

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

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

**Merus N.V.**

(Exact Name of Registrant as Specified in its Charter)

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

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

2834  
(Primary Standard Industrial  
Classification Code Number)

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

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

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(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:*

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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. ☐

**CALCULATION OF REGISTRATION FEE**

Title of each Class of Securities to be Registered	Amount to Be Registered(1)	Proposed Maximum Offering Price per Share(2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common shares, nominal value €0.09 per share	6,299,997	\$12.04	\$75,851,964	\$9,193

(1) Pursuant to Rule 416(a) of the Securities Act of 1933, as amended, this registration statement also covers such additional shares as may hereafter be offered or issued to prevent dilution resulting from share splits, share dividends, recapitalizations or certain other capital adjustments.

(2) Calculated in accordance with Rule 457(c) under the Securities Act of 1933, as amended, based on the average of the high and low prices reported for the registrant's common shares on December 20, 2018.

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.

**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                      , 2019**

**PROSPECTUS**



**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 December 26, 2018, the last reported sale price of our common shares on The Nasdaq Global Market was \$13.40 per share.

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

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

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.

## **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;
- clinical development for MCLA-128 as part of a combination therapy for metastatic breast cancer and in other solid tumor cancers, MCLA-117 for the treatment of patients with acute myeloid leukemia, or AML, and MCLA-158 for the treatment of patients with solid tumors with an initial focus on metastatic colorectal cancer;
- research and development for MCLA-145, which is being co-developed with Incyte, 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 carefully, including the “Risk Factors,” “Business” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” sections and our audited financial statements, including the notes thereto, included in this prospectus, before deciding to invest in our common shares.*

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. 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 were effective in killing tumor cells, a result that we believe supports their potential efficacy in the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our 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 with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 blocks the HER3 signaling pathway by employing a DOCK & BLOCK® mechanism of action. 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 effectively 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. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and non-small cell lung cancer, or NSCLC, is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress, or ESMO, in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients), with MCLA-128 being well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored to date, and showing a low risk of immunogenicity. Promising single agent antitumor activity was seen in heavily pretreated gastric cancer/gastro-oesophageal junction, or GC/GEJ, cancer patients progressing on anti-HER2 therapy.

In May 2016, we commenced a Phase 1, single-arm, open-label, global clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML, and we announced the filing of the Investigational New Drug application, or IND, 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 binds to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of AML tumor cells and stem cells in newly diagnosed and relapsed patients. MCLA-117 is designed to recruit and activate T-cells to kill AML tumor

cells and stem cells. In our pre-clinical studies, MCLA-117 killed tumor cells in blood samples of AML patients. We plan to seek orphan drug designation for MCLA-117 for the treatment of AML from the 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 a Phase 1, open-label, multicenter clinical trial of MCLA-158 and expect emerging data by the end of 2019. MCLA-158 is designed to kill cancer stem cells using two different mechanisms of action. The first mechanism of action involves blocking growth and survival pathways in tumor stem cells. The second mechanism of action involves the recruitment and enhancement of immune effector cells.

Additionally, we also have a pipeline of proprietary antibody candidates in preclinical development, including the bispecific antibody candidate MCLA-145, which is being developed in collaboration with Incyte Corporation and is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. We expect to provide further information on this program upon acceptance of an IND for MCLA-145. We also have several other antibody candidates in pre-clinical development that bind to other target combinations. Each of our antibody candidates in our preclinical and clinical pipeline are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA.

Our Biclomics® technology platform employs an array of proprietary technologies and techniques to generate bispecific human antibodies. We utilize our patented MeMo® mouse harboring a common light chain in its germline that is capable of producing an array of antibodies with diverse heavy chains that are capable of binding virtually any antigen, the information from which can then be used to generate bispecific antibody candidates. We 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 Biclomics® therapeutic candidates with differentiated modes of action. The Biclomics® technology also includes use of proprietary host cells and patented dimerization technology for efficient bispecific antibody production. The Biclomics® format retains the IgG format of conventional mAbs, designed to preserve the format's key features, including stability, long half-life and low immunogenicity, when developing our bispecific antibody candidates. We leverage industry-standard manufacturing processes and infrastructure to efficiently produce Biclomics®.

## Our 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 cancer. We commenced a Phase 1/2 clinical trial of MCLA-128 in Europe in February 2015. In the dose escalation phase of the trial, the recommended dose of MCLA-128 was established. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies. In January 2018, we commenced a combination Phase 2 clinical trial in the United States for MCLA-128 and we plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial

evaluating single agent activity for MCLA-128 in gastric cancer and NSCLC is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at ESMO in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients), with MCLA-128 being well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored to date and showing a low risk of immunogenicity. Promising single-agent trial antitumor activity was seen in heavily pretreated GC/GEJ cancer patients progressing on anti-HER2 therapy. We believe that if MCLA-128 is successfully developed and obtains regulatory approval, it has the potential to address disease-specific challenges that are not currently being met by existing therapies.

- **Successfully develop our second most advanced bispecific antibody candidate, MCLA-117, for the treatment of AML.** We are developing MCLA-117 for the treatment of patients with AML. We commenced a Phase 1 clinical trial of MCLA-117 in Europe in May 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity and filed an IND in the United States in January 2018, for which we obtained authorization to proceed from the FDA in February 2018. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. If the results of this clinical trial are favorable, we plan to seek orphan drug designation from the FDA and the EMA for MCLA-117 for the treatment of AML. We believe that if MCLA-117 is successfully developed and obtains regulatory approval, it has the potential to transform the treatment of AML. We also intend to evaluate MCLA-117 for the treatment of MDS.
- **Successfully develop our third bispecific antibody candidate, MCLA-158, for the treatment of metastatic colorectal cancer and other solid tumors.** We are developing MCLA-158 for the treatment of solid tumors with an initial focus on the treatment of metastatic colorectal cancer. MCLA-158 has received approval of a CTA in several European countries for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018, 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 and expect emerging data by the end of 2019. MCLA-158 is an ADCC-enhanced Biclonics® 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. 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.
- **Accelerate the internal discovery and development of additional immunotherapeutic antibody candidates.** We believe we are well positioned to expand our pipeline of Biclonics® 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 Biclonics® therapeutic candidates with differentiated modes of action that have the potential to kill tumor cells with high potency. We are conducting pre-clinical studies of MCLA-145 in collaboration with Incyte and expect to provide further information on this program upon acceptance of an IND for MCLA-145. We are also conducting pre-clinical studies in an array of proprietary preclinical candidates binding to other target combinations that are the subject of our internal programs.
- **Seek strategic collaborative relationships.** We intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Biclonics® technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We have entered into



collaborations with Incyte, ONO Pharmaceutical Co., Ltd., and Simcere Pharmaceutical Group, 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:

Program	Targets	Indication/drug combination	Pre-IND/CTA	Phase 1	Phase 2	Merus rights
MCLA-128	HER2, HER3	Breast (HER2+) + Herceptin + chemo				worldwide
		Breast (ER+) + hormone therapy				worldwide
		Solid tumors (monotherapy)*				worldwide
MCLA-117	CD3, CLEC12A	AML				worldwide
MCLA-158	EGFR, Lgr5	Solid tumors				worldwide
MCLA-145	PD-L1, undisc.	Solid tumors		Collaboration with Incyte Corporation		US
.....	Undisclosed	Autoimmune disease		Collaboration with Ono Pharmaceutical		N/A

\*Phase 1/2

## 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 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, including MCLA-128, MCLA-117 and MCLA-158, 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, such as our agreement with Incyte Corporation, 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	22,750,867 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 22,750,867 common shares outstanding as of October 31, 2018 and excludes the following:	
<ul style="list-style-type: none"><li>• 2,621,256 common shares issuable upon the exercise of share options outstanding as of October 31, 2018 at a weighted average exercise price of €14.63 per share;</li><li>• 109,412 common shares issuable upon the vesting of restricted share units outstanding as of October 31, 2018; and</li><li>• 552,249 common shares reserved for future issuance under our 2016 Incentive Award Plan as described in "Management—Long-Term Incentive Plan."</li></ul>	

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 October 31, 2018.

## SUMMARY FINANCIAL DATA

You should read the following summary financial data together with our financial statements and the related notes thereto included elsewhere and incorporated by reference in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the statement of profit or loss and comprehensive loss data for the years ended December 31, 2016 and 2017 and the statement of financial position data as of December 31, 2017 from our audited financial statements incorporated by reference in this prospectus. We have derived the statement of profit or loss and comprehensive loss data for the six months ended June 30, 2017 and 2018 and the statement of financial position data as of June 30, 2018 from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

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

	Year ended December 31,		Six-month period ended	
	2017 Restated**	2016 Restated**	2018	2017 Restated**
(euros in thousands, except per share data)				
<b>Revenue</b>	21,915	2,510	16,464	10,121
Research and development costs	(34,125)	(18,424)	(22,821)	(15,427)
Management and administration costs	(13,697)	(4,258)	(5,491)	(7,694)
Other expenses	(9,395)	(7,709)	(5,983)	(4,120)
<b>Total operating expenses</b>	<b>(57,217)</b>	<b>(30,391)</b>	<b>(34,295)</b>	<b>(27,241)</b>
<b>Operating result</b>	<b>(35,302)</b>	<b>(27,881)</b>	<b>(17,831)</b>	<b>(17,120)</b>
Finance income	1,112	88	4,945	610
Finance cost	(30,335)	(19,644)	(1)	(22,696)
<b>Net finance income / (expense)</b>	<b>(29,223)</b>	<b>(19,556)</b>	<b>4,944</b>	<b>(22,086)</b>
<b>Result before taxation</b>	<b>(64,525)</b>	<b>(47,437)</b>	<b>(12,887)</b>	<b>(39,206)</b>
Income tax expense	(249)	—	(139)	(118)
<b>Result after taxation</b>	<b>(64,774)</b>	<b>(47,437)</b>	<b>(13,026)</b>	<b>(39,324)</b>
<b>Other comprehensive income</b>				
Exchange differences from the translation of foreign operations	89	8	21	18
<b>Total other comprehensive income for the period</b>	<b>89</b>	<b>8</b>	<b>21</b>	<b>18</b>
<b>Total comprehensive loss for the period</b>	<b>(64,685)</b>	<b>(47,429)</b>	<b>(13,005)</b>	<b>(39,306)</b>
<b>Basic (and diluted) loss per share*</b>	<b>(3.37)</b>	<b>(3.58)</b>	<b>(0.60)</b>	<b>(2.07)</b>
<b>Weighted average shares outstanding</b>				
<b>Basic (and diluted)*</b>	<b>19,196,440</b>	<b>13,236,649</b>	<b>21,809,950</b>	<b>18,976,446</b>

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

\*\* Revenue for the periods noted has been restated due to the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition. Revenue for the year ended December 31, 2017 has been restated to reflect additional revenue of €8.3 million, or €0.43 per share,

primarily related to the amortization of the up-front license payment received from Incyte. Revenue for the year ended December 31, 2016 has been restated to reflect a reduction in revenue of €0.2 million, or €0.01 per share, related to lower amortization of the up-front license payment received from ONO. Revenue for the six months ended June 30, 2017 has been restated to reflect additional revenue of €3.8 million, or €0.20 per share, related to the amortization of the up-front license payment received from Incyte.

	As of <u>June 30, 2018</u> (euros in thousands)
<b>Statement of Financial Position Data:</b>	
Cash and cash equivalents	€ 170,327
Total assets	231,955
Total liabilities	139,083
Accumulated loss	(167,226)
Total equity	92,872

## 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 €64.7 million, €47.4 million, and €23.3 million for the years ended December 31, 2017, 2016, and 2015, respectively, and €13.0 million and €39.3 million for the six months ended June 30, 2018 and 2017, respectively.

As of June 30, 2018, we had an accumulated loss of €167.2 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;
- continue the research and development of our other bispecific antibody candidates, including completing pre-clinical studies and commencing clinical trials for MCLA-145, which is being co-developed with Incyte Corporation, or Incyte;
- 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 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 (i) the initial public offering of our common shares, (ii) a placement of equity securities with Incyte Corporation, or Incyte, (iii) an upfront milestone payment received from Incyte under a collaboration and license agreement, or the Collaboration Agreement and (iv) a private placement of common shares in February 2018. 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®, our technology platform, identifying potential bispecific antibody candidates, conducting pre-clinical studies of a variety of candidates, including MCLA-145 and conducting our clinical trials of MCLA-128, MCLA-117 and MCLA-158. We are in the early stages of development of our bispecific antibody candidates, and we have not completed development of any Biclomics® or any other drugs or biologics.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our bispecific antibody candidates, discovering and developing additional 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 continue to research, develop and conduct pre-clinical studies of MCLA-145 and 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 June 30, 2018 and the proceeds received from the \$15.0 million investment by Regeneron Pharmaceuticals in December 2018 will be sufficient to fund our operations into the second quarter of 2021. We have based this estimate on assumptions that may prove to be wrong, and



we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost, progress and results of our ongoing clinical trials of MCLA-128 and the Phase 1 clinical trials of MCLA-117 and MCLA-158;
- the success of our collaboration with Incyte to develop bispecific antibodies candidates, including research and development and clinical trials 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 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 Biclonics® 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 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, 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;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

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

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

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

We are subject to a number of anti-corruption laws, including the Foreign Corrupt Practices Act, or FCPA, in the United States, the Bribery Act in the United Kingdom and the anti-corruption provisions of the Dutch Criminal Code in the Netherlands. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or keeping business and/or other benefits. 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, 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, 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 establishing the appropriate dosage levels in clinical trials;
- delays in or failure to recruit suitable patients to participate in a trial;
- the difficulty in certain countries in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or Health Authorities, as applicable, to suspend or terminate a trial if we or our collaborators or Health Authorities, find that the participants are being exposed to unacceptable health risks;
- delays in or failure to obtain regulatory approval to commence a trial;

- delays in or failure to obtain institutional review board, or IRB, approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of bispecific antibody candidate for use in clinical trials;
- the quality or stability of a bispecific antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our bispecific antibody candidates no longer relevant;
- third party actions claiming infringement by our bispecific antibody candidates in clinical trials outside of the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

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

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

Clinical trials must be conducted in accordance with the FDA, the EU and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our bispecific antibody candidates produced under current good manufacturing practice, or cGMP, requirements and other regulations. Furthermore, we rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and while we have agreements governing their committed activities, we have limited influence over their actual performance. We depend on our collaborators and on medical institutions and CROs to conduct our clinical trials in compliance with good clinical practice, or GCP, requirements. To the extent our collaborators or the CROs fail to enroll participants for our clinical trials, fail to conduct the study to GCP standards or are delayed for a significant time in the execution of trials, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business. In addition, clinical trials that are conducted in countries outside the EU and the United

States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

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

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

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

Any of these events could prevent us, our collaborators or our potential future partners from achieving or maintaining market acceptance of the affected product or could substantially increase commercialization costs



and expenses, which in turn could delay or prevent us from generating significant revenue from the sale of our products.

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

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

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

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

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

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

Patient enrollment depends on many factors, including the size and nature of the patient population, eligibility criteria for the trial, the proximity of patients to clinical sites, the design of the clinical protocol, the availability of competing clinical trials, the availability of new drugs approved for the indication the clinical trial is investigating, and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies. These factors may make it difficult for us to enroll enough patients to complete our clinical trials in a timely and cost-effective manner. Delays in the completion of any clinical trial of our bispecific antibody candidates will increase our costs, slow down our bispecific antibody candidate development and approval process and delay or potentially jeopardize our ability to commence product sales and generate revenue. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our bispecific antibody candidates.

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

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

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

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

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

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

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

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

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that a bispecific antibody candidate is safe and effective for its proposed indication;

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

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

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

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

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

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

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

A key element of our strategy is to use and expand our Biclomics® 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 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;
- new requirements to report certain financial arrangements with physicians and certain others, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;

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- 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 will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. However, 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 bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act, 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, the Cures Act, among other things, which is intended to modernize the regulation of drugs and biologics and spur innovation, has not yet been implemented and its ultimate implementation is unclear. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our bispecific antibody candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

***We 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, 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 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 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 two of the more commonly used transfer mechanisms, the EU model clauses and the U.S. Privacy Shield, and all adequacy decisions may be subject to review by the European Commission at any time. It is uncertain whether these mechanisms will be invalidated by the EU courts or following review. Invalidation of any mechanism on which we rely could require operational changes and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business. 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, collaborators may decide to market and sell products that compete with the bispecific antibody candidates that we have agreed to license to them, and any competition by our collaborators could also have a material adverse effect on our future business, financial condition and results of operations.

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

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

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

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

We plan to seek orphan drug designation from the FDA and the EMA for our assets in clinical development, including MCLA-128 or MCLA-117, 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 collaboration partners to invest in the development of our bispecific antibody candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our bispecific antibody candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our bispecific antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our bispecific antibody candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our bispecific antibody candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

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

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

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

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

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

Even if the FDA, the EMA or any other regulatory authority approves the marketing of any bispecific antibody candidates that we develop on our own or with a 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 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 and Simcere Pharmaceutical Group 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 collaboration partner devotes to the product development program;

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

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

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

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

#### **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 technology, including our bispecific antibody and antibody candidates, products and methods used to manufacture those antibody and antibody candidates, the methods for treating patients using those products, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and bispecific antibody candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or 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 bispecific antibody candidates, third parties may initiate opposition, interference, re-examination, post-grant review, inter

partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or 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. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

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

To protect our competitive position, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being required to pay us any license fees. In addition, 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 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 novelty, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the U.S. Patent and Trademark Office, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our technologies, products, methods or certain aspects of our Biclomics® technology platform. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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

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

It is also possible that we failed to identify relevant patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technology could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to gain broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, 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 infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products.

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

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

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

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 proceedings or other intellectual property proceedings inside and outside of the United States may divert management from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, incorporating, manufacturing or using our products in the United States and/or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;
- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or
- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

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

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, we could have a substantial adverse effect on the price of our common shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

We currently have rights to the intellectual property, including patent applications relating to our bispecific antibody candidates. Because our programs may require the use of proprietary rights held by third parties, the

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

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

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain a license to third-party intellectual property rights necessary for the development of a bispecific antibody candidate or program, we may have to abandon development of that bispecific antibody candidate or program and our business and financial condition could suffer.

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

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

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

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

Depending upon the timing, duration and conditions of FDA marketing approval of our bispecific antibody candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug



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

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

We generally file our first patent application (*i.e.*, priority filing) at the EPO. International applications under the Patent Cooperation Treaty, or PCT, are usually filed within 12 months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our bispecific antibody candidates may be marketed. We have so far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same bispecific antibody candidate and/or technology.

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

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

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

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

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

- others may be able to make compounds that are the same as or similar to our bispecific antibody candidates but that are not covered by the claims of the patents that we own or have exclusively licensed.

- the patents of third parties may have an adverse effect on our business.
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed.
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions.
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights.
- it is possible that our pending patent applications will not lead to issued patents.
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license.
- we may not develop additional technologies that are patentable.

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

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

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

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

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

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

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

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

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

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

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

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our licensors or 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. 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. 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, 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 related technologies. These key management individuals include the members of our board of directors. For example, our founder and President & Chief Executive Officer, Ton Logtenberg, holds a Ph.D. in medical biology, was a professor in the Department of Immunology at Utrecht University and co-founded the Dutch biotechnology company, Crucell N.V.

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

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

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

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

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

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

- positive or negative results of testing and clinical trials by us, strategic partners or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our bispecific antibody candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;

- public concern relating to the commercial value or safety of any of our bispecific antibody candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical industry or in the economy as a whole; or
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our securities to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their common shares and may otherwise negatively affect the liquidity of our common shares. In addition, the stock market in general, and biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

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

As a public company, and particularly after we no longer qualify as an emerging growth company, we will continue to incur significant legal, accounting and other expenses related to our operation as a public company. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of 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 identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements and cause shareholders to lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.***

As a public reporting company, we are subject to the rules and regulations established from time to time by the SEC and Nasdaq. These rules and regulations require, among other things, that we have, and periodically evaluate, procedures with respect to our internal control over financial reporting. Reporting obligations as a public company are likely to continue to place a considerable strain on our financial and management systems, processes and controls, as well as on our personnel.

In addition, as a public company, we are required to document and test our internal control over financial reporting pursuant to Section 404 so that our management can certify as to the effectiveness of our internal control over financial reporting, which requires us to document and make significant changes to our internal control over financial reporting. While we are an “emerging growth company,” our independent registered public accounting firm will not be required to test the effectiveness of our internal control over financial reporting in connection with an auditor attestation pursuant to Section 404.

In its review of our internal control over financial reporting in connection with the annual audit for 2017, management has identified a material weakness associated with a lack of adequate cut-off procedures to ensure the timely recognition, measurement and classification of operating expenses and recording of certain period-end accruals. Specifically, we did not design and maintain effective internal control over the assessment of the accounting for significant contractual arrangements related to our clinical research and manufacturing agreements and the classification of operating expenses. In its review of our internal control over financial reporting in connection with the annual audit for the year ended December 31, 2016, management identified the following material weaknesses: insufficient accounting resources required to fulfill IFRS and SEC reporting requirements and the absence of comprehensive IFRS accounting policies and financial reporting procedures. As of December 31, 2017, these material weaknesses were not remediated. As a result of these material weaknesses, our management concluded that our internal control over financial reporting was not effective as of December 31, 2017. Notwithstanding these material weaknesses, our management, based on the substantial work performed, concluded that our consolidated financial statements for the periods covered by and included in this prospectus are fairly stated in all material respects in accordance with IFRS for each of the periods presented in this prospectus.

As described in the “Internal Control Over Financial Reporting” section of this prospectus, we have taken and plan to take additional steps intended to address the underlying causes of the material weakness. There can be no assurance that any measures we take will remediate the material weaknesses identified, nor can there be any assurance as to how quickly we will be able to remediate these material weaknesses. In addition, we may encounter problems or delays in completing the implementation of these measures. If these material weaknesses are not remediated, or if other undetected material weaknesses in our internal controls exist, it could result in material misstatements in our financial statements requiring us to restate previously issued financial statements. In addition, 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, including the ones noted above, 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.

***In preparing our financial statements, our management is required to apply accounting standards that require significant interpretation. If our interpretation is incorrect or if regulatory or other authorities disagree with our interpretation, we may be required to restate or revise previously issued financial statements, which could have a material adverse impact on our financial position and the perception of our company.***

The preparation of our financial statements in accordance with IFRS as issued by the IASB requires our management to make significant interpretations of accounting standards. Certain of these standards require our management to make particularly subjective or complex judgments about matters that are uncertain and such judgments can result in materially different amounts than would be recorded using a different interpretation of these standards. In addition, in implementing any new or revised accounting standards, our management must interpret these standards. If our interpretation of any accounting standard is incorrect or if regulatory or other authorities disagree with our interpretation, we may need to revise or restate previously issued financial statements.

On September 11, 2018, we received a comment letter from the staff of the Division of Corporation Finance of the SEC, or the Staff, relating to our Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and our Report on Form 6-K furnished on August 10, 2018, which included our unaudited interim financial statements for the six months ended June 30, 2018. We responded to these comments and received a second comment letter on November 1, 2018 to which we responded on December 3, 2018. We received a third comment letter on December 20, 2018 and are in the process of responding to the Staff. The Staff requested information regarding our recognition and measurement of revenue under our license and collaboration agreement and the related share subscription agreement with Incyte, or the Incyte Agreements. More specifically, the Staff requested information regarding our accounting for the \$80.0 million purchase by Incyte of our common shares under the share subscription agreement and our valuation of such purchase, our analysis of the allocation of the transaction price, including the \$120.0 million upfront payment under the license and collaboration agreement the timing of our accounting of the transaction, and our consideration of payments we may receive in connection with our collaboration with Incyte in light of our adoption of “IFRS 15—Revenue from Contracts with Customers,” or IFRS 15, which became effective for annual and interim reporting periods beginning on or after January 1, 2018. We have been discussing the comments with the Staff, and we cannot predict when these comments will be resolved or the outcome. If the Staff ultimately disagrees with our accounting related to the Incyte Agreements, the impact to our previously issued financial statements for the year ended December 31, 2017 and the subsequent interim periods could be material and we could be required to restate these financial statements, which could have a material adverse impact on our financial position. Such revision or restatement could also negatively affect the perception of our company’s financial operations, which could materially adversely impact our business and the trading price of our common shares.

***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 October 31, 2018, members of our senior management, our board of directors and shareholders affiliated with members of our board of directors, in the aggregate, owned approximately 9% 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.

In addition, in the event we receive an offer from a third party to acquire us or prior to our soliciting an offer from, or negotiating terms with, any third party, with respect to a sale or license of two of our undisclosed



product candidates in pre-clinical development, we must first notify one of our existing shareholders of such opportunity and negotiate in good faith with such shareholder the terms of a purchase or license agreement for such product candidates. This obligation may have the effect of delaying or preventing a change in control of us that shareholders may consider favorable, including transactions in which shareholders might otherwise receive a premium for your shares.

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

We have entered into a registration rights agreement pursuant to which we agreed, under certain circumstances, to file a registration statement to register the resale of the shares held by certain of our existing shareholders, as well as to cooperate in certain public offerings of such shares. In addition, we have registered and intend to continue to register all common shares that we may issue under our equity compensation plans. Once registered, these common shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates who hold such shares. In addition, in connection with entering into the Collaboration Agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which we issued and sold to Incyte 3,200,000 of our common shares. Incyte's ability to sell these common shares is subject to certain limitations, including 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.

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

We have not paid any cash dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that cash dividends will not be paid until we have an established revenue stream to support continuing cash dividends. Payment of any future dividends to shareholders will in addition effectively be at the discretion of the general meeting, upon proposal of the 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.

***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 Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, our shareholders may not have the same protections afforded to shareholders of companies that are not foreign private issuers. However, we are subject to Dutch laws and regulations with regard to such matters and 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) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors may not be United States citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board.

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

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

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

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

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

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

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not believe we were a “passive foreign investment company,” or PFIC, for our taxable year ended December 31, 2017; however, we may be a PFIC for the current taxable year. A non-U.S. company will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income, or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder (as defined 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 you to significant monetary penalties and may prevent the statute of limitations from starting with respect to your 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.***

The U.S. government has recently enacted comprehensive tax legislation that includes significant changes to the taxation of business entities, referenced herein as the Tax Reform Act. 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 this tax reform legislation may have on our business. The effect of the Tax Reform Act 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 any such legislation 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, Biclronics 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 June 30, 2018 derived from our unaudited interim financial statements included elsewhere 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,” “Selected Financial Data” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

<u>(euro in thousands)</u>	<u>As of June 30, 2018</u>
Cash and cash equivalents	€ 170,327
Borrowings (including current portion)	—
Shareholders’ equity:	
Issued capital:	
Common shares	2,037
Share premium	258,061
Accumulated loss	(167,226)
Total equity	92,872
Total capitalization	€ 92,872

The table above excludes:

- 2,631,822 common shares issuable upon the exercise of share options outstanding as of June 30, 2018 at a weighted average exercise price of €14.24 per share;
- 118,301 common shares issuable upon the vesting of restricted share units outstanding as of June 30, 2018; and
- 638,490 common shares reserved for future issuance under our 2016 Incentive Award Plan as of June 30, 2018.

## SELECTED FINANCIAL DATA

You should read the following selected financial data together with our financial statements and the related notes thereto included elsewhere and incorporated by reference in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” section of this prospectus. We have derived the statement of profit or loss and comprehensive loss data for the years ended December 31, 2015, 2016 and 2017 and the statement of financial position data as of December 31, 2016 and 2017 from our audited financial statements incorporated by reference in this prospectus. We have derived the statement of profit or loss and comprehensive loss data for the six months ended June 30, 2017 and 2018 and the statement of financial position data as of June 30, 2018 from our unaudited financial statements included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected in the future.

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

	Year Ended December 31				Six Months Ended June 30	
	2017 Restated**	2016 Restated**	2015 Restated**	2014 Restated***	2018	2017 Restated**
(euros in thousands, except share and per share data)						
<b>Statement of Profit or Loss and Comprehensive Loss Data:</b>						
<b>Revenue</b>	€ 21,915	€ 2,510	€ 1,905	€ 1,973	€ 16,464	€ 10,121
Research and development costs	(34,125)	(18,424)	(16,181)	(12,388)	(22,821)	(15,427)
Management and administration costs	(13,697)	(4,258)	(768)	(550)	(5,491)	(7,694)
Other expenses	(9,395)	(7,709)	(8,067)	(5,785)	(5,983)	(4,120)
<b>Total operating expenses</b>	<u>(57,217)</u>	<u>(30,391)</u>	<u>(25,016)</u>	<u>(18,723)</u>	<u>(34,295)</u>	<u>(27,241)</u>
<b>Operating result</b>	<u>(35,302)</u>	<u>(27,881)</u>	<u>(23,111)</u>	<u>(16,750)</u>	<u>(17,831)</u>	<u>(17,120)</u>
Finance income	1,112	88	50	50	4,945	610
Finance expense	(30,335)	(19,644)	(195)	(39)	(1)	(22,696)
<b>Net finance income / (expense)</b>	<u>(29,223)</u>	<u>(19,556)</u>	<u>(145)</u>	<u>11</u>	<u>4,944</u>	<u>(22,086)</u>
<b>Result before taxation</b>	<u>(64,525)</u>	<u>(47,437)</u>	<u>(23,256)</u>	<u>(16,739)</u>	<u>(12,887)</u>	<u>(39,206)</u>
Income tax expense	(249)	—	—	—	(139)	(118)
<b>Result after taxation</b>	<u>(64,774)</u>	<u>(47,437)</u>	<u>(23,256)</u>	<u>(16,739)</u>	<u>(13,026)</u>	<u>(39,324)</u>
<b>Other comprehensive income</b>						
Exchange differences from the translation of foreign operations	89	8	—	—	21	18
<b>Total other comprehensive income for the period</b>	<u>89</u>	<u>8</u>	<u>—</u>	<u>—</u>	<u>21</u>	<u>18</u>
<b>Total comprehensive loss for the period</b>	<u>€ (64,685)</u>	<u>€ (47,429)</u>	<u>€ (23,256)</u>	<u>€ (16,739)</u>	<u>€ (13,005)</u>	<u>€ (39,306)</u>
<b>Basic (and diluted) loss per share*</b>	<u>€ (3.37)</u>	<u>€ (3.58)</u>	<u>€ (3.96)</u>	<u>€ (5.92)</u>	<u>€ (0.60)</u>	<u>€ (2.07)</u>
<b>Weighted average shares outstanding, basic and diluted</b>						
	<u>19,196,440</u>	<u>13,236,649</u>	<u>5,871,237</u>	<u>2,829,500</u>	<u>21,809,950</u>	<u>18,976,446</u>

- \* For the periods included in these financial statements, share options were excluded from the diluted loss per share calculation as we were in a loss position in each period presented above. As a result, basic and diluted loss per share is equal.
- \*\* Revenue for the years ended December 31, 2017, 2016 and 2015 and for the six months ended June 30, 2017 have been restated due to the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition. Revenue for the year ended December 31, 2017 has been restated to reflect additional revenue of €8.3 million, or €0.43 per share, primarily related to the amortization of the up-front license payment received from Incyte. Revenue for the year ended December 31, 2016 has been restated to reflect a reduction in revenue of €0.2 million, or €0.01 per share, related to lower amortization of the up-front license payment received from ONO. Revenue for the year ended December 31, 2015 has been restated to reflect a reduction in revenue of €0.1 million, or €0.01 per share, related to lower amortization of the up-front license payment received from ONO. Revenue for the six months ended June 30, 2017 has been restated to reflect additional revenue of €3.8 million, or €0.20 per share, related to the amortization of the up-front license payment received from Incyte.
- \*\*\* Revenue for the year ended December 31, 2014 has been restated for the impact of the retrospective effects of the adoption of IFRS 15, which resulted in additional revenue of €0.7 million, or €0.23 per share, related to higher amortization of the up-front license payment received from ONO.

	As of December 31,		As of June 30	
	2017 Restated*	2016 Restated*	2018	2017 Restated*
(euros in thousands)				
<b>Statement of Financial Position Data:</b>				
Cash and cash equivalents	€ 149,678	€ 56,917	€ 170,327	€ 215,778
Total assets	196,803	72,310	231,955	223,629
Total liabilities	140,211	37,889	139,083	146,672
Accumulated loss	(158,775)	(106,905)	(167,226)	(138,331)
Total equity	56,592	34,421	92,872	76,957

- \* Total liabilities, accumulated loss and total equity have been restated for the impact of the retrospective effects of the adoption of IFRS 15, an accounting standard related to revenue recognition. The result of the restatement was a decrease to total liabilities and accumulated loss and an increase to total equity of €8.7 million, €0.4 million, and €4.2 million as of December 31, 2017, December 31, 2016 and June 30, 2017, respectively.

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

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

### Overview

We are a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics. 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 were effective in killing tumor cells, a result that we believe supports their potential efficacy in the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our 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 with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 blocks the HER3 signaling pathway by employing a DOCK & BLOCK® mechanism of action. 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 effectively 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. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and non-small cell lung cancer, or NSCLC, is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at the European Society for Medical Oncology Congress in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients), with MCLA-128 being well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored to date and showing a low risk of immunogenicity. Promising single agent antitumor activity was seen in heavily pretreated gastric cancer/gastro-oesophageal junction cancer patients progressing on anti-HER2 therapy.

In May 2016, we commenced a Phase 1, single-arm, open-label, global clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of acute myeloid leukemia, or AML, and we announced the filing of the IND in the United States for MCLA-117 in 2018 and the subsequent authorization to proceed with clinical studies by 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 binds to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of

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

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

Additionally, we also have a pipeline of proprietary antibody candidates in preclinical development, including the bispecific antibody candidate MCLA-145, which is being developed in collaboration with Incyte Corporation and is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. We expect to provide further information on this program upon acceptance of an IND for MCLA-145. We also have several other antibody candidates in pre-clinical development that bind to other target combinations. Each of our antibody candidates in our preclinical and clinical pipeline are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA.

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

We have financed our operations primarily through (i) the initial public offering of our common shares, (ii) a public placement of equity securities with Incyte Corporation, or Incyte, (iii) an upfront milestone payment received from Incyte under a collaboration and license agreement, or the Collaboration Agreement and (iv) a private placement of common shares on February 15, 2018. Commencing on May 9, 2016, we raised net proceeds of €51.1 million from the IPO of our common shares, received net proceeds of €74.4 million from placements of equity securities with Incyte and received aggregate net proceeds of €112.0 million from a license payment from Incyte in February of 2017. In February 2018, we issued and sold an aggregate of 3,099,997 of our common shares to certain new and existing investors for aggregate gross proceeds of approximately \$55.8 million, at a purchase price of \$18.00 per share. In December 2018, we issued and sold an aggregate of 600,000 shares to Regeneron Pharmaceuticals, Inc., or Regeneron, in connection with our settlement of certain litigation with Regeneron for aggregate gross proceeds of \$15.0 million. See “Business—Legal Proceedings.” As of June 30, 2018, we held cash and cash equivalents of €170.3 million.

In December 2016, we entered into a collaboration and license agreement, or the Collaboration Agreement, with Incyte Corporation, or Incyte. Under the terms of the Collaboration Agreement, we and Incyte agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing our proprietary bispecific technology platform. The collaboration encompasses up to 11 independent programs,

including two of our current preclinical immuno-oncology discovery programs. In January 2017, upon the Collaboration Agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120 million. For more on the Collaboration Agreement, see “Collaboration Agreements” below. In connection with the Collaboration Agreement, we entered into a Share Subscription Agreement, pursuant to which, in January 2017, we issued and sold to Incyte 3,200,000 common shares for an aggregate purchase price of \$80.0 million.

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

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

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

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

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of June 30, 2018 and the proceeds received from the \$15.0 million investment by Regeneron Pharmaceuticals in December 2018 will be sufficient to fund our operations into the second quarter of 2021. For this assessment we have taken into consideration our existing cash and cash equivalents of €170.3 million, which include the \$55.8 million, or €44.8 million, in proceeds received from our private placement offering that closed in February 2018, and investments of €53.7 million as of June 30, 2018 as well as \$15.0 million, or €13.1 million, in proceeds from Regeneron Pharmaceuticals. See “—Liquidity and Capital Resources.”

### **Collaboration Agreements**

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

### ***Incyte Corporation***

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

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

In January 2017, upon the Collaboration Agreement becoming effective, Incyte made an upfront non-refundable payment to us of \$120 million or €112.0 million for the rights granted under the Collaboration Agreement. For each program as to which we do not have commercialization or co-development rights, we are eligible to receive up to \$100 million in future contingent development and regulatory milestones and up to \$250 million in commercialization milestones, as well as tiered royalties ranging from 6% to 10% of global net sales. For each program as to which we have exercised our option to co-fund development, we are eligible to receive a 50% share of profits (or sustain 50% of any losses) in the United States and tiered royalties ranging from 6% to 10% of net sales of products outside of the United States. If we opt to cease co-funding a program as to which we exercised our co-development option, then we will no longer receive a share of profits in the United States but will be eligible to receive the same milestones from the co-funding termination date and the same tiered royalties described above with respect to non-co-developed programs and, depending on the stage at which we choose to cease co-funding development costs, additional royalties ranging up to 4% of net sales in the United States. For MCLA-145, for which we retain all commercial rights in the United States, we and Incyte are each eligible to receive tiered royalties on net sales in the other's territory at rates ranging from 6% to 10%.

The Collaboration Agreement will continue on a program-by-program basis until neither party has any royalty payment obligations with respect to such program or, if earlier, the termination of the Collaboration Agreement or any program in accordance with the terms of the Collaboration Agreement. The Collaboration Agreement may be terminated in its entirety, or on a program-by-program basis, by Incyte for convenience. The Collaboration Agreement may also be terminated by either party under certain other circumstances, including material breach, or on a program-by-program basis for patent challenge of patents under the applicable program, in each case as set forth in the Collaboration Agreement. If the Collaboration Agreement is terminated in its entirety or with respect to one or more programs, all rights in the terminated programs revert to us, subject to payment to Incyte



of a reverse royalty of up to 4% on sales of future products, if we elect to pursue development and commercialization of products arising from the terminated programs.

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

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

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

ONO paid us a non-refundable upfront fee of €1.0 million. We are eligible to receive up to an aggregate of €34.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved three of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €2.8 million in milestone payments. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we and our affiliates are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combinations that are the subject of this agreement. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO also provides funding for our research and development activities under an agreed-upon plan. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

On March 14, 2018, we entered into a second contract research and license agreement with ONO. Pursuant to an exclusive option granted to ONO in a prior agreement executed in April 2014, ONO exercised its option to enter into the March 2018 agreement. We granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on our Biclomics® technology platform against two undisclosed targets directed to a particular undisclosed target combination. ONO identifies and selects the licensed bispecific antibodies for which it is responsible for conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. ONO controls and has exclusive rights over the worldwide commercialization of any approved products, including worldwide supply, and is solely responsible for all costs and expenses related to commercialization. ONO has agreed to fund our research and development activities and be responsible for the payment of all costs and expenses for its own research and development activities, which are set out in a mutually agreed upon research plan. We retain all rights to use and commercialize any antibodies that are generated under the collaborative research program, excluding the up to five lead and/or selected antibodies against the targets ONO is pursuing, provided that the use and commercialization is not with respect to the particular target combination.

ONO has agreed to pay an upfront non-refundable payment of €700,000 for the rights granted and we are also eligible to receive an aggregate of €33.7 million in milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under the License Agreement, if any, the Company is eligible to receive a mid-single digit royalty on net sales.

For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combination that are the subject of this agreement. ONO also provides funding for our research and development activities under an agreed-upon plan. This research and license agreement will

expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

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

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

We received an upfront, non-refundable payment of \$2.75 million, or €2.3 million, relating to three separate research programs. We will be eligible to receive milestone payments contingent upon Simcere achieving certain specified development and commercial goals. We will be eligible to receive tiered royalty payments on sales of any products resulting from the collaboration in China from Simcere. Simcere will be eligible to receive tiered royalty payments on sales outside of China from us.

## **Financial Operations Overview**

### ***Revenue***

To date, our revenue has consisted principally of the amortization of up-front payments, milestones and cost reimbursements in support of our license and collaboration agreements and revenue from several government grants, primarily with respect to research and development activities related to the use of our Biclonics® technology in various indication areas. We have no products approved for sale. We do not expect to receive any revenue from any bispecific antibody candidates that we develop, including MCLA-128, MCLA-117 and MCLA-158 and our pre-clinical bispecific antibody candidates, including MCLA-145, until we obtain regulatory approval and commercialize such products, or until we potentially enter into collaborative agreements with third parties for the development and commercialization of such candidates.

We enter into collaboration agreements which are within the scope of IFRS 15, under which we license rights to certain of our product candidates and perform research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

Revenue is recognized when our customer obtains control of the goods or services, in an amount that reflects the consideration that we determine to expect to receive in exchange for those goods or services. To determine revenue recognition for arrangements that are within the scope of IFRS 15, We perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies the performance obligation. We apply the five-step model to contracts only when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services we transfer to the customer. As part of the accounting for these arrangements, we must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

We currently generate a portion of our revenue through collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of IFRS 15.

The adoption of IFRS 15 impacts the amortization of our up-front license payments. We previously recognized revenue from up-front license payments on a straight-line basis over the contractual term or the period of continuing involvement which was previously estimated to be 21 years for the collaboration and license agreement we entered into with Incyte on December 20, 2016, and 4.5 years for the research and license agreement the Company entered into with ONO on April 8, 2014. In applying IFRS 15, we evaluated the distinct performance obligations in each agreement. Specifically, for Incyte, the total period for which we expect to provide access to our proprietary technology is currently estimated to be nine years, which is the research term initially agreed to in the Incyte collaboration and license agreement.

We adopted the new standard effective January 1, 2018, using the retrospective method, with the effect of initially applying this standard recognized at the beginning of the earliest period presented. We had two open contracts on the adoption date and have assessed these contracts under the new revenue standard. In addition, we elected to apply the practical expedient to not apply this guidance to contracts that were completed before the beginning of the earliest period presented, or January 1, 2015, and the practical expedients for contract modifications (assessing the contracts in combination with any modifications before January 1, 2017). Under the practical expedient, we excluded certain option and exclusivity agreements that expired in 2015 and 2014, respectively. As a result of the adoption of IFRS 15, our prior year financial statements have been restated. We have accounted for the impact of adopting IFRS 15 as a cumulative catch-up as a decrease of approximately €8.7 million to deferred revenue with an offset to accumulated deficit, effective January 1, 2018.

#### *Up-front License Payments*

If the license to our intellectual property is determined to be distinct from the other performance obligations identified in the agreement, we recognize revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other performance obligations in the contract. For licenses that are combined with other performance obligations, we assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purpose of recognizing revenue. We evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition.

Pursuant to our research and license agreements with our collaborators, we have received upfront license payments relating to the integrated packages of deliverables under the contracts. Each contract contains either one single performance obligation or multiple performance obligations that the up-front consideration was allocated to. These upfront license payments are initially recorded in deferred revenue on the consolidated statements of financial position and are recognized as revenue on either: (i) a straight-line basis over the period of the related performance obligation or the contractual term of the arrangement; or (ii) based on another appropriate depiction of the Company's performance over the period of the related performance obligation or the contractual term, such as costs incurred relating to full-time equivalent research employees. The applicable period over which to recognize the upfront payment is a significant judgment, which is re-assessed at each reporting date.

We record revenue from our collaboration and license agreements with Incyte, ONO and Simcere. Under each agreement, we have received upfront license payments, which are initially recorded in deferred revenue.

#### *Collaboration Income*

Collaboration income, which is typically related to reimbursements from collaborators for our performance of research and development services under the respective agreements, is recognized on the basis of labor hours

valued at a contractually agreed rate. Collaboration income includes reimbursements for related out-of-pocket expenses. Cost reimbursements to which we are entitled under agreements are recognized as revenue in the same period as the cost for which they are intended to compensate. We act as the principal and therefore record these reimbursements as collaboration income. Under our agreements, Incyte and ONO reimburse us for these external expenses and compensate us for time spent on the project by our employees. We recognize these reimbursements and compensation as collaboration income. In addition, we record collaboration income in the same quarter of the recorded cost they are intended to compensate.

In determining the appropriate amount of revenue to be recognized as we fulfill our obligations under the agreements, we perform the five steps listed above. As part of the accounting for the arrangement, we must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. We use key assumptions to determine the stand-alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success. Finally, we capitalize the incremental costs of obtaining a contract with a customer if we expect to recover those costs. Such incremental costs would not have been incurred if the contract with a customer had not been obtained. To date, we have not capitalized any incremental costs for obtaining a contract.

Our contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, we re-evaluates the probability of achievement of development milestones and any related constraint, and if necessary, adjusts the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

#### *Government Grants*

Government grants are recognized when there is reasonable assurance that the conditions underlying the grant have been met and that the grant will be received. Government grants to cover research and development expenses incurred are recognized as revenue on a gross basis in the consolidated statement of profit or loss and comprehensive loss on a systematic basis over the periods in which we recognize expenses for the related costs for which the grants are intended to compensate. In the case of grants related to assets, the received grant will be deducted from the carrying amount of the asset. For these grants, we have reporting obligations at the end of the grant contract term. The unconditional receipt of the grant allowances is dependent on the final review of the reporting provided by us at the end of the contract term.

#### *Research and Development Costs*

Research and development costs consist principally of the costs associated with our research and development activities, conducting preclinical studies and clinical trials and activities related to our regulatory filings. Our research and development expenses consist of:

- salaries for research and development staff and related expenses, including share-based compensation expenses;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, and consultants that conduct and support clinical trials and preclinical studies
- costs to develop product candidates, including raw materials and supplies, product testing, and facility related expenses;
- costs associated with obtaining and maintaining patents and other intellectual property; and

- amortization and depreciation of tangible and intangible fixed assets used to develop our product candidates.

We expense research and development costs when we incur them. We record costs for certain development activities, such as clinical trials, based on an evaluation of the progress to completion of specific tasks using data such as subject enrollment, clinical site activations or information our vendors provide to us. We expense the manufacturing costs of our internally-developed product candidates that are used in clinical trials as they are incurred, as research and development expense. We do not allocate employee-related costs, depreciation, rental and other indirect costs to specific research and development programs because these costs are deployed across multiple programs under research and development and, as such, are separately classified as unallocated research and development expenses.

Research and development expenses are expected to increase as we advance the clinical development of MCLA-128, MCLA-117 and MCLA-158 and further advance the research and development of our pre-clinical bispecific antibody candidates and other earlier stage products. IND-enabling studies for MCLA-145, our most advanced drug candidate in our collaboration and license agreement with Incyte Corporation, are ongoing. The successful development of our bispecific antibody candidates is highly uncertain. At this time, we cannot reasonably estimate the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, or the period, if any, in which material net cash inflows may commence from, any of our bispecific antibody candidates. This is due to numerous risks and uncertainties associated with developing drugs, including the uncertainty of:

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

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

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our development programs progress, as we continue to support the clinical trials of our bispecific antibody candidates as treatments for various cancers and as we move these candidates into additional clinical trials. There are numerous factors associated with the successful commercialization of any of our bispecific antibody candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control may impact our clinical development programs and plans.

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

Our management and administration costs consist principally of salaries and related expenses for employees other than research and development staff, including share-based compensation expenses. We expect that our

management and administration costs will increase in the future as our business expands and we increase our headcount to support the expected growth in our operating activities.

### ***Other Expenses***

Other expenses consist principally of:

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

We expect our other expenses will increase in the future as we expand our operating activities and we continue to incur additional costs associated with operating as a public company. We expect other expenses to increase in future periods to support our research and development efforts, including the continuation of the clinical trials of our bispecific antibody candidates as treatments for various cancers and the initiation of clinical trials for potential new antibody candidates. These cost increases will likely be due to increased headcount, increased share-based compensation expenses, expanded infrastructure and increased costs for insurance. Public company-related expense increases will include costs of additional legal fees, accounting and audit fees, consulting fees, director and officer liability insurance premiums and costs related to investor relations.

### ***Finance Income and Expense***

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

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

## Results of Operations

### Comparison of Six Months Ended June 30, 2018 and 2017

The below table summarizes our results of operations for the six months ended June 30, 2018 and 2017.

	Six Months Ended June 30		Change	
	2018	2017 Restated	€	%
			(euros in thousands)	
Revenue	€ 16,464	€ 10,121	€ 6,343	63%
Research and development costs	(22,821)	(15,427)	(7,394)	48%
Management and administration costs	(5,491)	(7,694)	2,203	-29%
Other expenses	(5,983)	(4,120)	(1,863)	45%
Operating result	(17,831)	(17,120)	(711)	4%
Finance income	4,945	610	4,335	711%
Finance expenses	(1)	(22,696)	22,695	-100%
Net finance income / (expenses)	4,944	(22,086)	27,030	-122%
Income tax expense	(139)	(118)	(21)	18%
Result after taxation	(13,026)	(39,324)	26,298	-67%
Other comprehensive income	21	18	3	17%
Total comprehensive loss for the year	€(13,005)	€(39,306)	26,301	-67%

## Revenue

Total revenue increased by €6.3 million to €16.5 million for the six months ended June 30, 2018, from €10.1 million for the six months ended June 30, 2017. The increase in total revenue was primarily attributable to progress made with our license and collaboration agreements with Incyte, ONO and Simcere.

The adoption of IFRS 15 impacts the amortization of our up-front license payments. We previously recognized revenue from up-front license payments on a straight-line basis over the contractual term or the period of continuing involvement. In applying IFRS 15, we evaluated the distinct performance obligations for our Incyte Agreements, or the total period for which we expect to provide access to our proprietary technology which is currently estimated to be nine years, and resulted in the recognition of additional revenue of €3.8 million for up-front payment amortization.

The following table summarizes our components of revenue for the six months ended June 30, 2018 and June 30, 2017, respectively:

	Six Months ended June 30		Change	
	2018	2017 Restated	€	%
			(euros in thousands)	
Up-front payment amortization	€ 9,087	€ 6,898	€2,189	32%
Collaboration income	7,195	2,391	4,804	201%
Revenue from contracts with customers	16,282	9,289	6,993	75%
Income from grants on research projects	182	832	(650)	-78%
	€16,464	€10,121	6,343	63%

Up-front payment amortization was €9.1 million and €6.9 million for the six months ended June 30, 2018 and 2017, respectively. During the six months ended June 30, 2018, up-front payment amortization included amounts

related to our Incyte, ONO and Simcere Agreements. The increase in up-front payment amortization revenue related to €1.0 million for our Incyte Agreement, which did not begin until the end of the first quarter of 2017 and €1.1 and €0.1 million related to our 2018 ONO Agreement and Simcere Agreement, respectively, both of which began during the first quarter of 2018.

Collaboration income for the six months ended June 30, 2018 was €7.2 million and consisted of cost reimbursements and research milestones achieved in support of our research and license agreements with Incyte, ONO and Simcere. During the six months ended June 30, 2018, we recognized €4.3 million and €0.2 million of cost reimbursements in support of our research and license agreements with Incyte and ONO, respectively. We recognized an aggregate of €2.5 million and €0.1 million in research milestones under our ONO and Simcere agreements, respectively, for the six months ended June 30, 2018. During the six months ended June 30, 2017, €2.4 million of cost reimbursements in support of our research and license agreements with Incyte and ONO, respectively. We did not recognize any research milestones during 2017.

During 2018, we recognized €0.2 million in grant income compared to €0.8 million in grant income for the six months ended June 30, 2017. On June 12, 2017, the European Commission approved for reimbursement the final installment of the FP-7 grant for €0.7 million. Revenue for this final installment was recorded in income from grants on research projects during the six months ended June 30, 2017.

### Research and Development Costs

	Six Months ended June 30		Change	
	2018	2017	€	%
	(euros in thousands)			
Research and development costs	<u>€22,821</u>	<u>€15,427</u>	<u>7,394</u>	<u>48%</u>

Research and development costs increased €7.4 million, or 48%, to €22.8 million for the six months ended June 30, 2018, from €15.4 million for the six months ended June 30, 2017. The increase was primarily due to the following:

- €7.6 million and €2.2 increases in spending for our MCLA-128 and MCLA-145 programs in support of our ongoing clinical trial, pre-clinical and discovery programs incurring higher costs associated with development, manufacturing and production design activities;
- €3.7 million decrease in expenses in connection with our pre-clinical and discovery programs in support of ongoing development activities for MCLA-158 (€3.0 million) and clinical activities for MCLA-117 (€0.7 million);
- Increase of €0.5 million for conducting research and development, preclinical, manufacturing and production design in connection with various pre-clinical and discovery programs;
- €1.4 million increase in employee salary and related benefits attributable to the hiring of more development personnel during the six months ended June 30, 2018, a decrease of €0.1 million of subsidies under the WBSO Act, offset, in part, by a €0.5 million decrease in share compensation expenses; and
- €0.1 million decrease related to lower spending on intellectual property and license costs for legal and professional services.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials.



### Management and Administration Costs

Management and administrative costs consist of salaries and related expenses for employees in finance, legal, human resources and business development functions. These costs include all salary, salary related expenses and share-based compensation expenses.

	Six Months ended June 30		Change	
	2018	2017	€	%
	(euros in thousands)			
Management and administration costs	€5,491	€7,694	(2,203)	-28.6%

Management and administration costs decreased €2.2 million, or 28.6%, during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The decrease was primarily attributable to lower share-based compensation expenses of €3.0 million offset, in part, by the expansion of our headcount in finance, legal and business development functions to support the expansion of our operations and included increases in salary and related expenses of €0.8 million.

### Other Expenses

	Six Months ended June 30		Change	
	2018	2017	€	%
	(euros in thousands)			
Other expenses	€5,983	€4,120	1,863	45%

Other expenses increased €1.9 million, or 45%, during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. The increase was due to higher consulting, accounting and professional fees of €1.1 million in support of maintaining public company status, higher facilities expenses in support of higher headcount of €0.5 million and board oversight costs of €0.3 million.

	Six Months ended June 30		Change	
	2018	2017	€	%
	(euros in thousands)			
Finance income				
Interest income and similar income	834	610	224	37%
Net gain on foreign exchange	4,111	—	4,111	100%
	4,945	610	4,335	711%
Finance costs				
Interest expense	(1)	(10,667)	(10,666)	100%
Net loss on foreign exchange	—	(12,029)	(12,029)	-100%
	(1)	(22,696)	(22,695)	-100%

### Finance Income and Expense

Finance income increased €4.3 million, or 711%, during the six months ended June 30, 2018 as compared to the six months ended June 30, 2017. This increase was due to gains on our U.S. dollar denominated cash, cash equivalents and investments of approximately of €4.1 million due to a strengthening U.S. dollar during 2018. As of June 30, 2018, we held approximately \$92.6 million and \$40.9 million in U.S. dollar denominated cash and cash equivalent accounts and investment accounts, respectively, subject to the fluctuation in foreign currency

between the euro and U.S. dollar. Interest income primarily results from interest earned on cash held on account and accretion of investment earnings. Our current year increase in cash equivalents and investments was due primarily from the funds received as part of the private placement during the first quarter of 2018. We experienced increased losses on our U.S. dollar denominated cash, cash equivalents and investments of approximately €12.0 million during the six months ended June 30, 2017.

On December 20, 2016, we signed the Incyte Agreements whereas these contracts were denominated in U.S. dollars. We determined that the subscription agreement to sell our own shares to which we became committed on December 20, 2016, should be accounted for as a forward contract or a derivative financial instrument which was recognized in the statement of financial position as of December 31, 2016. Interest expense for the six months ended June 30, 2017 includes an amount of €10.7 million related to the effective settlement of the forward contract on January 23, 2017, the date the shares were issued and the date through which the related expense was incurred.

### **Income Tax Expense**

Income tax expenses were €0.1 million and €0.1 million for the six months ended June 30, 2018 and 2017, respectively. Income tax expense is attributable to our U.S. operating subsidiary which provides general management services and strategic advisory services to us.

### **Comparison of Years Ended December 31, 2017 and 2016**

The below table summarizes our results of operations for the years ended December 31, 2017 and 2016.

	Year Ended December 31		Change	
	2017 Restated	2016 Restated	€	%
	(euros in thousands)			
Revenue	€ 21,915	€ 2,510	€ 19,405	773.1%
Research and development costs	(34,125)	(18,424)	(15,701)	85.2%
Management and administration costs	(13,697)	(4,258)	(9,439)	221.7%
Other expenses	(9,395)	(7,709)	(1,686)	21.9%
Operating result	(35,302)	(27,881)	(7,421)	26.6%
Finance income	1,112	88	1,024	1164%
Finance expense	(30,335)	(19,644)	(10,691)	54%
Net finance income / (expense)	(29,223)	(19,556)	(9,667)	49.4%
Income tax expense	(249)	—	(249)	100.0%
Result after taxation	(64,774)	(47,437)	(17,337)	36.5%
Other comprehensive income	89	8	81	1,013%
Total comprehensive loss for the year	€(64,685)	€(47,429)	(17,256)	36.4%

### **Revenue**

Total revenue increased by €19.4 million, or 773%, to €21.9 million for the year ended December 31, 2017, from €2.5 million for the year ended December 31, 2016. The increase was primarily attributable to our license and collaboration agreement with Incyte, or the Incyte Agreement, which became effective during the first quarter of 2017 and for which we recognized revenue throughout 2017.

The adoption of IFRS 15 impacted the amortization of our up-front license payments. We previously recognized revenue from up-front license payments on a straight-line basis over the contractual term or the period of

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continuing involvement. In applying IFRS 15, we evaluated the distinct performance obligations for our Incyte and ONO Agreements, or the total period for which we expect to provide access to our proprietary technology. This evaluation resulted in a restatement to increase our revenue by €8.3 million primarily relating to up-front payments for our Incyte Agreements for the year ended December 31, 2017 and a restatement to decrease our revenue by €0.2 million relating to up-front payments for our ONO Agreement for the year ended December 31, 2016.

The following table summarizes our components of revenue:

	Year Ended December 31		Change	
	2017 Restated	2016 Restated	€	%
	(euros in thousands)			
Up-front payment amortization	€14,931	€ 14	14,917	106,550%
Collaboration income	5,789	1,109	4,680	422%
Income from grants on research projects	1,195	1,387	(192)	(14)%
Total revenue	<u>€21,915</u>	<u>€ 2,510</u>	<u>19,405</u>	<u>773%</u>

For the year ended December 31, 2017, up-front payment amortization increased €14.9 million and related entirely to the amortization of up-front payment received under our Incyte Agreements. For the year ended December 31, 2016, we recognized less than €0.1 million of amortization of the up-front payment related to our April 2014 ONO agreement.

Collaboration income for the year ended December 31, 2017 was €5.8 million and consisted of cost reimbursements in support of our research and license agreements with Incyte and ONO. We did not recognize any research milestones during 2017. During 2016, we recognized one research milestone reached by our agreement with ONO which amounted to €0.7 million. Additionally, we received an amount of €0.4 million revenue from a new consultancy agreement that was signed with ONO on March 7, 2016. During 2017, we had two active grants consisting of cash allowances for specific research and development projects. For the years ended December 31, 2017 and 2016, we recognized €1.2 million and €1.4 million in grant income, respectively.

### **Research and Development Costs**

	Year Ended December 31		Change	
	2017	2016	€	%
	(euros in thousands)			
Research and development costs	<u>€34,125</u>	<u>€18,424</u>	<u>€15,701</u>	<u>85%</u>

Research and development costs increased €15.7 million, or 85%, to €34.1 million for the year ended December 31, 2017, from €18.4 million for the year ended December 31, 2016. The increase was primarily due to the following:

- €9.1 million increase in expenses in connection with our pre-clinical and discovery programs in support of ongoing development activities for MCLA-158 (€3.5 million) and MCLA-145 (€3.2 million) and other expenses for conducting research and development, preclinical, manufacturing and production design in connection with various pre-clinical and discovery programs (€2.4);;
- €2.0 million increase in spending for our MCLA-128 and €0.4 million increase in spending for MCLA-117 programs in support of our ongoing clinical trials expenses;
- €2.6 million increase in employee salary and related benefits and €2.5 million increase in share compensation expenses, offset, in part, by the receipt of an additional €1.8 million in subsidies under

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the WBSO Act, all of which were attributable to the hiring of more development personnel during the year ended December 31, 2017; and

- €0.7 million increase related to higher spending on intellectual property and license costs for legal and professional services.

Our research and development expenses may vary substantially from period to period based on the timing of our research and development activities, including due to timing of initiation of clinical trials and enrollment of patients in clinical trials.

### **Management and Administration Costs**

Management and administrative costs consist of salaries and related expenses for employees in finance, legal, human resources and business development functions. These costs include all salary, salary related expenses and share-based compensation expenses.

	Year Ended December 31		Change	
	2017	2016	€	%
	(euros in thousands)			
Management and administration costs	€13,697	€4,258	€9,439	222%

Management and administration costs increased €9.4 million, or 222%, during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The increase was primarily attributable to an increase in employee headcount and compensation-related expenses of €2.5 million for non-research and development personnel and higher share-based compensation expenses of €6.9 million.

### **Other Expenses**

	Year Ended December 31		Change	
	2017	2016	€	%
	(euros in thousands)			
Other expenses	€9,395	€7,709	1,686	22%

Other expenses increased €1.7 million, or 22%, during the year ended December 31, 2017 as compared to the year ended December 31, 2016. The increase was due to higher consulting, accounting and professional fees of €1.7 million in support of maintaining public company status, higher facilities expenses in support of higher headcount of €0.4 million which were offset in part, by lower litigation costs of €0.4 million.

### **Finance Income (Expenses)**

	Year Ended December 31		Change	
	2017	2016	€	%
	(euros in thousands)			
Interest and similar income	€ 1,112	€ 88	€ 1,024	1164%
Net loss and foreign exchange	(19,449)	(409)	(19,040)	4655%
Interest expense	(10,696)	(19,235)	8,539	(44)%
Financing costs	(190)	—	(190)	100%
Total finance income (expense)	€(29,223)	€(19,556)	(9,667)	49%

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Finance expense increased €9.7 million during the year ended December 31, 2017 as compared to the year ended December 31, 2016. This increase was due to an increase in foreign exchange expense of €19.0 million, offset, in part, by an €8.5 million decrease in interest expense and higher interest income of €1.0 million.

Interest income primarily results from interest earned on cash held on account and accretion of investment earnings. Our current year increase in cash, cash equivalents and investments was due primarily from the \$200 million of funds received as part of the Incyte Agreements during the first quarter of 2017.

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

On December 20, 2016, we signed the Incyte Agreements whereas these contracts were denominated in U.S. dollars. We determined that the subscription agreement to sell our own shares to which we became committed on December 20, 2016, should be accounted for as a forward contract or a derivative financial instrument which was recognized in the statement of financial position as of December 31, 2016. The interest expense and similar expenses for the year ended December 31, 2017 include an amount of €10.7 million related to the effective settlement of the forward contract on January 23, 2017, the date the shares were issued and the date through which the related expense was incurred.

During 2017, we expensed €0.2 million of prepaid share issuance costs related to a potential future issuance of shares under our F-3 Registration Statement when the future issuance was no longer consider probable.

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

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

### ***Comparison of Years Ended December 31, 2016 and 2015***

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

	Year Ended December 31		Change	
	2016 Restated	2015 Restated	€	%
	(euros in thousands)			
Revenue	€ 2,510	€ 1,905	€ 605	31.8%
Research and development costs	(18,424)	(16,181)	(2,243)	13.9%
Management and administration costs	(4,258)	(768)	(3,490)	454.4%
Other expenses	(7,709)	(8,067)	358	(4.4%)
Operating result	(27,881)	(23,111)	(4,770)	20.6%
Finance income	88	50	38	76%
Finance expense	(19,644)	(195)	(19,449)	9,974%
Net finance income / (expense)	(19,556)	(145)	(19,411)	13,387%
Result after taxation	€(47,437)	€(23,256)	(24,181)	104.0%

### ***Revenue***

Total revenue increased by €0.6 million, or 32%, to €2.5 million for the year ended December 31, 2016, from €1.9 million for the year ended December 31, 2015. The increase was primarily attributable to the €0.7 million

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increase in grant revenue, mainly related to additional research activities performed under the FP7 grant, a research grant provided by the European Union.

The adoption of IFRS 15 also impacted the amortization of our up-front license payments. We previously recognized revenue from up-front license payments on a straight-line basis over the contractual term or the period of continuing involvement. In applying IFRS 15, we evaluated the distinct performance obligations for our ONO Agreements, or the total period for which we expect to provide access to our proprietary technology. This evaluation resulted in a restatement to decrease our revenue by €0.2 million and less than €0.1 million relating to up-front payment from our ONO Agreement for the years ended December 31, 2016 and 2015, respectively, as a result of the change in the estimated period of performance.

The following table summarizes our components of revenue:

	Year Ended December 31		Change	
	2016 Restated	2015 Restated	€	%
	(euros in thousands)			
Up-front payment amortization	€ 14	€ 151	(137)	(91%)
Collaboration income	1,109	1,092	17	2%
Income from grants on research projects	1,387	662	725	110%
Total revenue	<u>€ 2,510</u>	<u>€ 1,905</u>	<u>605</u>	<u>32%</u>

For the years ended December 31, 2016 and 2015, up-front payment amortization related entirely to our ONO agreement, which was fully amortized in the first quarter of 2016. Collaboration income for the year ended December 31, 2016 was €1.1 million and consisted of one research milestone recognized with ONO which amounted to €0.7 million and cost reimbursements in support of our research and license agreement with ONO. We recognized one research milestone during 2015 which amounted to €1.0 million. During 2016 and 2015, we had three and two active grants, respectively, consisting of cash allowances for specific research and development projects.

### **Research and Development Costs**

	Year Ended December 31		Change	
	2016	2015	€	%
	(euros in thousands)			
Research and development costs	<u>€18,424</u>	<u>€16,181</u>	<u>€2,243</u>	<u>14%</u>

Research and development costs increased €2.2 million, or 14%, to €18.4 million for the year ended December 31, 2016, from €16.2 million for the year ended December 31, 2015. The increase was primarily due to the following:

- €3.5 million increase in expenses in connection with the expansion of various pre-clinical and discovery programs during 2016;
- €2.1 million increase in expenses related to our MCLA-128 program, due to higher contract manufacturing costs and costs associated with pre-clinical studies;
- €1.3 million increase in employee salary and related benefits and €0.3 million increase in share compensation expenses, offset, in part, by the receipt of an additional €1.4 million in subsidies under

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the WBSO Act, all of which were attributable to the hiring of more development personnel during the year ended December 31, 2016; offset, in part by

- €3.8 million decrease in expenses related to our MCLA-117 program.

### **Management and Administration Costs**

	Year Ended December 31		Change	
	2016	2015	€	%
	(euros in thousands)			
Management and administration costs	€4,258	€768	€3,490	454%

Management and administration costs increased €3.5 million, or 454%, during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The increase was primarily attributable to an increase in employee headcount and compensation-related expenses of €1.5 million for non-research and development personnel and higher share-based compensation expenses of €2.0 million.

### **Other Expenses**

	Year Ended December 31		Change	
	2016	2015	€	%
	(euros in thousands)			
Other expenses	€7,709	€8,067	-358	-4%

Other expenses decreased €0.4 million, or 4%, during the year ended December 31, 2016 as compared to the year ended December 31, 2015. The decrease was primarily attributable to a decrease of €2.9 million in lower litigation costs, offset by increases of €1.9 million for consulting, accounting and legal fees in support of our IPO and maintaining public company status and €0.6 million in Board fees and related share-based compensation expenses.

### **Finance Income (Expenses)**

	Year Ended December 31		Change	
	2016	2015	€	%
	(euros in thousands)			
Interest and similar income	€ 88	€ 50	€ 38	76%
Net loss and foreign exchange	(409)	—	(409)	100%
Interest expense	(19,235)	(195)	(19,040)	9,764%
Total finance income (expense)	€(19,556)	€(145)	(19,411)	13,387%

Finance expense increased €19.4 million during the year ended December 31, 2016 as compared to the year ended December 31, 2015. This increase was due to increases in interest expense of €19.0 million and foreign exchange losses of €0.4 million. We experienced losses on our U.S. dollar denominated cash and cash equivalents of approximately €0.4 million during 2016 on our U.S. dollar denominated cash and cash equivalent accounts subject to the fluctuation in foreign currency between the euro and U.S. dollar. The increase in cash during 2016 was primarily a result of the receipt of net proceeds of approximately \$53.3 million from our IPO during 2016.

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The increase in interest expense of €19.0 million is primarily related to the accounting impact on the financial derivative recognized under the Incyte Agreement. The subscription agreement to sell our own shares in which we became committed on December 20, 2016, was accounted for as a forward contract or a derivative financial instrument. The change in fair value of the derivative financial instrument of approximately €19.2 million was recognized as interest expense for the year ended December 31, 2016.

## **Liquidity and Capital Resources**

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

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

On May 24, 2016, we closed an initial public offering of 5,500,000 of our common shares and, on May 26, 2016, of an additional 639,926 of our common shares, at a price to the public of \$10 per share. We received net proceeds, after deducting underwriting discounts and commissions and offering expenses, of \$53.3 million. On May 19, 2016, our common shares were listed on the Nasdaq and all of our preferred shares converted into common shares.

In December 2016, we entered into a collaboration and license agreement, or the Collaboration Agreement, and a share subscription agreement, or the Share Subscription Agreement, with Incyte Corporation, or Incyte. In January 2017, we received an upfront payment of \$120.0 million (€110.2 million) from Incyte pursuant to the Collaboration Agreement and \$80.0 million (€74.7 million) upon the issuance and sale by us of 3.2 million common shares to Incyte pursuant to the Share Subscription Agreement, for total cash proceeds to us of \$200.0 million (€184.9 million).

On February 13, 2018, we entered into a Purchase Agreement with the purchasers named therein (the “Investors”). Pursuant to the Purchase Agreement, we agreed to sell an aggregate of 3,099,997 of our common shares, nominal value €0.09 per share, to the Investors for aggregate gross proceeds of approximately \$55.8 million, at a purchase price equal to \$18.00 per share. The closing of the private placement occurred on February 15, 2018.

On December 20, 2018, we issued and sold an aggregate of 600,000 shares to Regeneron in connection with our settlement of certain litigation with Regeneron for aggregate gross proceeds of \$15.0 million. See “Business — Legal Proceedings.”

As of June 30, 2018, we had cash and cash equivalents of €170.3 million and investments of €53.7 million.

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

### ***Cash Flows***

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

	Year ended December 31,			Six Months Ended June 30	
	2017	2016	2015	2018	2017
Net cash used in operating activities	(37,413)	(25,733)	(23,031)	(15,132)	(15,576)
Net cash used in investing activities	(41,625)	(408)	(53)	(10,751)	(29)
Net cash from in financing activities	186,222	50,201	54,367	44,731	186,322
Net increase in cash and cash equivalents	107,184	24,060	31,283	18,848	170,727



During 2017, we used €37.4 million of cash in operating activities, as compared to the use of €25.7 million in cash during 2016, an increase in the use of cash of €11.7 million. This increase in net cash used in operating activities was the result of the increase in net loss adjusted for non-cash items of €10.4 million and changes in working capital of €1.2 million. Our non-operating and non-cash charges during the year ended December 31, 2017 primarily consisted of unrealized foreign exchange results of €15.8 million, share option expenses of €12.8 million and the change in fair value of the derivative financial instrument of €10.7 million.

During 2016, we used €25.7 million of cash in operating activities, as compared to the use of €23.0 million in cash during 2015, an increase in the use of cash of €2.7 million. This increase in net cash used in operating activities was the result of the increase in net loss adjusted for non-cash items of €1.9 million and changes in working capital of €1.0 million. Our non-cash charges during the year ended December 31, 2016 primarily consisted of the change in change in the fair value of the derivative financial instrument of €19.2 million and share option expenses of €3.3 million.

Net cash used in investing activities for 2017 and 2016 was €41.6 million and €0.4 million, respectively. The increase in net cash used in investing activities during 2017 related primarily to €41.8 million for purchases of investments, offset, in part, by higher interest received of €0.8 million. The increase in net cash used in investing activities to €0.4 million for the year ended December 31, 2016 from €0.05 million for the year ended December 31, 2015 was primarily due to an increase in investments in laboratory and office equipment.

Net cash provided by financing activities in 2017 was €186.2 million which was primarily due to receipt of €186.7 million from the Incyte Agreements, offset, in part, by the full repayment of the loan from Rabobank of €0.5 million. Net cash provided by financing activities in 2016 was €50.2 million which was primarily related to proceeds from our IPO in May of 2016.

Net cash provided by financing activities in 2015 was €54.4 million and related to aggregate private placements resulting in gross cash proceeds of €46.5 million and the receipt of an €8.0 million convertible bridge loan granted by several shareholders in June 2015.

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

We have not achieved profitability since our inception and, as of June 30, 2018, we had an accumulated loss of €167.2 million. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our bispecific antibody candidates.

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

- conduct the clinical trials for MCLA-128, our most advanced bispecific antibody candidate in Phase 2 for metastatic breast cancer populations and Phase 1/2 in other solid tumors;
- conduct the Phase 1 clinical trial of MCLA-117, our second most advanced bispecific antibody candidate;
- conduct the Phase 1 clinical trial of MCLA-158, our third most advanced bispecific antibody candidate;
- continue the research and development of our other bispecific antibody candidates in preclinical development, including MCLA-145;
- seek to enhance our technology platform, which generates our pipeline of Biclomics®, and discover and develop additional antibody candidates;

- seek regulatory approvals for any bispecific antibody candidates that successfully completes clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approval;
- maintain, expand and protect our intellectual property portfolio, including litigation costs associated with defending against alleged patent infringement claims or enforcing our intellectual property rights;
- add clinical, scientific, operational, financial and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operation as a public company; and
- experience any delays or encounter any issues any of the above, including but not limited to failed studies, complex results, safety issues or other regulatory challenges.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of June 30, 2018 and the proceeds received from the \$15.0 million investment by Regeneron Pharmaceuticals in December 2018 will be sufficient to fund our operations into the second quarter of 2021. For this assessment we have taken into consideration our existing cash and cash equivalents of €170.3 million, which include the \$55.8 million, or €44.8 million, in proceeds received from our private placement offering that closed in February 2018, and investments of €53.7 million as of June 30, 2018 as well as \$15.0 million, or €13.1 million, in proceeds from Regeneron Pharmaceuticals.

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

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

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

Adequate additional funds may not be available to us on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends and may require the issuance of warrants, which could potentially dilute your ownership interest.

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

### Contractual Obligations and Commitments

The table below summarizes our contractual obligations at June 30, 2018.

	Payments Due by Period				
	Total	Less than 1 year	1- 3 years	3- 5 years	More than 5 years
	(euros in thousands)				
Operating lease obligations(1)	€4,654	€ 1,297	€2,859	€ 498	€ —
Total	€4,654	€ 1,297	€2,859	€ 498	€ —

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

### Internal Control Over Financial Reporting

We have identified control deficiencies associated with a lack of adequate cut-off procedures to ensure the proper and timely recognition, measurement and classification of operating expenses and 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. There is a reasonable possibility that these deficiencies could result in a material misstatement of our financial statements or in related disclosures in our annual or interim consolidated financial statements that we would not be able to prevent or detect on a timely basis. Accordingly, we have determined that these control deficiencies constitute a material weakness.

For the year ended December 31, 2016, we identified two material weaknesses related to insufficient accounting resources required to fulfill IFRS and SEC reporting requirements and insufficient comprehensive IFRS accounting policies and financial reporting procedures. Due to the material weakness described above, we determined that these material weaknesses were not remediated as of December 31, 2017.

We have implemented and continue to implement various measures to address these internal control deficiencies. These measures are outlined below. With the oversight of management and our Audit Committee, we have taken

and plan to take steps intended to address the underlying causes of the material weaknesses identified, primarily through the redesign of specific processes and controls associated with review of contractual agreements, including a quarterly identification and review of significant agreements with the management team to ensure that the relevant accounting implications are identified and considered. Additionally, we are in the process of redesigning our controls over operating expenses, including the related balance sheet accounts. We are also continuing the hiring of additional financial resources, enhancing our IFRS accounting policies and procedures and developing review controls related to our financial close and reporting processes.

Although we plan to complete this remediation process as quickly as possible, we cannot, at this time, estimate when such remediation may occur, and our initiatives may not prove successful in remediating the material weakness. We may determine to enhance other existing controls and/or implement additional controls as the remediation process progresses. It will take time to determine whether the additional controls we are implementing will be sufficient to accomplish their intended purpose. Accordingly, the material weaknesses may continue for a period of time.

Our Audit Committee and management are closely monitoring the remediation process. Until the remediation efforts discussed in this section, including any additional remediation efforts that our management identifies as necessary, are completed, tested and determined effective, we will not be able to conclude that the material weaknesses have been remediated. In addition, we may need to incur incremental costs associated with this remediation, primarily due to the hiring and training of finance and accounting personnel and the implementation and validation of improved accounting and financial reporting procedures.

#### **Unresolved Staff Comments**

On September 11, 2018, we received a comment letter from the staff of the Division of Corporation Finance of the SEC, or the Staff, relating to our Annual Report on Form 20-F for the fiscal year ended December 31, 2017 and our Report on Form 6-K filed on August 10, 2018, which included our unaudited interim financial statements for the six months ended June 30, 2018. We responded to these comments and received a second comment letter on November 1, 2018 to which we responded on December 3, 2018. We received a third comment letter on December 20, 2018 and are in the process of responding to the Staff. The Staff requested information regarding our recognition and measurement of revenue under our license and collaboration agreement and the related share subscription agreement with Incyte, or the Incyte Agreements. More specifically, the Staff requested information regarding our accounting for the \$80.0 million purchase by Incyte of our common shares under the share subscription agreement and our valuation of such purchase, our analysis of the allocation of the transaction price, including the \$120.0 million upfront payment under the license and collaboration agreement, the timing of our accounting of the transaction, and our consideration of payments we may receive in connection with our collaboration with Incyte in light of our adoption of IFRS 15, which became effective for annual and interim reporting periods beginning on or after January 1, 2018. We believe that our interpretation of IFRS 15 and our revenue recognition under the Incyte Agreements, as described in the notes to our financial statements that are included or incorporated into this prospectus and that are included in our other filings with the SEC, is appropriate. As of the date of this prospectus, we are discussing the comments with the Staff, and we cannot predict when these comments will be resolved. If the Staff ultimately disagrees with our accounting related to the Incyte Agreements, the impact to our previously issued financial statements for the year ended December 31, 2017 and the subsequent interim periods could be material and we could be required to restate these financial statements. See “Risk Factors—*In preparing our financial statements, our management is required to apply accounting policies that require significant interpretation. If such interpretations are incorrect or if regulatory or other authorities disagree with such interpretations, we may be required to restate or revise previously issued financial statements, which could have an adverse impact on our financial position or the perception of our company in the market.*”

## Off-Balance Sheet Arrangements.

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

## Quantitative and Qualitative Disclosure About Market Risk

We are exposed to market risk. Market risk is the risk that changes in market prices – such as foreign exchange rates and interest rates – will affect the our income or the value of our holdings of financial instruments. The objective of market risk management is to manage and control market risk exposures within acceptable parameters, while optimizing the return. Our market risk relates to foreign exchange and to a lesser extent, interest rate risks.

### Foreign currency risk

Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities in foreign currencies. With respect to monetary assets and liabilities denominated in foreign currencies, our primary currency exposure is impacted by monetary assets and liabilities denominated in U.S. Dollars. Changes in sensitivity rates reflect various changes in the economy year-over-year.

The following table provides a sensitivity analysis for a change in our primary currency exposure relating to monetary assets and liabilities denominated in U.S. Dollars as of June 30, 2018. The analysis shows the impact that a change in the exchange rate at that date would have on our total comprehensive loss:

Financial Statement Line Item Exposure	Balance (in thousands)	Effect on profit before tax if USD strengthens 5% (in thousands)	Effect on profit before tax if USD weakens 5% (in thousands)
Cash and cash equivalents	58,820	2,941	(2,941)
Total investments	53,727	2,686	(2,686)
Trade and other receivables	3,677	184	(184)
Trade payables, other liabilities and accruals	(579)	(29)	29
<b>Net Assets</b>	<b>115,645</b>	<b>5,782</b>	<b>(5,782)</b>

The closing exchange rates per the European Central Bank utilized above for converting U.S. dollars to Euros at June 30, 2018 was €0.8578 per dollar.

### Exposure to interest rate risk

The interest rate profile of our interest-bearing financial instruments is as follows:

	Carrying amount June 30, 2018 (euros in thousands)
<b>Fixed-rate instruments</b>	
Investments	53,727
Financial liabilities	—
<b>Variable rate instruments</b>	
Cash and cash equivalents	170,327

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

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

Our operating and financial review is based on our financial statements, which we have prepared in accordance with IFRS as issued by the IASB. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. Actual results may differ from these estimates under different assumptions or conditions. There have been no material adjustments to prior period estimates for any of the periods included in this prospectus, other than those amounts that have been restated as a result of the adoption of IFRS 15.

Our significant accounting policies are more fully described in the notes to our financial statements which are incorporated by reference in this prospectus. We believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our financial condition and results of operations.

### ***Revenue Recognition***

Revenue is recognized when our customer obtains control of the goods or services we provide. Revenue is recognized in an amount that reflects the consideration that we expect to receive in exchange for those goods or services.

We maintain research and license agreements with Incyte, ONO and Simcere. In connection with these arrangements, we received upfront license payments relating to the integrated package of deliverables under the contracts. Each contract contains either one single performance obligation or multiple performance obligations that the up-front consideration was allocated to. These upfront license payments are initially recorded in deferred revenue on the consolidated statements of financial position and are recognized as revenue on either: (i) a straight-line basis over the period of the related performance obligation or the contractual term of the arrangement; or (ii) based on another appropriate depiction of our performance over the period of the related performance obligation or the contractual term, such as costs incurred relating to full-time equivalent research employees. The applicable period over which to recognize the upfront payment is a significant judgment, which is re-assessed at each reporting date.

Collaboration income, which is typically related to reimbursements from collaborators for our performance of research and development services under the respective agreements, is recognized on the basis of labor hours valued at a contractually agreed rate. Collaboration income includes reimbursements for related out-of-pocket expenses. Cost reimbursements to which we are entitled under agreements are recognized as revenues in the same quarter of the recorded cost they are intended to compensate. We act as the principal and therefore record these reimbursements as collaboration income.

We receive certain government and regional grants, which support our research efforts in defined projects, and include contributions towards the cost of research and development. When there is reasonable assurance that we will comply with the conditions attached to a received grant, and when there is reasonable assurance that the grant will be received, government grants are recognized as revenue on a gross basis in the profit or loss account on a systematic basis over the periods in which the entity recognizes expenses for the related costs for which the grants are intended to compensate. In the case of grants related to assets, the received grant will be deducted from the carrying amount of the asset.

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

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

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

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

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

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

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

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

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

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

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

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eighth anniversary of the date of grant for options granted under the Merus B.V. 2010 Employee Option Plan (the “2010 Plan”) and on the tenth anniversary of the date of grant for the options granted under the 2016 Incentive Award Plan (the “2016 Plan”).

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

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

Share-based compensation reflects the compensation expense of our share option and RSU programs granted to employees or others providing similar services, which are measured at the grant date fair value of the options or RSU.

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

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

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

	Year ended December 31,						Six months ended June 30, 2018	
	2017		2016		2015		Key Management Personnel	All Other Personnel
	Key Management Personnel	All Other Employees	Key Management Personnel	All Other Employees	Key Management Personnel	All Other Employees	Key Management Personnel	All Other Personnel
Expected volatility (weighted-average)	95.05%	94.88%	95.30%	97.15%	94.85%	94.85%	95.1%	94.6%
Expected life (weighted-average)	10 years	10 years	10 years	8-10 years	4 years	8 years	10 years	10 years
Expected dividends	0%	0%	0%	0%	0%	0%	0%	0%
Risk-free interest rate (based on government bonds)	2.29%-2.51%	2.24%-2.62%	1.84%-1.86%	0.10%-1.87%	0.16%-0.70%	0.16% 0.70%	2.79%-2.94%	2.84%-2.94%

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

The options outstanding at June 30, 2018 and December 31, 2017 had exercise prices in the range of €1.93 to €27.47 per share. On October 5, 2015, we amended the exercise price of all options granted under the 2010



Option Plan prior to January 2015 to be €1.93 per share to reflect the relative decrease in estimated fair value for each common share. As a result, we recognized an additional share option expense that was immaterial.

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

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

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

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

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

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

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

The “prior sale of company stock” method, a form of the market approach, had been applied to estimate the total enterprise value. The prior sale of company stock method considers any prior arm’s length sales of our equity securities. Considerations factored into the analysis included: the type and amount of equity sold, the estimated volatility, the estimated time to liquidity, the relationship of the parties involved, the risk-free rate, the timing compared to the common shares valuation date and the financial condition and our structure at the time of the

sale. As such, the value per share was benchmarked to the external transactions of our securities and external financing rounds. Throughout this period, a number of financing rounds were held, which resulted in the issuance of preferred shares. The preferred shares were transacted with numerous existing and new investors, and therefore the pricing in these financing rounds was considered a strong indication of fair value.

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

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

### ***Income Taxes***

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

Federal and state income taxes were paid in the United States because of our United States subsidiary; however, no tax charge or income was recognized in our Dutch entity during the reporting periods since we are in a loss-making position and have a history of losses. As a result of the adoption of IFRS 15, tax losses carried forward have been revised to reflect the impact of the retrospective effects of the adoption of IFRS 15. We have revised tax loss carry-forwards of €140.5 million, €100.7 million, and €75.9 million as of December 31, 2017, 2016, and 2015, respectively. As a result of Dutch income tax law, tax loss carry-forwards incurred through December 31, 2018 are subject to a time limitation of nine years. All tax loss carry-forwards incurred after December 31, 2018 will be subject to a time limitation of six years. In November 2018, the Dutch tax authorities confirmed that the \$120.0 million upfront license fee received from Incyte can be fully recognized in 2017 for corporate income tax purposes, which will significantly reduce our tax loss carryforwards. There will be no impact on our consolidated statements of financial position or consolidated statement of profit or loss and comprehensive loss as no deferred tax asset is recognized.

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

In order to promote innovative technology development activities and investments in new technologies, a corporate income tax incentive has been introduced in Dutch tax law called the “Innovation Box.” Based on the Innovations Box ruling, we would owe on the first 75% of qualifying profits under the Dutch jurisdiction effectively 5% (or 7% beginning in 2018) for Dutch income taxes. The remaining profit would be taxed at the Dutch statutory tax rate of 25%. Taxable profits will only qualify for the Innovations Box once the tax losses

carried forward are completely utilized. The agreement with the tax authorities was originally signed for the tax years beginning in 2011 through 2015 and was subsequently extended through the year 2019. Since we are loss-making, no Dutch income tax is recognized in profit or loss.

### ***Investments***

Prior to the adoption of IFRS 9 – Financial Instruments (“IFRS 9”) on January 1, 2018, investments are classified as held-to-maturity and are initially measured at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest rate method. Investments are classified as held-to-maturity and carried at amortized cost as management has the positive intent and ability to hold them until maturity. Interest income from these securities is included in finance income.

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

### **Recent Accounting Pronouncements**

A number of new standards, amendments to standards and interpretations are effective for annual periods beginning after January 1, 2018, and have not been applied in preparing these financial statements. The standard which may be relevant to us is set out below. We do not plan to adopt this standard early.

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

In January 2016, the IASB issued IFRS 16, Leases. The standard established the principles that lessees and lessors will apply to report useful information to users of financial statements about the amount, timing and uncertainty of cash flows arising from a lease. The standard is effective for periods beginning on or after January 1, 2019. Early adoption is permitted; however, we expect to adopt this standard in the first quarter of 2019. We are still evaluating the full impact this standard will have on our consolidated financial statements and related disclosures, but expect to recognize substantially all of our leases in our statements of financial position by recording a right-to-use asset and a corresponding lease liability.

## BUSINESS

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 were effective in killing tumor cells, a result that we believe supports their potential efficacy in the treatment of cancer. In February 2015, we commenced a Phase 1/2 clinical trial of our 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 with enhanced antibody-dependent cell-mediated cytotoxicity, or ADCC, targeting HER2 and HER3 receptors. MCLA-128 blocks 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 effectively blocked. The Phase 2 clinical trial is designed to observe the activity of this HER2/HER3-targeted candidate in combination with current standards of care in areas of unmet need. The trial is ongoing and is enrolling patients at sites in the United States and Europe. We plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric, cancer and non-small cell lung cancer or NSCLC is ongoing.

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

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

AML generally has a poor prognosis and limited progress has been made in disease outcomes despite a growing AML patient population. Clinical and pre-clinical studies suggest that treatment-resistant leukemic stem cells are a potential cause of disease relapse. MCLA-117 binds to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on approximately 90 to 95% of AML tumor cells and stem cells in newly diagnosed and relapsed patients. MCLA-117 is designed to recruit and activate T-cells to kill AML tumor cells and stem cells. In our pre-clinical studies, MCLA-117 killed tumor cells in blood samples of AML patients. If the results of this clinical trial are favorable, we plan to seek orphan drug designation for MCLA-117 for the treatment of AML from the FDA and the European Medicines Agency, or EMA. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. We also intend to evaluate MCLA-117 for the treatment of myelodysplastic syndrome, or MDS.

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

Additionally, we also have a pipeline of proprietary antibody candidates in preclinical development, including the bispecific antibody candidate MCLA-145, which is being developed in collaboration with Incyte Corporation and is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target. MCLA-145, the first drug candidate co-developed under our global research collaboration with Incyte, continues to progress in IND-enabling studies and we expect to provide further information on this program upon IND acceptance. We have full rights to develop and commercialize MCLA-145 in the United States and Incyte is responsible for its development and commercialization outside the U.S. We also have several other antibody candidates in pre-clinical development that bind to other target combinations. Each of our antibody candidates in our preclinical and clinical pipeline are designed to bind to targets believed to be useful in the treatment of cancer with an intention to establish efficacy and obtain information for submission to the FDA.

Our Biclonics® technology platform employs an array of proprietary technologies and techniques to generate bispecific human antibodies. We utilize our patented MeMo® mouse harboring a common light chain in its germline that is capable of producing an array of antibodies with diverse heavy chains that are capable of binding virtually any antigen, the information from which can then be utilized to generate bispecific antibody candidates. 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 proprietary host cells and patented dimerization technology useful to produce bispecific 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 breast, gastric and non-small cell lung cancer. We commenced a Phase 1/2 clinical trial of MCLA-128 in Europe in February 2015. In the dose escalation phase of the trial, the recommended dose of MCLA-128 was established. Preliminary efficacy data suggests consistent antitumor activity in heavily pretreated metastatic breast cancer patients progressing on HER2 therapies. In January 2018, we commenced a combination Phase 2 clinical trial in the United States for MCLA-128 and we plan to provide an update on the Phase 2 clinical trial in the second half of 2019. Concurrently, our Phase 1/2 clinical trial evaluating single agent activity for MCLA-128 in gastric cancer and NSCLC is ongoing. We reported data from the gastric cancer patient cohort in the single-agent trial of MCLA-128 at ESMO in October 2018. The data showed a clinical benefit rate of 24% (6 of 25 patients.), with MCLA-128 being well tolerated with mainly grade 1/2 adverse events in patients treated with MCLA-128 across all indications explored to date and showing a low risk of immunogenicity. Promising single agent antitumor activity was seen in heavily pretreated GC/GEJ cancer patients progressing on anti-HER2 therapy. We believe that if MCLA-128 is successfully developed and obtains regulatory approval, it has the potential to address disease-specific challenges that are not currently being met by existing therapies.
- **Successfully develop our second most advanced bispecific antibody candidate, MCLA-117, for the treatment of AML.** We are developing MCLA-117 for the treatment of patients with AML. We commenced a Phase 1 clinical trial of MCLA-117 in Europe in May 2016 for the treatment of patients with AML to assess its safety, tolerability and anti-tumor activity and filed an IND in the United States in January 2018, for which we obtained authorization to proceed from the FDA in February 2018. We are continuing our dose escalation of the Phase 1 clinical trial for MCLA-117. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. If the results of this clinical trial are favorable, we plan to seek orphan drug designation from the FDA and the EMA for MCLA-117 for the treatment of AML. We believe that if MCLA-117 is successfully developed and obtains regulatory approval, it has the potential to transform the treatment of AML. We also intend to evaluate MCLA-117 for the treatment of MDS.
- **Successfully develop our third bispecific antibody candidate, MCLA-158, for the treatment of metastatic colorectal cancer and other solid tumors.** We are developing MCLA-158 for the treatment of solid tumors with an initial focus on the treatment of metastatic colorectal cancer. MCLA-158 has received approval of a CTA in several European countries for the potential treatment of metastatic colorectal cancer, including patients with the RAS-mutation, which represent a substantial unmet need. We also filed an IND for MCLA-158 with the FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018. In May 2018, we commenced an open-label, multicenter Phase 1 clinical trial of MCLA-158 and expect emerging data by the end of 2019. MCLA-158 is an ADCC-enhanced Biclonics® 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. 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.
- **Accelerate the internal discovery and development of additional immunotherapeutic antibody candidates.** We believe we are well positioned to expand our pipeline of Biclonics® 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 Biclonics® therapeutic candidates with differentiated modes of action that have the potential to kill tumor cells with high potency. We are conducting pre-clinical studies of MCLA-145 in collaboration with Incyte and expect to provide further information on this program upon acceptance of an IND for MCLA-145. We are also conducting pre-clinical studies of an array of proprietary candidates binding to other target combinations that are the subjects of our internal programs.

- **Seek strategic collaborative relationships.** We intend to continue to seek strategic collaborations to facilitate the capital-efficient development of our Biclonics® technology platform and to identify potential target combinations in immuno-oncology and other therapeutic areas. We have entered into collaborations with Incyte, ONO Pharmaceutical Co., Ltd., and Simcere Pharmaceutical Group, to develop bispecific antibody candidates based on our Biclonics® technology platform and plan to work with other collaborators to validate and expand the use of our Biclonics® platform and the development of bispecific antibody candidates. We believe 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 Biclonics® for the treatment of various types of cancer. The following table summarizes our bispecific antibody candidate pipeline:

Program	Targets	Indication/drug combination	Pre-IND/CTA	Phase 1	Phase 2	Merus rights
MCLA-128	HER2, HER3	Breast (HER2+) + Herceptin + chemo				worldwide
		Breast (ER+) + hormone therapy				worldwide
		Solid tumors (monotherapy)*				worldwide
MCLA-117	CD3, CLEC12A	AML				worldwide
MCLA-158	EGFR, Lgr5	Solid tumors				worldwide
MCLA-145	PD-L1, undisc.	Solid tumors		Collaboration with Incyte Corporation		US
*****	Undisclosed	Autoimmune disease		Collaboration with Ono Pharmaceutical		N/A

\*Phase 1/2

## Overview of Existing Immunotherapeutics

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

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



**Monoclonal Antibodies with Enhanced ADCC.** Monoclonal antibodies bind to a single target expressed by tumor cells and have been modified to more efficiently attract immune effector cells, such as NK cells and macrophages, to effectively kill tumor cells. Several mAbs with enhanced ADCC for the treatment of solid and leukemic tumors have yielded promising results in clinical trials.

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

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

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

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

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

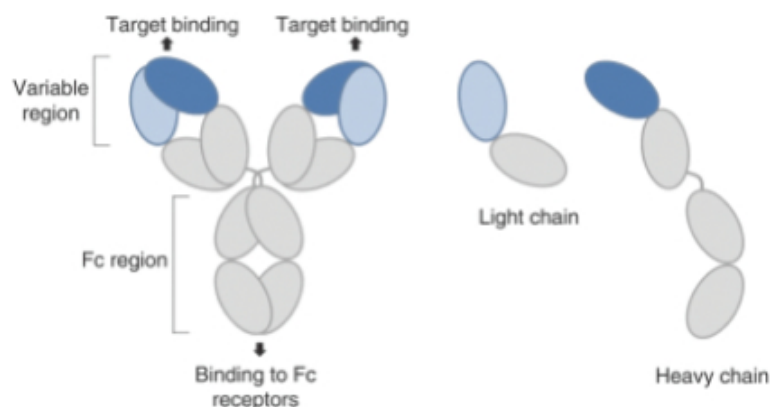
We believe a key limitation of CAR-T and TCR therapies is the need to retrieve non-compromised immune effector cells from a cancer patient, which requires a complex and costly individualized process to develop the therapy. These challenges limit their potential and use in a variety of indications, including the treatment of solid tumors.

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



## Background on Antibodies

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



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

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

## Our Biclomics® Platform

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

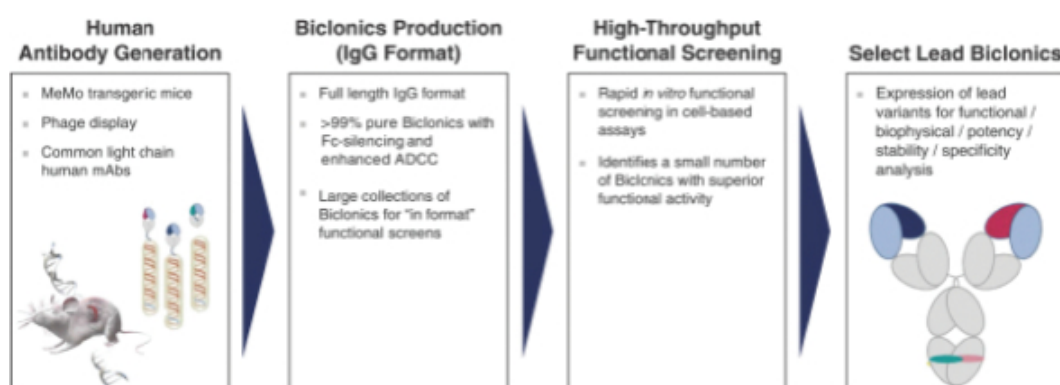
By binding to two different targets, Biclomics® can be designed to block receptors that drive tumor cell growth and survival and to mobilize the patient's immune response by activating various killer cells to eradicate tumors. We believe our Biclomics® platform allows us to approach cancer treatment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

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

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

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

#### Selection of Lead Biclonics®



Our Biclonics® technology platform includes the following:

- **Human antibody generation.** Our platform for generating human antibodies is comprised of transgenic mice, which we refer to as MeMo®, which harbors a common light chain in its germline. The antibody sequence information obtained from MeMo® can be used to generate human antibodies and phage

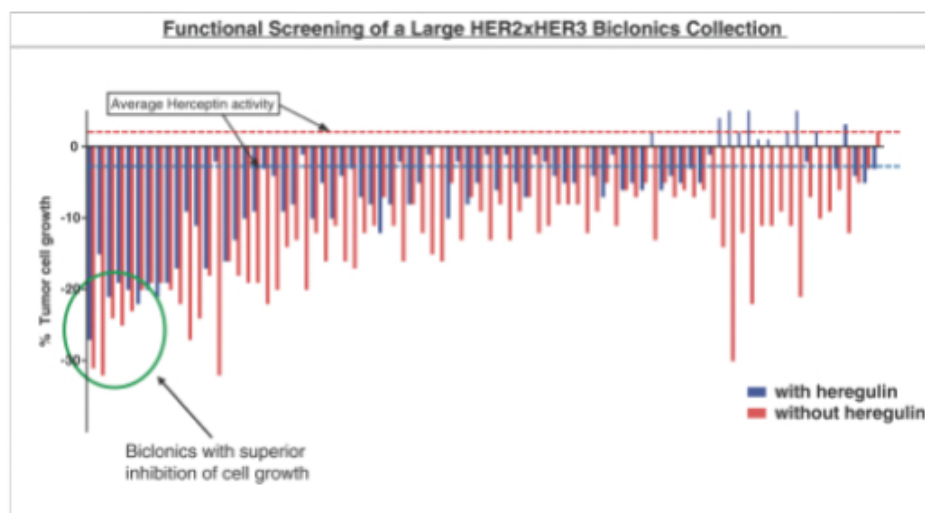
display for the generation of panels of common light chain human mAbs. MeMo® harnesses the power of the *in vivo* immune system to yield human antibodies with high potency, specificity, solubility and low immunogenicity. Using this technology, we produce large and diverse panels of high-affinity antibodies against a broad variety of targets. We believe this approach enhances the discovery and development of high-quality human antibodies that, through the common light chain, generates sequences that are ready to be converted into the Biclonics® format.

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

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

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

For example, the chart below shows the results of a pre-clinical study in which hundreds of different Biclonics targeting HER2 and HER3 were functionally screened against tumor cell samples, with and without heregulin present. Of the antibody candidates depicted in the chart, 40 exhibited superior inhibition of cell growth compared to trastuzumab, a drug commonly prescribed for the treatment of breast cancer, and were selected in the process leading to identification of MCLA-128.



### Benefits of Biclonics®

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

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

90% of bispecific antibody formation using these processes and the IgG-based purification process results in up to greater than 98% purity for our Biclomics®.

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

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

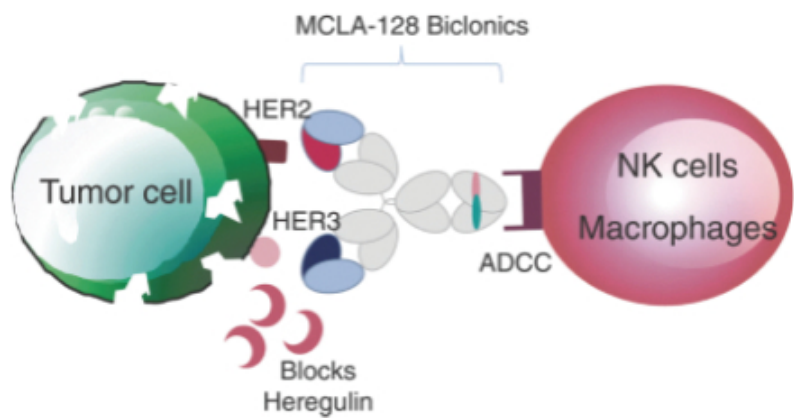
We commenced a Phase 2, open-label, multi-center, international clinical trial of our most advanced bispecific antibody candidate, MCLA-128 for the treatment of patients with MBC in January 2018 and plan to provide an update in the second half of 2019. Concurrently, our Phase 1/2 study of MCLA-128 in gastric and non-small cell lung cancers is ongoing. Additionally, we commenced a Phase 1, single-arm, open-label clinical trial of our second bispecific antibody candidate, MCLA-117, for the treatment of patients with AML in May 2016, and announced the filing of an IND in the United States for MCLA-117 in January 2018, which subsequently received authorization from the FDA. Dose escalation in the Phase 1 trial is ongoing. We plan to provide an update on our MCLA-117 program upon announcement of the maximum tolerated dose for MCLA-117 and anticipate data readouts for the Phase 1 clinical trial in the second half of 2019. In May 2018, we commenced a Phase 1, open-label, multicenter clinical trial of MCLA-158, for the treatment of solid tumors with an initial focus on metastatic colorectal cancer, for which we have received CTA approvals in several European countries. We filed an IND with FDA in the first quarter of 2018, which received authorization to proceed from the FDA in April 2018, and have expanded the trial to the United States. We expect emerging data from this trial by the end of 2019. In addition, we have several other bispecific antibody candidates in pre-clinical development, including MCLA-145, which binds PD-L1 and an undisclosed target, on which we are collaborating with Incyte and on which we expect to provide further information upon acceptance of an IND, among other preclinical candidates in various stages of development.

### **MCLA-128**

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

We have designed MCLA-128 to overcome the inherent and acquired resistance of tumor cells using two different mechanisms. The first mechanism blocks growth and survival pathways to stop tumor expansion, while preventing tumor cells from escaping through activation of the HER3/heregulin pathway. The second mechanism, enhanced ADCC, involves the recruitment and enhancement of immune effector cells, such as NK cells and macrophages, to directly kill the tumor through a modification of the Fc region. This dual mechanism of action is illustrated in the graphic below. MCLA-128 blocks 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 effectively blocked.

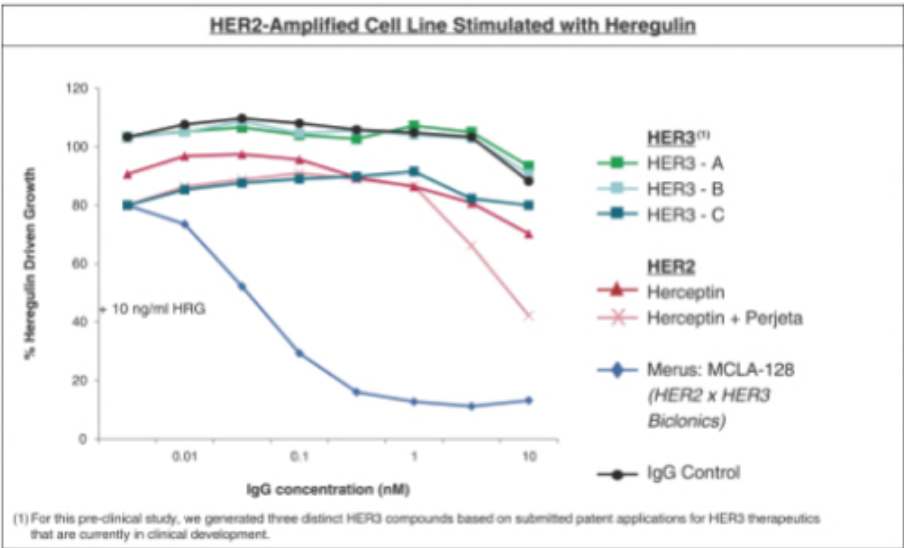
**MCLA-128 Mechanism of Action**



*Pre-Clinical Studies*

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

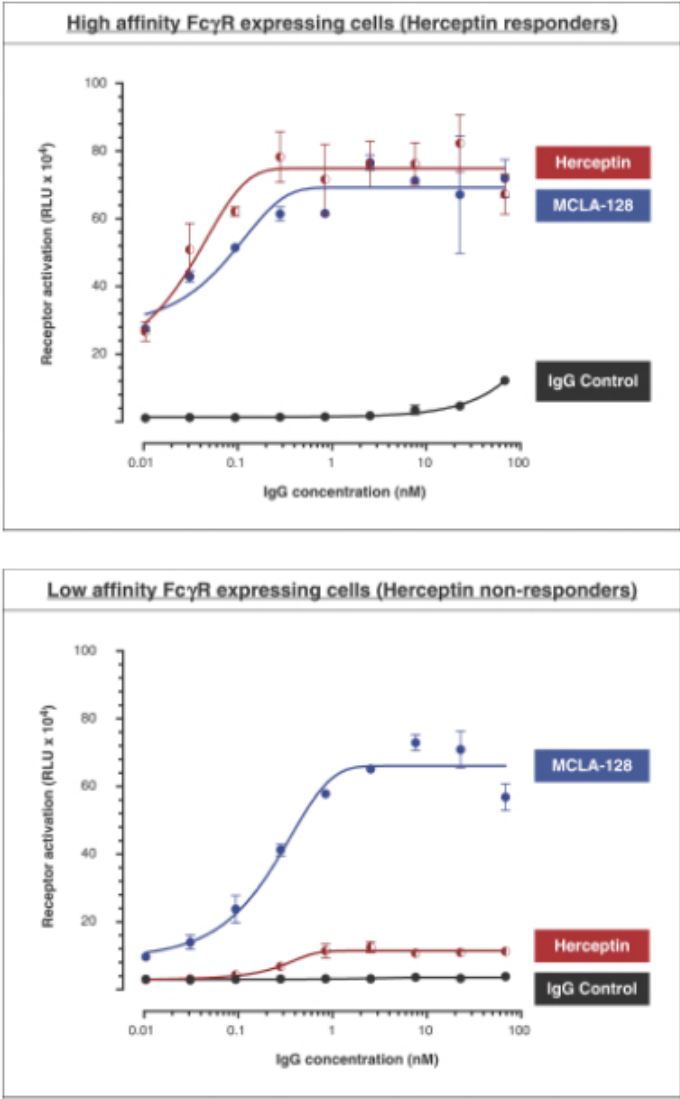
As shown in the chart below, the administration of MCLA-128 reduced heregulin-driven tumor growth at significantly lower concentrations than mAbs targeting HER2 or HER3 and the combination of Herceptin and Perjeta.



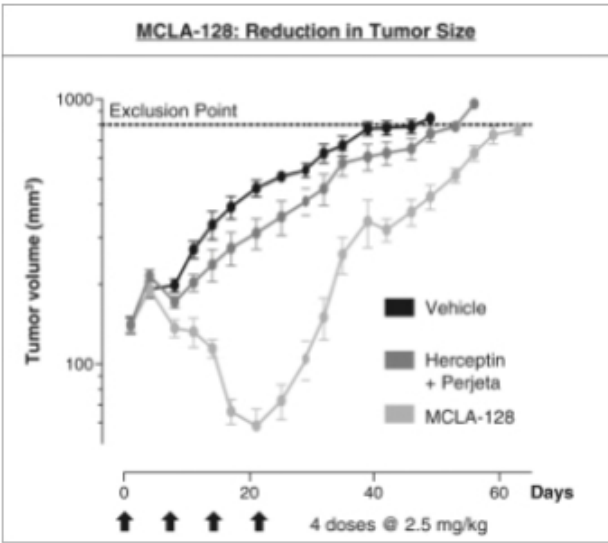
MCLA-128 also blocked phosphorylation and activation of key proteins in the signaling pathways for the cell growth and survival of cancer cell lines, a result that was not observed with the combination of HER2 mAbs, Herceptin and Perjeta.

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

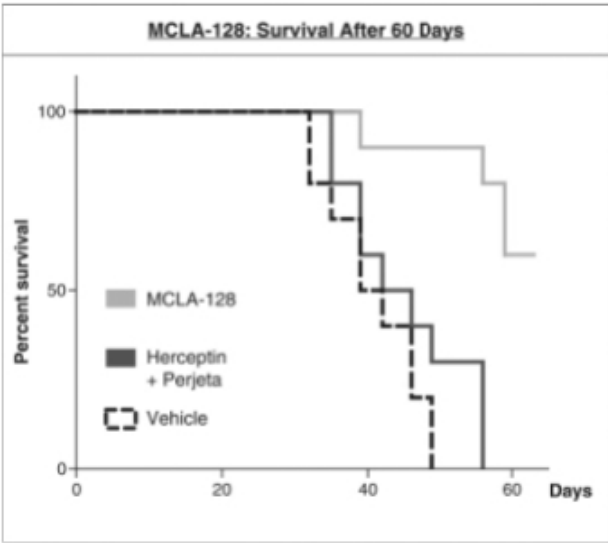
**Fc Receptor Activation by MCLA-128 (FcγR Subtype)**



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



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





### *Clinical Development of MCLA-128*

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

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

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

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

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

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

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

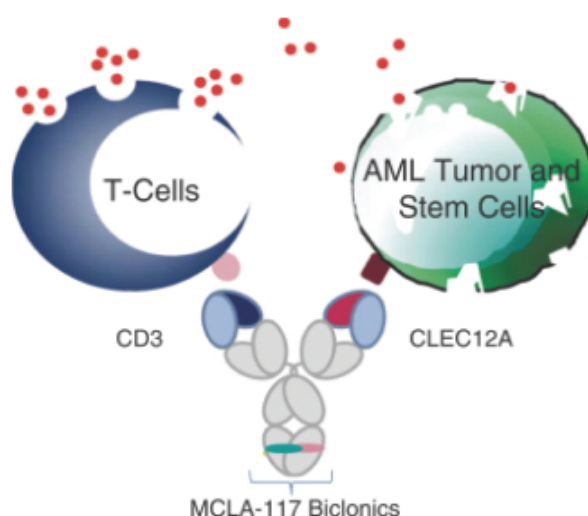
## **MCLA-117**

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

MCLA-117 is a Biclonics® that is designed to bind to CD3, a cell-surface molecule present on all T-cells, and to CLEC12A, a cell surface molecule present on AML tumor cells and stem cells. CLEC12A is not found on normal blood stem cells nor on cells that give rise to red blood cells and platelets nor is it present on other non-hematopoietic cells in the body. This is in contrast to the expression patterns of CD123 and CD33, which are present on normal blood stem cells, and in the case of CD33, also the cells that give rise to red blood cells and platelets. Both CD123 and CD33 are being explored by others as targets for AML therapy. We believe that the expression pattern of CLEC12A makes it an attractive and differentiated molecule for targeted therapy in cancer patients. Moreover, CLEC12A is expressed on approximately 90 to 95% of newly diagnosed and relapsed cases of AML, and we believe that many patients with AML could potentially benefit from treatment with MCLA-117.

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

### **MCLA-117 Mechanism of Action**



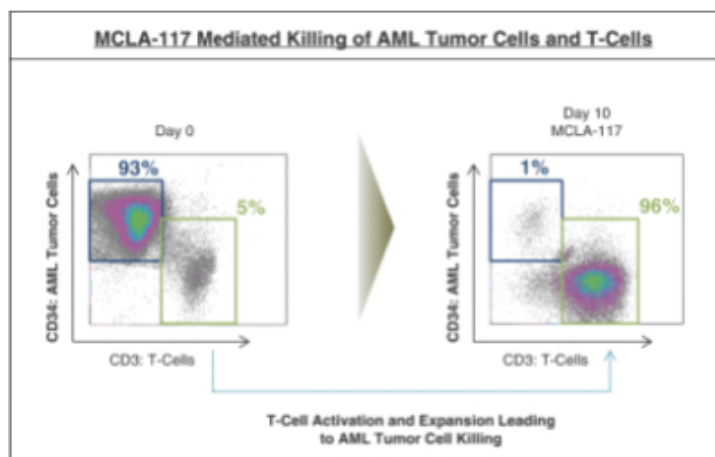
Unlike some other bispecific antibody formats, the full-length IgG format of MCLA-117 and its associated longer half-life is designed to keep it from having to be administered through continuous infusion using infusion pumps. In addition, through Fc-silencing, MCLA-117 is designed to avoid binding to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

We believe that MCLA-117 could be developed as induction therapy, as consolidation therapy to treat minimal residual disease and as rescue therapy for patients with relapsed or refractory AML. We intend to explore its use both as a single agent and in combination with commonly used chemotherapy agents and other treatment regimens of AML. We expect the safety profile of MCLA-117 to be favorable based on the restricted expression of CLEC12A in human tissues which is anticipated to result in manageable neutropenia. We also expect infusion related reactions based on the observed level of cytokine release upon co-culture with blood cells, which can be

mitigated by gradual dose increments and by providing co-medication when required. As CLEC12A is not expressed on megakaryocyte and erythroid progenitor cells, we expect the application of MCLA-117 would not result in a decrease of platelet counts or red blood cells.

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

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



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

The primary endpoint of the Phase 1 trial is the assessment of the safety and tolerability of MCLA-117 in order to determine the maximum tolerated dose and frequency of administration. Secondary endpoints include pharmacokinetic measures, anti-tumor response and clinical benefit.

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

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

#### *MCLA-117 for MDS*

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

#### **MCLA-158**

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

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

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

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

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

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

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

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

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

MCLA-145 is a Biclomics® that is designed to bind to PD-L1 and a second immunomodulatory target. MCLA-145 is designed to enhance the activation of tumor specific tumor infiltrating lymphocytes. MCLA-145, the first drug candidate co-developed under our global research and collaboration with Incyte Corporation, continues to progress in IND-enabling studies. We expect to provide further information on this program upon acceptance of an IND for MCLA-145. We have full rights to develop and commercialize MCLA-145 in the United States and Incyte is responsible for its development and commercialization outside the United States.

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

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

### ***Collaboration Agreements***

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

### ***Incyte Corporation***

We have entered into a collaboration and license agreement, or the Collaboration Agreement, with Incyte Corporation, or Incyte. Under the terms of the Collaboration Agreement, we and Incyte have agreed to collaborate with respect to the research, discovery and development of bispecific antibodies utilizing our proprietary bispecific technology platform. The collaboration encompasses up to 11 independent programs, including some of our current preclinical immuno-oncology discovery programs. For one of the current preclinical programs, concerning MCLA-145, we retain the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte has the exclusive right to develop and

commercialize products and product candidates arising from such program outside the United States. For MCLA-145, we and Incyte will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in our respective territories. We have the option to co-fund development of products arising from one specified program, and subject to certain conditions, to a second specified program, in each case exchange for a share of profits in the United States, as well as the right to participate in a specified proportion of detailing activities in the United States for one of such programs. In addition, if MCLA-145 fails to complete IND-enabling toxicology studies successfully, we will be granted an additional option to co-fund development of a specified program other than MCLA-145 in exchange for a share of profits in the United States. If we exercise our co-funding option for a program, we would be responsible for funding 35% of the associated future global development costs and, for certain of such programs, would be responsible for reimbursing Incyte for certain development costs incurred prior to the option exercise. All products as to which we have exercised our option to co-fund development would be subject to joint development plans and overseen by a joint development committee, with Incyte having final determination as to such plans in cases of dispute.

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

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

The Collaboration Agreement will continue on a program-by-program basis until neither party has any royalty payment obligations with respect to such program or, if earlier, the termination of the Collaboration Agreement or any program in accordance with the terms of the Collaboration Agreement. The Collaboration Agreement may be terminated in its entirety, or on a program-by-program basis, by Incyte for convenience. The Collaboration Agreement may also be terminated by either party under certain other circumstances, including material breach, or on a program-by-program basis for patent challenge of patents under the applicable program, in each case as set forth in the Collaboration Agreement. If the Collaboration Agreement is terminated in its entirety or with respect to one or more programs, all rights in the terminated programs revert to us, subject to payment to Incyte of a reverse royalty of up to 4% on sales of future products, if we elect to pursue development and commercialization of products arising from the terminated programs.

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

### ***ONO Pharmaceutical***

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

ONO paid us a non-refundable upfront fee of €1.0 million, and we are eligible to receive up to an aggregate of €34.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved three of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €1.8 million in milestone payments. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we and our affiliates are prohibited from researching, developing or commercializing bispecific antibodies against the undisclosed target combination that are the subject of this agreement. ONO also provides funding for our research and development activities under an agreed-upon plan. This research and license agreement will expire after all milestone payments have been received and all related patent rights have expired, unless terminated earlier. ONO has the right to terminate this agreement at any time for any reason, with or without cause. The licenses granted to ONO may convert to royalty-free, fully-paid, perpetual licenses if ONO terminates the agreement for uncured material breach.

On March 14, 2018, we entered into a second contract research and license agreement with ONO. Pursuant to an exclusive option granted to ONO in the prior agreement executed in April 2014, ONO exercised its option to enter into the March 2018 agreement. We granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on our Biclonics® technology platform against two undisclosed targets directed to a particular undisclosed target combination. ONO identifies and selects the licensed bispecific antibodies for which it is responsible for conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. ONO controls and has exclusive rights over the worldwide commercialization of any approved products, including worldwide supply, and is solely responsible for all costs and expenses related to commercialization. ONO has agreed to fund our research and development activities and be responsible for the payment of all costs and expenses for its own research and development activities, which are set out in a mutually agreed upon research plan. We retain all rights to use and commercialize any antibodies that are generated under the collaborative research program, excluding the up to five lead and/or selected antibodies against the targets ONO is pursuing, provided that the use and commercialization is not with respect to the particular target combination.

ONO has agreed to pay an upfront non-refundable payment of €700,000 for the rights granted and we are also eligible to receive an aggregate of €33.7 million in milestone payments upon achievement of specified research and clinical development milestones. For products commercialized under the License Agreement, if any, the Company is eligible to receive a mid-single digit royalty on net sales.

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

### ***Sincere Pharmaceutical Group***

On January 8, 2018, we entered into an agreement with Sincere Pharmaceutical Group, or Sincere, granting Sincere an exclusive license to develop and commercialize in China three bispecific antibodies utilizing our proprietary Biclonics® technology platform in the area of immuno-oncology. We retain all rights outside of China.

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

### **Manufacturing**

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

### **Sales and Marketing**

We have not yet defined our sales, marketing or product distribution strategy for MCLA-128, MCLA-117, MCLA-158 or any of our other bispecific antibody candidates because our bispecific antibody candidates are still in pre-clinical or early-stage clinical development. Our commercial strategy may include the use of strategic partners, distributors, a contract sales force, or the establishment of our own commercial and specialty sales force. We plan to further evaluate these alternatives as we approach approval for one of our bispecific antibody candidates.

### **Competition**

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

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



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

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

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

## **Intellectual Property**

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

As of December 12, 2018:

- Our patent portfolio related to our bispecific antibody candidate MCLA-128 consists of one PCT application, filed on February 27, 2015 which entered national phases in the United States, Europe and 17 other foreign countries with an expected expiry not earlier than February 27, 2035. Claims are directed to the MCLA-128 composition of matter and methods of using MCLA-128 to treat subjects having or at risk of having an ErbB-2 and/or ErbB3 positive tumor. In addition, our portfolio includes four PCT patent application covering further methods of using MCLA-128, including in combination therapies, to treat patients, three of which were filed on April 3, 2018, and one filed on May 17, 2018.
- Our patent portfolio related to our bispecific antibody candidate MCLA-117 consists of a first PCT application, filed on September 27, 2013, which entered national phases in the United States, Europe and 14 foreign countries with an expected expiry not earlier than September 27, 2033. There is currently one pending US application, one issued EP patent, 13 pending foreign applications, and four issued patents in several foreign jurisdictions. In addition, we filed a second PCT application related to MCLA-117 on July 8, 2016, which has entered national phases in the United States, Europe and 13 foreign countries with an expected expiry not earlier than July, 2036. There is currently one issued U.S. patent and one pending U.S. application, one issued and one pending EP applications, and 12 pending foreign applications. Claims are related to the MCLA-117 composition of matter and methods of using MCLA-117 in the treatment or prevention of MDS, chronic myelogenous leukemia, or CML, or AML;
- Our patent portfolio related to our bispecific antibody candidate MCLA-158 consists of one PCT filed on October 21, 2016, which entered or will enter national phases in the United States, Europe and 14

other foreign countries with an expiry no earlier than October 21, 2036. Claims are directed to the MCLA-158 composition of matter and methods of using MCLA-158 in the treatment or prevention of various solid tumors.

- Our patent portfolio related to our MeMo® mouse consists of three issued U.S. patents, eight pending U.S. applications, 12 issued foreign patents including one issued European patent that has been validated in many countries, and 11 pending foreign applications, all with an expected expiry not earlier than June 29, 2029. Claims are directed to a common light chain mouse and methods of producing antibodies by exposing the mouse to an antigen. For a discussion concerning opposition proceedings against this patent family see “—Legal Proceedings” and Note 11 to our Consolidated Financial Statements included in this prospectus.
- Our patent portfolio related to our Spleen to Screen™ technology consists of two issued U.S. patents, one pending U.S. application, one issued European Patent, and two issued foreign patents, with four foreign pending applications, all with an expected expiry not earlier than September 16, 2035. For a discussion concerning opposition proceedings against this patent family see “—Legal Proceedings” and Note 11 to our Consolidated Financial Statements included in this prospectus.
- Our patent portfolio related to recombinant production of mixtures of antibodies, and includes claims directed to host cells generating multi-specific antibodies consists of five issued U.S. patents, and four pending U.S. applications, two issued European patents, 15 issued foreign patents, and four pending foreign applications, all with an expected expiry not earlier than July, 2022. For a discussion concerning opposition proceedings against this patent family see “—Legal Proceedings” and Note 11 to our Consolidated Financial Statements included in this prospectus.

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

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

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

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

## **Government Regulation**

We are subject to extensive regulation. We expect our bispecific antibody candidates to be regulated as biologics. Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FD&C Act, and

the Public Health Service Act, or PHS Act, and other federal, state, local and foreign statutes and regulations. Both the FD&C Act and the PHS Act and their corresponding regulations govern, among other things, the testing, manufacturing, safety, efficacy, labeling, packaging, storage, record keeping, distribution, reporting, advertising and other promotional practices involving biological products.

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

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

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

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

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

Clinical trials involve the administration of the biological bispecific antibody candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of

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

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

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

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

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

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

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

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

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

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

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe and potent, or effective, for its intended use, and has an acceptable purity profile, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy, or REMS, is necessary to assure the safe use of the biological bispecific antibody candidate. If the FDA concludes a REMS is needed, the sponsor of the BLA must submit a proposed REMS; the FDA will not approve the BLA without a REMS, if required.

Before approving a BLA, the FDA will inspect the facilities at which the product is manufactured. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance

with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure that the clinical trials were conducted in compliance with IND trial requirements and GCP requirements.

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

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

One of the performance goals agreed to by the FDA under the PDUFA is to review 90% of standard BLAs in 10 months from the filing date and 90% of priority BLAs in six months from the filing date, whereupon a review decision is to be made. The FDA does not always meet its PDUFA goal dates for standard and priority BLAs and its review goals are subject to change from time to time. The review process and the PDUFA goal date may be extended by three months if the FDA requests or the BLA sponsor otherwise provides additional information or clarification regarding information already provided in the submission within the last three months before the PDUFA goal date.

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

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

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity or where the manufacturer with orphan exclusivity is unable to assure sufficient quantities of the approved orphan designated product. Competitors, however, may receive approval of different products for the indication for which the orphan product has exclusivity or obtain approval for the same product but for a different indication for which the orphan product has exclusivity. Orphan product exclusivity also could block the approval of one of our products for seven years if a competitor obtains approval of the same biological product as defined by the FDA or if our bispecific antibody candidate is determined to be

contained within the competitor's product for the same indication or disease. If a drug or biological product designated as an orphan product receives marketing approval for an indication broader than what is designated, it may not be entitled to orphan product exclusivity.

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

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

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical trials establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a biological product subject to accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

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

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

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

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

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

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

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

Depending upon the timing, duration and specifics of the FDA approval of the use of our bispecific antibody candidates, some of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. However, patent term restoration cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. The patent term restoration period is generally one-half the time between the effective date of an IND and the submission date of a BLA plus the time between the submission date of a BLA and the approval of that application, except that the review period is reduced by any time during which the applicant failed to exercise due diligence. Only one patent applicable to an approved biological product is eligible for the



extension and the application for the extension must be submitted prior to the expiration of the patent and within a 60-day period from the date the product is first approved for commercial marketing. The U.S. PTO, in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. In the future, we may apply for restoration of patent term for one of our currently owned patents to add patent life beyond its current expiration date, depending on the expected length of the clinical trials and other factors involved in the filing of the relevant BLA; however, there can be no assurance that any such extension will be granted to us.

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

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

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

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

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

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

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

We expect that our bispecific antibody candidates may require use of an *in vitro* diagnostic to identify appropriate patient populations for our products. These diagnostics, often referred to as companion diagnostics,

are regulated as medical devices. In the United States, the FD&C Act and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, pre-clinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA approval. We expect that any companion diagnostic developed for our bispecific antibody candidates will utilize the PMA pathway.

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

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

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

conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution.

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

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

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

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

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

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

To obtain regulatory approval of an investigational biological product under European Union regulatory systems, we must submit a marketing authorization application. The application used to file the BLA in the United States is similar to that required in the European Union, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. For example, in the European Union, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the

expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity. Products receiving orphan designation in the European Union can receive ten years of market exclusivity; during this period, no marketing authorization application may be accepted and no marketing authorization may be granted for a similar medicinal product for the same indication. An orphan product can also obtain an additional two years of market exclusivity in the European Union for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications.

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

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

- the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior;
- the applicant consents to a second orphan medicinal product application; or
- the applicant cannot supply enough orphan medicinal product.

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

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

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

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

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting, receiving or providing any remuneration, directly or indirectly, overtly or

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

Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. The majority of states also have anti-kickback laws, which establish similar prohibitions and in some cases may apply to items or services reimbursed by any third-party payor, including commercial insurers.

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

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

that a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

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

We may also be subject to data privacy and security regulation by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final HIPAA Omnibus Rule published on January 25, 2013, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA’s security standards directly applicable to “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney’s fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts.

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

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

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

We are subject to European laws relating to our and our suppliers’, partners’ and subcontractors’ (where they act as processors) collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, and where we process personal data in the context of the activities of that establishment (e.g., undertaking clinical trials). We and our suppliers, partners and subcontractors process personal data including in relation to our employees,

employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation, or GDPR, and national laws and regulations implementing or supplementing it.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner compatible with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the European Economic Area, or EEA (unless certain steps are taken to ensure an adequate level of protection), and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure, and to be able to demonstrate, protection. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, requires the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with service providers.

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

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer “adequate” protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. There is currently ongoing litigation challenging two of the more commonly used transfer mechanisms, the EU model clauses and the U.S. Privacy Shield, and all adequacy decisions may be subject to review by the European Commission at any time. It is uncertain whether these mechanisms will be invalidated by the EU courts or following review. Invalidation of any mechanism on which we rely could require operational changes, including finding alternative bases for the compliant transfer of personal data from the EEA to the United States, and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

There are costs and administrative burdens associated with compliance with the GDPR and the resultant changes in the EU and EEA member states’ national laws. Any failure or perceived failure to comply with global privacy laws carries with it the risk of significant penalties and sanctions of up to €20 million or 4% of global turnover. These laws or new interpretations, enactments or supplementary forms of these laws, could create liability for us, could impose additional operational requirements on our business, could affect the manner in which we use and transmit patient information and could increase our cost of doing business. Claims of violations of privacy rights or contractual breaches, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

## **Coverage and Reimbursement**

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



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

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

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

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

### **Healthcare Reform**

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medical products. For example, in March 2010, the ACA was enacted, which, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers'



outpatient drugs coverage under Medicare Part D; subjected drug manufacturers to new annual fees based on pharmaceutical companies' share of sales to federal healthcare programs; and created a new Patient Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The current presidential administration and U.S. Congress will likely continue to seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. However, the ultimate content, timing or effect of any healthcare reform legislation on the U.S. healthcare industry is unclear.

We expect that other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria and lower reimbursement, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. Moreover, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which have resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical and biological products. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs.

Additionally, on August 2, 2011, the Budget Control Act of 2011 was enacted, which, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will stay in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

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

## **Employees**

As of October 31, 2018, we had 96 employees, 48 of whom hold M.D. or Ph.D. degrees. Seventy-four of our employees work in research and development and 22 work in management and administrative areas. All of our employees are located in the Netherlands except for 18 employees located in the United States. None of our employees is subject to a collective bargaining agreement or represented by a trade or labor union. We are in the process of establishing a works council for our employees, which we expect will go into effect on January 1, 2019.

## **Facilities**

We lease approximately 12,320 square meters of office and laboratory space in Utrecht, the Netherlands. This facility serves as our corporate headquarters and central laboratory facility. The leases for this space expire on October 31, 2021.

## Legal Proceedings

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

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

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

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

On December 20, 2018, we signed a global settlement and cross-license agreement with Regeneron, where the parties have agreed to end all pending litigation and opposition proceedings pertaining to certain of our and Regeneron's respective antibody generation technologies. Regeneron also purchased 600,000 of our common shares at a price of \$25 per share for total aggregate proceeds to us of \$15 million. Under the terms of the settlement, Regeneron has agreed to withdraw its appeal of the decision awarding attorneys' fees to us as a result of the U.S. District Court litigation described above, and we have agreed to dismiss our fee award. In addition, Regeneron has agreed to dismiss its stayed case in the Netherlands asserting the EP 1 360 287 B1 patent, and both parties have agreed to withdraw all pending oppositions.

On April 5, 2018, Regeneron and an unnamed third party filed notices of opposition against our EP 2604625 patent entitled "Generation of Binding Molecules," in the EPO. The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron will no longer be pursuing this opposition pursuant to the December 20, 2018 settlement. On August 20, 2018, we timely responded to these

submissions, with proceedings to be ongoing. As this opposition proceeding continues, we cannot assure you that we will ultimately prevail.

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

## MANAGEMENT

### Senior Management and Board of Directors

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

Name	Age	Position
<b>Senior Management</b>		
Lex Bakker, Ph.D.	51	Chief Development Officer
John Crowley	45	Chief Financial Officer
John de Kruif	54	Chief Technology Officer
Hui Liu, Ph.D.	46	Chief Business Officer
Ton Logtenberg, Ph.D.	60	President & Chief Executive Officer and President of Merus US, Inc.
Peter B. Silverman	41	General Counsel, and Chief Intellectual Property Officer
L. Andres Sirulnik, M.D., Ph.D.	51	Chief Medical Officer
Mark Throsby, Ph.D.	51	Chief Scientific Officer
<b>Board of Directors</b>		
Ton Logtenberg, Ph.D.	60	President & Chief Executive Officer (Executive Director)
Russell G. Greig, Ph.D.	66	Chairman of the Board (Non-Executive Director)
Mark Iwicki	52	Member (Non-Executive Director)
Len Kanavy	57	Member (Non-Executive Director)
John de Koning, Ph.D.	50	Member (Non-Executive Director)
Anand Mehra, M.D.	43	Member (Non-Executive Director)
Gregory Perry	58	Member (Non-Executive Director)

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

There are no family relationships among any of the members of our board of directors or senior management.

### Senior Management

**Alexander (“Lex”) Berthold Hendrik Bakker, Ph.D.** has served as our Chief Development Officer since October 2010. His responsibilities include strategic scientific leadership, management of preclinical and clinical development and manufacturing, business development support, external collaboration and partnership management. Prior to joining Merus, Dr. Bakker directed preclinical and clinical development at Crucell N.V., a biotechnology company. Mr. Bakker holds a Ph.D in Tumor Immunology from the University of Nijmegen and was a postdoctoral fellow at the DNAX Research Institute.

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

**John de Kruif, Ph.D.** has served as our Chief Technology Officer since January 2013 and previously served as our Chief Scientific Officer from April 2007 to January 2013. His responsibilities include management of antibody discovery, antibody engineering, external collaborations, partnerships management and operational activities. Before joining Merus, from October 2000 to October 2006, he served as a director of antibody discovery for Crucell N.V., a biotechnology company specializing in vaccines and biopharmaceutical technology. Dr. de Kruif holds a PhD in Antibody Engineering from Utrecht University.

**Hui Liu, Ph.D.** has served as our Chief Business Officer since December 2015, since September 2018. His responsibilities include all aspects of business development, including in- and out- licensing, acquisitions and alliance management, and expansion of Merus in the United States. Prior to joining Merus, Dr. Liu served as Vice President and Global Head, Business Development & Licensing, Oncology at Novartis AG, a pharmaceutical company, from 2013 to 2015, and as Vice President and Global Head, Business Development & Licensing, Vaccines & Diagnostics, from 2009 to 2012. Prior to Novartis, Dr. Liu held various management positions at Pfizer, Inc., a pharmaceutical company, from 2004 to 2009 and at Pfizer, Inc. and its predecessor company Warner-Lambert from 1997 to 2001. From 2001 to 2004, Dr. Liu was an investment banker at Goldman Sachs and Citigroup. Dr. Liu holds a Ph.D. in molecular biology and an M.B.A. in finance from the University of Michigan and a B.S. in biology from Peking University.

**Ton Logtenberg, Ph.D.** has served as our President & Chief Executive Officer and an executive board member since co-founding our company in June 2003. Dr. Logtenberg also serves as President of our subsidiary, Merus US, Inc. Prior to joining Merus, Dr. Logtenberg co-founded Crucell N.V., a biotechnology company specializing in vaccines and biopharmaceutical technology, and served as its executive vice president and chief scientific officer from July 2000 until November 2003. Dr. Logtenberg has served as a member of the board of directors of the Jenner Foundation since 2008 and a member of the board of directors of Utrecht Science Park since November 2014. Dr. Logtenberg holds a Ph.D. in medical biology from Utrecht University.

**Peter B. Silverman, J.D.** has served as our General Counsel since February 2018 and our Chief Intellectual Property Officer since February 2017. His responsibilities include management of the company's legal strategy and overseeing all aspects of the company's legal operations. Prior to joining Merus, Mr. Silverman was a Partner at Kirkland & Ellis LLP, where he represented numerous life sciences companies concerning an array of legal matters. Mr. Silverman also served as judicial law clerk to U.S. District Court Judge Anne E. Thompson of the District of New Jersey. He holds a J.D. from Fordham University School of Law. He is admitted to practice law in New York. Mr. Silverman also holds a B.A. in biology from the University of Rochester.

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

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

## Board of Directors

**Ton Logtenberg, Ph.D.** has served as an executive director of our company since founding our company in June 2003. See “—Senior Management.”

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

**Mark Iwicki** has been a non-executive member of our board of directors since June 2015. From June 2015 until July 2018, Mr. Iwicki served as the Chairman of our board of directors. Mr. Iwicki is the chief executive officer and chairman of the board of directors of Kala Pharmaceuticals, Inc. and serves as a member of the boards of directors of Aimmune Therapeutics, Inc., Nimbus Therapeutics, Oxeia Biopharmaceuticals and Akero Therapeutics, Inc. In addition, Mr. Iwicki has served on the board of the Wellesley Youth Hockey Association. Mr. Iwicki served as president and chief executive officer and a member of the board of directors of Civitas Therapeutics, Inc. from January 2014 until its acquisition by Acorda Therapeutics, Inc. in October 2014. From December 2012 to January 2014, Mr. Iwicki served as president and chief executive officer and director at Blend Therapeutics, Inc. From 2007 to June 2012, Mr. Iwicki was president and chief executive officer and director of Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc. Mr. Iwicki holds an M.B.A. from Loyola University.

**Len Kanavy** has been a non-executive member of our board of directors since July 2018. Mr. Kanavy most recently served as Senior Vice President, Commercial Business Operations at Genentech where he was responsible for strategic decisions of the U.S. commercial business including product launches, valuation of business development opportunities, clinical development plan options and pricing. He was a Board Member of the Genentech Access to Care Foundation. Prior to joining Genentech, Mr. Kanavy was Vice President, Commercial Operations at Novartis Pharmaceuticals, where he led teams in business analytics, strategy, and product launches. He currently serves on the board of privately held KMK Consulting. Mr. Kanavy holds a B.S. in Business Administration and an MBA with a specialization in Finance from the University of Scranton.

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

**Anand Mehra, M.D.** was nominated to serve on our board of directors by Sofinnova Venture Partners IX, L.P., one of our shareholders, and has been a non-executive member of our board of directors since August 2015. Dr. Mehra has been with Sofinnova Ventures since 2007, most recently holding the position of a general partner where he focuses on working with entrepreneurs to build drug development companies. He has led the firm’s investments in Vicept Therapeutics (acquired by Allergan), Aerie Pharmaceuticals, Inc., Aclaris Therapeutics, Inc., and Prothena Corporation PLC. He currently serves as a member of the boards of directors of Spark

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Therapeutics, Inc., Aclaris Therapeutics, Inc. and Marinus Pharmaceuticals Inc. as well as on the boards of several private companies. Dr. Mehra holds his M.D. from Columbia University's College of Physicians and Surgeons.

**Gregory D. Perry** has been a non-executive member of our board of directors since May 2016 and Vice Chairman of our board of directors since August 2018. Mr. Perry is the Chief Financial Officer at Finch Therapeutics Group and serves as a member of the Board of Directors of Kala Pharmaceuticals. Mr. Perry served as Chief Financial and Administrative Officer of Novelion Therapeutics Inc. or Novelion, a public company, from November 2016 to December 2017. Prior to this, Mr. Perry was Chief Financial Officer of Aegerion Pharmaceuticals Inc, a public company, from July 2015 until its merger with Novelion in November 2016. Prior to that, he served as Chief Financial and Business Officer of Eleven Biotherapeutics, Inc., a public company, from January 2014 to June 2015. Before joining Eleven Biotherapeutics, Mr. Perry served as the Interim Chief Financial Officer of InVivo Therapeutics, a public company, from September 2013 to December 2013, and prior to that he served as the Senior Vice President and Chief Financial Officer of ImmunoGen, Inc., a public company, from 2009 until he was promoted in 2011 to Executive Vice President and Chief Financial Officer, a role he held until 2013. Before that, he was the Chief Financial Officer of Elixir Pharmaceuticals. Mr. Perry previously was Senior Vice President and Chief Financial Officer of Transkaryotic Therapies. He has also held various financial leadership roles within PerkinElmer Inc., Domantis Ltd., Honeywell and General Electric. Since February 2018, Mr. Perry has served on the Board of Directors of Kala Pharmaceuticals, including as Chair of its Audit Committee. From December 2011 to February 2016, Mr. Perry served on the Board of Directors of Ocata Therapeutics (a public biotechnology company), including as Chair of its Audit Committee and a member of its Compensation Committee, until it was acquired by Astellas Pharma Inc. Mr. Perry received a B.A. in Economics and Political Science from Amherst College.

## Corporate Governance

### Board Composition

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

The expiration of the current terms of the members of our Board of Directors and the period each member has served in that term are as follows:

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

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

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

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

Our board of directors has established an Audit Committee, Compensation Committee, and Nomination and Corporate Governance Committee, which operate pursuant to written charters adopted by our board of directors.

#### ***Audit Committee***

The audit committee, which consists of Gregory Perry, Anand Mehra and John de Koning, assists our board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Mr. Perry serves as Chairman of the committee.

The audit committee's responsibilities include:

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

The audit committee meets as often as one or more members of the audit committee deem necessary, but in any event, meets at least four times per year. The audit committee meets at least once per year with our independent accountant, without our management being present.

#### ***Compensation Committee***

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

The compensation committee's responsibilities include:

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



*Nomination and Corporate Governance Committee*

The nomination and corporate governance committee, which consists of Russell Greig, Mark Iwicki and John de Koning, assists our board of directors in identifying individuals qualified to become members of our board and part of our management consistent with criteria established by our board and in developing our corporate governance principles. Mr. Greig serves as Chairman of the nomination and corporate governance committee.

The nomination and corporate governance committee's responsibilities include:

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

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

The following is a summary of the Nasdaq listing rules with which we do not comply:

- Nasdaq Listing Rule 5620(c): In accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders in the United States. To this extent, our practice varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.
- Nasdaq Listing Rule 5620(b): 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 varies from the requirement of Nasdaq Listing Rule 5620(b).
- Nasdaq Listing Rule 5605(d) and (e): As permitted by the listing requirements of Nasdaq, we have also opted out of the requirements of Nasdaq Listing Rule 5605(d), which requires an issuer to have a compensation committee that consists entirely of independent directors, and Nasdaq Listing Rule 5605(e), which requires an issuer to have independent director oversight of director nominations. Although we have chosen not to comply with Nasdaq Rule 5605(d) regarding the independence of our compensation committee, all of the current members of our compensation committee meet the heightened independence requirements under this rule.
- Nasdaq Listing Rule 5635: We have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

## Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics, or the Code of Conduct, that is applicable to all of our employees, management, including our principal executive officer, principal financial officer and principal accounting officer, board of directors, consultants, and others temporarily assigned to perform work or services for us. The Code of Conduct is available on our website at [www.merus.nl](http://www.merus.nl). Our board of directors is responsible for administering the Code of Conduct. The board of directors is allowed to amend, alter or terminate the Code of Conduct.

## Compensation

### Senior Management Remuneration

The following table sets forth the approximate remuneration paid during our 2017 fiscal year to our senior management.

Name and Principal Position	Salary	Bonus(1)	Equity Awards(2)	All Other Compensation(3)	Total
Lex B.H. Bakker Senior Vice President, Chief Development Officer	€266,612	€ 85,583	€ 206,097	€ 35,270	€ 593,563
John Crowley Executive Vice President, Chief Financial Officer	€320,882	€120,170	€ 874,795	€ —	€1,315,847
John de Kruif Senior Vice President, Chief Technology Officer	€237,944	€ 76,380	€ 152,672	€ 37,527	€ 504,523
Hui Liu Executive Vice President, Chief Business Officer	€305,187	€114,369	€1,085,341	€ —	€1,504,897
Ton Logtenberg, Ph.D. President & Chief Executive Officer and President of Merus US	€432,782	€337,945	€4,675,590	€ 51,528	€5,497,845
Peter B. Silverman(4) Executive Vice President, General Counsel and Chief IP Officer	€238,082	€ 86,238	€ 437,220	€ —	€ 761,540
L. Andres Sirulnik Executive Vice President, Chief Medical Officer	€389,484	€147,756	€1,144,148	€ —	€1,681,388
Mark Throsby Executive Vice President, Chief Scientific Officer	€305,792	€114,519	€1,270,960	€ 35,618	€1,726,889

- (1) Amount shown reflects bonuses awarded for achievement of performance goals in our 2017 fiscal year.
- (2) Amount shown represents the grant date fair value of option awards and restricted stock units, or RSUs, granted in 2017. Option awards are measured using the Hull & White option pricing model. For a description of the assumptions used in valuing these awards, see note 14 to our financial statements incorporated by reference in this prospectus.
- (3) Amount shown represents pension, retirement or other similar contributions made by us.
- (4) Mr. Silverman's salary was prorated to reflect the start of his employment with the Company on February 15, 2017.

Below is a brief description of the compensation plans and arrangements in which our senior management participate.

### **Base Compensation**

We pay our senior management a base salary to compensate them for the satisfactory performance of services rendered to our company. Base salary is intended to provide a fixed component of compensation reflecting the senior management's level of responsibility and performance. Our senior management's base salaries for 2017 are set forth in the table above entitled "Senior Management Remuneration."

### **Short-Term Incentive Plan**

We maintain a short-term incentive plan pursuant to which we may grant our employees, including our senior management, incentive cash bonuses based upon corporate and/or individual performance. We generally pay annual cash bonuses based upon the achievement of set financial targets, non-financial and personal goals and company milestones for the period. Achievement of the targets is measured following year-end and the actual bonus amounts paid to our senior management, including our executive officers, are determined by our board of directors.

The corporate objectives set for 2017 pursuant to our short-term incentive plan accounted for 75% of the senior management's bonus opportunity and were generally related to clinical developments, intellectual property, business developments and funding initiatives. Individual objectives are established annually for each member of the senior management and, in 2017, accounted for 25% of the senior management's bonus opportunity. The actual bonus amounts paid to our senior management for 2017 are set forth in the table above entitled "Senior Management Remuneration".

### **Long-Term Incentive Plan**

We maintain the 2016 Plan under which we may grant cash and equity-based incentive awards to eligible service providers, including our board members, in order to attract, retain and motivate the persons who make important contributions to our company. The plan administrator has the authority to take all actions and make all determinations under the 2016 Plan, to interpret the 2016 Plan and award agreements and to adopt, amend and repeal rules for the administration of the 2016 Plan as it deems advisable. The plan administrator also has the authority to determine which eligible service providers receive awards, grant awards and set the terms and conditions of all awards under the 2016 Plan, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2016 Plan. The 2016 Plan provides for the grant of stock options, stock appreciation rights, restricted stock, dividend equivalents, restricted stock units, and other stock or cash based awards. In connection with any spin-off, change in control, or change in any applicable laws or accounting principles, the plan administrator has broad discretion to take action under the 2016 Plan to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. The plan administrator may generally amend or terminate the 2016 Plan at any time.

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The following table summarizes the options that we granted to our senior management in 2017 under the 2016 Plan:

Name	Grant Date	Number of Shares Subject to Option (#)(1)	Exercise Price Per Share (\$)	Expiration Date	Restricted Share Units
Lex Bakker, CDO	1/1/2017	15,739	21.11	12/30/2026	5,162
John Crowley, CFO	—	—	—	—	—
John de Kruif, CTO	1/1/2017	11,479	21.11	12/30/2026	3,765
Hui Liu, CBO	1/1/2017	85,156	21.11	12/30/2026	27,931
Ton Logtenberg, CEO	1/1/2017	377,271	21.11	12/30/2026	123,745
Peter Silverman, GC	2/15/2017	50,000	25.90	2/14/2027	—
L. Andres Sirulnik, CMO	—	—	—	—	—
Mark Throsby, CSO	1/1/2017	103,484	21.11	12/30/2026	33,943

- (1) The options and RSUs vest as to 25% of the shares on the first anniversary of the grant date and as to the remaining 75% of the shares in equal monthly installments for the 36 calendar months thereafter.

### Pension Benefits

We offer some of our senior management the opportunity to participate in a post-retirement plan in order to provide competitive post-retirement benefits. For 2017, we contributed a total of € 0.1 million to provide pension, retirement or similar benefits to our senior management.

### Employment Agreements

#### *Lex B.H. Bakker, Chief Development Officer*

In May 2010, we entered into an employment agreement with Mr. Bakker pursuant to which he serves as our Chief Development Officer. The agreement is for an unspecified term and may be terminated at the end of a calendar month by either Mr. Bakker or the company, subject to the applicable statutory notice periods. Pursuant to the employment agreement, Mr. Bakker is entitled to a base salary, an annual vacation allowance of 8% of his gross salary, participation in a pension scheme, reimbursement for certain commuting expenses and, in the event if his disability, certain continued payments of his base salary.

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

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

#### *John Crowley, Chief Financial Officer*

On October 5, 2016, we and our wholly-owned subsidiary Merus US, Inc., which we refer to as Merus US, entered into an employment agreement with John Crowley. Pursuant to the employment agreement, Mr. Crowley serves as Executive Vice President and Chief Financial Officer of us and Merus US. The employment agreement provides for an initial annual base salary of \$362,500 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 35% of Mr. Crowley's annual base salary. If Mr. Crowley's

employment is terminated by Merus US without cause or due to Mr. Crowley's resignation for good reason, then subject to his executing a general release of claims and continuing compliance with the Company's proprietary information agreement, Mr. Crowley will be entitled to receive (i) base salary continuation payments for 6 months and (ii) potential accelerated vesting of any portion of his initial option award that is unvested as of the date of his termination. If Mr. Crowley's employment is terminated without cause or due to Mr. Crowley's resignation for good reason within 12 months following a change in control of us, then subject to his executing a general release of claims and continuing compliance with the proprietary information agreement, Mr. Crowley will be entitled to receive (i) a lump sum payment equal to six months of his base salary and 50% of his target annual bonus; (ii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to nine months, and (iii) accelerated vesting of any portion of his unvested equity awards, except that performance-based equity awards will only vest subject to the attainment of the applicable performance goals.

***John de Kruif, Chief Technology Officer***

In April 2007, we entered into an employment agreement with Dr. de Kruif for an unspecified term, which agreement may be terminated at the end of a calendar month by either Dr. de Kruif or the company subject to the applicable statutory notice periods. Pursuant to the employment agreement, Dr. de Kruif is entitled to a base salary, an annual vacation allowance equal to 8% of his gross salary, participation in a pension scheme and, in the event if his disability, certain continued payments of his base salary.

The agreement contains restrictive covenants which restrict Dr. de Kruif's ability to compete with us for a period of 12 months following termination. Dr. de Kruif is subject to a penalty of €10,000 for each violation of this covenant and an additional fine of €1,000 for each day the violation continues. Dr. de Kruif is also prohibited from performing work for another employer or client during the course of his employment with us and is subject to a per violation fine of €5,000 and per day fine of €1,000 for as long as the violation continues.

The agreement also contains covenants regarding Dr. de Kruif's protection of our confidential information for a period of five years following termination of his employment, violation of which subjects him to penalties of €50,000 for each violation and €1,000 for each day the violation continues. Dr. de Kruif has also entered into a separate agreement with us regarding ownership of our intellectual property.

***Hui Liu, Chief Business Officer***

On December 1, 2015, we and Merus US entered into an employment agreement with Hui Liu, which was amended and restated on March 2, 2016, pursuant to which Mr. Liu serves as Executive Vice President and Chief Business Officer of us and Merus US. The employment agreement provides for an initial annual base salary of \$335,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 35% of Mr. Liu's annual base salary. If Mr. Liu's employment is terminated by Merus US without cause or due to Mr. Liu's resignation for good reason, then subject to his executing a general release of claims and continuing compliance with the Company's proprietary information agreement, Mr. Liu will be entitled to receive (i) base salary continuation payments for 6 months and (ii) potential accelerated vesting of any portion of his initial option award that is unvested as of the date of his termination. If Mr. Liu's employment is terminated without cause or due to Mr. Liu's resignation for good reason within 12 months following a change in control of us, then subject to his executing a general release of claims and continuing compliance with the proprietary information agreement, Mr. Liu will be entitled to receive (i) a lump sum payment equal to six months of his base salary and 50% of his target annual bonus; (ii) direct payment of or reimbursement for continued medical, dental or vision coverage pursuant to COBRA for up to nine months, and (iii) accelerated vesting of any portion of his initial option award that is unvested as of his date of termination.

***Ton Logtenberg, President & Chief Executive Officer and Executive Director and President of Merus US***

We have entered into an employment agreement, as amended from time to time, with Ton Logtenberg pursuant to which Dr. Logtenberg serves as our President & Chief Executive Officer. The agreement is for an unspecified

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

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

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

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

***Peter B. Silverman, General Counsel and Chief Intellectual Property Officer***

Effective February, 2017, we and Merus US entered into an employment agreement with Peter B. Silverman. The employment agreement provides for an initial annual base salary of \$315,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 30% of Mr. Silverman's annual base salary. If Mr. Silverman's employment is terminated by Merus US without cause or due to Mr. Silverman's resignation for good reason, then subject to his executing a general release of claims and continuing compliance with our proprietary information agreement, Mr. Silverman will be entitled to receive (i) an amount in cash equal to the sum of 0.5 times his annual base salary and (ii) a pro-rata portion of his target annual bonus for the calendar year in which the date of termination occurs, which shall be paid in the form of salary continuation in regular installments over the six-month period following his termination in accordance with the Company's customary payroll practices. On February 21, 2018, Mr. Silverman was appointed Executive Vice President and General Counsel.

***L. Andres Sirulnik, Chief Medical Officer***

On November 1, 2016, we and Merus US entered into an employment agreement with L. Andres Sirulnik. Pursuant to the employment agreement, Mr. Sirulnik serves as Executive Vice President and Chief Medical Officer of us and Merus US. The employment agreement provides for an initial annual base salary of \$390,000 and the opportunity to earn an annual cash incentive award based on performance with a target value equal to 40% of Mr. Sirulnik's annual base salary. In addition, the Company agreed to pay Mr. Sirulnik an amount equal to \$50,000, within thirty (30) days following each of November 8, 2017 and November 8, 2018, subject to Mr. Sirulnik's continued employment with the Company through each such date.

### **Mark Throsby, Chief Science Officer**

In July 2008, we entered into an employment agreement with Mr. Throsby for an unspecified term, which agreement may be terminated at the end of a calendar month by either Mr. Throsby or the company subject to the applicable statutory notice periods. Pursuant to the employment agreement, Mr. Throsby is entitled to a base salary, an annual vacation allowance equal to 8% of his gross salary, participation in a pension scheme and, in the event of his disability, certain continued payments of his base salary.

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

The agreement also contains covenants regarding Mr. Throsby's protection of our confidential information for a period of 5 years following his termination, violation of which subjects him to penalties of €50,000 for each violation and €1,000 for each day the violation continues. Mr. Throsby has also entered into a separate agreement with us regarding ownership of our intellectual property.

### **Compensation of Board of Directors**

The following table sets forth the remuneration paid during our 2017 fiscal year to members of our board of directors.

Name	Fees earned or paid in Cash	Option Awards(2) (in euros)	Total
Ton Logtenberg, Ph.D.(1)	€ 822,255	€ 4,675,590	€ 5,497,845
Mark Iwicki	€ 59,840	€ 120,956	€ 180,436
Wolfgang Berthold, Ph.D.(3)	€ 41,700	€ 90,944	€ 132,644
Lionel Carnot(4)	€ 35,445	€ 61,870	€ 97,315
John de Koning, Ph.D.	€ 38,573	€ 113,613	€ 152,186
Anand Mehra, M.D.	€ 42,743	€ 83,683	€ 126,426
Jack B. Nielsen(5)	€ —	€ —	€ —
Gregory Perry	€ 47,955	€ 103,169	€ 151,124

- (1) Dr. Logtenberg did not receive any additional compensation for his service on our board during 2017. Amounts paid to Dr. Logtenberg for his service as an executive officer are set forth above in the section "Senior Management Remuneration" above.
- (2) Amount shown represents the grant date fair value of option awards granted in 2017 measured using the Hull & White option pricing model. For a description of the assumptions used in valuing these awards, see note 14 to our financial statements incorporated by reference in this prospectus.
- (3) Dr. Berthold resigned from our board of directors on June 28, 2018.
- (4) Mr. Carnot resigned from our board of directors on July 20, 2018.
- (5) Dr. Nielsen resigned from our board of directors on May 24, 2017 and did not receive any compensation for his service on our board during 2017.

### **Remuneration of Board of Directors**

Although Dutch law does not require that we establish a remuneration program for our members of our board of directors, we have established a Non-Executive Director Compensation Program. Under this program, remuneration for the members of our board of directors consists of cash and initial and annual equity awards.

Each board member is entitled to receive an annual retainer of \$35,000. The chairman of the board is entitled to an additional annual retainer of \$50,000 and the chairman of the audit committee, compensation committee and nomination and corporate governance committee are each entitled to an additional annual retainer of \$15,000, \$13,000 and \$13,000, respectively. A board member serving as a member of a committee other than the chairman is entitled to receive an additional annual retainer of \$7,500 for service on the audit committee, \$5,000 for service on the compensation committee, and \$3,750 for service on the nomination and corporate governance committee. Retainers under the program are payable in arrears in four equal quarterly installments within 15 days following the end of each calendar quarter, provided, that the amount of each payment will be prorated for any portion of a quarter that a board member is not serving on our board. The remuneration program further provides for an automatic increase of the annual retainers on the first day of each calendar year by an amount equal to 3% of the value of such annual retainer in effect as of the immediately preceding calendar year. The board of directors may appoint observers to the board of directors, pending their formal appointment as a board member, in which case, unless the board of directors decides otherwise, the date service as an observer commences shall be considered the effective date of commencing service as a board member for purposes of the remuneration program for the board of directors.

Each board member who is initially appointed to our board is eligible to receive an option to purchase the number of common shares of our company having an aggregate grant date fair value of \$200,000 on the date of grant. Unless otherwise determined by the board of directors, options to purchase common shares granted to an observer while serving, or upon commencing service, as an observer shall be considered an initial award described in the previous sentence. In addition, if a board member has served on the board (as a non-executive director or as an observer) for at least six months and continues to serve as a board member following any annual general meeting of shareholders held following his or her initial appointment as a board member, such board member is eligible to receive, on the date of each such annual meeting or as soon as practical thereafter, an option to purchase the number of common shares of our company having an aggregate grant date fair value of \$100,000 on the date of grant. Options granted to our board members under the program have an exercise price equal to the fair market value of our common shares on the date of grant and expire not later than ten years after the date of grant. The options granted as initial awards vest as to 33% of the shares subject to the award on the first anniversary of the date of grant and in 24 substantially equal monthly installments thereafter. The options granted annually to board members vest in 12 substantially equal monthly installments following the date of grant. In each case, vesting is subject to continued service as a board member or an observer through each such vesting date. In addition, all unvested options vest in full upon the occurrence of a change in control. The grant date fair value of each initial award and annual award is, subject to approval by our board of directors, increased on the first day of each calendar year by an amount equal to 3% of the grant date fair value in effect as of the immediately preceding calendar year, provided, that in no event shall the number of shares awarded pursuant to an initial award exceed 17,000 common shares and an annual award exceed 8,500 common shares, in each case, subject to adjustment as provided in the 2016 Plan. Our board of directors approved such 3% increase on September 18, 2018, with effect from 2018.

Each board member is entitled to be reimbursed for reasonable travel and other expenses incurred in connection with attending meetings of the board and any committee of the board on which he or she serves.



### Board of Directors 2017 Fiscal Year Equity Awards

During the fiscal year 2017, members of our board of directors were granted options to purchase common shares under the 2016 Plan as follows:

Name	Grant Date	Number of Shares Subject to Option (#)(1)	Exercise Price Per Share (\$)	Expiration Date
Ton Logtenberg, Ph.D.	1/1/2017	377,271	21.11	12/30/2026
Mark Iwicki	5/24/2017	5,650	19.12	5/24/2027
Wolfgang Berthold, Ph.D.(2)	5/24/2017	5,650	19.12	5/24/2027
Lionel Carnot(3)	5/24/2017	5,650	19.12	5/24/2027
John de Koning, Ph.D.	5/24/2017	5,650	19.12	5/24/2027
Anand Mehra, M.D.	5/24/2017	5,650	19.12	5/24/2027
Jack B. Nielsen(4)	—	—	—	—
Gregory Perry	5/24/2017	5,650	19.12	5/24/2027

- (1) The options vest as to 33% of the shares subject to each award on the first anniversary of the date of grant and in 24 substantially equal monthly installments thereafter, subject to accelerated vesting upon the occurrence of a change in control event, except that for Dr. Logtenberg, the options vest as to 25% of the shares on the first anniversary of the grant date and as to the remaining 75% of the shares in equal monthly installments for the 36 calendar months thereafter.
- (2) Dr. Berthold resigned from our board of directors on June 28, 2018.
- (3) Mr. Carnot resigned from our board of directors on July 20, 2018.
- (4) Dr. Nielsen resigned from our board of directors on May 24, 2017.

## PRINCIPAL AND SELLING SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our common shares as of October 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 October 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 October 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 22,750,867 common shares as of October 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
5% or greater shareholders and selling shareholders:					
BVF(1)	4,514,913	19.8%	2,124,443	2,390,470	10.5%
Incyte Corporation(2)	3,200,000	14.1%	3,200,000	—	—
Bay City Capital Coöperatief U.A.(3)	2,113,574	9.3%	—	2,113,574	9.3%
Sofinnova Venture Partners IX, L.P.(4)	1,961,039	8.6%	222,222	1,738,817	7.6%
Cooperatief LSP IV UA(5)	1,225,661	5.4%	—	1,225,661	5.4%
Johnson & Johnson—JJDC, Inc.(6)	1,195,943	5.3%	—	1,195,943	5.3%
Aquilo Capital Management, LLC(7)	1,352,184	5.9%	531,110	821,074	3.6%
Wellington Management Group LLP(8)	1,181,946	5.2%	—	1,181,946	5.2%
Baker Brothers Life Sciences L.P.(9)	1,160,014	5.1%	—	1,160,014	5.1%
LSP Life Sciences Fund N.V.(10)	222,222	1.0%	222,222	—	—
Senior management and Board of Directors:					
Ton Logtenberg, Ph.D.(11)	683,263	3.0%	—	683,263	3.0%
John Crowley(12)	83,992	*	—	83,992	*
Hui Liu(13)	127,753	*	—	127,753	*
L. Andres Sirulink(14)	109,022	*	—	109,022	*
Mark Throsby, Ph.D.(15)	141,206	*	—	141,206	*
Lex B.H. Bakker, Ph.D.(16)	42,987	*	—	42,987	*
Peter B. Silverman(17)	19,056	*	—	19,056	*
John de Kruif(18)	29,312	*	—	29,312	*
Russell G. Greig, Ph.D.	—	—	—	—	—
Mark Iwicki(19)	70,579	*	—	70,579	*
Len Kanavy(20)	6,098	*	—	6,098	*
John de Koning, Ph.D.(21)	22,353	*	—	22,353	*
Anand Mehra(4)(22)	1,983,392	8.7%	222,222	1,761,170	7.7%
Gregory Perry(23)	22,353	*	—	22,353	*

\* 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 presented is as of December 19, 2018 and is based on a Schedule 13G/A filed with the SEC on June 19, 2018 and information known to us. The address for each of these entities is 44 Montgomery Street, 40th Floor, San Francisco, CA 94104.
- (2) Consists of 3,200,000 common shares held directly by Incyte Corporation (“Incyte”).
- (3) Consists of (a) 2,062,025 common shares held directly by Bay City Capital Fund V, L.P. (“Fund V”), (b) 39,295 common shares held by Bay City Capital Fund V Co-Investment Fund, L.P. (“Fund V-SBS”) are the

two sole investors of COOP. Bay City Capital Management V LLC (“BCCM V”) is the general partner of Fund V and Fund V-SBS, and (c) 12,254 common shares held directly by Bay City Capital LLC (“BCC”). BCC is the adviser and manager of BCCM V. BCCM V and BCC represent Fund V and Fund V-SBS, respectively. Thus, BCCM V and BCC share voting and investment power over the shares held by each of Fund V and Fund V-SBS. Lionel Carnot is a member of BCCM V and is employed as a managing director of BCC together with Fred Craves, Carl Goldfischer, Dayton Misfeldt and Rob Hopfner. As such, each of these individuals may be deemed to share voting and investment power over these entities, and they disclaim beneficial ownership of all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on a Schedule 13D filed with the SEC on November 28, 2018. The mailing address for BCC, Fund V, Fund V-SBS and BCCM V is De Boelelaan 7, 1083 HJ Amsterdam, Netherlands.

- (4) Consists of 1,961,039 common shares held directly by Sofinnova Venture Partners IX, L.P. (“Sofinnova VP”). Sofinnova Management IX, L.L.C. (“Sofinnova Management”) is the general partner of Sofinnova VP and Anand Mehra, Michael Powell and James Healy are the managing members of Sofinnova Management. Sofinnova Management, Anand Mehra (a member of our board), Michael Powell and James Healy may be deemed to have shared voting and dispositive power over the shares owned by Sofinnova VP. Such entities and individuals disclaim beneficial ownership over all shares except to the extent of any pecuniary interest therein. Beneficial ownership information is based on information known to us and a Schedule 13D filed with the SEC on September 27, 2017. The address for Sofinnova VP and Sofinnova Management is 3000 Sand Hill Road, Building 4, Suite 250, Menlo Park, California 94025.
- (5) Consists of 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.
- (6) Consists of 1,195,943 common shares held directly by Johnson & Johnson Innovation—JJDC, Inc. (“JJDC”). JJDC is a wholly-owned subsidiary of Johnson & Johnson (“J&J”). JJDC and J&J have shared voting and dispositive power over the shares and J&J may be deemed to indirectly beneficially own the shares. Beneficial ownership information is based on a Schedule 13G filed with the SEC on January 18, 2017. The address of JJDC is One Johnson & Johnson Plaza, New Brunswick, NJ 08933.
- (7) Consists of (a) 1,075,913 common shares held directly by Aquilo Capital, L.P. (“Aquilo”) and (b) 276,271 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 as of December 18, 2018 and is based on a Schedule 13F-HR filed with the SEC on November 14, 2018 and information known to us. The address for Aquilo and Aquilo II is One Letterman Drive, Suite D4900, San Francisco, California, 94129.
- (8) The shares are held directly by Wellington Management Group LLP. Wellington Investment Advisors Holdings LLP which controls directly, or indirectly through Wellington Management Global Holdings, Ltd., (“Wellington Investment Advisers”). Wellington Investment Advisors Holdings LLP is owned by Wellington Group Holdings LLP, Wellington Group Holdings LLP is owned by Wellington management Group LLP. Beneficial ownership information is based on a Schedule 13G filed with the SEC on February 8, 2018. The address for each of these entities is c/o Wellington Management Company LLP, 280 Congress Street, Boston, MA 02210.
- (9) Consists of (a) 1,054,257 common shares held directly by Baker Brothers Life Sciences, L.P. (“Life Sciences”) and (b) 105,757 common shares held directly by 667, L.P. (“667”, and together with Life

Sciences, the “Baker Funds”). Baker Bros. Advisors LP (“Advisors”) is the Investment Adviser for the Baker Funds and has sole voting and investment power with respect to the shares held by the Baker Funds. Baker Bros. Advisors (GP) LLC is the sole general partner of Advisors. Baker Bros. Advisors (GP) LLC, Julian C. Baker and Felix J. Baker as principals of the Baker Bros. Advisors (GP) LLC, and Advisors disclaim beneficial ownership of all shares. Beneficial ownership information is based on a Schedule 13G filed with the SEC on February 14, 2017. The address for each of these entities is 667 Madison Avenue, 21st Floor, New York, NY 10065.

- (10) 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.
- (11) Consists of (a) 160,814 common shares held by BioPhrase, B.V. (“BioPhrase”), Dr. Logtenberg’s personal holding company, (b) 126,235 common shares held by Dr. Logtenberg, (c) 391,058 options to purchase common shares held by Dr. Logtenberg, including options that vest within 60 days following October 31, 2018 and (d) 5,156 restricted stock units (“RSUs”) held by Dr. Logtenberg, including RSUs that vest within 60 days following October 31, 2018.
- (12) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (13) Consists of (a) 12,221 common shares, (b) 114,368 options to purchase common shares including options that vest within 60 days following October 31, 2018 and (c) 1,164 restricted stock units (“RSUs”), including RSUs that vest within 60 days following October 31, 2018.
- (14) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (15) Consists of (a) 10,358 common shares, (b) 129,432 options to purchase common shares including options that vest within 60 days following October 31, 2018 and (c) 1,416 restricted stock units (“RSUs”), including RSUs that vest within 60 days following October 31, 2018.
- (16) Consists of (a) 8,794 common shares, (b) 33,977 options to purchase common shares including options that vest within 60 days following October 31, 2018 and (c) 216 restricted stock units (“RSUs”), including RSUs that vest within 60 days following October 31, 2018.
- (17) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (18) Consists of (a) 1,653 common shares, (b) 27,501 options to purchase common shares including options that vest within 60 days following October 31, 2018 and (c) 158 restricted stock units (“RSUs”), including RSUs that vest within 60 days following October 31, 2018.
- (19) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (20) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (21) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (22) Consists of (a) 1,961,039 shares held by Sofinnova Venture Partners IX LP prior to this offering and (b) 22,353 options to purchase common shares, including options that vest within 60 days following October 31, 2018.
- (23) Consists of options to purchase common shares, including options that vest within 60 days following October 31, 2018.

To our knowledge, there has been no significant change in the percentage ownership held by the major shareholders listed above since January 1, 2015, except as discussed elsewhere in this prospectus.

## RELATED PARTY TRANSACTIONS

The following is a description of material related party transactions with any members of our board of directors, senior management and the holders of more than 5% of our common shares since January 1, 2015.

### Private Placement

On February 13, 2018, we entered into a Securities Purchase Agreement, or the Purchase Agreement, with certain new and existing investors, whom we refer to in this prospectus as the “selling shareholders.” Pursuant to the Purchase Agreement, on February 15, 2018, we issued and sold 3,099,997 of our common shares to the selling shareholders in a private placement, or the Private Placement, at a price per share of \$18.00 for total aggregate gross proceeds to us of \$55.8 million. On February 13, 2018, we entered into a Registration Rights Agreement with the investors in the Private Placement, pursuant to which we agreed to register the resale of the common shares sold to the selling shareholders in the Private Placement. Sofinnova Venture Partners IX, L.P. purchased 222,222 common shares in the Private Placement.

### Incyte Agreements

In December 2016, we entered into a License and Collaboration Agreement, or the Collaboration Agreement, with Incyte Corporation, or Incyte. See “Business—Collaboration Agreements—Incyte Corporation.”

In connection with the Collaboration Agreement, we entered into a Share Subscription Agreement, or the Subscription Agreement, pursuant to which, in January 2017, Incyte purchased 3,200,000 common shares, or the Shares, at a purchase price per share of \$25.00 for total aggregate proceeds to us of \$80.0 million.

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

Incyte agreed that for a period ending on the earlier of 18 months after the closing date of the Subscription Agreement or the end of the Standstill Period, or the Lock-Up Period, it would not, subject to certain exceptions, sell or otherwise transfer or agree to transfer the Shares. The Lock-Up Period ended in July 2018. In addition, if the Standstill Period has not been terminated early, for a period of three years after the end of the Lock-Up Period, Incyte will be restricted from selling or otherwise transferring more than one-third of the Shares during any 12-month period or ten percent of the Shares during any three-month period, unless we consent otherwise. Incyte has further agreed that during the Standstill Period, it will vote all of the voting securities that it holds in accordance with the recommendation of a majority of our board of directors. However, Incyte may vote its securities at its own discretion for certain extraordinary matters, including a change in control of our company.

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

### Registration Rights Agreement

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

#### *Demand Registration Rights*

If the holders of, at least, 30% of the registrable securities then outstanding request that we effect a registration with respect to all or part of their registrable securities, we may be required to register all or part of the registrable securities then outstanding. We are obligated to effect at most two registrations in response to these demand registration rights. If the holders requesting registration intend to distribute their shares by means of an underwriting, the managing underwriter of such offering has the right to limit the number of shares to be underwritten for reasons related to the marketing of the shares.

#### *Piggyback Registration Rights*

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

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

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

#### *Expenses*

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

#### *Termination of Registration Rights*

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

#### **Agreements with Executive Officers**

For a description of our agreements with our executive officers, see "Management—Compensation."

#### **Indemnification Agreements**

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

## DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

Set forth below is a summary of certain information concerning our share capital as well as a description of certain provisions of our articles of association and relevant provisions of Dutch law. Because the following is only a summary, it does not contain all of the information that may be important to you. The summary includes certain references to and descriptions of material provisions of our articles of association and Dutch law in effect as of the date of this prospectus. The summary below does not purport to be complete and is qualified in its entirety by reference to applicable Dutch law and our articles of association, which is incorporated by reference as an exhibit to the registration statement of which this prospectus is a part.

### General

We were incorporated on June 16, 2003 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. In connection with the initial public offering of our common shares, we converted into a Dutch public company with limited liability (*naamloze vennootschap*).

We are registered with the Dutch Trade Register (*handelsregister*) under number 30189136. Our corporate seat is in Utrecht, the Netherlands, and our registered office is Yalelaan 62, 3584 CM Utrecht, the Netherlands.

### Share Capital

#### Common Shares

As of October 31, 2018, our issued share capital was €2.0 million, comprised of 22,750,867 common shares, nominal value €0.09 per share. As of October 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 October 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, 2015, our issued share capital has changed as provided below.

On January 26, 2015, we issued 492,514 Class B preferred shares to certain investors for aggregate consideration of €5.0 million in cash. In connection with this issuance of Class B preferred shares, we also issued an additional 844,834 of our Class B preferred shares pursuant to anti-dilution provisions included in the subscription agreement for the Class B preferred shares. These additional shares were issued for no cash consideration.

On August 21, 2015, we issued 4,149,884 Class C preferred shares to certain investors in exchange for aggregate consideration of approximately €49.7 million, which included the conversion of our existing €8.0 million convertible bridge loan and interest thereon into Class C preferred shares.

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.



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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.

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 and we issued 4,055 common shares upon the vesting of RSUs.

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 March 2018, we issued 4,055 common shares upon the vesting of RSUs.

In April 2018, we issued 4,055 common shares upon the vesting of RSUs.

In May 2018, we issued 4,055 common shares upon the vesting of RSUs.

In June 2018, we issued 4,055 common shares upon the vesting of RSUs.

In July 2018, we issued 47,279 common shares upon the exercise of options by employees for aggregate consideration of €583,111 in cash and we issued 4,055 common shares upon the vesting of RSUs.

In August 2018, we issued 1,750 common shares upon the exercise of options by employees for aggregate consideration of €23,865 in cash and we issued 4,055 common shares upon the vesting of RSUs.

In September 2018, we issued 40,564 common shares upon the exercise of options by employees for aggregate consideration of €97,598 in cash and we issued 4,055 common shares upon the vesting of RSUs.

In October 2018, we issued 12,254 common shares upon the exercise of options by employees for aggregate consideration of €106,179 in cash and we issued 4,055 common shares upon the vesting of RSUs.

### **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 October 31, 2018, there were options and RSUs outstanding to purchase 2,730,668 common shares.

The table below summarizes our share options as of October 31, 2018 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.

Share Options Granted Under the Merus B.V. 2010 Employee Option Plan		
Grant Date	Number of Share Options	Exercise Price Per Share Option
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

**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

### Articles of Association

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

### Amendment of Articles of Association

The general meeting of shareholders can only resolve to amend the articles of association at the proposal of the board of directors. A resolution by the general meeting of shareholders to amend the articles of association requires a simple majority of the votes cast.

### Company's Shareholders' Register

We must keep our shareholders' register accurate and up-to-date. The board of directors keeps our shareholders' register and records names and addresses of all holders of registered shares, showing the date on which the shares were acquired, the date of the acknowledgement of the transfer by or notification of the transfer to us as well as the amount paid on each share. The register also includes the names and addresses of those with a right to use and enjoyment in common shares belonging to another person (*vruchtgebruik*) or a pledge in respect of registered

shares, as well as any other particulars which must be recorded in our shareholders' register pursuant to Dutch law.

### ***Corporate Objectives***

Our corporate objectives are: (1) to develop products and services in the area of biotechnology, (2) to finance group companies or other parties, (3) to borrow, to lend to raise funds, including the issue of bonds, promissory notes or other financial instruments or evidence of indebtedness as well as to enter into agreements in connection with the aforementioned, (4) to supply advice and to render services to group companies and other parties, (5) to render guarantees, to bind us, to provide security, to warrant performance in any other way and to assume liability, whether jointly and severally or otherwise, in respect of obligations of group companies or other parties, (6) to incorporate, to participate in any way whatsoever in, to manage, to supervise and to hold any other interest in other entities, companies, partnerships and businesses, (7) to obtain, alienate, encumber, manage and exploit registered property and items of property in general, (8) to trade in currencies, securities and items of property in general, (9) to develop and trade in patent, trademarks, licenses, know-how and other intellectual property rights, and (10) to perform any and all activity of an industrial, financial or commercial nature and to do anything which in the broadest sense is connected with or may be conducive to the above-mentioned objects.

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

Under Dutch law, directors may be held liable by us or by third parties for damages in the event of improper or negligent performance of their duties, including as a result of infringement of our articles of association or of certain provisions of the Dutch Civil Code. In certain circumstances, they may also incur additional specific civil and criminal liabilities. Directors and certain other officers are insured under an insurance policy taken out by us against damages resulting from their conduct when acting in the capacities as such directors or officers. In addition, our articles of association provide for indemnification of our current and former directors (and such other of our current or former officer or employee as designated by our board of directors), including reimbursement for reasonable legal fees and damages or fines based on acts or failures to act in their duties. No indemnification shall be given to an indemnified officer (1) 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, expenses, suit, claim, action or legal proceedings resulted from either an improper performance of his or her duties as an officer of the company or an unlawful or illegal act, (2) to the extent that his or her financial losses, damages and expenses are covered by insurance and the insurer has settled, or has provided reimbursement for, these financial losses, damages and expenses (or has irrevocably undertaken to do so) and (3) 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 which has been approved by our board of directors. Furthermore, indemnification under our articles of association will generally not be available in instances of willful misconduct (*opzet*), intentionally reckless (*bewust roekeloos*) or seriously culpable (*ernstig verwijtbaar*) conduct unless Dutch law provides otherwise.

### ***Shareholders' Meetings and Consents***

#### ***General Meeting***

General meetings of shareholders are held in Utrecht, Amsterdam, Rotterdam, The Hague or in the municipality of Haarlemmermeer (Schiphol Airport), all of which are in the Netherlands. The annual general meeting of shareholders must be held within six months of the end of each financial year. Additional extraordinary general meetings of shareholders may also be held, whenever considered appropriate by the board of directors. An additional extraordinary general meeting of shareholders must also be held within three months after our board of directors has considered it to be likely that our shareholders' equity has decreased to an amount equal to or lower than half of our paid up and called up capital, in order to discuss the measures to be taken if so required. If our

board of directors has failed to ensure the annual general meeting of shareholders or the mandatory extraordinary general meeting of shareholders is held, each shareholder or others with meeting rights under Dutch law may be authorized by the competent Dutch court in preliminary relief proceedings to do so.

Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law, who jointly represent at least one-tenth of the issued capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If our board of directors has not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party/parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting of shareholders.

General meetings of shareholders can be convened by a notice to be published in a Dutch daily newspaper with national circulation, which shall include an agenda stating the items to be voted and/or discussed and any other particulars required under Dutch law. The agenda shall include such items as have been included therein by the board of directors. The agenda shall also include such items requested by one or more shareholders or others with meeting rights under Dutch law, representing at least 3% of the issued share capital. Requests must be made in writing and received by us at least 60 days before the day of the meeting. No resolutions shall be adopted on items other than those which have been included in the agenda, unless by a unanimous vote of all shareholders and others with voting rights.

In accordance with the Dutch Corporate Governance Code, or DCGC, shareholders are expected to exercise the right of requesting the convening of a general meeting of shareholders or of putting an item on the agenda only after consulting the board of directors in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in our strategy (e.g., the removal of directors), the board of directors should be given the opportunity to invoke a reasonable response time of up to 180 days after the board of directors is informed of the intentions of the shareholder(s). The board of directors should use this period for further deliberation, constructive consultation (in any event with the shareholder(s) who have made the request) and the exploration of alternatives. At the end of the response period, the board of directors should report its actions to the general meeting of shareholders. The response time may be invoked only once for any given general meeting of shareholders and may not be invoked for an agenda item in respect of which the response period has been invoked previously or for a general meeting of shareholders if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public offer (irrespective of whether the offer was friendly or hostile).

The general meeting is presided over by the chairman of the board of directors. If no chairman has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by the chief executive officer. If no chief executive officer has been elected or if he or she is not present at the meeting, the general meeting shall be presided over by another director present at the meeting. If no director is present at the meeting, the general meeting shall be presided over by any other person appointed by the general meeting. In each case, the person who should chair the general meeting pursuant to the rules described above may appoint another person to chair the general meeting instead. Directors may always attend a general meeting of shareholders. In these meetings, they have an advisory vote. The chairman of the meeting may decide at his or her discretion to admit other persons to the meeting.

All shareholders and others with meeting rights under Dutch law are authorized to attend the general meeting of shareholders, to address the meeting and, in so far as they have such right, to vote. For this purpose, those who have voting rights and/or meeting rights under Dutch law on the record date for a general meeting of shareholders (i.e., the 28th day prior to the meeting) and are recorded as such in a register designated by the board of directors shall be considered to have those rights, irrespective of whoever is entitled to the shares at the time of the general meeting of shareholders. The board of directors is free to determine, when convening a general meeting of shareholders, whether to apply a record date.

### *Quorum and Voting Requirements*

Each common share and each preferred share carries the right to cast one vote at the general meeting of shareholders. This right can be exercised in person or by proxy. No vote may be cast at a general meeting of shareholders in respect of a share belonging to us or any of our subsidiaries or in respect of a share for which we or any of our subsidiaries holds the depository receipts. Persons with a right to the use and enjoyment of our shares held by another person and pledgees of shares belonging to us or our subsidiaries are not precluded from exercising their voting rights if the right to use and enjoyment or pledge was created before the relevant share belonged to us or one of our subsidiaries. We and our subsidiaries may not vote shares in respect of which we or any of our subsidiaries hold(s) a right of use and enjoyment or a pledge. Shares which cannot be voted pursuant to these rules will not be taken into account for the purpose of determining the number of votes cast, or the amount of the share capital that is represented, at a general meeting of shareholders.

In accordance with Dutch law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Quorum requirements will only apply pursuant to Dutch law in case of a limited number of situations. Decisions of the general meeting of shareholders are taken by a simple majority of votes cast, except where Dutch law or our articles of association provide for a qualified majority or unanimity.

### ***Board of Directors***

#### *Election of Directors*

Under our articles of association, the directors are appointed by the general meeting of shareholders upon nomination by our board of directors. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of shareholders overrules the binding nomination, the board of directors shall make a new nomination. If the nomination comprises one candidate for a vacancy, a resolution concerning the nomination shall result in the appointment of the candidate, unless the nomination is overruled.

At a general meeting of shareholders, a resolution to appoint a director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting of shareholders or in the explanatory notes thereto. Upon the appointment of a person as a director, the general meeting of shareholders shall determine whether that person is appointed as executive director or as non-executive director.

#### *Duties and Liabilities of Directors*

Under Dutch law, the board of directors as a collective is responsible for our management, strategy, policy and operations. The executive directors manage our day-to-day business and operations and implement our strategy. The non-executive directors focus on the supervision on the policy and functioning of the performance of the duties of all directors and our general state of affairs. Each director has a statutory duty to act in the corporate interest of the company and its business. Under Dutch law, the corporate interest extends to the interests of all corporate stakeholders, such as shareholders, creditors, employees, customers and suppliers. The duty to act in the corporate interest of the company also applies in the event of a proposed sale or break-up of the company, provided that the circumstances generally dictate how such duty is to be applied and how the respective interests of various groups of stakeholders should be weighed. Any resolution of the board of directors regarding a material change in our identity or character requires approval of the general meeting of shareholders.

### ***Dividends and Other Distributions***

#### *Amount Available for Distribution*

As a Dutch public company with limited liability (*naamloze vennootschap*), we may only make distributions to the extent that our shareholders' equity exceeds the sum of the paid-in and called-up share capital plus the

reserves as required to be maintained by Dutch law. Under our articles of association, a dividend is first paid out of the profit, if available for distribution, with respect to any preferred shares. After that, the board of directors shall determine which part of the remaining profit shall be added to our reserves. After reservation by the board of directors of any profit, the remaining profit will be at the disposal of the general meeting of shareholders for distribution on our common shares. However, a distribution to the holders of common shares can only be resolved upon by the general meeting upon a proposal of the board of directors.

We may only make a distribution of dividends after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The board of directors is permitted, subject to certain requirements, to declare interim dividends (or other interim distributions) without the approval of the general meeting of shareholders. The general meeting of shareholders, subject to certain requirements and a proposal to that effect made by the board of directors, may decide to make distributions from our distributable reserves. The board of directors, however, may resolve to charge amounts to be paid up on shares against our reserves, irrespective of whether those shares are issued to existing shareholders.

Dividends and other distributions shall be payable on such date and, if it concerns a distribution in cash, in such currency as determined by the board of directors. If it concerns a distribution in the form of assets, the board of directors shall determine the value attributed to such distribution for purposes of recording the distribution in our accounts with due observance of applicable law (including the applicable accounting principles). Claims to dividends and other distributions not paid within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*). For the purpose of calculating the amount or allocation of any distribution, shares held by us in our own capital shall not be taken into account. No distribution shall be made to us in respect of shares held by us in our own capital.

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

#### *Squeeze out Procedures*

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

#### ***Protective measures***

Under Dutch law, various protective measures are possible and permissible within the boundaries set by Dutch law and Dutch case law. Our governance arrangements include several provisions that may have the effect of making a takeover of our company more difficult or less attractive. In this respect, our general meeting of shareholders has granted the right to the Protective Foundation to acquire preferred shares pursuant to a call option agreement entered into on May 6, 2016, or the call option agreement. This call option is continuous in nature and can be exercised repeatedly on multiple occasions. If the Protective Foundation exercises the call option pursuant to the call option agreement, 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 will be issued to the Protective Foundation. These preferred shares will be issued to the Protective Foundation under the obligation to pay up to 25% of their nominal value upon issuance. In order for the Protective Foundation to finance the issue price in



relation to the preferred shares, the Protective Foundation intends to enter into a finance arrangement with a bank. As an alternative to securing financing with a bank, subject to applicable restrictions under Dutch law, the call option agreement provides that the Protective Foundation may request us (1) to provide, or cause our subsidiaries to provide, sufficient funding to the Protective Foundation to enable it to satisfy the payment obligation (or part thereof) in cash and/or (2) to charge an amount equal to the payment obligation (or part thereof) against our profits and/or reserves in satisfaction of such payment obligation. The Protective Foundation's articles of association provide that it will promote and protect the best interests of us, our associated business and our stakeholders and opposing influences that conflict with these interests and threaten our strategy, continuity, independence and/or identity. These influences may include a third party acquiring a significant percentage of our common shares, the announcement of an unsolicited public offer for our common shares, other concentration of control over our common shares or any other form of undue pressure on us to alter our strategic policies. The Protective Foundation is structured to operate independently of us.

As indicated above, if the Protective Foundation would exercise its call option, the preferred shares to be issued pursuant thereto shall be issued against the obligation to pay up to 25% of their nominal value. The voting rights of our shares are based on nominal value and, as we expect our common shares to trade substantially in excess of nominal value, preferred shares issued at 25% of their nominal value can carry significant voting power for a substantially reduced price compared to the price of our common shares and thus can 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 pre-determined rate.

The Protective Foundation would be expected to require us to cancel its preferred shares once the perceived threat to the company and its stakeholders has been removed or sufficiently mitigated or neutralized. However, subject to the same limitations described above, the Protective Foundation would continue to have the right to exercise the call option in the future in response to a new threat to the interests of us, our business and our stakeholders from time to time.

In addition, our articles of association contain certain provisions which might have the effect of delaying or preventing a change in control or otherwise discouraging a potential acquirer from attempting to obtain control of us. These provisions include:

- requirements that certain shareholder matters, including the amendment of our articles of association may only be voted on by the general meeting of shareholders at the proposal of our board of directors;
- a provision that our directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital if such removal is not proposed by our board of directors; and
- our directors being appointed on the basis of a binding nomination by our board of directors, which can only be overruled by the general meeting of shareholders by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital (in which case the board of directors shall make a new nomination).

Also, we may implement staggered terms of up to four years for our directors, as a result of which only approximately one-fourth of our directors will be subject to election in any one year.

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

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

## **Corporate Governance**

### *Duties of Directors*

*The Netherlands.* We have a one-tier board structure consisting of one or more executive directors and one or more non-executive directors. Under Dutch law, the board of directors as a collective is responsible for the management and the strategy, policy and operations of the company. See “—Board of Directors—Duties and Liabilities of Directors.”

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

### *Director Terms*

*The Netherlands.* The DCGC provides the following best practice recommendations on the terms for directors’ service:

- Executive directors should be appointed for a maximum period of four years, without limiting the number of consecutive terms executive directors may serve.
- Non-executive directors should be appointed for two consecutive periods of no more than four years. Thereafter, non-executive directors may be reappointed for a maximum of two consecutive periods of no more than two years, provided that any reappointment after an eight-year term of office should be disclosed and explained in the company’s annual board report.

Our executive director currently has an employment agreement with us for an indefinite period of time.

The general meeting of shareholders shall at all times be entitled to suspend or remove a director. Under our articles of association, the general meeting of shareholders may only adopt a resolution to suspend or remove such director by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital, unless the resolution is passed at the proposal of the board of directors, in which case a simple majority of the votes cast is sufficient.

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

### *Director Vacancies*

*The Netherlands.* Under Dutch law, directors are appointed and reappointed by the general meeting of shareholders. Under our articles of association, directors are appointed by the general meeting of shareholders upon the binding nomination by our board of directors. However, the general meeting of shareholders may at all times overrule the binding nomination by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital. If the general meeting of

shareholders overrules the binding nomination, the board of directors shall make a new nomination. If the nomination comprises one candidate for a vacancy, a resolution concerning the nomination shall result in the appointment of the candidate, unless the nomination is overruled.

Under our articles of association, a resolution of the general meeting of shareholders to appoint a director can only be passed in respect of candidates whose names are stated for that purpose in the agenda of that general meeting of shareholders or in the explanatory notes thereto. Upon the appointment of a person as a director, the general meeting of shareholders shall determine whether that person is appointed as executive director or as non-executive director.

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

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

*The Netherlands.* Under Dutch law and our articles of association, our directors shall not take part in any discussion or decision-making that involves a subject or transaction in relation to which he or she has a conflict of interest with us. Our articles of association provide that if as a result thereof no resolution of the board of directors can be adopted, the resolution can nonetheless be adopted by the board of directors as if none of the directors had a conflict of interest. In that case, each director is entitled to participate in the discussion and decision-making process and to cast a vote.

The DCGC provides the following best practice recommendations in relation to conflicts of interests:

- a director should report any potential conflict of interest in a transaction that is of material significance to the company and/or to such director to the other directors without delay, providing all relevant information in relation to the conflict;
- the board of directors should then decide, outside the presence of the director concerned, whether there is a conflict of interest;
- transactions in which there is a conflict of interest with a director should be agreed on arms' length terms; and
- a decision to enter into such a transaction in which there is a conflict of interest with a director that is of material significance to the company and/or to such director shall require the approval of the board of directors, and such transactions should be disclosed in the company's annual board report.

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

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

### ***Proxy Voting by Directors***

*The Netherlands.* An absent director may issue a proxy for a specific board meeting but only to another director in writing (including in electronic form).

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

## **Shareholder Rights**

### *Voting Rights*

*The Netherlands.* In accordance with Dutch law and our articles of association, each issued common share confers the right to cast one vote at the general meeting of shareholders. No vote may be cast at a general meeting of shareholders in respect of a share belonging to us or any of our subsidiaries or in respect of a share for which we or any of our subsidiaries holds the depository receipts. Persons with a right to the use and enjoyment of our shares held by another person and pledgees of shares belonging to us or our subsidiaries are not precluded from exercising their voting rights if the right to use and enjoyment or pledge was created before the relevant share belonged to us or one of our subsidiaries. We and our subsidiaries may not vote shares in respect of which we or any of our subsidiaries hold(s) a right of use and enjoyment or a pledge. Shares which cannot be voted pursuant to these rules will not be taken into account for the purpose of determining the number of votes cast, or the amount of the share capital that is represented, at a general meeting of shareholders.

For each general meeting of shareholders, the board of directors may apply a record date in order to establish which shareholders are entitled to attend and vote at the general meeting of shareholders. The record date and the manner in which shareholders can register and exercise their rights will be set out in the notice of the meeting.

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

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

### *Shareholder Proposals*

*The Netherlands.* Pursuant to our articles of association, extraordinary general meetings of shareholders will be held whenever required under Dutch law or whenever our board of directors deems such to be appropriate or necessary. Pursuant to Dutch law, one or more shareholders or others with meeting rights under Dutch law representing at least one-tenth of the issued share capital may request us to convene a general meeting, setting out in detail the matters to be discussed. If our board of directors has not taken the steps necessary to ensure that such meeting can be held within six weeks after the request, the requesting party/parties may, on their application, be authorized by the competent Dutch court in preliminary relief proceedings to convene a general meeting of shareholders.

Also, under our articles of association, the agenda for a general meeting of shareholders shall include such items requested by one or more shareholders, and others with meeting rights under Dutch law, representing at least 3% of the issued share capital. Requests must be made in writing and received by us at least 60 days before the day of the meeting. In accordance with the DCGC, shareholders are expected to exercise the right of requesting the

convening of a general meeting of shareholders or of putting an item on the agenda only after consulting the board of directors in that respect. If one or more shareholders intend to request that an item be put on the agenda that may result in a change in our strategy (e.g., the removal of directors), the board of directors should be given the opportunity to invoke a reasonable response time of up to 180 days after the board of directors is informed of the intentions of the shareholder(s). The board of directors should use this period for further deliberation, constructive consultation (in any event with the shareholder(s) who have made the request) and the exploration of alternatives. At the end of the response period, the board of directors should report its actions to the general meeting of shareholders. The response time may be invoked only once for any given general meeting of shareholders and may not be invoked for an agenda item in respect of which the response period has been invoked previously or for a general meeting of shareholders if a shareholder holds at least 75% of our issued share capital as a consequence of a successful public offer (irrespective of whether the offer was friendly or hostile).

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

#### *Action by Written Consent*

*The Netherlands.* Our articles of association do not allow shareholders' resolutions to be adopted in writing without holding a meeting of shareholders. However, holders of preferred shares may pass resolutions in writing instead of at a meeting by a unanimous vote of all shareholders concerned. These votes may be cast electronically.

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

#### *Appraisal Rights*

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

However, pursuant to Dutch law a shareholder who, alone or together with one or more group companies, for his/their own account contribute(s) at least 95% of our issued share capital may initiate proceedings against our minority shareholders jointly for the transfer of their shares to the claimant. See "—Shareholder Vote on Certain Reorganizations—The Netherlands."

Furthermore, Dutch law provides that, to the extent that the acquiring company in a cross-border merger is organized under the laws of another Member State of the European Economic Area, a shareholder of a Dutch disappearing company who has voted against the cross-border merger may file a claim with the Dutch company for compensation. Such compensation is to be determined by one or more independent experts. The shares of such shareholder that are subject to such claim will cease to exist as of the moment of entry into effect of the cross-border merger.

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

#### *Shareholder Suits*

*The Netherlands.* In the event a third party is liable to a Dutch company, only the company itself can bring a civil action against that party. The individual shareholders do not have the right to bring an action on behalf of the

company. If individual shareholders bring an action for damages against such a third party in their name, a court will under normal circumstances dismiss such a claim. Only in the event that the cause for the liability of a third party to the company also constitutes a tortious act directly against a shareholder could that shareholder have an individual right of action against such third party in its own name. The Dutch Civil Code provides for the possibility to initiate actions collectively. A foundation or an association whose objective is to protect the rights of a group of persons having similar interests can institute a collective action. The collective action itself cannot result in an order for payment of monetary damages but may only result in a declaratory judgment (*verklaring voor recht*). In order to obtain compensation for damages, the foundation or association and the defendant may reach—often on the basis of such declaratory judgment—a settlement. A Dutch court may declare the settlement agreement binding upon all the injured parties with an opt-out choice for an individual injured party. An individual injured party may also itself institute a civil claim for damages.

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

### ***Repurchase of Shares***

*The Netherlands.* Under Dutch law, a limited liability company may not subscribe for newly issued shares in its own capital. A limited liability company may, however, subject to certain restrictions of Dutch law and its articles of association, acquire shares in its own capital. We may acquire fully paid shares in our own capital at any time for no valuable consideration. Furthermore, subject to certain provisions of Dutch law and our articles of association, we may repurchase fully paid shares in our own capital for valuable consideration to the extent that (i) such repurchase would not cause our shareholders' equity to fall below an amount equal to the sum of the paid-up and called-up part of the issued share capital and the reserves we are required to maintain pursuant to applicable law and (ii) we would not as a result of such repurchase hold more than 50% of our own issued share capital, including shares held by our subsidiaries and shares in respect of which a pledge has been created in our favor.

Other than shares acquired for no valuable consideration, common shares may only be acquired following a resolution of our board of directors, acting pursuant to an authorization for the repurchase of shares granted by the general meeting of shareholders. An authorization by the general meeting of shareholders for the repurchase of shares can be granted for a maximum period of 18 months. Such authorization must specify the number and class of shares that may be acquired, the manner in which these shares may be acquired and the price range within which the shares may be acquired. At our annual general meeting of shareholders held on July 20, 2018, our board of directors was authorized, for a period of 18 months following the date of such meeting, to cause the repurchase of shares (or depository receipts for shares) by us of up to 10% of our issued share capital (determined as at the close of business on the date of that meeting), for a price per share not exceeding 110% of the average closing price of our common shares on Nasdaq for the five trading days prior to the date the acquisition is agreed upon by us.

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

*Delaware.* Under the Delaware General Corporation Law, a corporation may purchase or redeem its own shares unless the capital of the corporation is impaired or the purchase or redemption would cause an impairment of the

capital of the corporation. A Delaware corporation may, however, purchase or redeem out of capital any of its preferred shares or, if no preferred shares are outstanding, any of its own shares if such shares will be retired upon acquisition and the capital of the corporation will be reduced in accordance with specified limitations.

### ***Protective Measures***

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

- the authorization of a class of preferred shares that can be issued to the Protective Foundation upon the exercise by the Protective Foundation of its call option, in such a manner as to dilute the voting interest of any potential acquirer or activist;
- the possibility to appoint our board members for staggered terms, as a result of which only approximately one-fourth of our directors may be subject to election in any one year;
- a provision that our directors may only be removed by the general meeting of shareholders by a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital, if such removal is not proposed by our board of directors;
- our directors being appointed on the basis of a binding nomination by our board of directors, which can only be overruled by the general meeting of shareholders by a resolution adopted by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital (in which case the board of directors shall make a new nomination); and
- requirements that certain shareholder matters, including an amendment of our articles of association, may only be voted on by the general meeting of shareholders at the proposal of our board of directors.

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

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

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

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

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

*The Netherlands.* The board of directors should provide the general meeting of shareholders with all information requested by the general meeting of shareholders, unless this would be contrary to an overriding interest of ours. If the board of directors invokes an overriding interest, it must give its reasons.

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

### ***Removal of Directors***

*The Netherlands.* The general meeting of shareholders shall at all times be entitled to suspend or remove a director. Under our articles of association, the general meeting of shareholders may only adopt a resolution to suspend or remove such a director by at least a two-thirds majority of the votes cast, provided such majority represents more than half of the issued share capital, unless the resolution is passed at the proposal of the board of directors, in which latter case a simple majority of the votes cast is sufficient.

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

### ***Preemptive Rights***

*The Netherlands.* Under Dutch law and our articles of association, in the event of an issuance of common shares, each holder of common shares will have a pro rata preemptive right in proportion to the aggregate nominal value of the common shares held by such holder (with the exception of common shares to be issued to our employees or employees of our group companies, common shares issued against a contribution other than in cash, or common shares issued to a party exercising a previously acquired right to subscribe for such common shares). Under our articles of association, the preemptive rights in respect of newly issued common shares may be restricted or excluded by a resolution of the general meeting of shareholders at the proposal of the board of directors.

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

At our annual general meeting of shareholders held on July 20, 2018, our board of directors was authorized for a period of five years from the date of such meeting to limit or exclude preemptive rights in connection with the issue of common shares or the granting of rights to subscribe for common shares pursuant to the use of the authorization also granted at such annual general meeting of shareholders to the board of directors to issue common shares and grant rights to subscribe for common shares.

Under our articles of association, no preemptive rights apply in respect of preferred shares.



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

### ***Dividends***

*The Netherlands.* Dutch law provides that dividends may be distributed after adoption of the annual accounts by the general meeting of shareholders from which it appears that such dividend distribution is allowed. Moreover, dividends, interim dividends (or other interim distributions) and distributions from distributable reserves may only be made to the extent that shareholders' equity exceeds the amount of the paid-up and called-up part of the issued share capital and the reserves that must be maintained under Dutch law or the company's articles of association.

Under our articles of association, a dividend is first paid out of the profit, if available for distribution, with respect to any preferred shares. After that, the board of directors shall determine which part of the remaining profit shall be added to our reserves. After reservation by the board of directors of any profit, the remaining profit will be at the disposal of the general meeting of shareholders for distribution on our common shares. However, a distribution to the holders of common shares can only be resolved upon by the general meeting at the proposal of the board of directors. We may only make a distribution of dividends after the adoption of our annual accounts demonstrating that such distribution is legally permitted. The board of directors is permitted, subject to certain requirements, to declare interim dividends (or other interim distributions) without the approval of the general meeting of shareholders. The general meeting of shareholders, subject to certain requirements and a proposal to that effect made by the board of directors, may decide to make distributions from our distributable reserves. The board of directors, however, may resolve to charge amounts to be paid up on shares against our reserves, irrespective of whether those shares are issued to existing shareholders.

Dividends and other distributions shall be payable on such date and, if it concerns a distribution in cash, in such currency as determined by the board of directors. If it concerns a distribution in the form of assets, the board of directors shall determine the value attributed to such distribution for purposes of recording the distribution in our accounts with due observance of applicable law (including the applicable accounting principles). Claims to dividends and other distribution not paid within five years from the date that such dividends or distributions became payable, will lapse and any such amounts will be considered to have been forfeited to us (*verjaring*). For the purpose of calculating the amount or allocation of any distribution, shares held by us in our own capital shall not be taken into account. No distribution shall be made to us in respect of shares held by us in our own capital.

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

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

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

- a transfer of the business or virtually the entire business to a third party;

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

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

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

Under the Delaware General Corporation Law, no vote of the stockholders of a surviving corporation to a merger is needed, however, unless required by the certificate of incorporation, if (i) the agreement of merger does not amend in any respect the certificate of incorporation of the surviving corporation, (ii) the shares of stock of the surviving corporation are not changed in the merger and (iii) the number of shares of common stock of the surviving corporation into which any other shares, securities or obligations to be issued in the merger may be converted does not exceed 20% of the surviving corporation's common stock outstanding immediately prior to the effective date of the merger. In addition, stockholders may not be entitled to vote in certain mergers with other corporations that own 90% or more of the outstanding shares of each class of stock of such corporation, but the stockholders will be entitled to appraisal rights.

### ***Remuneration of Directors***

*The Netherlands.* Under Dutch law, we must adopt a remuneration policy for our directors. Such remuneration policy, and changes thereto, shall be adopted by the general meeting of shareholders at the proposal of the board of directors. The board of directors determines the remuneration of the directors in accordance with the remuneration policy. Our executive directors may not participate in the discussions or decision-making regarding the remuneration of executive directors. A proposal by the board of directors with respect to remuneration schemes in the form of shares or rights to shares is submitted by the board of directors to the general meeting for its approval. This proposal must set out at least the maximum number of shares or rights to shares to be granted to the directors and the criteria for granting or amendment.

Our shareholders approved our Supervisory Board Member Compensation Program at a general meeting on May 6, 2016. Our shareholders have approved certain amendments to such program, and the program has been renamed the Non-Executive Director Compensation Program.

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

### ***Dutch Corporate Governance Code***

The DCGC contains both principles and best practice provisions for boards of directors, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. A copy of the DCGC can be found on [www.mccg.nl](http://www.mccg.nl). As a listed Dutch company incorporated under Dutch law, we are subject to the DCGC and are required to disclose in our annual report, filed in the Netherlands, whether we comply with the provisions of the DCGC. If we do not comply with the provisions of the DCGC (for example, because of a conflicting Nasdaq requirement or otherwise), we must list the reasons for any deviation from the DCGC in our annual report.

We acknowledge the importance of good corporate governance. However, at this stage, we do not comply with all the provisions of the DCGC, to a large extent because such provisions conflict with or are inconsistent with the corporate governance rules of Nasdaq and U.S. securities laws that apply to us, or because such provisions do not reflect best practices of global companies listed on Nasdaq.

The discussions below summarize the most important differences between our governance structure and the principles and best practices of the DCGC:

- *Risk management and internal audit function (best practice provisions 1.2.2, 1.3.1 and 1.3.2)*

We have not established an internal audit department. Our board of directors is of the opinion that adequate alternative measures have been taken in the form of the company's risk management and control systems and that it is presently not necessary to establish an internal audit function.

- *Independence of non-executive directors (best practice provision 2.1.7)*

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

- *Remuneration (best practice provisions 3.1.2, 3.2.3, 3.3.2 and 3.3.3)*

The options granted under the 2010 Plan vest in instalments over a four-year period from the grant date. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly instalments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. The options granted are exercisable once vested. Options will lapse on the eighth anniversary of the date of grant. The options granted under the 2016 Plan will be subject to vesting in accordance

with the applicable award agreement and will be exercisable upon vesting. The term of options granted under the 2016 Plan may not be longer than ten years. We do not intend to comply with all of the requirements under best practice provisions 3.1.2, 3.2.3, 3.3.2 and 3.3.3 of the DCGC as we believe it is in the best interest of the company to attract and retain highly skilled management board members on conditions based on market practice, as we believe these are.

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

Consistent with market practice in the United States, our non-executive directors receive rights to acquire common shares in our capital as part of their remuneration and may also receive other equity-based remuneration. We believe that such remuneration structure is appropriate due to our listing on Nasdaq.

Under circumstances, the severance payment to which our President & Chief Executive Officer might become entitled could exceed the maximum recommended by the DCGC. This deviation from the DCGC is justified as it is consistent with market practice in the United States.

- *Majority requirements for dismissal and setting-aside binding nominations (best practice provision 4.3.3)*

Our directors are appointed by our general meeting of shareholders upon the binding nomination by our board of directors. Our general meeting of shareholders may only overrule the binding nomination by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of our issued share capital. In addition, except if proposed by our board of directors, our directors may be suspended or dismissed by our general meeting of shareholders at any time by a resolution passed by a two-thirds majority of votes cast, provided such majority represents more than half of the Company's issued share capital. The possibility to convene a new general meeting of shareholders as referred to in Section 2:120(3) of the Dutch Civil Code in respect of these matters has been excluded in our articles of association. We believe that these provisions support the continuity of the company and its business and that those provisions, therefore, are in the best interests of our shareholders and our other stakeholders.

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

- certain financial institutions;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding common shares as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to the common shares;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- tax exempt entities, including "individual retirement accounts" and "Roth IRAs";
- 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 the 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 common shares in connection with a trade or business conducted outside the United States.

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

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

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

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

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

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

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

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

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

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

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

Based on the current and anticipated value of our assets, including goodwill, and the composition of our income, assets and operations, we do not believe we were a PFIC for our taxable year ended December 31, 2017; however, we may be a PFIC for the current taxable year. 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

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- 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. Depending on our retention of cash and cash equivalents, and on the market price of our common shares, we may be a PFIC for the current taxable year.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the common shares, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the common shares, regardless of whether we continue to meet the tests described above unless (1) we cease to be a PFIC and (2) the U.S. Holder has made a “deemed sale” election under the PFIC rules.

If we are a PFIC for any taxable year, holders of our common shares 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 common shares. Distributions holder 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 holders of our common shares hold the common shares as capital assets.

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

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, holders of our common shares 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 the common shares and the potential availability of a mark-to-market or QEF election.

***Information Reporting and Backup Withholding***

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

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

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

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



## 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.

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	114,041
Accounting fees and expenses	76,552
Printing and miscellaneous expenses	105,000
Total	<u>\$ 304,786</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, 2017 and 2016, and for each of the years in the three-year period ended December 31, 2017, included in the Report on Form 6-K filed by the Company on December 27, 2018 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 documents set forth below that have previously been filed with the SEC:

- Our Annual Report on Form 20-F for the year ended December 31, 2017, filed with the SEC on April 30, 2018.
- Our Report on Form 6-K furnished with the SEC on December 27, 2018.

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.

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**Unaudited Condensed Consolidated Financial Statements for the Three- and Six-month Periods Ended June 30, 2018**

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**Merus N.V.**  
**Unaudited Condensed Consolidated Statement of Financial Position**  
*(after appropriation of result for the period)*

	Notes	June 30, 2018	December 31, 2017 Restated*
(euros in thousands)			
<b>Non-current assets</b>			
Property, plant and equipment		1,876	1,168
Intangible assets		381	312
Non-current investments	5	16,650	7,060
Other assets		167	129
		<u>19,074</u>	<u>8,669</u>
<b>Current assets</b>			
Trade and other receivables	6	5,477	4,413
Current investments	5	37,077	34,043
Cash and cash equivalents	2	170,327	149,678
		<u>212,881</u>	<u>188,134</u>
<b>Total assets</b>		<u>231,955</u>	<u>196,803</u>
<b>Shareholders' equity</b>	9		
Issued and paid-in capital		2,037	1,749
Share premium account		258,061	213,618
Accumulated loss		(167,226)	(158,775)
Total equity		<u>92,872</u>	<u>56,592</u>
<b>Non-current liabilities</b>			
Deferred revenue	8	105,718	112,551
<b>Current liabilities</b>			
Trade payables		5,433	2,855
Taxes and social security liabilities		100	243
Deferred revenue	8	16,972	15,935
Other liabilities and accruals	7	10,860	8,627
		<u>33,365</u>	<u>27,660</u>
<b>Total liabilities</b>		<u>139,083</u>	<u>140,211</u>
<b>Total equity and liabilities</b>		<u>231,955</u>	<u>196,803</u>

\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

*The footnotes are an integral part of these condensed consolidated interim financial statements.*



# **Unaudited Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss**

	Note	Three-month period ended June 30,		Six-month period ended June 30,	
		2018	2017 Restated**	2018	2017 Restated**
		(euros in thousands, except per share data)			
<b>Revenue</b>	10	6,543	6,237	16,464	10,121
Research and development costs	11	(12,523)	(8,420)	(22,821)	(15,427)
Management and administration costs	11	(2,639)	(3,492)	(5,491)	(7,694)
Other expenses	11	(3,297)	(2,277)	(5,983)	(4,120)
<b>Total operating expenses</b>		<b>(18,459)</b>	<b>(14,189)</b>	<b>(34,295)</b>	<b>(27,241)</b>
<b>Operating result</b>		<b>(11,916)</b>	<b>(7,952)</b>	<b>(17,831)</b>	<b>(17,120)</b>
Finance income		7,411	420	4,945	610
Finance cost		(1)	(11,962)	(1)	(22,696)
<b>Net finance income / (expense)</b>	13	<b>7,410</b>	<b>(11,542)</b>	<b>4,944</b>	<b>(22,086)</b>
<b>Result before taxation</b>		<b>(4,506)</b>	<b>(19,494)</b>	<b>(12,887)</b>	<b>(39,206)</b>
Income tax expense		(87)	(107)	(139)	(118)
<b>Result after taxation</b>		<b>(4,593)</b>	<b>(19,601)</b>	<b>(13,026)</b>	<b>(39,324)</b>
<b>Other comprehensive income</b>					
Exchange differences from the translation of foreign operations		36	13	21	18
<b>Total other comprehensive income for the period</b>		<b>36</b>	<b>13</b>	<b>21</b>	<b>18</b>
<b>Total comprehensive loss for the period</b>		<b>(4,557)</b>	<b>(19,588)</b>	<b>(13,005)</b>	<b>(39,306)</b>
<b>Basic (and diluted) loss per share*</b>		<b>(0.20)</b>	<b>(1.01)</b>	<b>(0.60)</b>	<b>(2.07)</b>
<b>Weighted average shares outstanding</b>					
<b>Basic (and diluted)*</b>		<b>22,628,611</b>	<b>19,392,495</b>	<b>21,809,950</b>	<b>18,976,446</b>

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

\*\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

*The footnotes are an integral part of these condensed consolidated interim financial statements.*

### Unaudited Condensed Consolidated Statement of Changes in Equity

	Note	Common share capital	Common share premium	Accumulated loss	Total equity
Balance at January 1, 2017, as previously reported		1,448	139,878	(107,295)	34,031
Impact of adoption of accounting standard	3	—	—	390	390
<b>Restated balance at January 1, 2017*</b>		<b>1,448</b>	<b>139,878</b>	<b>(106,905)</b>	<b>34,421</b>
Restated result after taxation for the period		—	—	(39,324)	(39,324)
Other comprehensive income		—	—	18	18
<b>Restated total comprehensive loss for the period</b>		<b>—</b>	<b>—</b>	<b>(39,306)</b>	<b>(39,306)</b>
Transactions with owners of the Company:					
Issuance of shares (net)	9	298	73,663	—	73,961
Equity settled shared-based payments	9	—	—	7,880	7,880
<b>Total contributions by owners</b>		<b>298</b>	<b>73,663</b>	<b>7,880</b>	<b>81,841</b>
<b>Restated balance at June 30, 2017*</b>		<b>1,746</b>	<b>213,541</b>	<b>(138,331)</b>	<b>76,956</b>
Balance at December 31, 2017, as previously reported		1,749	213,618	(167,480)	47,887
Impact of adoption of accounting standard	3	—	—	8,705	8,705
<b>Restated balance at January 1, 2018*</b>		<b>1,749</b>	<b>213,618</b>	<b>(158,775)</b>	<b>56,592</b>
Result after taxation for the period		—	—	(13,026)	(13,026)
Other comprehensive loss		—	—	21	21
<b>Total comprehensive loss for the period</b>		<b>—</b>	<b>—</b>	<b>(13,005)</b>	<b>(13,005)</b>
Transactions with owners of the Company:					
Issuance of shares (net)	9	288	44,443	—	44,731
Equity settled shared-based payments	9	—	—	4,554	4,554
<b>Total contributions by owners</b>		<b>288</b>	<b>44,443</b>	<b>4,554</b>	<b>49,285</b>
<b>Balance at June 30, 2018</b>		<b>2,037</b>	<b>258,061</b>	<b>(167,226)</b>	<b>92,872</b>

\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

*The footnotes are an integral part of these condensed consolidated interim financial statements.*

# Unaudited Condensed Consolidated Statement of Cash Flows

	Note	Six-month period ended June 30, 2018                      2017 Restated*	
(euros in thousands)			
<b>Cash flows from operating activities</b>			
Result after taxation		(13,026)	(39,324)
Adjustments for:			
Changes in fair value derivative	13	—	10,667
Unrealized foreign exchange results	13	(3,648)	12,357
Depreciation and amortization		218	147
Share-based payment expenses	12	4,554	7,880
Net finance (income) expenses		(531)	(593)
		(12,433)	(8,866)
Changes in working capital:			
Taxes and social security assets		—	(2,024)
Trade and other receivables	6	(959)	(1,946)
Other assets		(38)	—
Trade payables		2,307	1,673
Other liabilities and accruals	7	2,233	1,784
Deferred revenue	8	(5,796)	(6,899)
Taxes and social security liabilities		(143)	719
<b>Cash used in operations</b>		(14,829)	(15,559)
Interest paid	13	(1)	(5)
Taxes paid		(302)	(12)
<b>Net cash used in operating activities</b>		(15,132)	(15,576)
<b>Cash flow from investing activities</b>			
Purchases of investments	5	(29,560)	—
Proceeds from investment maturities	5	18,931	—
Purchase of intellectual property		(100)	—
Acquisition of property, plant and equipment		(624)	(525)
Interest received	6,13	602	496
<b>Net cash used in investing activities</b>		(10,751)	(29)
<b>Cash flow from financing activities</b>			
Proceeds from issuing shares, net of issuance costs	9	44,731	74,431
Proceeds from stock option exercises	9	—	227
Proceeds from collaboration and license agreement	9	—	111,993
Repayment of borrowings		—	(486)
Increase in restricted cash		—	167
<b>Net cash from financing activities</b>		44,731	186,332
<b>Net increase in cash and cash equivalents</b>		18,848	170,727
Effects of exchange rate changes on cash and cash equivalents		1,801	(11,856)
Cash and cash equivalents as at beginning of period		149,678	56,917
<b>Cash and cash equivalents as at end of period</b>		170,327	215,788
<b>Changes in accrued capital expenditures</b>		271	—

\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

*The footnotes are an integral part of these condensed consolidated interim financial statements.*

## Notes to the Unaudited Condensed Consolidated Financial Statements

### 1. General information

Merus N.V. is a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, headquartered in Utrecht, the Netherlands. Merus US, Inc. is a wholly-owned subsidiary of Merus N.V. located in Boston, Massachusetts, United States. These condensed consolidated interim financial statements as at and for the three- and six-month periods ended June 30, 2018, comprise Merus N.V. and Merus US, Inc. (collectively, the “Company”).

On February 13, 2018, the Company entered into a Securities Purchase Agreement (the “Purchase Agreement”) with the purchasers named therein (the “Investors”). Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 3,099,997 of its common shares, nominal value €0.09 per share (the “Common Shares”), to the Investors for aggregate gross proceeds of approximately \$55.8 million, at a purchase price equal to \$18.00 per share (the “Private Placement”). The Purchase Agreement contained customary representations and warranties from the Company and the Investors and customary closing conditions. On February 15, 2018, the Company completed the sale under the Private Placement and received aggregate gross proceeds of approximately \$55.8 million.

### Nature of Business

The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its bispecific antibody candidates advance through discovery, preclinical development and clinical trials, and as it seeks regulatory approval and pursues commercialization of any approved bispecific antibody candidate.

As a result, the Company may need additional financing to support its continuing operations. Until the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through public equity, debt financings, or other sources, which may include collaborations with third parties. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company’s inability to raise capital as and when needed would have a negative impact on its financial condition and ability to pursue its business strategy. The Company will need to generate significant revenues to achieve profitability and may never do so.

Based on the Company’s current operating plan, it expects its existing cash balances and investments to last through the end of 2020. For this assessment, the Company has taken into consideration its existing cash and cash equivalents of €170.3 million, which include the \$55.8 million, or €44.8 million, in proceeds received from the Private Placement offering that closed in February 2018, and investments of €53.7 million as of June 30, 2018.

### 2. Significant accounting policies

There have been no significant changes to the Company’s accounting policies that were previously disclosed in its Annual Report on Form 20-F for its fiscal year ended December 31, 2017, or in the methodology used in formulating these significant judgments and estimates that affect the application of these policies, except for the adoption of new accounting standards as disclosed more fully in Note 3.

### Basis of Presentation

These unaudited interim condensed consolidated financial statements (the “interim financial statements”) have been prepared in accordance with International Accounting Standard 34 “Interim Financial Reporting” as issued by the International Accounting Standards Board (“IASB”). Certain information and disclosures normally included in financial statements prepared in accordance with International Financial Reporting Standards

(“IFRS”) have been condensed or omitted. Accordingly, these interim financial statements should be read in conjunction with the Company’s annual financial statements for the year ended December 31, 2017. In the opinion of management, all adjustments (consisting of a normal recurring nature) considered necessary for a fair presentation have been included in the interim financial statements. All intercompany transactions and balances are eliminated in consolidation.

#### *Use of Estimates*

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment in the process of applying the Company’s accounting policies. The areas involving a higher degree of judgment or complexity or areas where assumptions and estimates are significant to these interim financial statements are disclosed in Note 4. The results of operations for the three- and six-month periods ended June 30, 2018, are not necessarily indicative of operations to be expected for the full fiscal year ending December 31, 2018.

#### *Foreign Currency Transactions*

Items recorded in each of the Company’s entities are measured using the currency of the primary economic environment in which the entity operates (the “functional currency”). The interim financial statements are presented in euros, which is Merus N.V.’s functional currency. The functional currency of Merus US, Inc. is the U.S. dollar. All amounts are rounded to the nearest thousand euros, except where otherwise indicated. Foreign currency gains and losses are reported on a net basis as either finance income or finance expense depending on whether foreign currency movements are in a net gain or net loss position.

#### *Seasonality*

The Company’s financial results have varied substantially, and are expected to continue to vary, from period to period. The Company believes that its ordinary activities are not linked to any particular seasonal factors.

#### *Segment Reporting*

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

#### *Cash and Cash Equivalents*

For the purpose of presentation in the statement of cash flows as well as the statement of financial position, cash and cash equivalents include deposits held with financial institutions with original maturities of less than three months. Cash and cash equivalents include €34.3 million of short-term investments with a three-month or less maturity, callable on demand. The carrying values of short-term investments approximate fair value due to their short-term maturities.

#### *Revenue Recognition*

The Company enters into collaboration agreements which are within the scope of IFRS 15—Revenue from Contracts with Customers (“IFRS 15”), under which the Company licenses rights to certain of the Company’s product candidates and performs research and development services. The terms of these arrangements typically include payment of one or more of the following: non-refundable, upfront fees; reimbursement of research and development costs; development, regulatory, and commercial milestone payments; and royalties on net sales of licensed products.

IFRS 15 requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. Under IFRS 15, the Company recognizes revenue when its customer

obtains control of the goods or services, in an amount that reflects the consideration that the Company determines it expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that the Company determines are within the scope of IFRS 15, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies the performance obligation. The Company applies the five-step model to contracts only when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services it transfers to the customer. As part of the accounting for these arrangements, the Company must make significant judgments, including identifying performance obligations in the contract, estimating the amount of variable consideration to include in the transaction price and allocating the transaction price to each performance obligation.

The Company currently generates a portion of its revenue through collaboration and license agreements with strategic collaborators for the development and commercialization of product candidates. The collaboration and license agreements are within the scope of IFRS 15.

#### *Up-front License Payments*

If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the agreement, the Company recognizes revenues from non-refundable, up-front fees allocated to the license when the license is transferred to the customer and the customer is able to use and benefit from the license. If not distinct, the license is combined with other performance obligations in the contract. For licenses that are combined with other performance obligations, the Company assesses the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purpose of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Pursuant to the Company's research and license agreements with its collaborators, the Company has received upfront license payments relating to the integrated packages of deliverables under the contracts. Each contract contains either one single performance obligation or multiple performance obligations that the up-front consideration was allocated to. These upfront license payments are initially recorded in deferred revenue on the consolidated statements of financial position and are recognized as revenue on either: (i) a straight-line basis over the period of the related performance obligation or the contractual term of the arrangement; or (ii) based on another appropriate depiction of the Company's performance over the period of the related performance obligation or the contractual term, such as costs incurred relating to full-time equivalent research employees. The applicable period over which to recognize the upfront payment is a significant judgment, which is re-assessed at each reporting date.

#### *Collaboration Income*

Collaboration income, which is typically related to reimbursements from collaborators for the Company's performance of research and development services under the respective agreements, is recognized on the basis of labor hours valued at a contractually agreed rate. Collaboration income includes reimbursements for related out-of-pocket expenses. Cost reimbursements to which the Company is entitled under agreements are recognized as revenue in the same period as the cost for which they are intended to compensate. The Company acts as the principal and therefore records these reimbursements as collaboration income.

In determining the appropriate amount of revenue to be recognized as the Company fulfills its obligations under the agreements, the Company performs the five steps listed above. As part of the accounting for the arrangement, the Company must develop assumptions that require judgment to determine the stand-alone selling price for each performance obligation identified in the contract. The Company uses key assumptions to determine the stand-

alone selling price, which may include market conditions, reimbursement rates for personnel costs, development timelines and probabilities of regulatory success.

The Company capitalizes the incremental costs of obtaining a contract with a customer if it expects to recover those costs. Such incremental costs would not have been incurred if the contract with a customer had not been obtained. To date, the Company has not capitalized any incremental costs for obtaining a contract.

The Company's contracts often include development and regulatory milestone payments which are assessed under the most likely amount method and constrained if it is probable that a significant revenue reversal would occur. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. At each reporting date, the Company re-evaluates the probability of achievement of development milestones and any related constraint, and if necessary, adjusts the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect collaboration revenues in the period of adjustment.

For agreements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any consideration related to sales-based royalty revenue resulting from any of the Company's collaboration agreements.

#### *Government Grants*

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

#### *Reclassifications*

Certain amounts were reclassified in the prior period condensed consolidated interim financial statements to conform to the current period presentation.

### **3. Recently Issued International Financial Reporting Standards**

Except as otherwise indicated, the accounting policies adopted in the preparation of these interim financial statements are consistent with those applied in the preparation of the Company's annual financial statements for the year ended December 31, 2017.

#### **Standards implemented since December 31, 2017**

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

In May 2014, the IASB issued IFRS 15, which supersedes existing revenue recognition guidance. Prior to the adoption of IFRS 15, revenue was recognized to the extent that it was probable that the economic benefits would flow to the Company and the revenue could be reliably measured. The new standard requires an entity to recognize the amount of revenue to which it expects to be entitled for the transfer of promised goods or services to customers. To achieve that core principle, an entity must identify the contract(s) with a customer, identify the

performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when (or as) the entity satisfies the performance obligation. IFRS 15 is effective for annual and interim reporting periods beginning on or after January 1, 2018 and should be applied retrospectively to each prior reporting period presented or retrospectively with the cumulative effect of initially applying this update recognized at the date of initial application.

The adoption of IFRS 15 impacts the amortization of the Company's up-front license payments. The Company previously recognized revenue from up-front license payments on a straight-line basis over the contractual term or the period of continuing involvement which was previously estimated to be 21 years for the collaboration and license agreement the Company entered into with Incyte Corporation ("Incyte") on December 20, 2016 (the "Incyte collaboration and license agreement"), and 4.5 years for the research and license agreement the Company entered into with ONO Pharmaceutical Co., Ltd. ("ONO") on April 8, 2014 (the "ONO research and license agreement"). In applying IFRS 15, the Company has evaluated the distinct performance obligations in each agreement. Specifically, for Incyte, the total period for which the Company expects to provide access to its proprietary technology is currently estimated to be nine years, which is the research term initially agreed to in the Incyte collaboration and license agreement.

The Company adopted the new standard effective January 1, 2018, using the retrospective method, with the effect of initially applying this standard recognized at the beginning of the earliest period presented. The Company had two open contracts on the adoption date and has assessed these contracts under the new revenue standard. In addition, the Company elected to apply the practical expedient to not apply this guidance to contracts that were completed before the beginning of the earliest period presented, or January 1, 2016, and the practical expedients for contract modifications (assessing the contracts in combination with any modifications before January 1, 2017). Under the practical expedient, the Company excluded certain option and exclusivity agreements that expired in 2015 and 2014, respectively. As a result of the adoption of IFRS 15, prior year financial statements have been restated. The Company has accounted for the impact of adopting IFRS 15 as a cumulative catch-up as a decrease of approximately €8.7 million to deferred revenue with an offset to accumulated deficit, effective January 1, 2018.

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

#### Condensed Consolidated Statement of Profit or Loss and Comprehensive Loss

	Three months ended June 30, 2017 (As originally presented)	IFRS 15 Adoption	Three months ended June 30, 2017 Restated
	(euros in thousands)		
Revenue	4,027	2,210	6,237
Operating result	(10,162)	2,210	(7,952)
Total comprehensive loss for the period	(21,798)	2,210	(19,588)
Basic (and diluted) loss per share	(1.12)	0.11	(1.01)

	Six months ended June 30, 2017 (As originally presented)	IFRS 15 Adoption	Six months ended June 30, 2017 Restated
	(euros in thousands)		
Revenue	6,313	3,808	10,121
Operating result	(20,928)	3,808	(17,120)
Total comprehensive loss for the period	(43,114)	3,808	(39,306)
Basic (and diluted) loss per share	(2.27)	0.20	(2.07)



## Condensed Consolidated Statement of Financial Position

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

## Condensed Consolidated Statement of Cash Flows

	June 30, 2017 As originally presented	IFRS 15 Adoption	June 30, 2017 Restated
	(euros in thousands)		
Result after taxation	(43,132)	3,808	(39,324)
Changes in working capital:			
Deferred revenue	(3,091)	(3,808)	(6,899)

## Financial Instruments—IFRS 9

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

## Standard issued but not yet effective

The IASB has issued a new standard on leases that will require lessees to recognize most leases on their balance sheets as lease liabilities with a corresponding right-of-use asset. The IASB has set an effective date to apply the new standard for periods beginning on or after January 1, 2019. The Company is assessing all effective agreements to determine whether there are embedded leases included under the definition in IFRS 16. Early adoption is permitted; however, the Company expects to adopt this standard in the first quarter of 2019. The Company is evaluating the impact that this guidance will have on the Company’s financial statements, including related disclosures, and expects the new standard to impact its internal controls, systems, and processes.

## 4. Use of Estimates, Judgments and Assumptions

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

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

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

### **Equity settled share-based payments**

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

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

The estimated fair value of each share option granted was determined utilizing the Hull & White option pricing model, which considers the terms and conditions attached to the grants made and is reflective of expected exercise behavior. Because the Company's shares have been publicly traded for a relatively short amount of time, the expected volatility was set by also giving weight to the historic share price volatility of a set of peer companies. The continuous yield on U.S. Treasury Bills with a term to maturity comparable to the expected life of the options, as published by the U.S. Department of Treasury, was applied.

The result of the share option valuations and the related compensation expense that is recognized for the respective vesting periods during which services are received are dependent on the model and input parameters used. Even though management considers the fair values reasonable and defensible based on the methodologies applied and the information available, others might derive a different fair value for the Company's share options. These assumptions and estimates are further discussed in Note 9 to the financial statements.

### **Capitalization of development costs**

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

### **Income taxes**

As of June 30, 2018, deferred tax assets have not been recognized in respect of tax losses as the Company has no history of generating taxable profits. Therefore, at the balance sheet date, there is no convincing evidence that sufficient taxable profit will be available against which the tax losses can be utilized.

Merus US, Inc., which is incorporated in the United States in the State of Delaware, is subject to statutory U.S. Federal corporate income taxes and state income taxes for Massachusetts. Current year income tax expense was attributable entirely to Merus US, Inc. which provides general management services and strategic advisory services to the Company. Corporate income tax expenses were €0.1 million for the three- and six-month periods ended June 30, 2018, as compared to €0.1 million for the three- and six-month periods ended June 30, 2017.

### **Deferred revenue**

Pursuant to the Company's research, collaboration and license agreements with ONO, Incyte, and Jiangsu Simcere Pharmaceutical Co. Ltd. ("Simcere"), the Company has received upfront non-refundable payments for certain rights granted under the respective agreements. The applicable period over which to recognize these upfront payments requires significant judgment and was impacted by the adoption of IFRS 15 (See Note 3 and Note 8).

Revenue related to ONO upfront payments is deferred and amortized based on a measure of progress in delivering research services under the contract. Revenue related to Incyte and Simcere upfront payments is deferred and amortized on a straight-line basis over the estimated research term (See Note 3 and Note 8).

### **Research and development expenses**

Research and development expenses represent costs that primarily include: (i) payroll and related costs (including share-based payment expenses) associated with research and development personnel; (ii) costs related to clinical trials and preclinical testing of the Company's technologies under development; (iii) costs to develop product candidates, including raw materials and supplies, product testing, depreciation, and facility related expenses; (iv) expenses for research services provided by universities and contract laboratories; and (v) other research and development expenses. Research and development expenses are recognized in the consolidated statement of profit or loss and comprehensive loss as incurred when these expenditures relate to the Company's research and development services and have no alternative future uses.

The Company has entered into various research and development contracts with research institutions and other companies. These agreements are generally cancelable. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies, including the phase or completion of events, invoices received and contracted costs. Significant judgments and estimates may be made in determining the accrued balances at the end of any reporting period. Actual results could differ from the Company's estimates. The Company's historical accrual estimates have not been materially different from the actual costs.

### **5. Investments**

On January 1, 2018, the Company adopted IFRS 9 and classifies and accounts for its investments at amortized cost. The Company's investments as of December 31, 2017, were classified and accounted for as held-to-maturity under IAS 39. The initial adoption of IFRS 9 had no impact on previously reported amounts (See Note 3). IFRS 9 replaces the 'incurred loss' model in IAS 39 with an 'expected credit loss' ("ECL") model. The new impairment model applies to financial assets measured at amortized cost, contract assets and debt investments at fair value through other comprehensive loss, but not to investments in equity instruments. Under IFRS 9, credit losses are recognized earlier than under IAS 39. Under IFRS 9, loss allowances are measured on either 12-month ECLs which result from possible default events within the 12 months after the reporting date or lifetime ECLs which result from all possible default events over the expected life of a financial instrument.

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

The Company's investments include investments in commercial paper, securities issued by several public corporations and the United States Treasury. Current investments include investments with a maturity date of greater than three months at the date of settlement. Investments with a maturity of 12 months or more from the original investment date are classified as non-current.

Investments as of June 30, 2018, and December 31, 2017, consist of the following:

	Balance as per	
	June 30, 2018	December 31, 2017
	(euros in thousands)	
Commercial paper	17,715	15,527
U.S. Treasury securities	2,574	9,177
Corporate fixed income bonds	15,289	7,886
Agency bond	1,499	1,453
Investments, current portion	37,077	34,043
Corporate fixed income bonds	16,650	7,060
Non-current investments	16,650	7,060
Total investments	53,727	41,103

During the six-month period ended June 30, 2018, the Company purchased investments totaling €29.6 million, which are held and denominated in U.S. dollars, and received proceeds of €18.9 million relating to investment maturities. As a result of the fluctuation in foreign currency between the euro and U.S. dollar, the Company recorded foreign currency exchange gains of approximately €3.1 million and €1.9 million as a component of finance income / (expense) for the three- and six-month periods ended June 30, 2018, respectively.

## 6. Trade and Other Receivables

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

	Balance as per	
	June 30, 2018	December 31, 2017
	(euros in thousands)	
Trade receivables	2,069	1,594
Unbilled receivables	446	710
VAT receivable	622	582
Prepaid expenses	1,640	427
Prepaid pension costs	359	838
Interest bank	275	170
Other receivables	66	92
	5,477	4,413

Trade and unbilled receivables relate primarily to invoicing for cost reimbursements relating to the Incyte collaboration and license agreement and the ONO research and license agreement. VAT receivable relates to value added tax receivable from the Dutch tax authorities based on the tax application for the second quarter of 2018.

Prepaid expenses reflected above in the form of prepaid expenses and prepaid pension costs consist of expenses that were paid during the reporting period but are related to activities taking place in subsequent periods. The increase in prepaid expenses at June 30, 2018 relate primarily to advanced payments made to contract research and contract manufacturing organizations in support of the Company's upcoming clinical trial activities.

## 7. Other Liabilities and Accruals

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

	Balance per	
	June 30, 2018	December 31, 2017
	(euros in thousands)	
Accrued auditor's fee	90	96
Personnel	315	446
R&D costs	8,777	5,272
IP – Legal fee	128	509
Bonuses	940	1,545
Subsidy advance received	145	224
Other accruals	465	535
	<u>10,860</u>	<u>8,627</u>

The research and development costs relate to accrued expenses for costs of certain development activities, such as clinical trials, and are recorded based on an evaluation of the progress to completion of specific tasks using data such as patient enrollment, clinical site activations, and information provided the Company by vendors on their actual costs incurred. The increase in research and development costs accrued expenses reflect the timing of enrollment in and support of the Company's clinical trials, manufacturing of drug candidates used for clinical purposes, pre-clinical research efforts to support the Company's internal research programs and the Incyte collaboration and license agreements and other collaboration agreements.

The bonuses relate to the employee bonuses for the financial year 2018, which will be paid out in February 2019. The decrease in bonuses accrual compared to December 31, 2017, related to the annual payment of the 2017 bonuses in the first quarter of 2018.

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

## 8. Deferred Revenue

Deferred revenue as of June 30, 2018, and December 31, 2017, consist of the following:

	Balance per	
	June 30, 2018	December 31, 2017 Restated*
	(euros in thousands)	
Deferred revenue – current portion	16,972	15,935
Deferred revenue	105,718	112,551
	<u>122,690</u>	<u>128,486</u>

\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

Of the total deferred revenue balance at June 30, 2018, €120.6 million related to the Incyte collaboration and license agreement and a share subscription agreement entered into by the Company with Incyte on December 20, 2016 (together, the "Incyte Agreements"), €2.0 million related to the collaboration and license agreement entered into by the Company with Simcere on January 8, 2018 (the "Simcere collaboration and license agreement"), and €0.1 million related to the ONO research and license agreement. The total deferred revenue balance at December 31, 2017, related solely to the Incyte Agreements.

Under the Incyte collaboration and license agreement, Incyte agreed to pay the Company a \$120 million non-refundable upfront payment, and under the share subscription agreement, Incyte agreed to purchase 3.2 million Common Shares at a price per share of \$25.00, for an aggregate purchase price of \$80 million. In January 2017, the Company completed the sale of its Common Shares under the share subscription agreement and received the \$80 million aggregate purchase price. In February 2017, the Company received the \$120 million non-refundable upfront payment.

As the contract for the share subscription agreement was denominated in U.S. dollars, the Company determined that the forward contract to sell its own shares at a future date to which the Company became committed on December 20, 2016, represented a derivative financial instrument. The fair values of the derivative, or €31.4 million, and the non-refundable upfront payment, or €112.0 million, were recorded as deferred revenue. The Company identified a single performance obligation, providing access to its proprietary technology, relating to the Incyte Agreements and allocated all of the consideration received to this obligation. Both the upfront license payment and the derivative financial asset are being amortized as revenue over time by measuring the progress toward the complete satisfaction of a performance obligation or specifically, the total period for which the Company expects to provide access to its proprietary technology under the Incyte Agreements, which is currently estimated to be nine years in total, of which approximately 7.5 years remain.

Under the Simcere collaboration and license agreement, the Company agreed to grant Simcere an exclusive license to develop and commercialize in China three bispecific antibodies utilizing the Company's Biclomics® technology platform in the area of immuno-oncology. The Company will retain all rights outside of China. As part of the agreement, the Company has agreed to lead research and discovery activities while Simcere has agreed to be responsible for the Investigational New Drug enabling studies, clinical development, regulatory filings and commercialization of these product candidates in China. The Company received an upfront, non-refundable payment of \$2.75 million, or €2.3 million, relating to three separate research programs. Each research program was determined to be a separate performance obligation and consideration was allocated to each separate obligation.

The Company will amortize the upfront payment to revenue over time based on the estimated duration of each research program. As of June 30, 2018, the first research program had commenced. For the three- and six-month periods ended June 30, 2018, the Company recognized revenue of €0.3 million relating to this program for both amortization of upfront payments and the achievements of milestones. The remaining two research programs had not commenced as of June 30, 2018. Accordingly, no revenue has been recognized related to the remaining two research programs.

On March 14, 2018, the Company entered into a second contract research and license agreement with ONO (the "second ONO research and license agreement"). Pursuant to an exclusive option granted to ONO in the ONO research and license agreement, ONO exercised its option to enter into the second ONO research and license agreement. The Company granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market bispecific antibody candidates based on the Company's Biclomics® technology platform against two undisclosed targets directed to a particular undisclosed target combination.

Under the terms of the agreement, ONO identifies and selects the licensed bispecific antibodies for which it is responsible for conducting further non-clinical and clinical development activities for such licensed bispecific antibodies and pharmaceutical products containing such antibodies, including manufacture and process development. Additionally, ONO controls and has exclusive rights over the worldwide commercialization of any approved products, including worldwide supply, and is solely responsible for all costs and expenses related to commercialization. ONO has also agreed to fund the Company's research and development activities and be responsible for the payment of all costs and expenses for its own research and development activities, which are set out in a mutually agreed upon research plan. The Company retains all rights to use and commercialize any antibodies that are generated under the collaborative research program, excluding the up to five lead and/or

selected antibodies against the targets ONO is pursuing, provided that the use and commercialization is not with respect to the particular target combination.

ONO agreed to pay the Company an upfront non-refundable payment of €0.7 million, €0.3 million intended to compensate the Company for research services already completed upon entering into the agreement, and €0.2 million to be paid to the Company over time for full time equivalent funding. The Company identified a single performance obligation of providing research services to ONO and recognized as revenue approximately €0.1 million and €1.1 million during the three and six months ended June 30, 2018, respectively.

## **9. Shareholders' Equity**

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

On February 13, 2018, the Company entered into the Purchase Agreement. Pursuant to the Purchase Agreement, the Company agreed to sell an aggregate of 3,099,997 of its Common Shares to the Investors for aggregate gross proceeds of approximately \$55.8 million, at a purchase price equal to \$18.00 per share. The Purchase Agreement contains customary representations and warranties from the Company and the Investors and customary closing conditions. On February 15, 2018, the Company completed the sale under the Private Placement and received gross proceeds of approximately \$55.8 million, or €44.8 million.

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

Concurrent with the Incyte collaboration and license agreement discussed above under Note 8, the Company entered into a share subscription agreement with Incyte on December 20, 2016. On January 23, 2017, under the terms of the share subscription agreement, the Company issued 3,200,000 of its Common Shares to Incyte at the agreed price per share of \$25.00, for an aggregate purchase price of \$80.0 million or €74.7 million. During the six months ended June 30, 2017, the Company received proceeds, net of issuance costs, of €74.4 million. A €1.1 million discount on the subscription share price, combined with a €0.4 million foreign currency translation accompanying the issuance of these shares, increased share capital by €0.3 million and share premium by €73.4 million.

### **Issued and paid-in share capital**

All issued shares have been fully paid in cash.

### ***Common shares***

For the six-month period ended June 30, 2018, 34,041 options were exercised at a weighted average exercise price of €1.93 per share. As a result, 34,041 Common Shares were issued, share capital increased by €3,064 and share premium increased by €62,635.

For the six-month period ended June 30, 2017, 110,869 options were exercised with a weighted average exercise price of €2.05 per share. As a result, 110,869 Common Shares were issued, share capital increased by €9,978 and share premium increased by €216,830.

At June 30, 2018, a total of 22,632,800 Common Shares were issued and paid up. At June 30, 2017, a total of 19,396,720 Common Shares were issued and paid up.

### ***Share Premium Reserve***

The share premium reserve relates to amounts contributed by shareholders at the issue of shares in excess of the nominal value of the shares issued.

All share premium can be considered as free share premium as referred to in the Netherlands Income Tax Act.

### ***Share-based Payment Arrangements***

Share-based payment expenses included in personnel expenses were €4.6 million and €7.9 million in the six-month periods ended June 30, 2018, and June 30, 2017, respectively. For details on the related share-based payment expenses recognized as employee benefit expenses, see Note 12.

In June 2016, the Company established the 2016 Incentive Award Plan (the “2016 Plan”). Options granted under the 2016 Plan are exercisable once vested. The options granted under the 2016 Plan vest in installments over a four-year period from the grant date. Twenty-five percent of the options vest on the first anniversary of the vesting commencement date, and the remaining 75% of the options vest in 36 monthly installments for each full month of continuous service provided by the option holder thereafter, such that 100% of the options shall become vested on the fourth anniversary of the vesting commencement date. Options will lapse on the tenth anniversary of the date of grant.

The Restricted Stock Units (“RSUs”) granted under the 2016 Plan also vest in installments over a four-year period from the grant date. Each RSU represents the right to receive one Common Share.

As stated in the 2016 Plan, the Company has established the Non-Executive Director Compensation Program whereas Non-Executive Directors are entitled to cash compensation as well as equity compensation. The equity compensation consists of an initial option grant as well as annual awards. The initial awards granted under the Non-Executive Director Compensation Program vest in installments over a three-year period. Thirty-three percent of the options vest on the first anniversary of the vesting commencement date, and the remaining 67% of the options in 24 substantially equal monthly installments thereafter, such that the award shall be fully vested on the third anniversary of the vesting commencement date. Each subsequent award shall vest and become exercisable in 12 substantially equal monthly installments following the vesting commencement date, such that the subsequent award shall be fully vested on the first anniversary of the date of grant.

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

During the six months ended June 30, 2018, the Company granted options to purchase 469,068 Common Shares with a grant date fair value of €4.4 million to employees under the 2016 Plan.

Pursuant to the “evergreen” provisions of the 2016 Plan, the number of Common Shares authorized for issuance under the plan automatically increased by 777,194 Common Shares to 1,090,368 Common Shares effective January 1, 2018.

### ***Measurement of fair values of the equity-settled share-based payment arrangements***

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



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The inputs used in the measurement of the fair values and the related fair values at the grant dates were as follows for the options granted during the six-month period ended June 30, 2018:

	<b>Key Management Personnel (€)</b>	<b>All Other Personnel (€)</b>
Fair value at grant date	9.34-9.45	9.30-10.37
Share price at grant date	14.57-14.87	14.57-18.24
Exercise price	14.57-14.87	14.57-18.24
Expected volatility (weighted-average)	<b>95.1%</b>	<b>94.6%</b>
Contractual life	<b>10 years</b>	<b>10 years</b>
Expected dividends	<b>0%</b>	<b>0%</b>
Risk-free interest rate (based on government bonds)	<b>2.79%-2.94%</b>	<b>2.84%-2.94%</b>

### *Reconciliation of outstanding share options*

The number of share options and the weighted average exercise prices of share options granted were as follows for the six-month period ended June 30, 2018:

	<b>Weighted average exercise price (€)</b>	<b>Number of options</b>
Outstanding at January 1, 2018	<b>13.99</b>	<b>2,213,985</b>
Forfeited during the six-month period	<b>19.67</b>	<b>(12,044)</b>
Expired during the six-month period	<b>14.02</b>	<b>(5,146)</b>
Exercised during the six-month period	<b>1.93</b>	<b>(34,041)</b>
Granted during the six-month period	<b>14.68</b>	<b>469,068</b>
Outstanding at June 30, 2018	<b>14.24</b>	<b>2,631,822</b>
Exercisable at June 30, 2018	<b>12.18</b>	<b>1,105,059</b>

The options outstanding at June 30, 2018, had an exercise price in the range of €1.93 to €27.47 and a weighted-average remaining contractual life of 8.2 years. The weighted-average share price at the date of exercise for share options exercised during the six months ended June 30, 2018 was €17.12.

There were 2,631,822 outstanding share options at June 30, 2018, with a weighted average exercise price of €14.24.

The number of options outstanding as of June 30, 2018, was as follows:

<b>Group of employees entitled</b>	<b>June 30, 2018</b>
Key management personnel	2,153,810
All other employees	478,012
<b>Total</b>	<b>2,631,822</b>

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During the six months ended June 30, 2018, the Company did not grant any new RSUs. The number of RSUs outstanding is summarized as follows:

	Weighted average grant price (€)	Number of RSU's
Outstanding at January 1, 2018	20.03	194,546
Forfeited during the six-month period	—	—
Vested during the six-month period	20.03	(76,245)
Granted during the six-month period	—	—
Outstanding at June 30, 2018	20.03	118,301

## 10. Revenue

Revenue is recognized at the amount to which the Company expects to be entitled for the transfer of promised goods or services to customers.

### Disaggregation of Revenue

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

	Three months ended June 30, 2018		Six months ended June 30, 2018	
	June 30, 2017 Restated*		June 30, 2017 Restated*	
	(euros in thousands)		(euros in thousands)	
Upfront payment amortization	4,250	3,973	9,087	6,898
Collaboration income	2,179	1,471	7,195	2,391
Revenue from contracts with customers	6,429	5,444	16,282	9,289
Income from grants on research projects	114	793	182	832
	6,543	6,237	16,464	10,121

\* See Note 3 for details regarding the restatement as a result of a change in accounting policy.

For the three- and six-month periods ended June 30, 2018, the Company recognized amortization of €4.0 million and €7.9 million on upfront payments related to the Incyte collaboration and license agreement, respectively, amortization of €0.2 million and €1.1 million on upfront payments related to the ONO research and license agreement, respectively, and €0.1 million and €0.1 million on upfront payments related to the Simcere collaboration and license agreement, respectively. For the three- and six-month periods ended June 30, 2017, the Company recognized €4.0 million and €6.9 million of amortization of the upfront payment related to the Incyte collaboration and license agreement, respectively.

Collaboration income for the three and six months ended June 30, 2018, was €2.2 million and €7.2 million, respectively, and consisted of cost reimbursements and research milestones achieved in support of the Company's research and license agreements with Incyte, ONO and Simcere. During the three and six months ended June 30, 2018, the Company recognized €2.0 million and €4.3 million of cost reimbursements in support of the Company's research and license agreements with Incyte, respectively, and €0.1 million and €0.2 million of cost reimbursements in support of the Company's research and license agreements with ONO, respectively.

The Company recognized an aggregate of €2.5 million in research milestones under its ONO agreements for the six months ended June 30, 2018 and €0.1 million in research milestones under its Simcere agreements for the three and six months ended June 30, 2018. During the three and six months ended June 30, 2017, the Company recognized €1.5 million and €2.4 million of cost reimbursements in support of the Company's research and license agreements with Incyte and ONO, respectively.

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The Company has been awarded grants consisting of cash allowances for specific research and development projects. The unconditional receipt of the grant allowances is dependent on the final review of the reporting provided by the Company at the end of the contract term. For the three and six months ended June 30, 2018, the Company recognized €0.1 million and €0.2 million in grant income, respectively, compared to €0.8 million in grant income for the three and six months ended June 30, 2017. On June 12, 2017, the European Commission approved for reimbursement the final installment of the FP-7 grant for €0.7 million. Revenue for this final installment was recorded in income from grants on research projects during the three and six months ended June 30, 2017.

### **Contract Balances**

A trade receivable is recorded when the Company satisfies a performance obligation by transferring a promised good or service and has earned the unconditional right to consideration from its customer. Trade receivables relate to invoicing for cost reimbursements and research milestones achieved in support of the Company's research and license agreements with Incyte, ONO and Simcere. Payment terms relating to these receivables are 30 days.

A contract asset is recorded when the Company satisfies a performance obligation by transferring a promised good or service and has earned the right to consideration from its customer. These assets represent a conditional right to consideration. Contract assets relate to unbilled amounts for cost reimbursements and research milestones achieved in support of the Company's research and license agreements with Incyte and ONO.

A contract liability is recorded when consideration is received, or such consideration is unconditionally due, from a customer prior to transferring goods or services under the terms of the contract. Contract liabilities are recognized as revenue as control of the products or services is transferred to the customer and all revenue recognition criteria have been met. Contract liabilities relate to upfront payments received related to the Incyte Agreements, ONO research and license agreement, and the Simcere research and license agreement (See Note 8).

The following table presents changes in the Company's trade receivables, contract assets and contract liabilities during the six months ended June 30, 2018:

	Balance at December 31, 2017 Restated	Additions	Deductions	Balance at June 30, 2018
		(euros in thousands)		
Trade & other receivables				
Trade receivables	1,594	12,103	(11,628)	2,069
Total trade & other receivables	1,594	12,103	(11,628)	2,069
Contract assets				
Unbilled receivables	710	693	(957)	446
Total contract assets	710	693	(957)	446
Contract liabilities				
Deferred revenue	128,486	3,430	(9,226)	122,690
Total contract liabilities	128,486	3,430	(9,226)	122,690

As a result of the adoption of IFRS 15, total deferred revenue was reduced by €8.7 million as of December 31, 2017. See Note 3 for details regarding the restatement as a result of a change in accounting policy.

Deductions from deferred revenue are comprised of revenue recognized that was included in deferred revenue at the beginning of the period totaling €7.9 million and revenue recognized that was not included in deferred revenue at the beginning of the period totaling €1.3 million for the six months ended June 30, 2018.

## 11. Total Operating Expenses

Research and development costs are comprised of allocated employee costs, the costs of materials and laboratory consumables, intellectual property and license costs and allocated other costs.

A breakdown of total operating expenses is presented as follows:

	Three-month period ended June 30,		Six-month period ended June 30,	
	2018	2017	2018	2017
	(euros in thousands)			
Manufacturing costs	5,580	2,236	9,858	5,611
IP and license costs	492	603	844	968
Personnel related R&D	2,107	1,771	3,808	3,303
Other research and development costs	4,344	3,810	8,311	5,545
<i>Total research and development costs</i>	<b>12,523</b>	<b>8,420</b>	<b>22,821</b>	<b>15,427</b>
Management and administration costs	2,639	3,492	5,491	7,694
Litigation costs	552	104	849	394
Other operating expenses	2,745	2,173	5,134	3,726
<i>Total other expenses</i>	<b>3,297</b>	<b>2,277</b>	<b>5,983</b>	<b>4,120</b>
<b>Total operating expenses</b>	<b>18,459</b>	<b>14,189</b>	<b>34,295</b>	<b>27,241</b>

Research and development costs were €12.5 million and €22.8 million for the three and six months ended June 30, 2018, respectively, as compared to €8.4 million and €15.4 million for the three- and six-month periods ended June 30, 2017, respectively. The increase in research and development costs is primarily attributable to the increase in manufacturing costs, higher research and development headcount and related costs, as well as additional spending in support of the Company's clinical development programs for MCLA-128, MCLA-117, MCLA-158 and MCLA-145. The significant increase in manufacturing costs and other research and development costs during 2018 relate primarily to the expansion of the Company's Phase 1 and Phase 1/2 clinical programs. Specifically, the Company incurred higher costs relating to outsourced contract manufacturing for process development and drug delivery in support of the Company's MCLA-128 and MCLA-158 clinical development programs.

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

	Three-month period ended June 30,		Six-month period ended June 30,	
	2018	2017	2018	2017
	(euros in thousands)			
Discovery and pre-clinical costs	1,078	1,698	1,763	2,076
Clinical costs	1,850	1,292	4,248	2,002
Other research and development costs	1,416	820	2,300	1,467
<i>Total other research and development costs</i>	<b>4,344</b>	<b>3,810</b>	<b>8,311</b>	<b>5,545</b>

Other research and development costs consist mainly of laboratory supplies and depreciation expense related to research and development activities, which cannot be specifically allocated to a research project.

### *Litigation costs*

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

On November 21, 2014, the Court found that there was clear and convincing evidence that a claim term present in each of the patent claims was indefinite and granted the Company’s proposed claim constructions. On February 24, 2015, the Court entered partial judgment in the proceeding, on the grounds that the Company did not infringe each of the patent claims, and that each of the patent claims were invalid due to indefiniteness. On November 2, 2015, the Court found Regeneron had withheld material information from the United States Patent and Trademark Office during prosecution of the patent, and Regeneron had engaged in inequitable conduct and affirmative egregious misconduct in connection with the prosecution of the patent. On December 18, 2015, Regeneron filed an appeal of the Court’s decision. On July 27, 2017, the U.S. Court of Appeals for the Federal Circuit affirmed the trial court’s conclusion that Regeneron had engaged in inequitable conduct before the United States Patent and Trademark Office and affirmed that the ‘018 patent is unenforceable. Regeneron petitioned for a panel rehearing and rehearing en banc of this decision by the Federal Circuit on September 12, 2017, which the Company responded to and opposed on November 2, 2017. On December 26, 2017, the full Federal Circuit denied Regeneron’s request to rehear the matter.

The case returned to the District Court to adjudicate the Company’s motion requesting that Regeneron pay the Company’s attorneys’ fees and costs incurred as a result of Regeneron filing suit. On March 26, 2018, the trial court granted the Company’s motion for attorneys’ fees, expert fees, and costs and ordered the parties to address the amount of award. The Company provided a detailed explanation of its attorneys’ fees, expert fees, and costs of such award, which Regeneron responded to seeking a reduction of the amount. The matter was fully briefed as of May 18, 2018, and the Court issued an Order on June 25, 2018, which published on July 10, 2018, granting the Company’s motion for \$8,332,453.46 in attorneys’ fees, \$465,390.34 in expert fees, and \$1,717,100.69 in litigation expenses and costs, along with interest. Regeneron has appealed the decision awarding attorneys’ fees to the Company to the Federal Circuit. On May 25, 2018, Regeneron filed a petition for writ of certiorari seeking review by the Supreme Court of the United States of the decision affirmed by the Federal Circuit. The Company’s brief in opposition was filed on August 8, 2018.

On March 11, 2014, Regeneron served a writ in the Netherlands alleging that the Company was infringing one or more claims of the European patent EP 1 360 287 B1. The Company opposed the patent in June 2014. On September 17, 2014, Regeneron’s patent EP 1 360 287 B1 was revoked in its entirety by the European Opposition Division of the European Patent Office (the “EPO”). In Europe, an appeal hearing occurred in October and November 2015 at the Technical Board of Appeal for the EPO at which time the patent was reinstated to Regeneron with amended claims. On May 25, 2018, at Regeneron’s request, a hearing before the Technical Board of Appeals for the EPO was scheduled for September 13, 2018, to address whether the description of EP 1 360 287 B1 patent having claims amended during the course of opposition complies with Art. 84 EPC, Art. 123(2) EPC and Rule 80 EPC. The Company believes that its current business operations do not infringe the patent reinstated to Regeneron with amended claims because it believes it has not used the technology or methods claimed under the amended claims. The Dutch litigation procedure is stayed.

The costs incurred in the above litigation and opposition were €0.6 million and €0.8 million for the three- and six-month periods ended June 30, 2018, respectively, as compared to €0.1 million and €0.4 million for the three- and six-month periods ended June 30, 2017, respectively, and are included in the statement of profit or loss and comprehensive loss for the period.

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On July 15, 2014, Regeneron filed a notice of opposition against the Company's EP 2314629 patent (the "EP '629 patent"), entitled "Recombinant Production of Mixtures of Antibodies," in the EPO. The notice asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. The Company responded on February 24, 2015. Following an oral hearing before the Opposition Division of the EPO on June 22, 2016, the Opposition Division upheld the EP '629 Patent with amendments. Both Regeneron and the Company filed a notice of appeal followed by grounds of appeal on December 1 and 4, 2017, respectively, with further proceedings to follow.

On August 11, 2014, Regeneron filed a notice of opposition against the Company's EP 2147594 (the "EP '594 patent"), entitled "Antibody Producing Non-Human Mammals," in the EPO. The notice asserted, as applicable, lack of novelty, lack of inventive step, and insufficiency. The Company's response to the oppositions was filed on April 2, 2015. Following an oral hearing before the Opposition Division of the EPO on October 28, 2016, the Opposition Division upheld the EP '594 Patent without amendments. Regeneron filed grounds of appeal on July 19, 2017, and the Company responded on November 30, 2017.

On April 5, 2018, Regeneron and an unnamed third party filed notices of opposition against the Company's EP 2604625 patent (the "EP '625 patent"), entitled "Generation of Binding Molecules," in the EPO. The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. The Company intends to timely respond to these submissions with proceedings to be ongoing.

As each of these proceedings continues, the Company is not able to predict the outcome of, or estimate a possible gain or a range of possible loss, if any, related to the above actions. Based on the current facts and circumstances, no provision has been recognized under IAS 37 related to contingent liabilities.

## 12. Employee Benefits

Details of the employee benefits are as follows:

	Three-month period ended June 30,		Six-month period ended June 30,	
	2018	2017	2018	2017
	(euros in thousands)			
Salaries and wages	2,876	2,451	5,505	4,182
WBSO subsidy	(733)	(953)	(1,900)	(2,005)
Social security premiums	198	146	449	293
Health insurance	69	36	188	62
Pension costs	188	181	390	322
Share award expense	2,109	3,254	4,554	7,880
Other personnel expense	224	148	433	264
Total employee benefits expense	<u>4,931</u>	<u>5,263</u>	<u>9,619</u>	<u>10,998</u>

Share-based payment expenses (see Note 9) were recognized as employee benefit expenses as follows:

	Three-month period ended June 30,		Six-month period ended June 30,	
	2018	2017	2018	2017
	(euros in thousands)			
Research and development costs	714	673	1,525	1,798
Management and administrative costs	1,343	2,376	2,852	5,782
Other expenses	52	205	177	300
	<u>2,109</u>	<u>3,254</u>	<u>4,554</u>	<u>7,880</u>

Subsidies earned under the WBSO relating to eligible research and development costs are deferred and recognized in the Company's income statement as a reduction to labor costs over the period labor costs are expected to be incurred. The Company has received and recognized subsidies of €0.7 million and €1.9 million for the three- and six-month periods ended June 30, 2018, respectively, as compared to €1.0 million and €2.0 million for the three- and six-month periods ended June 30, 2017, respectively. The decrease in subsidies is primarily attributable to the decrease in eligible payroll tax withholdings during the same period.

The Company's headcount at June 30, 2018 was approximately 85 full-time equivalents and consisted of 70 employees in the Netherlands and 15 employees in the United States. A total of 18 employees who are devoted to activities other than research and development and overall management of the Company were included under management and administration costs for the three- and six-month periods ended June 30, 2018.

The Company's headcount at June 30, 2017 was approximately 64 full-time equivalents and consisted of 55 employees in the Netherlands and nine employees in the United States. A total of 13 employees who were devoted to activities other than research and development and overall management of the Company were included under management and administration costs for the three- and six-month periods ended June 30, 2017.

### 13. Finance Income and Expense

	Three-month period ended June 30,		Six-month period ended June 30,	
	2018	2017	2018	2017
	(euros in thousands)			
<b>Finance income</b>				
Interest income and similar income	494	420	834	610
Net gain on foreign exchange	6,917	—	4,111	—
	<u>7,411</u>	<u>420</u>	<u>4,945</u>	<u>610</u>
<b>Finance costs</b>				
Interest expense	(1)	—	(1)	(10,667)
Net loss on foreign exchange	—	(11,962)	—	(12,029)
	<u>(1)</u>	<u>(11,962)</u>	<u>(1)</u>	<u>(22,696)</u>

Interest income primarily results from interest earned on cash held on account and accretion of investment earnings. The Company's current year increase in cash, cash equivalents and investments was due primarily to the \$55.8 million of funds received as part of the Private Placement during the first quarter of 2018.

The Company experienced gains on its U.S. dollar denominated cash, cash equivalents and investments of approximately €6.9 million and €4.1 million for the three and six months ended June 30, 2018, respectively, as compared to losses of €12.0 million for the three and six months ended June 30, 2017. The Company presents foreign currency gains and losses on a net basis as either finance income or finance expense depending on whether foreign currency movements are in a net gain or net loss position. The Company experienced foreign exchange losses on its U.S. dollar denominated cash, cash equivalents and investments of approximately €2.8 million during the three months ended March 31, 2018, which are reclassified to net gain on foreign exchange for the six months ended June 30, 2018. As of June 30, 2018, the Company held approximately \$40.9 million and \$92.6 million in U.S. dollar denominated cash and cash equivalent accounts and investment accounts, respectively, subject to the fluctuation in foreign currency between the euro and U.S. dollar.

On December 20, 2016, the Company entered into the Incyte Agreements. As these contracts are denominated in U.S. dollars, the Company determined that the subscription agreement to sell its own shares to which the Company became committed on December 20, 2016, should be accounted for as a forward contract or a derivative financial instrument. Interest expense for the three and six months ended June 30, 2017, related entirely to the effective settlement of the forward contract on January 23, 2017.

#### **14. Operating Leases**

The Company leases its corporate headquarters under an agreement term of five years which expires in the fourth quarter of 2021. If the lease is not terminated by Merus N.V. it will be automatically renewed for a period of two years. The agreed rental price is €0.4 million per year. On May 1, 2018, the Company leased additional space to expand its corporate headquarters under a separate agreement. Under the terms of the new agreement, the term began on May 1, 2018, and expires in the fourth quarter of 2021. The agreed upon rental price is €0.5 million per year.

For leases that contain fixed increases in the minimum annual lease payment during the original term of the lease, the Company recognizes rental expense on a straight-line basis over the lease term and records the difference between rent expense and the amount currently payable as deferred rent as a component of other liabilities and accruals. For the three and six months ended June 30, 2018, the Company recognized €0.3 million and €0.5 million, respectively, compared to €0.2 million and €0.3 million for the three and six months ended June 30, 2017, respectively, for rent and service charges related to the office space. In addition, the Company has provided a deposit of €0.1 million included in other assets as of June 30, 2018, and December 31, 2017.

#### **15. Subsequent Events**

The Company has evaluated subsequent events through August 10, 2018, the date of issuance of the unaudited consolidated financial statements for the three months ended June 30, 2018.

Except for the items described in Note 11 under litigation, there were no additional events requiring disclosure in the notes to these financial statements.



**6,299,997 Shares**

**Merus N.V.**

**Common Shares**



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**PRELIMINARY 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. These indemnification agreements may require us, among other things, to indemnify our directors for judgments, settlements, fines, and some expenses, including attorneys' fees, incurred by a director in any action or proceeding arising out of his or her service as a director, 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**

***Class C Investment Agreement***

On August 21, 2015, the registrant issued 4,149,884 Class C preferred shares to certain investors in exchange for an aggregate consideration of €49.7 million, which includes the conversion of the registrant's existing €8.0 million convertible bridge loan and interest thereon into Class C preferred shares. The foregoing issuance was made outside of the United States pursuant to Regulation S or to U.S. entities pursuant to Section 4(a)(2) of the Securities Act.

***Share Issuances***

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.

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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.

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

(a)

<b>Exhibit Number</b>	<b>Exhibit Description</b>	<b>Form</b>	<b>Incorporated by Reference to Filings Indicated</b>		
			<b>File No.</b>	<b>Exhibit No.</b>	<b>Filing Date</b>
3.1	<a href="#">Articles of Association (English Translation)</a>	20-F	001-37773	1.1	4/30/18
5.1	Opinion of NautaDutilh, counsel of the Registrant				**
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>				*
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 October 5, 2016, by and among Merus US, Inc., the Registrant and John J. Crowley</a>	6-K	001-37773	10.1	11/3/16
10.7#	<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
10.8#	<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
10.9#	<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
10.10#	<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
10.11#	<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

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10.12#	<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
10.13	<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
10.14	<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
10.15	<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
10.16†	<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
10.17†	<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
10.18	<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
10.19†	<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
10.20	<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
10.21	<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
10.22	<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
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	Consent of NautaDutilh, counsel to the Registration (included in Exhibit 5.1)				**
24.1	<a href="#">Powers of attorney (included on signature page to the registration statement)</a>				*
101.INS	XBRL Instance Document.				*
101.SCH	XBRL Taxonomy Extension Schema Document.				*

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101.CAL	XBRL Taxonomy Calculation Linkbase Document.	*
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.	*
101.LAB	XBRL Taxonomy Label Linkbase Document.	*
101.PRE	XBRL Taxonomy Presentation Linkbase Document.	*

\* Filed herewith.

\*\* To be filed by amendment.

# 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, 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

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(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 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.

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(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 AND POWER OF ATTORNEY**

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 December 27, 2018.

**MERUS N.V.**By: /s/ Ton Logtenberg

Name: Ton Logtenberg

Title: President and Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints Ton Logtenberg and John Crowley and each of them, individually, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead in any and all capacities, in connection with this registration statement, including to sign in the name and on behalf of the undersigned, this registration statement and any and all amendments thereto, including post-effective amendments and registrations filed pursuant to Rule 462 under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the U.S. Securities and Exchange Commission, granting unto such attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or his substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons on December 27, 2018 in the capacities indicated:

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



**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 December 27, 2018.

Authorized U.S. Representative

Merus US, Inc.

By: /s/ Ton Logtenberg

Name: Ton Logtenberg

Title: President

## MERUS N.V.

## NON-EXECUTIVE DIRECTOR COMPENSATION PROGRAM

The non-executive directors (the “**Non-Executive Directors**” and each, a “**Non-Executive Director**”) of Merus N.V. (the “**Company**”) shall receive cash and equity compensation as set forth in this Non-Executive Director Compensation Program (this “**Program**”). The compensation described in this Program shall be paid or be made, as applicable, automatically and without further action of the Board of Directors (the “**Board**”) or the general meeting of shareholders (the “**General Meeting**”) of the Company, to each Non-Executive Director who is entitled to receive such cash or equity compensation, unless such Non-Executive Director declines the receipt of such cash or equity compensation by written notice to the Company. This Program shall remain in effect until it is revised or rescinded by further action taken by the Board at the recommendation of the Compensation Committee. This Program may be amended, modified or terminated at any time by action taken by the Board at the recommendation of the Compensation Committee. Except as otherwise provided in this Program with respect to Observers (as defined below), the terms and conditions of this Program shall supersede any prior cash and/or equity compensation arrangements for service as a Non-Executive Director (or as a supervisory director) between the Company and any of its Non-Executive Directors.

Time spent in office and service as a supervisory director of the Company prior to the amendment to the articles of association of the Company on May 29, 2017 shall, for purposes of this Program, be considered to be time spent in office and service as Non-Executive Director.

## I. CASH COMPENSATION

A. Annual Retainers. Each Non-Executive Director shall receive an annual retainer of \$35,000 for service on the Board.

B. Additional Annual Retainers. In addition, each Non-Executive Director shall receive the following annual retainers:

1. *Chairperson of the Board*. A Non-Executive Director serving as Chairperson of the Board shall receive an additional annual retainer of \$50,000 for such service.
2. *Audit Committee*. A Non-Executive Director serving as Chairperson of the Audit Committee shall receive an additional annual retainer of \$15,000 for such service. A Non-Executive Director serving as a member other than the Chairperson of the Audit Committee shall receive an additional annual retainer of \$7,500 for such service.
3. *Compensation Committee*. A Non-Executive Director serving as Chairperson of the Compensation Committee shall receive an additional annual retainer of \$13,000 for such service. A Non-Executive Director serving as a member other than the Chairperson of the Compensation Committee shall receive an additional annual retainer of \$5,000 for such service.
4. *Nomination and Corporate Governance Committee*. A Non-Executive Director serving as Chairperson of the Nomination and Corporate Governance

Committee shall receive an additional annual retainer of \$13,000 for such service. A Non-Executive Director serving as a member other than the Chairperson of the Nomination and Corporate Governance Committee shall receive an additional annual retainer of \$3,750 for such service.

C. Payment of Retainers. The annual retainers described in Sections I(A) and I(B) shall be earned on a quarterly basis based on a calendar quarter and shall be paid in cash by the Company in arrears not later than the fifteenth day following the end of each calendar quarter. In the event a Non-Executive Director does not serve as a Non-Executive Director, or in the applicable positions described in Section I(B), for an entire calendar quarter, the retainer paid to such Non-Executive Director shall be prorated for the portion of such calendar quarter actually served as a Non-Executive Director, or in such position, as applicable.

D. Annual Increase. Each annual retainer described in Sections I(A) and I(B) shall, without further action taken by the Board or the General Meeting, automatically increase on the first day of each calendar year by an amount equal to 3% of the value of such annual retainer in effect as of the immediately preceding calendar year.

E. Observers. Unless the Board decides otherwise, the date service as an observer on the Board (an “**Observer**”) commences pursuant to, and as from the effective date of, a written services agreement entered into between such Observer and the Company shall be considered the effective date of commencing service as a Non-Executive Director for purposes of Section I.

## II. EQUITY COMPENSATION

Non-Executive Directors shall be eligible to be granted the equity awards described below. The awards described below shall be granted under and shall be subject to the terms and provisions of the Company’s 2016 Incentive Award Plan or any other applicable Company equity incentive plan then-maintained by the Company (the “**Equity Plan**”), shall be granted by the Board, and subject to such award or other agreements as approved by the Board. Subject to Section II(G), all applicable terms of the Equity Plan apply to this Program as if fully set forth herein, and all grants of stock options hereby are subject in all respects to the terms of the Equity Plan and the applicable award agreement.

A. Initial Awards. Each Non-Executive Director who is initially appointed to the Board shall be eligible to receive an option to purchase the number of common shares of the Company having an aggregate Grant Date Fair Value (as defined below) of \$200,000, with any partial shares that result being rounded down to the nearest whole share. The awards described in this Section II(A) shall be referred to as “**Initial Awards**.” No Non-Executive Director shall be granted more than one Initial Award. “**Grant Date Fair Value**” shall mean the value of the option as of the date of grant, which value shall be determined using a Black-Scholes option pricing model and the valuation assumptions used by the Company in accounting for options as of such date; provided, that the fair market value of the common shares of the Company used in such calculation shall be based on the average trading price of the common shares of the Company over the preceding thirty day period. Unless otherwise determined by the Board,

options to purchase common shares granted to an Observer while serving, or upon commencing service, as an Observer shall be considered an Initial Award under this Program.

B. Subsequent Awards. A Non-Executive Director who (i) has been serving as a Non-Executive Director or Observer for at least six months and (ii) will continue to serve as a Non-Executive Director immediately following any annual General Meeting held following his or her initial appointment as a Non-Executive Director, is eligible to be granted, at the occasion of or as soon as practically possible following each such annual General Meeting an option to purchase the number of common shares of the Company having an aggregate Grant Date Fair Value of \$100,000, with any partial shares that result being rounded down to the nearest whole share. The awards described in this Section II(B) shall be referred to as “**Subsequent Awards**.”

C. Acceptance. For the avoidance of doubt, any grant of Initial Awards and Subsequent Awards under this Program will require a written or electronic notice of acceptance of the relevant Non-Executive Director, in the absence of which such Non-Executive Director will be deemed to have waived its rights to such a grant.

D. Terms of Awards Granted to Non-Executive Directors

1. *Exercise Price*. The per share exercise price of each option granted to a Non-Executive Director shall equal the Fair Market Value (as defined in the Equity Plan) of a common share of the Company on the date the option is granted.

2. *Vesting*. Each Initial Award shall vest and become exercisable as to 33% of the shares subject to such Initial Award on the first anniversary of the date of grant and in 24 substantially equal monthly installments thereafter, such that the Initial Award shall be fully vested on the third anniversary of the date of grant, subject to the Non-Executive Director continuing in service as a Non-Executive Director (or an Observer) through each such vesting date. Each Subsequent Award shall vest and become exercisable in 12 substantially equal monthly installments following the date of grant, such that the Subsequent Award shall be fully vested on the first anniversary of the date of grant, subject to the Non-Executive Director continuing in service on the Board as a Non-Executive Director (or an Observer) through each such vesting date. Unless the Board decides otherwise, any portion of an Initial Award or Subsequent Award which is unvested or unexercisable at the time of a Non-Executive Director's termination of service on the Board shall be immediately forfeited upon such termination of service and shall not thereafter become vested and exercisable. All Initial Awards and Subsequent Awards shall vest in full immediately prior to the occurrence of a Change in Control (as defined in the Equity Plan), to the extent outstanding at such time.

3. *Term*. The maximum term of each Initial Award and each Subsequent Award granted hereunder shall be ten (10) years from the date the option is granted.

E. Annual Increase; Award Limit. The Grant Date Fair Value of each Initial Award and Subsequent Award described in this Program shall, subject to approval by the Board, increase on the first day of each calendar year by an amount equal to 3% of the Grant Date Fair Value applicable to Initial Awards and Subsequent Awards in effect as of the immediately preceding calendar year; provided, that, in no event shall the number of shares awarded pursuant

to (i) an Initial Award exceed 17,000 common shares of the Company and (ii) a Subsequent Award exceed 8,500 common shares of the Company, in each case, subject to adjustment as provided in the Equity Plan.

F. Tax deductions. To the extent required to comply with applicable tax laws, the Company shall be allowed to make necessary deductions on any compensation payable under this Program, including (without limitation) for purposes of any payroll tax or income tax.

G. Prevailing terms. In the event of any inconsistency between the terms of the Equity Plan and this Program, the terms of this Program shall prevail. Notwithstanding anything in this Program to the contrary, the terms of an Initial Award granted to an Observer shall be subject to the terms of the award agreement pursuant to which such Initial Award is granted.

\* \* \* \* \*

**Consent of Independent Registered Public Accounting Firm**

The Board of Directors  
Merus N.V.:

We consent to the use of our report dated April 30, 2018, except as to Note 4 which is as of December 27, 2018, with respect to the consolidated statements of financial position of Merus N.V. as of December 31, 2017 and 2016, 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, 2017, and the related notes (collectively, the “consolidated financial statements”), incorporated herein by reference to the Form 6-K of Merus N.V. dated December 27, 2018, 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  
December 27, 2018