets;

- e. the resolutions recorded in the Resolutions were in full force and effect at each Relevant Moment, the factual statements made and the confirmations given in the Resolutions and the Deeds of Issue were, at each Relevant Moment, complete and correct, the Resolutions correctly reflect the resolutions recorded therein and the “Investor” as referred to and defined in the Resolutions of the Management Board and the Supervisory Board is Incyte;
- f. at each Relevant Moment, no works council (*ondernemingsraad*) was established or was in the process of being established with respect to the business of the Company; and
- g. none of the members of the Management Board, the Supervisory Board or the Board of Directors has or had a direct or indirect personal interest which conflicts with the interest of the Company and the business connected with it in respect of any of their respective resolutions recorded in the Resolutions or the matters contemplated thereby, except as noted specifically in the Resolutions.

Based upon and subject to the foregoing and subject to the qualifications set forth in this opinion letter and to any matters, documents or events not disclosed to us, we express the following opinions:

**Corporate Status**

- 1. The Company has been duly incorporated as a *besloten vennootschap met beperkte aansprakelijkheid* and is validly existing as a *naamloze vennootschap*.

**Registered Shares**

- 2. The Registered Shares have been validly issued and are fully paid and non-assessable.

The opinions expressed above are subject to the following qualifications:

- A. Opinion 1 must not be read to imply that the Company cannot be dissolved (*ontbonden*). A company such as the Company may be dissolved, *inter alia* by the competent court at the request of the company’s board of directors, any interested party (*belanghebbende*) or the public prosecution office in certain circumstances, such as when there are certain defects in the incorporation of the company. Any such dissolution will not have retro-active effect.

- B. Pursuant to Section 2:7 NCC, any transaction entered into by a legal entity may be nullified by the legal entity itself or its liquidator in bankruptcy proceedings (*curator*) if the objects of that entity were transgressed by the transaction and the other party to the transaction knew or should have known this without independent investigation (*wist of zonder eigen onderzoek moest weten*). The Netherlands Supreme Court (*Hoge Raad der Nederlanden*) has ruled that in determining whether the objects of a legal entity are transgressed, not only the description of the objects in that legal entity's articles of association (*statuten*) is decisive, but all (relevant) circumstances must be taken into account, in particular whether the interests of the legal entity were served by the transaction. Based on the objects clauses contained in the Prior Articles and the Current Articles, we have no reason to believe that, by entering into the Deeds of Issue, the Company transgressed the description of the objects contained in the Articles of Association. However, we cannot assess whether there are other relevant circumstances that must be taken into account, in particular whether the interests of the Company were served by entering into the Deeds of Issue since this is a matter of fact.
- C. Pursuant to Section 2:98c NCC, a *naamloze vennootschap* may grant loans (*leningen verstrekken*) only in accordance with the restrictions set out in Section 2:98c NCC, and may not provide security (*zekerheid stellen*), give a price guarantee (*koersgarantie geven*) or otherwise bind itself, whether jointly and severally or otherwise with or for third parties (*zich op andere wijze sterk maken of zich hoofdelijk of anderszins naast of voor anderen verbinden*) with a view to (*met het oog op*) the subscription or acquisition by third parties of shares in its share capital or depository receipts. This prohibition also applies to its subsidiaries (*dochtervennootschappen*). It is generally assumed that a transaction entered into in violation of Section 2:98c NCC is null and void (*nietig*). Based on the content of the Deeds of Issue, we have no reason to believe that the Company or its subsidiaries violated Section 2:98c NCC in connection with the issue of the Registered Shares. However, we cannot confirm this definitively, since the determination of whether a company (or a subsidiary) has provided security, has given a price guarantee or has otherwise bound itself, with a view to the subscription or acquisition by third parties of shares in its share capital or depository receipts, as described above, is a matter of fact.

- D. The opinions expressed in this opinion letter may be limited or affected by:
- a. any applicable bankruptcy, insolvency, reorganisation, moratorium or other similar laws or procedures now or hereafter in effect, relating to or affecting the enforcement or protection of creditors' rights generally;
  - b. the provisions of fraudulent preference and fraudulent conveyance (*Actio Pauliana*) and similar rights available in other jurisdictions to liquidators in bankruptcy proceedings or creditors;
  - c. claims based on tort (*onrechtmatige daad*);
  - d. sanctions and measures, including but not limited to those concerning export control, pursuant to European Union regulations, under the Sanctions Act 1977 (*Sanctiewet 1977*) or other legislation;
  - e. the Anti-Boycott Regulation and related legislation; and
  - f. the rules of force majeure (*niet toerekenbare tekortkoming*), reasonableness and fairness (*redelijkheid en billijkheid*), suspension (*opschorting*), dissolution (*ontbinding*), unforeseen circumstances (*onvoorziene omstandigheden*) and vitiated consent (i.e., duress (*bedreiging*), fraud (*bedrog*), abuse of circumstances (*misbruik van omstandigheden*) and error (*dwaling*)) or a difference of intention (*wil*) and declaration (*verklaring*).
- E. The term “non-assessable” has no equivalent in the Dutch language and for purposes of this opinion letter such term should be interpreted to mean that a holder of a share will not by reason of merely being such a holder be subject to assessment or calls by the Company or its creditors for further payment on such share.
- F. This opinion letter does not purport to express any opinion or view on the operational rules and procedures of any clearing or settlement system or agency.



We consent to the filing of this opinion letter as an exhibit to the Registration Statement and also consent to the reference to NautaDutilh in the Registration Statement under the caption “Legal Matters”.

Sincerely yours,

/s/ NautaDutilh N.V.

NautaDutilh N.V.

**EXHIBIT A**

**LIST OF DEFINITIONS**

<b>“Anti-Boycott Regulation”</b>	The Council Regulation (EC) No 2271/96 of 22 November 1996 on protecting against the effects of the extra-territorial application of legislation adopted by a third country, and actions based thereon or resulting therefrom.
<b>“Articles of Association”</b>	The Company’s articles of association ( <i>statuten</i> ) as they read from time to time.
<b>“Board of Directors”</b>	The Company’s board of directors ( <i>bestuur</i> ) following the execution of the Deed of Amendment.
<b>“Commercial Register”</b>	The Netherlands Commercial Register ( <i>handelsregister</i> ).
<b>“Common Shares”</b>	Common shares in the Company’s capital, with a nominal value of EUR 0.09 each.
<b>“Company”</b>	Merus N.V., a public company with limited liability ( <i>naamloze vennootschap</i> ), registered with the Commercial Register under number 30189136.
<b>“Corporate Documents”</b>	The Deed of Incorporation, the Deed of Conversion, the Deed of Amendment, the Prior Articles, the Current Articles, the Resolutions and the Registration Statement.
<b>“Current Articles”</b>	The Articles of Association as they read immediately after the execution the Deed of Amendment.
<b>“Deed of Amendment”</b>	The deed of amendment to the Articles of Association, dated May 29, 2017.
<b>“Deed of Incorporation”</b>	The Company’s deed of incorporation ( <i>akte van oprichting</i> ), dated June 16, 2003.
<b>“Deed of Conversion”</b>	The deed of conversion and amendment to the Articles of Association, dated May 19, 2016.

<b>“Deeds of Issue”</b>	The following deeds of issue of Registered Shares: <ul style="list-style-type: none"><li>i. the deed of issue of 3,200,000 Common Shares to Incyte, dated January 23, 2017; and</li><li>ii. the deed of issue of 3,099,997 Common Shares to the respective Investors, dated February 15, 2018.</li></ul>
<b>“General Meeting”</b>	The Company’s general meeting of shareholders ( <i>algemene vergadering van aandeelhouders</i> ).
<b>“Incyte”</b>	Incyte Corporation.
<b>“Investors”</b>	Biotechnology Value Fund, L.P., Biotechnology Value Fund II, LP, Investment 10, LLC, MSI BVF SPV, L.L.C., Biotechnology Value Trading Fund OS, L.P., Aquilo Capital, L.P., Aquilo Capital II, L.P., Sofinnova Venture Partners IX, L.P. and LSP Life Sciences Fund N.V.
<b>“Management Board”</b>	The Company’s management board ( <i>bestuur</i> ) prior to the execution of the Deed of Amendment.
<b>“NautaDutilh”</b>	NautaDutilh N.V.
<b>“NCC”</b>	The Netherlands Civil Code ( <i>Burgerlijk Wetboek</i> ).
<b>“the Netherlands”</b>	The European territory of the Kingdom of the Netherlands.
<b>“Prior Articles”</b>	The Articles of Association as they read immediately after the execution the Deed of Conversion.
<b>“Registered Shares”</b>	The 6,299,997 Common Shares issued pursuant to the respective Deeds of Issue.
<b>“Registration Statement”</b>	The Company’s registration statement on Form F-1 filed or to be filed with the SEC in connection with the registration of the Registered Shares on or about the date of this opinion letter, in the form reviewed by us.

<b>“Relevant Moment”</b>	Each moment when Registered Shares were issued pursuant to the respective Deeds of Issue.
<b>“Resolutions”</b>	<ol style="list-style-type: none"><li>i. the written resolution of the General Meeting, dated May 6, 2016;</li><li>ii. the written resolution of the meeting of holders of preferred shares in the Company’s capital, dated May 6, 2016;</li><li>iii. the written resolution of the Management Board, dated December 19, 2016;</li><li>iv. the written resolution of the Supervisory Board, dated December 19, 2016;</li><li>v. the minutes of the General Meeting held on May 24, 2017, together with the convening notice for such General Meeting and the explanatory notes tehereto as available on the Company’s website on the date of this opinion letter; and</li><li>vi. the written resolution of the Board of Directors, dated February 13, 2018, together with Exhibit A to the Securities Purchase Agreement (as defined in such written resolution).</li></ol>
<b>“SEC”</b>	The United States Securities and Exchange Commission.
<b>“Supervisory Board”</b>	The Company’s supervisory board ( <i>raad van commissarissen</i> ) prior to the execution of the Deed of Amendment.

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Merus N.V.:

We consent to the use of our report dated April 3, 2019, with respect to the consolidated statements of financial position of Merus N.V. as of December 31, 2018 and 2017, and the related consolidated statements of profit or loss and comprehensive loss, changes in equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes incorporated herein by reference and to the reference to our firm under the heading “Experts” in the prospectus. Our report refers to the adoption of International Financial Reporting Standard 15 Revenue from Contracts with Customers.

/s/ KPMG Accountants N.V.

Amstelveen, the Netherlands  
April 3, 2019