UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number **001-37773**

MERUS N.V.

(Exact name of Registrant as specified in its Charter)

The Netherlands (State or other jurisdiction of incorporation or organization)	**Not Applicable** (I.R.S. Employer Identification No.)
Yalelaan 62 **3584 CM Utrecht** **The Netherlands** (Address of principal executive offices)	**Not Applicable** (Zip Code)

Registrant's telephone number, including area code:

+31 30 253 8800

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares, nominal value €0.09 per share	**MRUS**	**The Nasdaq Stock Market LLC (Nasdaq Global Market)**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, 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. ☒

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2020, was approximately $464.9 million.

The number of shares of registrant's Common Shares outstanding as of February 28, 2021 was 38,126,976.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement that the registrant intends to file with the Securities and Exchange Commission pursuant to Regulation 14A in connection with the registrant's 2021 Annual General Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K to the extent stated herein.

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CAUTIONARY NOTE REGARDING FORWARD LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are 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,” “project,” “contemplate,” “believe,” “estimate,” “forecast,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements contained in this Annual Report on Form 10-K, include without limitation statements regarding our plans to develop and commercialize our product candidates, the timing of our ongoing or planned clinical trials, the timing of and our ability to obtain and maintain regulatory approvals, the clinical utility of our product candidates, our commercialization, marketing and manufacturing capabilities and strategy, our expectations surrounding our collaborations, our expectations about the willingness of healthcare professionals to use our product candidates, the sufficiency of our cash, cash equivalents and investments, and the plans and objectives of management for future operations and capital expenditures.

The forward-looking statements in this Annual Report on Form 10-K are only predictions and are based 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 Annual Report on Form 10-K and are subject to a number of known and unknown risks, uncertainties and assumptions and other important factors, including those described under the sections in this Annual Report on Form 10-K entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this Annual Report on Form 10-K.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. We intend the forward-looking statements contained in this Annual Report on Form 10-K to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act.

SUMMARY RISK FACTORS

Our business is subject to numerous risks and uncertainties, including those described in Part I, Item 1A. “Risk Factors” in this Annual Report on Form 10-K. You should carefully consider these risks and uncertainties when investing in our common shares. The principal risks and uncertainties affecting our business include the following:

- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.
- We have a limited operating history, have not completed any clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.
- The clinical trial and regulatory approval processes are lengthy, time consuming and inherently unpredictable, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our 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 antibody candidates or following approval, if any, we may need to abandon our development of such 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

- We depend on enrollment of patients in our clinical trials for our antibody candidates, including patients having NRG1 fusion positive tumors, which are rare, tumorigenic genomic events. If we are unable to enroll patients in our clinical trials, including those having these rare tumorigenic events, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations or 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 antibody candidates and our business could be substantially harmed.
- Due to our limited resources and access to capital, we must, and have in the past decided to, prioritize development of certain antibody candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.
- We operate in highly competitive and rapidly changing industries, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we are unable to adequately protect our intellectual property and our proprietary technologies, or obtain and maintain issued patents which are sufficient to protect our product candidates, others could compete against us more directly, which would negatively impact our business.
- Our existing collaborations are important to our business and future licenses may also be important to us, and if we are unable to maintain any of these collaborations, or if these arrangements are not successful, our business could be adversely affected.
- The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations.

PART I

Item 1. Business.

Overview

We are a clinical-stage oncology company developing innovative antibody therapeutics. Our pipeline of full-length human multispecific antibody candidates are generated from our proprietary technology platforms, which are able to generate a diverse array of antibody binding domains, or Fabs, against virtually any target. Each antibody binding domain consists of a target-specific heavy chain paired with a common light chain. Multiple binding domains can be combined to produce novel bispecific and trispecific antibodies that bind to a wide range of targets and display novel and innovative biology. These platforms, referred to as Biclonics® and Triclonics®, allow us to generate large numbers of diverse panels of bispecific and trispecific antibodies, respectively, which can then be functionally screened in large-scale cell-based assays to identify those unique molecules that possess novel biology, which we believe are best suited for a given therapeutic application. Further, by binding to multiple targets, Biclonics® and Triclonics® may be designed to provide a variety of mechanisms of action, including simultaneously blocking receptors that drive tumor cell growth and survival and mobilizing the patient's immune response by engaging T cells, and/or activating various killer cells to eradicate tumors.

Our technology platforms employ an assortment of patented technologies and techniques to generate human antibodies. We utilize our patented MeMo® mouse to produce a host of antibodies with diverse heavy chains and a common light chain that are capable of binding to virtually any antigen target. We use our patented heavy chain and CH3 domain dimerization technology to generate substantially pure bispecific and trispecific antibodies. We also employ our patented Spleen to Screen® technology to efficiently screen panels of diverse heavy chains, designed to allow us to more rapidly identify Biclonics® and Triclonics® therapeutic candidates with differentiated modes of action for pre-clinical and clinical testing.

Using our Biclonics® platform we have produced, and are currently developing, the following candidates: MCLA-128 (zenocutuzumab) for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions; MCLA-158 for the potential treatment of solid tumors; and MCLA-145, developed in collaboration with Incyte Corporation, for the potential treatment of solid tumors. In 2021, we are planning to commence a clinical trial in the United States for MCLA-129, for the potential treatment of solid tumors, which is also the subject to collaboration and license agreement, which permits Betta Pharmaceuticals Co. Ltd. (Betta) to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights. Furthermore, we have a pipeline of proprietary antibody candidates in pre-clinical development and intend to further leverage our Biclonics® and Triclonics® technology platforms to identify multiple additional antibody candidates and advance them to clinical development.

Our Strategy

Our goal is to become a leading oncology company developing innovative multispecific antibodies to treat various types of cancer. Our business strategy comprises the following components:

- ***Successfully develop our most advanced bispecific antibody candidate, zenocutuzumab, for the treatment of NRG1 fusion solid tumors.*** We are developing our most advanced bispecific antibody candidate, zenocutuzumab, for the potential treatment of solid tumors that contain NRG1 gene fusions. The NRG1 protein is the ligand for the HER3 receptor—a known cause of cancer cell growth. The gene encoding NRG1 can form genetic rearrangements referred to as NRG1 gene fusions. The protein product of the NRG1 gene fusion can drive signaling through the HER3 receptor and thus drive cancer cell growth. NRG1 gene fusions occur infrequently in a wide range of different cancer types. Zenocutuzumab has been shown pre-clinically to potently disrupt binding of NRG1 (and NRG1-fusion proteins) to HER3 and halt NRG1-stimulated tumor cell growth. In October 2019, we reported on the 9 patients with NRG1 gene fusion cancers who had received zenocutuzumab as of that date, either while participating in the clinical trial or in connection with an Early Access Program (EAP), including, for several patients, clinical responses and stable disease with tumor reduction and reductions in serum tumor markers. We expect to present data from our Phase 1/2 NRG1 fusion-positive solid tumor trial, *eNRGy*, at a medical conference in the second quarter of 2021. We believe that if zenocutuzumab is successfully developed and obtains regulatory approval, it has the potential to address an important unmet medical need that is not currently being met by existing therapies. In July 2020, the U.S. Food and Drug Administration (FDA) granted zenocutuzumab Orphan Drug Designation for pancreatic cancer and in January 2021, the FDA granted Fast Track Designation to zenocutuzumab for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy.

- ***Successfully develop our bispecific antibody candidate MCLA-158.*** We are developing MCLA-158 for a potential dual EGFR/LRG5 blockade for the treatment of solid tumors. Our Phase 1 clinical trial of MCLA-158 is ongoing in the dose expansion phase. On January 15, 2021, we presented in a poster session interim clinical data from the phase 1 dose escalation of MCLA-158 at the American Society of Clinical Oncology 2021 Gastrointestinal Cancers Symposium. As of a data cut-off of September 2020, MCLA-158 was administered to 33 patients over 11 dose levels (5-1500 mg, flat dose), a heavily pretreated population with a median of four lines of prior therapy. As of the cut-off date, MCLA-158 was observed to be well tolerated, and no dose limiting toxicities occurred. The recommended Phase 2 dose was established at 1500 mg

administered intravenously once every two weeks. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues at this dose in the expansion phase of the open-label, multicenter trial, and preliminary evidence of antitumor activity has been observed.

- ***Successfully develop our bispecific antibody candidate MCLA-145.*** We are developing MCLA-145, in collaboration with Incyte Corporation (Incyte), in an ongoing Phase 1 trial for the potential treatment of solid tumors. MCLA-145 is designed to recruit, activate and prevent the exhaustion of tumor-infiltrating T-cells, and we believe has the potential to avoid the known side effects experienced with CD137 agonists that have been tested in the clinic. We plan to present a clinical update at a major medical conference in the second half of 2021.

- ***Successfully develop our bispecific antibody candidate MCLA-129.*** We are developing MCLA-129, in collaboration with Betta, and are planning to commence a Phase 1 trial in 2021 to investigate MCLA-129 as a potential treatment for solid tumors, including non-small cell lung cancer (NSCLC). We presented at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics in October 2019 pre-clinical data showing that MCLA-129 inhibited tyrosine kinase inhibitor-resistant NSCLC in pre-clinical xenograft mouse models. We plan to dose the first patient in a clinical trial in the US in 2021.

- ***Accelerate the discovery and development of additional internal and collaboration-related bispecific antibody candidates and internal trispecific antibody candidates.*** We believe we are well positioned to expand our pipeline of Biclonics® and Triclonics® molecules for the potential treatment of cancer and potentially other forms of disease. We are conducting pre-clinical studies for our internal proprietary bispecific and trispecific pipeline as well as leveraging our bispecific platform with our collaborators including Incyte, Eli Lilly and Company (Eli Lilly), Simcere Pharmaceutical Group (Simcere), and Betta.

- ***Seek strategic collaborations***. We intend to seek strategic collaborations to facilitate the capital-efficient development of our pipeline and to maximize the value of our Biclonics® and Triclonics® technology platforms and to access unique partner capabilities and capacity. We have entered into collaborations with Incyte, Eli Lilly, Simcere, and Betta to develop bispecific antibody candidates based on our Biclonics® technology platform. We plan to work with other potential future collaborators to further validate and expand the use of our Biclonics® and Triclonics® platforms in developing bispecific and trispecific antibody candidates. We have also worked with ONO Pharmaceutical Co., Ltd., under a research license agreement to generate bispecific antibodies for indications outside oncology, which further underscore the breadth of the Merus platform. We believe these collaborations, license and future agreements could potentially provide significant funding to advance our pipeline and allow us to benefit from the additional resources, development and commercialization expertise of our collaborators.

Our Biclonics® and Triclonics® Candidate Portfolio

We currently have bispecific candidates in clinical development, with a variety bispecific and trispecific candidates in pre-clinical development. The following table summarizes our development candidate pipeline:

PROGRAM	BISPECIFIC TARGETS	INDICATION(S)	PRECLINICAL	PHASE 1	PHASE 1/2	STATUS
Zenocutuzumab (Zeno) (MCLA-128)	HER3 x HER2	NRG1+ Pancreatic NRG1+ Lung NRG1+ Other solid tumors				Phase 1/2 trial ongoing Clinical data/program update planned 2Q 2021
MCLA-158	Lgr5 x EGFR	Solid tumors				Phase 1 Trial Ongoing
MCLA-145	CD137 x PD-L1	Solid tumors	Incyte (ex- U.S.)			Phase 1 Trial Ongoing Clinical update planned 2H21
MCLA-129	EGFR x c-MET	Solid tumors	BETTA (China)			First patient planned to be dosed in the U.S. 2021
ONO-4685*	PD-1 x CD3	Autoimmune disease	ONO			Phase 1 Trial Ongoing

* If commercialized, Merus to receive royalties

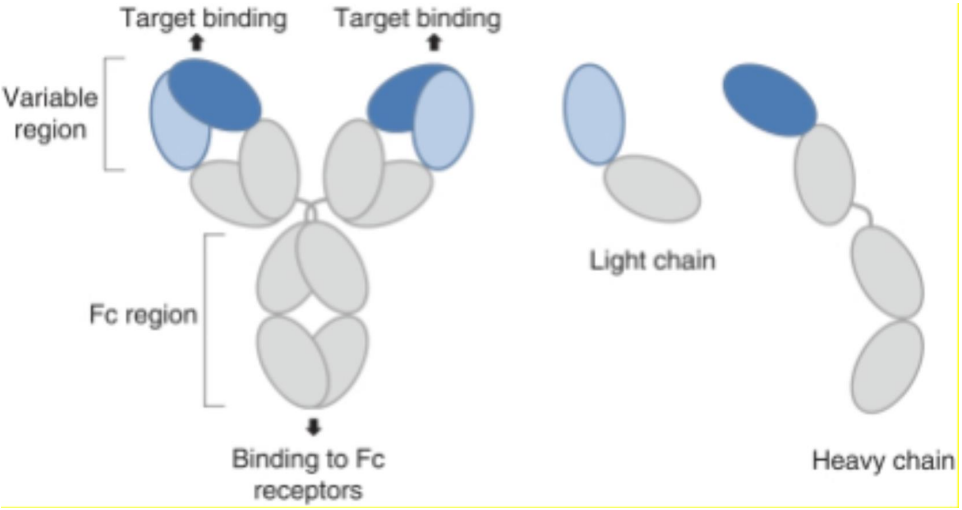
Cancer Immunotherapeutics

Immunotherapy is relatively a new class of cancer treatment that works to harness a patient's own immune system to attack the cancer cells. There are a number of immunotherapies that are designed to engage various aspects of the immune system, for example: (1) adaptive immunity, specifically directing genetically modified T cells to the tumor with chimeric antigen receptor, or CAR T cells or T-cell receptor modification; or modulating T-cell activity through co-stimulation or checkpoint signals; (2) innate immunity, including antibody-dependent cellular cytotoxicity (ADCC), cellular-dependent cytotoxicity (CDC), monocyte/macrophage cytotoxicity, natural killer (NK) cell cytotoxicity, or other forms of T-cell cytotoxicity; all directed at the cancer cells. 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.

While these approaches have advanced the field of oncology, each also have limitations. For example, the enhanced ADCC of monoclonal antibodies that bind to a single target expressed by tumor cells can potentially induce an autoimmune "on-target, off-tumor" toxicity to normal non-tumor tissues that may also express the same target antigen. Cell-based therapies such as genetically modified CAR-T cells can be difficult and expensive to manufacture, can persist in patients for many months, can be associated with a toxic cytokine release syndrome as safety concerns, or can become ineffective if the tumor loses expression of the single antigen against which the CAR-T cells are directed. We believe bispecific and trispecific antibody candidates developed from our novel platforms offer the potential to overcome these limitations.

Background on Antibodies

The conventional antibody in full length immunoglobulin G (IgG) format is a Y-shaped molecule that consists of two identical heavy chains and two identical light chains, as shown in the figure below. Each heavy chain pairs with the light chain to form two variable regions, or antigen binding fragment, Fab, that bind to antigens, or targets, and a constant region, which includes a region known as the fragment crystallizable (Fc) that binds to receptors present on effector cells in the immune system. In conventional full-length IgG, the variable regions are identical and bind to the same targets.



In bispecific antibodies, the two variable regions bind to two different targets. To achieve this in the full-length IgG format, two different heavy chain variable regions that can both use a common light chain are combined. In addition, modifications of the heavy chain Fc regions are engineered to drive the formation of full-length IgG that use two different heavy chains rather that two copies of the same heavy chain, which make a monospecific antibody.

In both conventional monoclonal antibodies (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. The Fc region can also be silenced to block interactions with the immune system.

Our Biclonics® and Triclonics® Platforms

Our two technology platforms use large-scale functional screening in molecular and cell-based assays to identify novel, innovative Biclonics® and Triclonics® with the specific characteristics desired for further development.

We believe our Biclonics® and Triclonics® platforms allow us to approach cancer treatment through multiple innovative modes of action:

- ***Blocking oncogenic growth factor signaling by disrupting the signaling pathways that drive tumor cell growth or resistance to monoclonal antibody therapy.*** This includes, for example tumor cell growth driven by NRG1 fusions interacting with the HER3 receptor. Hard-to-target receptors that may drive tumor growth or escape can be targeted by our Dock and Block® mechanism whereby the binding a tumor associated target prevalent on cancer cells facilitates a second domain to bind and block lesser expressed targets that are critical for cancer growth.

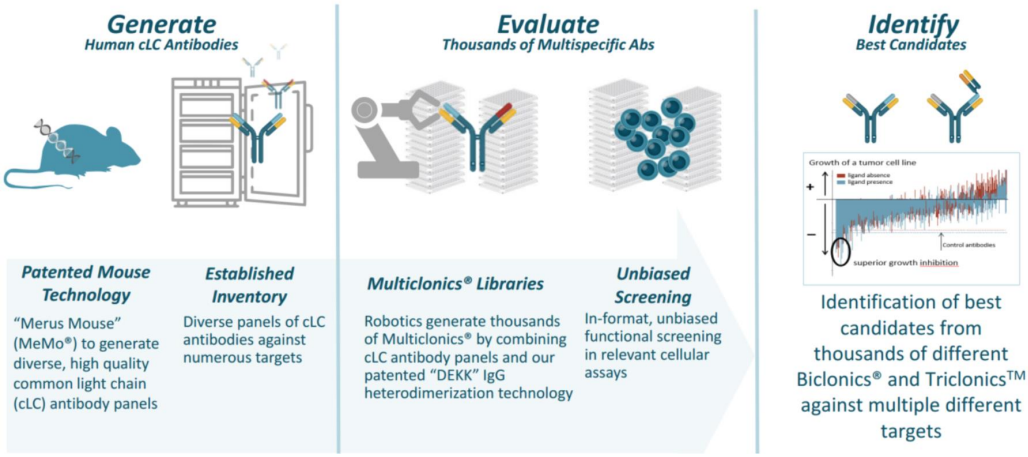
- ***Engaging an adaptive immune response by recruiting T-cells and/or modulating co-stimulation or checkpoint inhibition.*** We can produce multispecific antibodies that are designed to simultaneously bind to the T-cell antigen CD3 or other effector cell engaging antigens, and/or tumor-associated targets, for a potentially potent T cell or other effector cell recruitment and engagement to selectively kill tumor cells.

- ***Engaging the innate immune response through multiple mechanisms.*** We can produce enhanced ADCC modifications in the Fc region of our Biclonics® or Triclonics® designed to facilitate the recruitment of immune effector cells, such as natural killer cells, or NK cells, and macrophages, to directly kill tumor cells. Specific binding domains engineered in multispecific antibodies can directly bind to macrophages and monocytes; NK cells, each providing specific immune cell function to attack cancer cells.

- ***Employing combinations of the above mechanisms.*** Using our platforms, we can design antibodies to simultaneously target a growth factor receptor expressed by tumor cells and an immunomodulatory molecule involved in blocking and/or reactivating tumor-specific T cells. Biclonics® and Triclonics® can be designed to target growth factor receptors, like epidermal growth factor receptors (EGFR) and HER2 that are expressed on many tumors, while delivering an activation signal or checkpoint blockade to T cells.

Our process to select lead Biclonics® for clinical development 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® or Triclonics® directed against particular target combinations. We then test these collections in cell-based functional assays to identify multispecific antibodies that have the potential for novel and innovative modes of action. We select the most potent or efficacious 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:

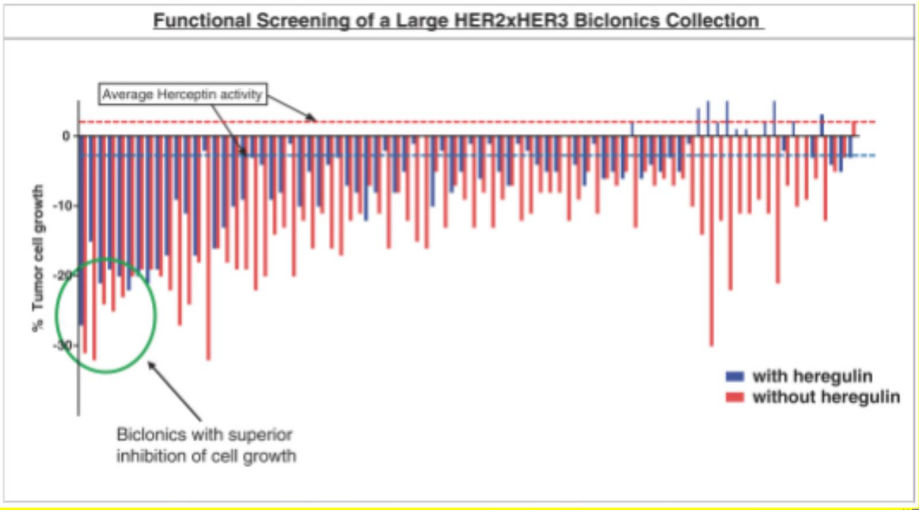
Human antibody generation. Our platform for generating human antibodies employs our patented transgenic murine technology, which we refer to as MeMo®, which harbors human heavy chain variable regions and a human common light chain in its germline. MeMo® harnesses the power of the *in vivo* immune system to yield human antibodies with the potential for high affinity, specificity, optimal biophysical characteristics and low immunogenicity. Upon immunization, MeMo® is capable of generating large and diverse panels of human common light chain antibodies against a broad variety of targets. These human common light chain antibodies are then used to generate large and diverse panels of Biclonics®, human multispecific antibodies capable of binding different targets of virtually any combination.

- ***Patented dimerization technology and the full-length Immunoglobulin G format.*** Our Biclonics® consist of two different heavy chains that need to stably form, or heterodimerize, inside a manufacturing cell line. Using our patented dimerization technology, we employ amino acid residues with opposite charges in the CH3 domains of these heavy chains to efficiently drive the formation of the heterodimer bispecific antibody rather than the homodimer antibody consisting of two copies of the same heavy chain. In addition, the use of a single, or common, light chain in our human Biclonics® antibodies ensures that each heavy chain pairs with the correct, common light chain to efficiently form the intended 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. In addition, the format is designed to retain 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. The resulting Biclonics® are bispecific heterodimeric IgG antibodies that are designed to 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 glycoengineered 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, zenocutuzumab, and other of our antibody candidates, MCLA-158 and MCLA-129. 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-145.

- ***High-throughput functional screening.*** We employ our patented Spleen to Screen® technology to rapidly screen panels of new target-specific heavy chains that form common light chain binding domains, or we employ our already established panels of common light chain antibodies. To date we have discovered over 10,000 unique common light chain antibodies directed at more than 40 different antigens, including tumor-associated antigens such as EGFR and cMET; T-cell binding, stimulating or co-stimulating proteins such as CD3 and CD137 (also called 4-1BB); and other immune-cell engaging antigens. For example, we have an established a panel of more than 175 unique and novel anti-CD3 common light chain antibodies from which to discover and develop the next generation of T-cell engaging bispecific and trispecific antibodies. We then generate DNA constructs that encode target-specific human antibodies and express them in mammalian cells. The common light chain format and proprietary dimerization modifications to the CH3 domain of the IgG promote the secretion of virtually pure Biclonics® into the cell culture medium. The medium of thousands of cell cultures that each express a different Biclonics® is harvested and individually used in high throughput molecular and cell-based functional assays to identify Biclonics® with specific novel characteristics for further development.

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 for cell growth inhibition of tumor cell samples in the presence or absence of the HER3 ligand NRG1. Forty of the Biclonics® depicted in the chart 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 zenocutuzumab.



Advantages of Biclonics®

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

- ***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 or modifications to force the correct pairing of heavy and light chain variable regions 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.

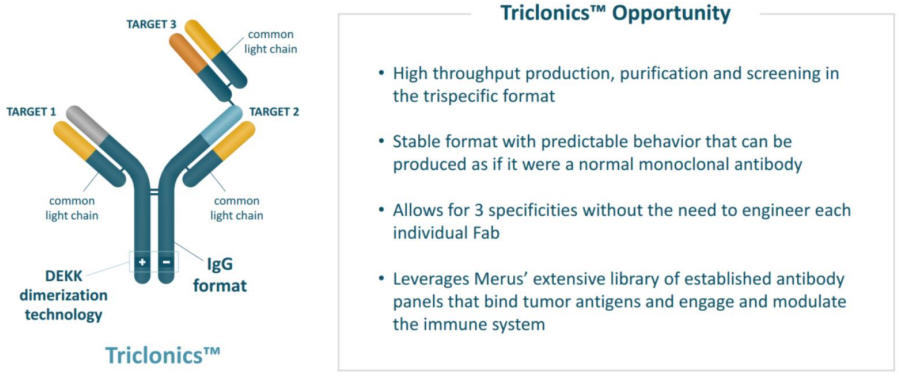
- ***Our Biclonics® technology platform allows for functional evaluation of Biclonics® in the relevant therapeutic format leading to the discovery of therapeutic candidates with novel and innovative properties.*** Our Biclonics® technology platform permits rapid functional screening of large collections 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 therapeutics, such as conventional mAbs as well as their combinations.

- ***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.

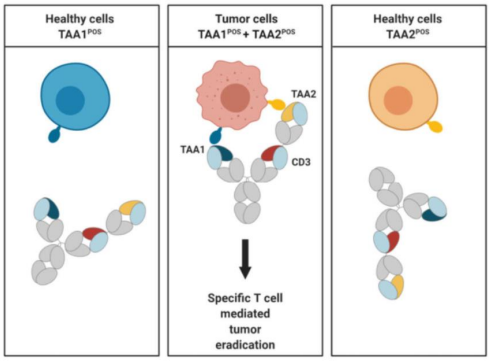
- ***Biclonics® can be reliably manufactured with high yields.*** Because our Biclonics® retain the IgG format of antibodies, our Biclonics® are manufactured using the large-scale industry-standard processes that are also used for the production of conventional mAbs, and the yields of Biclonics® we obtain 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 Biclonics®.

Our Triclonics® Platform

Our next generation proprietary Triclonics® technology is covered by existing Merus patents and other pending applications. This new format and the suite of technologies that underpin it permit the development of therapeutic candidates designed to bind three targets with a single multivalent molecule. In pre-clinical studies and modeling, Triclonics® have shown similar qualities of a natural IgG antibody, including favorable half-life, stability, low immunogenicity and favorable developability characteristics. We believe Triclonics® have the potential to produce tumor cell-killing activity and/or to modulate the immune system to promote more robust anti-tumor immune responses, and have the potential for less on-target off-tumor toxicity. This format allows us to leverage our proprietary genetically modified MeMo® mice, which as described above, harbors human heavy chain variable region gene segments and a human common light chain in its germline. MeMo® harnesses the power of the *in vivo* immune system to yield human antibodies with the potential for high affinity, specificity, optimal biophysical characteristics and low immunogenicity, which can be combined into a single trispecific antibody produced with relative high purity. The Triclonics® platform employs our proprietary technologies to produce large panels of substantially pure trispecific antibodies. In addition, we have engineered a panel of novel linkers that attach a third binding domain to the antibody. This panel of linkers vary in properties such as length and flexibility, and are empirically selected for stability and other drug-like properties, while remaining stable and are predicted to have low immunogenicity. The linker panel provides another lever of flexibility in optimizing functional characteristics in our high-throughput screening while maintaining high quality, stability and limiting risk of immunogenicity.



One application of the Triclonics® platform is as a T-cell engager for solid tumors. By binding to three targets, we can generate Triclonics® designed to specifically engage a combination of two tumor antigens for enhanced specificity, binding preferentially to tumor cells expressing both antigens, over normal tissues that may express either antigen, but not both or both at lower expression levels. In this construct, the third binding domain can for example engage an innate or adaptive immune effector cell protein, to stimulate killing of the tumor cell. We believe our Triclonics® platform will permit us to develop molecules with enhanced on target, on tumor specificity, while optimally engaging the immune system mechanisms.



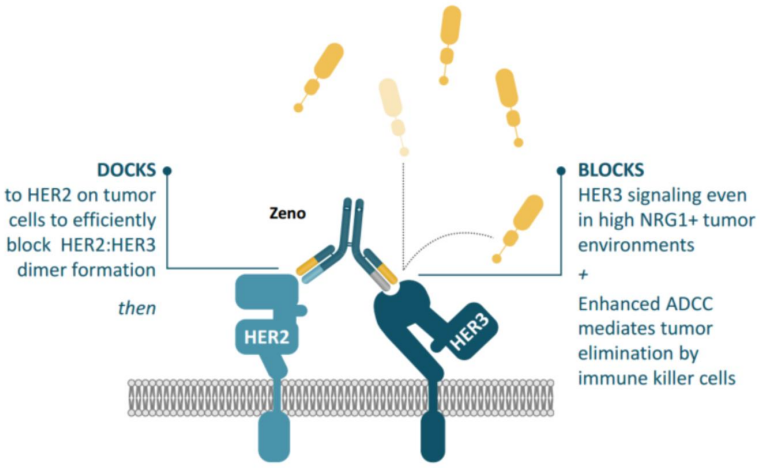
Our process to select lead Triclonics® leverages our patented MeMo® and Spleen to Screen® human antibody generation and heterodimerization technologies, along with our proprietary linkers based on natural structures to undertake high throughput unbiased functional screening of Triclonics®. With this approach, we have been able to evaluate up to 1,800 different trispecific antibodies targeting three different antigens to identify those unique combinations that pre-clinically have been observed to have desired characteristics for further development.

Our Bispecific and Trispecific Antibody Candidate Portfolio

We currently have four bispecific antibody candidates in clinical development, with additional bispecific and trispecific programs in pre-clinical development.

Zenocutuzumab (MCLA-128, HER3 x HER2 Biclonics®)

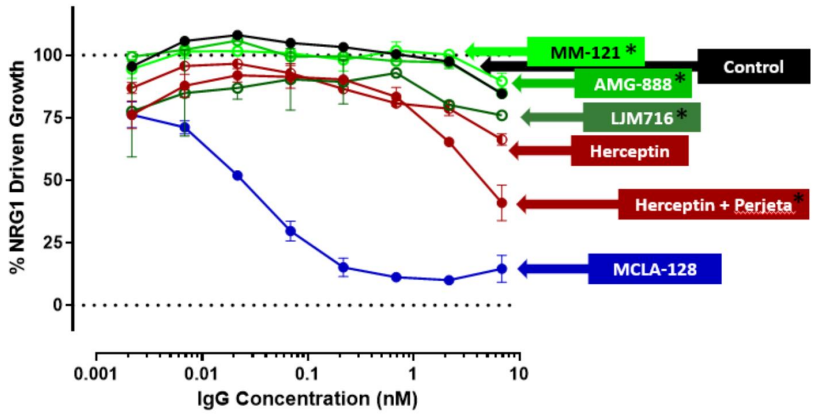
Zenocutuzumab is an antibody-dependent cell-mediated cytotoxicity (ADCC) -enhanced Biclonics® that utilizes Merus' Dock & Block® mechanism to bind to HER2, and bind to and disrupt the interaction between HER3 and ligand, NRG1, in solid tumors. HER2, or human epidermal growth factor receptor 2, is amplified in many solid tumors and is associated with poor prognosis, and the activation of HER3, or human epidermal growth factor receptor 3, is associated with tumor progression and treatment resistance. On the surface of tumor cells, HER2 pairs, or dimerizes, with HER3, and the resulting pair drives malignant progression of HER2-expressing cancer cells. NRG1, which is the ligand for HER3, causes cancer cells to grow and become resistant to treatment with HER2-targeted therapies. Zenocutuzumab is believed to target the HER3 signaling pathway by disrupting the interaction of Her3 with its ligand NRG1 and to overcome the resistance of tumor cells to HER2-targeted therapies using two mechanisms: blocking growth and survival pathways to stop tumor expansion and recruitment, and ADCC enhanced elimination of the tumor via effector cells. In addition, we have identified a rare, genetically defined patient population whose cancers harbor NRG1 fusions. The NRG1 gene encodes for neuregulin, the ligand for HER3. Fusions between NRG1 and other genes in the genome are rare genetic events occurring in lung, pancreatic and other solid tumors, and are associated with activation of HER2/HER3 signaling and growth of cancer cells. Overall estimates of the incidence of NRG1 fusions' occurrence are based on limited published information. Based on available literature, we estimate NRG1 fusions occur at a rate of approximately 0.3% – 3.0% in non-small cell lung cancer (NSCLC) 0.5% - 1.5% in pancreatic ductal adenocarcinoma (PDAC), and less than 1% in all other tumor types. Importantly, we believe NRG1 fusions occur more frequently in the invasive mucinous adenocarcinoma subtype of lung cancer, and in the subset of patients with PDAC lacking a mutation in the K-RAS gene. The NRG1 fusion is a powerful driver of cancer cell growth. We believe that pre-clinical studies and early clinical evaluation suggest zenocutuzumab (binding to HER2 and blocking NRG1 fusion protein interaction with HER3) has the potential to be particularly effective against tumors harboring NRG1 fusions.



Zeno blocks tumor cell growth and survival driven by HER3 ligands, including neuregulin (NRG-1) and NRG-1 gene fusions (NRG1+)

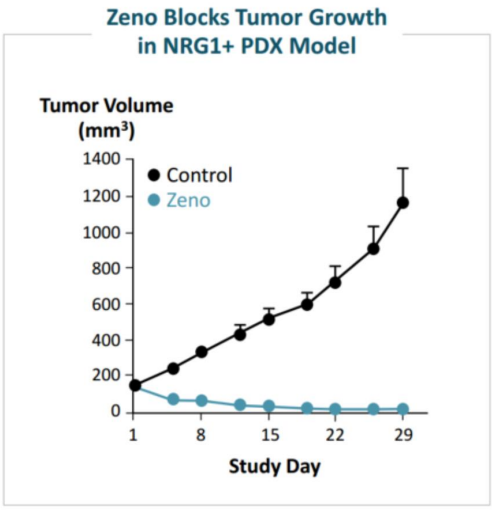
Development

In our pre-clinical studies, the administration of zenocutuzumab resulted in the inhibition of NRG-induced growth in cultures of cancer cells. Zenocutuzumab also blocked activation of two key signaling pathways for the growth and survival of tumor cells more than Herceptin (trastuzumab) or the combination of Herceptin and Perjeta (pertuzumab) (shown in red below) or experimental anti-HER3 mAbs (shown in green below). *See* Geuijen et al. Cancer Cell (2018).



* indicates analog antibodies.

In a patient-derived tumor xenograph mouse model (PDX model) zenocutuzumab significantly blocked tumor growth of a cancer containing an NRG1 gene fusion.



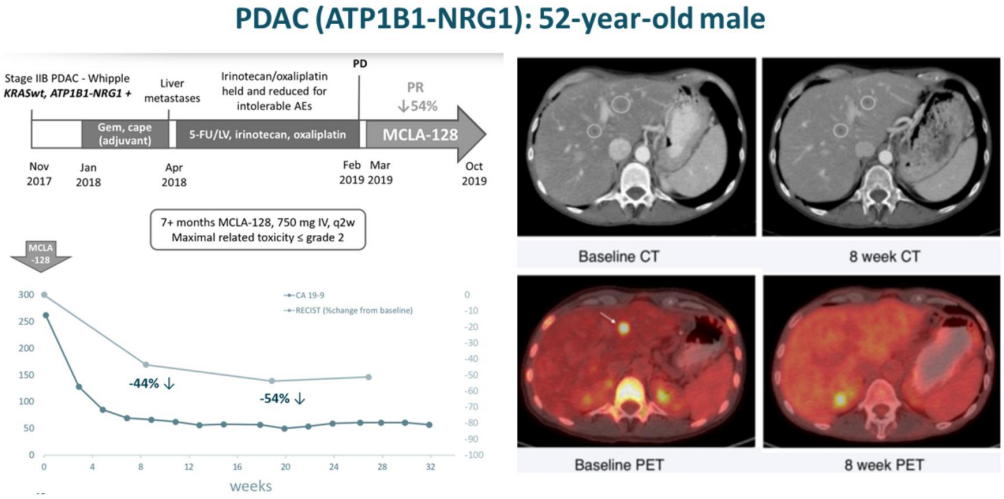
Based on encouraging pre-clinical results, we initiated a Phase 1/2 study of zenocutuzumab in solid tumors. As of January 2019, zenocutuzumab administered as a single-agent had been evaluated in 117 patients, who received the recommended Phase 2 doses. Zenocutuzumab was well-tolerated as a single agent, with low observed immunogenicity, and most reported adverse events (AEs) were mild to moderate. Also as of January 2019, the incidence of grade 3 and 4 AEs irrespective of causality was 37% and 3%, respectively, with the incidence of suspected drug-related grade 3 AEs of about 4%, no suspected drug-related grade 4 adverse events, and one patient experienced a grade 5 hypersensitivity reaction.

- **NRG1 Fusions**

In June 2019, we opened a zenocutuzumab EAP and amended the Phase 1/2 trial to focus on patients with solid tumors harboring an NRG1 fusion (the eNRGy trial). Patients treated under EAP and the protocol amendment receive zenocutuzumab at 750 mg administered intravenously every other week. As of October 27, 2019, nine patients identified with cancers harboring NRG1 fusions (three pancreatic ductal adenocarcinoma (PDAC) and six NSCLC) who had previously progressed through standard of care, had been enrolled and treated with zenocutuzumab across the EAP under single patient investigational new drug applications, and the eNRGy trial. Of the nine patients treated, six had at least one evaluation and thus were considered evaluable.

On October 27, 2019, investigators from the Memorial Sloan Kettering Cancer Center (MSKCC) provided an oral presentation at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics, in Boston, Massachusetts, entitled “Clinical proof-of-concept for zenocutuzumab, a bispecific HER2/3 antibody therapy, in NRG1 fusion-positive cancers”, reporting a summary and initial data concerning the treatment of three cancer patients harboring NRG1 fusions (NRG1+) with zenocutuzumab at 750 mg administered intravenously every other week. Assessments of these patients were conducted locally at MSKCC. All three patients, two having PDAC and one having NSCLC, exhibited tumor shrinkage, symptomatic improvement and durability up to the then most recent assessment. All three patients remained on treatment as of October 29, 2019.

Of the two patients having PDAC reported by MSKCC on October 27, 2019, one exhibited a 54% reduction in tumor diameter at a confirmatory 5 months scan (partial response (PR) by RECIST v1.1).



The other PDAC patient exhibited a 25% reduction in tumor diameter at a confirmatory 5 months scan (stable disease (SD) by RECIST v1.1). Both patients remained on treatment for over 7 months as of October 29, 2019.

The third patient reported by MSKCC on October 27, 2019 has NSCLC and exhibited a 41% reduction in tumor diameter at a confirmatory scan (PR by RECIST v1.1) and improvement in brain metastases. Prior to zenocutuzumab treatment the patient progressed on six lines of therapy, including the tyrosine kinase inhibitor afatinib. The patient remained on treatment for approximately 5 months as of October 29, 2019.

We also reported that as of October 29, 2019, we had previously treated six additional patients with NRG1+ cancers, one having PDAC and five having NSCLC. The one patient with PDAC, who was enrolled under a single patient IND outside of MSKCC, had received two treatments with zenocutuzumab, at a four-week non-standard interval due to the severity of the patient's illness, and was non-evaluable, passing away due to complications related to the underlying disease prior to a first tumor evaluation.

For the five of these additional six patients, each with NRG1+ NSCLC enrolled in the eNRGy clinical trial that received treatment with zenocutuzumab, one patient had SD for greater than 7 months but discontinued the trial due to poor adherence to the treatment protocol (unrelated to any AE or lack of efficacy); two patients had progressive disease and are no longer on the trial; and two patients as of October 29, 2019, had only recently started treatment and had not yet undergone initial assessment for tumor response.

We reported in October 2019 that the safety results observed for zenocutuzumab in patients with cancers harboring NRG1 gene fusions was observed to be well tolerated, consistent with what has been previously reported in the overall patient population treated with zenocutuzumab.

We are currently enrolling patients for the Phase 1/2 eNRGy trial to assess the anti-tumor activity of monotherapy zenocutuzumab in NRG1+ cancers. The eNRGy trial enrolls patients with NRG1+ pancreatic cancer, non-small cell lung cancer and other solid tumors. Enrolled patients will receive 750mg of zenocutuzumab every two weeks. We expect to present data at a medical conference in the second quarter of 2021. In January of 2021 the FDA granted Fast Track designation of zenocutuzumab for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy.

- **Her2 Amplified Metastatic Breast Cancer (mBC)**

In May 2020, we announced that we had completed enrollment of a Phase 2 trial of zenocutuzumab (zeno) in metastatic breast cancer, and would be presenting data at Annual Meeting of the American Society of Clinical Oncology ASCO20 Virtual Scientific Program. These data presented at that program showed that zeno in combination with trastuzumab and vinorelbine was active in heavily pretreated HER2+ metastatic breast cancer patients who have progressed on multiple lines of anti-HER2 therapies and that zeno was well tolerated. With a safety cut-off (sample size 28) of November 2019, and an efficacy data cut-off (sample size 39) of March 31, 2020, 39 patients were treated with the triplet combination – among the 39 patients, 12 were ongoing on study treatment, and the median numbers of prior therapies and prior anti-HER2 lines were 5 and 3, respectively. The most common severe adverse event (AE) reported with the triplet therapy was neutropenia considered related to vinorelbine, with few patients discontinuing due to AEs. As of March 31, 2020, anti-tumor activity was evaluated in 37 evaluable patients with locally confirmed Her2 amplification (3+ immunohistochemistry (IHC) or 2+ IHC confirmed by fluorescent in situ hybridization (FISH)) with a the clinical benefit rate (compete response (CR)+ partial response (PR)+ [stable disease (SD) at 24 weeks]) of 35.1% [90%CI 22.2-50.0], with one patent having a CR lasting 19.3 weeks, 6 patients having a PR (lasting from 5.3+ to 12.3 weeks), and 22 having SD (lasting from 5.9+ to 59.1+ weeks). As of the efficacy cut-off, among those with a best response of SD, 5 patients had an unconfirmed PR, 2 of which were

ongoing as of the presentation. Currently, certain patients remain on treatment in the Phase 2 trial. We plan to present data from the Phase 2 trial in a future medical conference when the studies are completed.

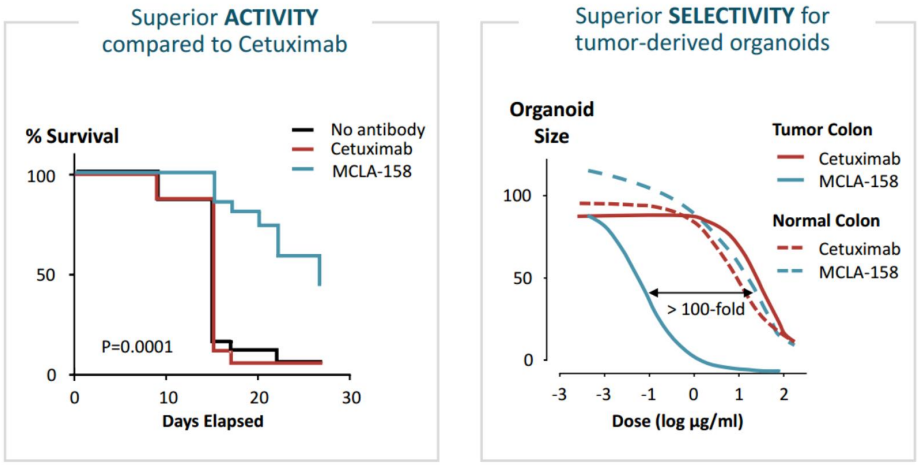
In October 2019, we previously disclosed that we plan to advance development in metastatic breast cancer only with a partner and intend to focus our efforts on the eNRGy trial of zeno in NRG1 fusion cancers.

MCLA-158 (Lgr5 x EGFR Biclonics®)

MCLA-158 is an investigational antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® for the potential treatment of solid tumors that is designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor receptor (EGFR). Lgr5 is a WNT target gene expressed in cancer cells with aberrations in the WNT signaling pathway, while EGFR is a member of the HER family of receptor tyrosine kinases and is important for growth and survival of cancer stem cells, including those with RAS mutations. MCLA-158 is designed to use two different mechanisms of action. The first is intended to block growth and survival pathways in cancer stem cells. The second involves the recruitment and enhancement of immune effector cells in an effort to directly kill cancer stem cells that persist in solid tumors and cause relapse and metastasis.

Development

In our pre-clinical studies, MCLA-158 demonstrated superior growth inhibition and selectivity versus the EGFR-targeting mAb, cetuximab. MCLA-158 was significantly more potent than cetuximab in inhibiting the growth of patient-derived colorectal cancer organoids. Additionally, MCLA-158 was 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. These ex-vivo observations of MCLA-158 with organoid models were further observed *in vivo* in xenograft models generated from the same patient-derived organoids.



- **Solid Tumors**

MCLA-158 is currently being evaluated in a Phase 1 open-label, multicenter study, currently in the expansion phase, in patients with solid tumors. The primary endpoint is safety and tolerability of the defined dose; secondary endpoints include single-agent preliminary anti-tumor activity. On January 15, 2021, we presented in a poster session interim clinical data from our Phase 1 dose escalation of MCLA-158 at the American Society of Clinical Oncology 2021 Gastrointestinal Cancers Symposium. As of a data cut-off of September 2020, MCLA-158 was administered to 33 patients over 11 dose levels (5-1500 mg, flat dose), a heavily pretreated population with a median of four lines of prior therapy. As of the cut-off date, MCLA-158 was observed to be well tolerated, and no dose limiting toxicities occurred. The recommended Phase 2 dose was established at 1500 mg administered intravenously once every two weeks. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues at this dose in the expansion phase of the open-label, multicenter trial, and preliminary evidence of antitumor activity has been observed.

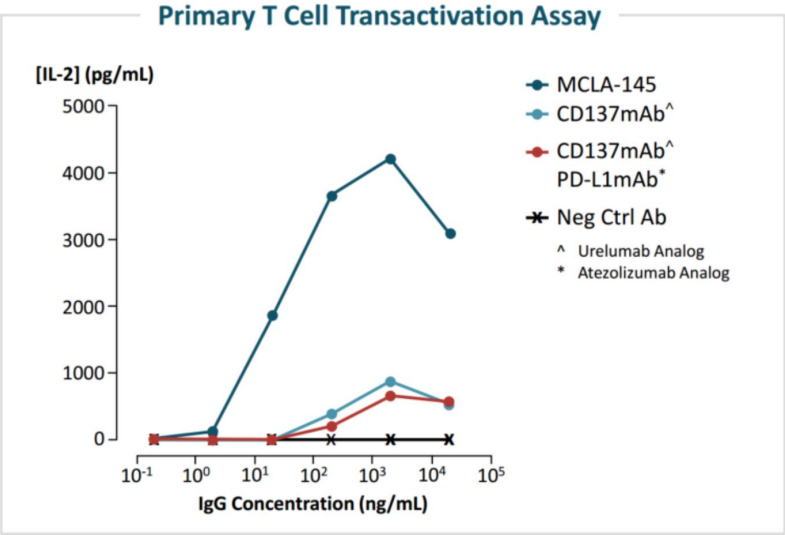
MCLA-145 (CD137 x PD-L1 Biclonics®)

MCLA-145 is a Biclonics® T-cell engager that binds to human programmed death-ligand 1 (PD-L1) and CD137. MCLA-145 is designed to recruit, activate and prevent the exhaustion of tumor-infiltrating T cells, and to cause a potent and durable T-cell activation in the tumor microenvironment. MCLA-145's binding to a cell is predicted to lead to clustering of CD137 on T cells when PD-L1 is expressed on adjacent cells, and block the T-cell inhibitory PD-1/PD-L1 interactions in the tumor. Because T-cell activation in our pre-clinical studies was shown to be context-dependent, requiring PD-L1 expression in the tumor microenvironment, we believe MCLA-145 has the potential to overcome the known side effects experienced with CD137 agonists that have been tested in the clinic

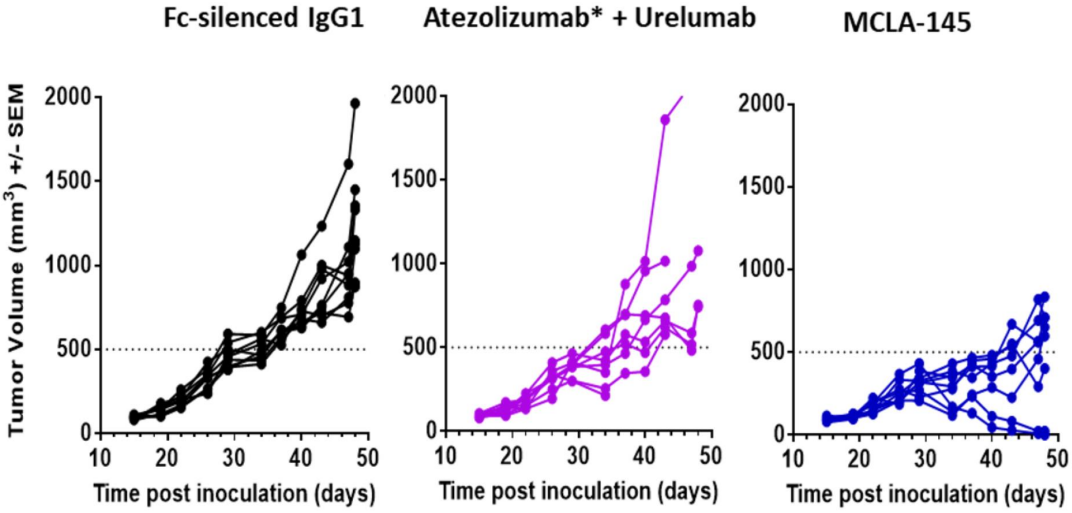
MCLA-145 is the first drug candidate co-developed under our global research and collaboration with Incyte Corporation (Incyte), which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. Under the terms of the collaboration, Merus retains all rights to develop and commercialize MCLA-145, if approved, in the United States, while Incyte has rights to develop and commercialize MCLA-145, if approved, outside the United States. We plan to present a clinical update on MCLA-145 at a major medical conference in the second half of 2021.

Development

In our pre-clinical studies, MCLA-145 showed binding to PD-L1 and CD137, recruitment of T cells into the tumor, blocking of inhibitory PD-1/PD-L1 axis and potent T-cell activation.



Further, MCLA-145 demonstrated superior tumor cell killing as compared to the administration of a combination of monospecific anti-PD-L1 and anti-CD137 antibodies in PDX models.



- **Solid Tumors**

In May 2019, we commenced a Phase 1 open-label, single-agent clinical trial of MCLA-145, consisting of dose escalation followed by dose expansion, for the potential treatment of patients with advanced solid tumors. The primary objectives of the Phase 1 trial are dose finding and evaluation of safety and tolerability in patients. The trial will also examine potential preliminary antitumor activity and functional target engagement of single-agent MCLA-145.

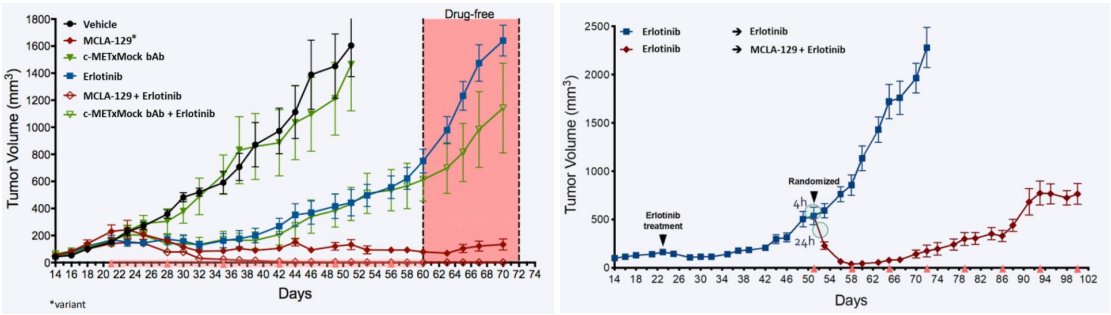
MCLA-129 (EGFR x c-MET Biclonics®)

MCLA-129 is an investigational Biclonics®, designed to bind EGFR and c-MET, for the potential treatment of solid tumors. EGFR is an important oncogenic driver in many cancers. The upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. MCLA-129 has two distinct mechanisms of action. First, MCLA-129 is designed to block the signaling of EGFR as well as c-MET, in an effort to inhibit tumor growth and survival. Second, MCLA-129 utilizes ADCC-enhancement technology, which is designed for greater cell-killing potential. Because both mechanisms of action are dependent on the co-expression of EGFR and c-MET, we believe MCLA-129 has the potential for less toxicity compared to agents targeting EGFR alone.

MCLA-129 is being developed in collaboration with Betta Pharmaceuticals Co. Ltd. (Betta). Under the terms of the collaboration, Betta is responsible for the clinical development and commercialization of MCLA-129, if approved, in China and we retain all rights to MCLA-129 outside of China. In January 2021, Betta announced that the Chinese National Medical Products Administration had accepted its IND for MCLA-129 injection. We have also announced we plan to dose the first patient in a clinical trial in the US in 2021.

Development

Pre-clinical data on MCLA-129 were presented in October 2019, at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. The poster, entitled “Pre-clinical evaluation of MCLA-129: a bispecific antibody targeting c-MET and EGFR,” showed that MCLA-129 inhibited and reversed resistance to tyrosine kinase resistant non-small cell lung cancer (NSCLC), cell lines resulting in tumor growth inhibition in xenograft models of NSCLC. In these xenograft models, MCLA-129 showed tumor shrinkage in mice whose tumors are resistant to the EGFR small molecule inhibitor erlotinib.



These pre-clinical data suggest MCLA-129, if successfully developed and approved, could benefit patients having NSCLC that become resistant to EGFR targeted therapies.

Pre-clinical Discovery Programs

We intend to further leverage our Biclonics® and Triclonics® technology platforms 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. Using our platform, we will continue to evaluate new targets and combinations to identify potential candidates with the highest therapeutic potential and select those candidates to be advanced into clinical trials.

Collaboration Agreements

As part of our business strategy, we collaborate with a range of partners, including pharmaceutical, biotechnology, and diagnostic companies as well as academic institutions. We intend to continue to seek collaborations and license agreements to develop and commercialize therapeutics in order to exploit the potential of our Biclonics® and Triclonics® platforms.

Incyte Corporation

We have entered into a collaboration and license agreement (Collaboration Agreement) with Incyte Corporation (Incyte). Under the terms of the Collaboration Agreement, we and Incyte have agreed to collaborate with respect to the research, discovery and development of monospecific or bispecific antibodies utilizing our proprietary Biclonics® technology platform. The collaboration encompasses up to 11 independent programs, including some of our current pre-clinical immuno-oncology discovery programs. For one of the current clinical programs, concerning MCLA-145, we retain the exclusive right to develop and commercialize the product candidate in the United States, while Incyte has the exclusive right to develop and commercialize the product candidate 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, if any, arising from one specified program, and subject to certain conditions, to a second specified program, in each case in exchange for a share of profits in the United States, as well as the right to participate in a specified proportion of detailing activities in the United States for one of such programs. 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, among other things, our Biclonics® 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.

Eli Lilly and Company (Eli Lilly)

In 2021, we entered into a collaboration and license agreement (the "Lilly Collaboration Agreement") and share subscription agreement (the "Lilly Subscription Agreement") with Eli Lilly and Company, an Indiana corporation ("Eli Lilly").

Under the terms of the Lilly Collaboration Agreement, we and Eli Lilly agreed to collaborate with respect to the discovery and research of bispecific antibodies utilizing our proprietary Biclonics® bispecific technology platform. The collaboration encompasses up to three (3) independent programs directed to the generation of T-cell re-directing bispecific antibodies that bind CD3 and a tumor associated antigen target selected by Eli Lilly ("Target") to be the subject of each such program.

We granted to Eli Lilly an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights and know-how to exploit certain compounds and products directed to designated Targets in combination with CD3, or directed to such designated Target(s) alone as a monospecific antibody or monospecific antibody drug conjugate, subject to rights granted by us to third parties under one or more existing third party agreements. We also retain all rights not granted to Eli Lilly.

Additionally, in the case of a change of control that may adversely impact certain rights and obligations of us and Eli Lilly under the Lilly Collaboration Agreement, (a) we have agreed to terminate or transfer its rights to third parties under certain research programs and (b) Eli Lilly has the option to take over certain of our research obligations.

Eli Lilly paid an upfront, non-refundable payment of $40 million for the rights granted under the Lilly Collaboration Agreement. Eli Lilly agreed to fund the research and development activities we conduct for each program under an agreed research plan and budget. With respect to each product arising from each program, we are eligible to receive up to $290 million in future contingent development and regulatory milestones and up to $250 million in commercial sales milestones, for a total of up to approximately $1.6 billion for a single product generated from all three programs. We are further eligible to receive, on a product-by-product and country-by-country basis, tiered royalties based on the level of worldwide aggregate annual net sales at percentages ranging from the mid-single digits to low double digits until the royalty term expires.

The Lilly Collaboration Agreement includes a three-year research term for us to perform research and development activities, subject to two extension terms of six months at Eli Lilly's discretion. The Lilly Collaboration Agreement will continue on a product-by-product basis until Eli Lilly has no royalty payment obligations with respect to such product or, if earlier, the termination of the Lilly Collaboration Agreement or any program in accordance with the terms of the Lilly Collaboration Agreement. The Lilly Collaboration Agreement may be terminated in its entirety or on a program-by-program basis at will by Eli Lilly. The Lilly Collaboration Agreement may also be terminated by either us or Eli Lilly under certain other circumstances, including material breach, as set forth in the Lilly Collaboration Agreement. If the Lilly Collaboration Agreement is terminated with respect to one or more programs, depending on the

stage of development, certain rights in the terminated programs revert to us, in accordance with the terms of the Lilly Collaboration Agreement.

Also in January 2021, in connection with entering into the Lilly Collaboration Agreement, pursuant to the Lilly Subscription Agreement, Eli Lilly agreed to purchase 706,834 common shares of the Company at a price per share of $28.295 for aggregate gross proceeds to us of approximately $20 million (the "Private Placement"). Eli Lilly agreed not to transfer, sell, or otherwise dispose of the shares purchased in the private placement for a period of time following the closing date, subject to certain customary exceptions.

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 €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved four of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €2.7 million in milestone payments. For products commercialized under this agreement, if any, we are also eligible to receive a mid-single digit royalty on net sales. For a designated period, which may include limited time periods following termination of this agreement, in certain circumstances we and our affiliates are prohibited from researching, developing or commercializing bispecific antibodies against the 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. We retain all rights to use and commercialize any antibodies directed to one target utilized under the collaborative research program, and any antibodies directed to the second target developed under the collaborative research program, excluding the up to five lead and/or selected antibodies against the second target ONO is pursuing, provided that the use and commercialization is not with respect to the particular target combination.

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 €57.0 million in milestone payments upon achievement of specified research and clinical development milestones. To date, we have achieved four of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €3.7 million in milestone payments. 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 (Simcere) granting Simcere an exclusive license to develop and commercialize in China up to three bispecific antibodies to be produced by Merus utilizing our proprietary Biclonics® technology platform. We retain all rights outside of China.

We have agreed to lead research and discovery activities while Simcere has agreed to be responsible for the IND-enabling studies, clinical development, regulatory filings and commercialization of these product candidates in China. Under the terms of the agreement, for a program achieving development candidate nomination, Simcere will retain a contract manufacturing organization with experience in filing IND applications with U.S. authorities and clinical trial agreements (CTAs) with European regulatory authorities in order to produce clinical trial materials. We received an upfront payment, and are eligible to receive milestone payments contingent upon Simcere achieving certain specified development and commercial goals. To date, we have achieved two undisclosed milestone payments under this agreement. We are eligible to receive tiered royalty payments on sales of any products resulting from the collaboration in China from Simcere. Simcere is eligible to receive tiered royalty payments on sales outside of China from us.

Betta Pharmaceuticals Co. Ltd.

On December 10, 2018, we entered into a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta) where we granted Betta an exclusive license to develop and commercialize in China MCLA-129, a Merus proprietary Biclonics® produced by our Biclonics® technology platform. We retain all rights outside of China. Under the terms of the agreement, Betta retained a contract manufacturing organization with experience in filing IND applications with U.S. authorities and CTAs with European regulatory authorities in order to produce clinical trial materials for the Chinese market and the rest of the world.

In addition to a non-refundable upfront payment, we and Betta will share equally the cost of the transfer of the manufacturing technology to a contract manufacturing organization. We are also eligible to receive milestone payments contingent upon Betta achieving certain specified development and commercial goals as well as tiered royalty payments of net sales of any products resulting from the collaboration in China. Betta is eligible to receive milestone payments contingent upon us achieving certain specified development and commercial goals, and is eligible to receive tiered royalty payments of net sales outside of China.

Manufacturing

Our 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 (CMOs) for the supply of current good manufacturing practice-grade (cGMP-grade) clinical trial materials and commercial quantities of our antibody candidates and products, if approved. We currently do not have any agreements for the commercial production of product candidates, but we have contracted several biopharmaceutical CMOs for the clinical manufacture of zenocutuzumab, MCLA-158, MCLA-145, and MCLA-129. 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 zenocutuzumab, MCLA-158, MCLA-145, MCLA-129 or any of our other antibody candidates because our antibody candidates are still in pre-clinical or early-to-middle-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, if any, for one of our antibody candidates.

Competition

We compete directly with companies that focus on 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 and new therapeutic candidates are clinically developed or approved therapies are explored for new indications. Any antibody candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future.

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

The key competitive factors affecting the success of all of our therapeutic 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 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, EpimAb Biotherapeutics, MacroGenics, Inc., NuMab Therapeutics, Elevation Oncology, Rain Therapeutics, Hummingbird Bioscience, Regeneron Pharmaceuticals, Inc. and Xencor, Inc. The 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 antibody candidates for which we obtain marketing approval.

Intellectual Property

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

As of January 31, 2021:

- Our patent portfolio related to our bispecific antibody candidate zenocutuzumab consists of one application filed under the Patent Cooperation Treaty (PCT) application, filed on February 27, 2015 with two issued patents in Europe and applications pending in the United States, Europe and 16 other foreign jurisdictions with an expected expiry not earlier than February, 2035. Claims are directed to the zenocutuzumab composition of matter and methods of using zenocutuzumab 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 applications covering further methods of using zenocutuzumab, including in combination therapies to treat patients, concerning methods of treating patients with cancer harbor NRG1 gene fusions, three of which were filed on April 3, 2018, and one filed on May 17, 2018. Three of these four PCT patent applications entered national phases in the United States, Europe and 17 other foreign jurisdictions. One of these four PCT patent applications entered national phases in the United States, Europe and four other foreign jurisdictions.
- Our patent portfolio related to our CD3 technology consists of a first PCT application, filed on July 8, 2016, with issued patents in the United States and Europe and applications pending in the United States, Europe and 13 foreign jurisdictions with an expected expiry not earlier than July 2036. A second PCT application was filed on March 27, 2020, as well as in two foreign jurisdictions with an expected expiry not earlier than March, 2040. Claims are related to the anti-CD3 binding domains, antibodies, their use, among other subject matter.
- Our patent portfolio related to our bispecific antibody candidate MCLA-158 consists of one PCT filed on October 21, 2016, with two issued patents in foreign jurisdictions and applications pending in the United States, Europe and 14 other foreign jurisdictions with an expiry no earlier than October, 2036. Claims are directed to the MCLA-158 composition of matter and methods of using MCLA-158 in the treatment or prevention of various solid tumors.
- Our patent portfolio related our bispecific antibody candidate MCLA-145 consists of one PCT filed on September 22, 2017, with application pending in the United States, Europe and 19 other foreign jurisdictions with an expiry no earlier than September 2037. Claims are directed to the MCLA-145 composition of matter and methods of using MCLA-145 in the treatment or prevention of various solid tumors.
- Our patent portfolio related our bispecific antibody candidate MCLA-129 consists of one PCT filed on August 9, 2018, with applications pending in the United States, Europe and 19 other foreign jurisdictions with an expiry of no earlier than August 2038. Claims are directed to the MCLA-129 composition of matter and methods of using MCLA-129 in the treatment or prevention of various solid tumors.
- Our patent portfolio related to our MeMo® transgenic animal consists of four issued U.S. patents, nine pending U.S. applications, two issued European patents that have been validated in many countries, and four pending European applications, 16 issued foreign patents and 15 pending foreign applications, all with an expected expiry not earlier than June

2029. Claims are directed to a common light chain animal and methods of producing hybridomas, host cells, and antibodies relating to the use of a common light chain and by exposing the animal to an antigen.

- Our patent portfolio related to our Spleen to Screen® technology consists of three issued U.S. patents, one pending U.S. application, one issued European Patent, which was revoked in opposition and currently subject to appeal before the Technical Board of Appeals, one pending European application and three issued foreign patents, with three foreign pending applications, all with an expected expiry not earlier than September 2032.
- Our patent portfolio related to recombinant production of mixtures of antibodies includes claims directed to host cells generating multispecific antibodies and consists of five issued U.S. patents, and three pending U.S. applications, two issued European patents, 16 issued foreign patents, and four pending foreign applications, all with an expected expiry not earlier than July, 2023.
- Our patent portfolio related to efficient dimerization of heavy chains promoting efficient production of Biclonics® and mixtures of antibodies, methods and host cells for recombinant production thereof, and consists of two PCT applications filed on April 19, 2013, which resulted in seven issued U.S. patents, one pending U.S. application, two issued European patents, 2 pending European applications, 25 issued foreign patents, and twenty-one pending foreign applications, all with an expected expiry not earlier than April, 2033.
- Our patent portfolio related to our trispecific antibody technology consists of one PCT application, filed on March 29, 2019, with pending applications in the United States, Europe, and 19 foreign jurisdictions, having with an expiry no earlier than March 2039. Claims are directed to a multivalent antibody format, including the Triclonics® format.

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, our next generation Triclonics® 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® and Triclonics® technology platforms used to generate them, related technologies and/or other aspects of the inventions that are important to our business, including our MeMo® mouse, Spleen to Screen® technology, and recombinant host cells capable of producing our antibody candidates, methods of purification, and heterodimerization, among other proprietary technology. We also rely on trademarks, trade secrets and careful monitoring of our proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

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

Our success will depend on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain our licenses to use intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing valid and enforceable patents and other proprietary rights of third parties. For important factors related to our proprietary technology, inventions, improvements, platforms and 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 antibody candidates to be regulated as biologics. Biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Public Health Service Act (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 (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 (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 Biologics License Application (BLA) 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 (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 antibody candidate in humans, the 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 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, 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 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 (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 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 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 antibody candidate has been associated with unexpected serious harm to patients.

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

Concurrent with clinical trials, companies usually complete additional animal trials and must also develop additional information about the physical characteristics of the biological 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 biological 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 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 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 (PREA) a BLA or supplement to a BLA must contain data to assess the safety and effectiveness of the biological 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 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 (PDUFA), as amended, each BLA must be accompanied by a user fee. The FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions are available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on BLAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any BLA that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the BLA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the BLA. The FDA reviews the BLA to determine, among other things, whether the proposed product is safe, pure and potent, and whether the product is being manufactured in accordance with cGMP requirements to assure and preserve the product's identity, safety, strength, quality, potency and purity. The FDA may refer applications for novel biological products or biological products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions. During the biological product approval process, the FDA also will determine whether a Risk Evaluation and Mitigation Strategy (REMS) is necessary to assure the safe use of the biological 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. 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 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. With regard to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Any product is eligible for priority review if it is intended to treat a serious disease or condition, if approved, would provide a significant improvement in safety or effectiveness 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. Biological products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required

post-market clinical trials or if such trials fail to verify the predicted clinical benefit. 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.

In addition, under the provisions of the Food and Drug Administration Safety and Innovation Act (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 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 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 antibody candidates, the FDA may later decide that our 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. Manufacturers of approved biologics 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.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 (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.

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 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 (PMA) approval. We expect that any companion diagnostic developed for use with our antibody candidates may 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 antibody candidates, a companion diagnostic device and its corresponding drug or biologic candidate may be required to be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product labeling, although the FDA may decide that it is appropriate to approve a therapeutic product even though a companion diagnostic device is not approved or cleared contemporaneously. In general, the FDA expects that a companion diagnostic that is intended for use with the therapeutic product will be later approved or cleared through an appropriate submission and the therapeutic product labeling will be revised to stipulate the use of the companion diagnostic. 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 (IDE) regulations. Thus, the sponsor of the diagnostic device will be required to comply with the IDE regulations. According to the guidance, if a diagnostic device and a drug are to be studied together to support their respective approvals, both products can be studied in the same investigational study, if the study meets both the requirements of the IDE regulations and the IND regulations. The guidance provides that depending on the details of the study plan and subjects, a sponsor may seek to submit an IND alone, or both an IND and an IDE. In July 2016, the FDA issued a draft guidance document intended to further assist sponsors of therapeutic products and sponsors of *in vitro* companion diagnostic devices on issues related to co-development of these products, and in December 2018, the FDA issued a draft guidance describing considerations for the development and labeling of *in vitro* companion diagnostic devices to support the indicated uses of multiple drug or biological oncology products.

The FDA generally requires companion diagnostics intended to select the patients who will respond to cancer treatment to obtain approval of a PMA for that diagnostic contemporaneously with approval of the therapeutic. The review of these *in vitro* companion diagnostics in conjunction with the review of a cancer therapeutic involves coordination of review by the FDA's Center for Biologics Evaluation and Research and by the FDA's Center for Devices and Radiological Health. The PMA process, including the gathering of clinical and pre-clinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and

labeling. PMA applications are subject to an application fee. In addition, PMAs for certain devices must generally include the results from extensive pre-clinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, the applicant must demonstrate that the diagnostic produces reproducible results when the same sample is tested multiple times by multiple users at multiple laboratories. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation (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 is 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 trials 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. In addition, ethical, social and legal concerns about gene-editing technology, gene therapy, genetic testing and genetic research could result in additional regulations restricting or prohibiting the processes we may use.

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. The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. 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.

Clinical Trials

Certain countries outside of the United States have a similar process that requires the submission of a clinical trial application (CTA) much like the IND prior to the commencement of human clinical trials. In the European Economic Area (EEA) (which is comprised of the 27 Member States of the European Union plus Norway, Iceland and Liechtenstein), 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 by the national health authority and the Ethics Committee has granted a positive opinion in relation to the conduct of the trial in the relevant Member State(s), in accordance with a country's requirements, clinical trial development may proceed.

Clinical trials of medicinal products in the European Union must be conducted in accordance with European Union and national regulations and the International Conference on Harmonization (ICH), guidelines on Good Clinical Practices (GCP) as well as the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Prior to commencing a clinical trial, the sponsor must obtain a CTA from the Competent Authority, and a positive opinion from an independent Ethics Committee. The CTA must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation.

Currently, CTAs must be submitted to the Competent Authority in each EU Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which is currently expected to take effect by early 2022, there will be a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the CTA must be notified to or approved by the relevant Competent Authorities and Ethics Committees. Medicines used in clinical trials must be manufactured in accordance with Good Manufacturing Practices (GMP). Other national and European Union-wide regulatory requirements may also apply.

During the development of a medicinal product, the European Medicines Agency (EMA) and national regulators provide the opportunity for dialogue and guidance on the development program. At the EMA level, this is usually done in the form of scientific advice, which is given by the Scientific Advice Working Party of the Committee for Medicinal Products for Human Use (CHMP). A fee is incurred with each scientific advice procedure. Advice from the EMA is typically provided based on questions concerning, for example, quality (chemistry, manufacturing and controls testing), nonclinical testing and clinical trials, and pharmacovigilance plans and risk-management programs. Advice is not legally binding with regard to any future marketing authorization application of the product concerned.

Marketing Authorizations

In the EEA, medicinal products can only be placed on the market after obtaining a Marketing Authorization (MA). To obtain regulatory approval of an investigational biological product in the EEA, we must submit a marketing authorization application (MAA). The application used to file the BLA in the United States is similar to that required in the EEA, with the exception of, among other things, country-specific document requirements. The European Union also provides opportunities for market exclusivity. The process for doing this depends, among other things, on the nature of the medicinal product.

The centralized procedure results in a single MA, issued by the European Commission, based on the opinion of the Committee for Medicinal Products for Human Use, or CHMP, of the EMA which is valid across the entire territory of the EEA. The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) designated orphan medicines and (iv) advanced-therapy medicines, such as gene therapy, somatic cell therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used in certain other cases.

Under the centralized procedure, the maximum timeframe for the evaluation of a MAA by the EMA is 210 days. This excludes so-called clock stops, during which additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. At the end of the review period, the CHMP provides an opinion to the European Commission. If this opinion is favorable, the Commission may then adopt a decision to grant an MA.

MAs have an initial duration of five years. After these five years, the authorization may be renewed on the basis of a reevaluation of the risk-benefit balance. Once renewed, the MA is valid for an unlimited period unless the European Commission or the national Competent Authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

In exceptional cases, the CHMP might perform an accelerated review of an MAA in no more than 150 days (not including clock stops). Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIME scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicines that target unmet medical needs. It is based on increased interaction and early dialogue with companies developing promising medicines, to optimize their product development plans and speed up their evaluation to help them reach patients earlier. Product developers that benefit from PRIME designation can expect to be eligible for accelerated assessment but this is however not guaranteed. The benefits of a PRIME designation includes the appointment of a rapporteur from the CHMP before submission of an MAA, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review earlier in the application process.

Data and Marketing Exclusivity

The EEA 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. The overall ten-year market exclusivity period may be extended to a maximum of eleven years if, during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved. If granted, data exclusivity prevents regulatory authorities in the EEA from referencing the innovator's data to assess a generic or biosimilar application. During the additional two-year period of market exclusivity, a generic or biosimilar marketing authorization can be submitted, and the innovator's data may be referenced, but no generic or biosimilar product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the EEA's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EEA are similar in principle to those in the United States. 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. Orphan medicinal products are eligible for financial incentives such as reduction of fees or fee waivers. During this period, the EMA cannot accept another application for a MA, or grant a MA or accept an application to extend an existing MA for the same indication, in respect of a similar medicinal product. An orphan medicinal product can also obtain an additional two years of market exclusivity in the EEA for pediatric studies. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. The application for orphan drug designation must be submitted before the MAA. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA 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.

Post-Approval Requirements

Similar to the United States, both marketing authorization holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the Member States. The holder of a MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports, or PSURs.

All new MAAs must include a risk management plan (RMP) describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the marketing authorization. Such risk-minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

The advertising and promotion of medicinal products is also subject to laws concerning promotion of medicinal products, interactions with physicians, misleading and comparative advertising and unfair commercial practices. All advertising and promotional activities for the product must be consistent with the approved summary of product characteristics, and therefore all off-label promotion is prohibited. Direct-to-consumer advertising of prescription medicines is also prohibited in the EEA. Although general requirements for advertising and promotion of medicinal products are established under EU directives, the details are governed by regulations in each Member State and can differ from one country to another.

Failure to comply with EU and Member State laws that apply to the conduct of clinical trials, manufacturing approval, marketing authorization of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the marketing authorization, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Approval and Regulation of Companion Diagnostics

In the EEA, *in vitro* diagnostic medical devices are regulated by Directive 98/79/EC which regulates the placing on the market, the CE-marking, the essential requirements, the conformity assessment procedures, the registration obligations for manufactures and devices as well as the vigilance procedure. *In vitro* diagnostic medical devices must comply with the requirements provided for in the Directive, and with further requirements implemented at national level (as the case may be).

Companion diagnostics can also be considered “combination products” which are governed by a different regulatory pathway depending on the mode of action of the products. A combination medicine/device product could either be regulated as a medicinal product or a medical device based on its primary mode of action. In principle, if a medical device incorporates a substance which, if used separately, is likely to be considered as a medicinal product and act on the human body by an action ancillary to that of the device, the device must be evaluated and authorized in accordance with the medical device regulations. However, if the medicinal substance constitutes the main function of the product then the product is considered as a medicinal product. Currently, for such combination products, the manufacturer will have to consult, prior to obtaining the CE marking of the device, the EMA or national Competent Authorities to obtain scientific advice on the quality and safety of the medicinal substance, including the benefit/risk profile of its incorporation into the device.

The regulation of companion diagnostics will be subject to further requirements as of the entry into force of the *in-vitro* diagnostic devices Regulation (No 2017/746) which introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue a CE certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national Competent Authorities or the EMA.

With respect to the United Kingdom, the transition period, during which EU pharmaceutical laws continued to apply to the United Kingdom, has expired on December 31, 2020. However, the EU and the United Kingdom have concluded a trade and cooperation agreement, or TCA, which is provisionally applicable since January 1, 2021.

The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of Good Manufacturing Practice, or GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of UK and EU pharmaceutical regulations.

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, 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 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 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. In addition, 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. 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 (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, 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 (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by physicians, as defined by statute, 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. 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 are not currently a covered manufacturer under the ACA, but may become one if successful in obtaining approval of one of our antibody candidates.

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 (HITECH) and their respective implementing regulations, impose specified requirements relating to the privacy, security and transmission of individually identifiable health information held by covered entities and their business associates. Among other things, HITECH made HIPAA's security standards directly applicable to "business associates," defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions. In addition, state laws govern the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same requirements, thus complicating compliance efforts. By way of example, California enacted the California Consumer Privacy Act (CCPA) effective January 1, 2020, which gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Additionally, the California Privacy Rights Act (CPRA), recently passed in California. The CPRA significantly amends the CCPA, and imposes additional data protection obligations on covered companies doing business in California, including additional consumer rights processes and opt outs for certain uses of sensitive data. It also creates a new California data protection agency specifically tasked to enforce the law, which would likely result in increased regulatory scrutiny of California businesses in the areas of data protection and security. The substantive requirements for businesses subject to the CPRA will go into effect on January 1, 2023, and become enforceable on July 1, 2023.

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

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

Privacy and Data Protection Laws in Europe

We are subject to European laws relating to our and our suppliers', collaborators' and subcontractors' (where they act as processors) collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, and where we process personal data in the context of the activities of that establishment (e.g., undertaking clinical trials). We and our suppliers, collaborators and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation (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 (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, may require the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a sufficiently large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with certain service providers.

In addition, to the extent a company processes, controls or otherwise uses "special category" personal data (including patients' health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. The GDPR provides a broad right for EU and EEA 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 EEA 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. From January 1, 2021, we are subject to the GDPR and also the United Kingdom (UK) GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. Currently there is a four to six-month grace period agreed in the EU and UK Trade and Cooperation Agreement, ending 30 June 2021 at the latest, whilst the parties discuss an adequacy decision. Further, recent legal developments in Europe have created complexity and compliance uncertainty regarding certain transfers of personal data from the EEA. For example, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield) under which personal data could be transferred from the EEA to United States entities who had self-certified under the Privacy Shield scheme. It is uncertain whether the standard contractual clauses will also be invalidated by the European courts or legislature.

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 up to 4% of total worldwide annual turnover of the preceding financial year. Additionally, following the United Kingdom's withdrawal from the EEA and the EU, and the expiry of the transition period, companies have to comply with the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of €20 million (£17.5 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.

Recent legal developments in Europe have created complexity and uncertainty regarding transfers of personal data from the EEA to the United States. Most recently, on July 16, 2020, the Court of Justice of the European Union (CJEU) invalidated the EU-US Privacy Shield Framework (Privacy Shield), under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the standard contractual clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer.

These recent developments may require us to review and amend the legal mechanisms by which we make and/ or receive personal data transfers to/ in the U.S. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results.

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. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. 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 EEA, 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. Member States are free to restrict the range of pharmaceutical products for which their national health insurance systems provide reimbursement, and to control the prices and reimbursement levels of pharmaceutical products for human use. 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. Member States may approve a specific price or level of reimbursement for the pharmaceutical product, or alternatively adopt a system of direct or indirect

controls on the profitability of the company responsible for placing the pharmaceutical product on the market, including volume-based arrangements, caps and reference pricing mechanisms. 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.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit affirmed the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal or replace the ACA will impact the law.

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

Additionally, on August 2, 2011, the Budget Control Act of 2011 was enacted, which, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 January 31, 2021, we had 93 full-time employees and 48 part-time employees, including 60 employees with M.D. or Ph.D. degrees. Of these employees, 93 were primarily engaged in research and development activities and 48 were primarily engaged in general and administrative activities. None of our employees are represented by a labor union, and we consider our employee relations to be good.

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. Information contained on, or that can be accessed through, our website does not constitute a part of this Annual Report on Form 10-K. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Available Information

We file electronically with the SEC our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, proxy statements and other information. Our SEC filings are available to the public over the Internet at the SEC's website at http://www.sec.gov. We make available on our website at www.merus.nl, under “Investors & Media,” free of charge, copies of these reports as soon as reasonably practicable after filing or furnishing these reports with the SEC.

Item 1A. Risk Factors.

RISK FACTORS

Risks Related to Our Business and Industry

Investing in our common stock involves a high degree of risk. You should consider carefully the risks described below, together with the other information included or incorporated by reference in this Annual Report on Form 10-K. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline. Other events that we do not currently anticipate or that we currently deem immaterial may also affect our business, prospects, financial condition and results of operations.

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 oncology company with a limited operating history. We have incurred net losses of $85.5 million, and $55.2 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated loss of $400.1 million. Our losses have resulted principally from expenses incurred in research and development of our 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 antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing, single agent, Phase 1/2 eNRGy clinical trial of zenocutuzumab, our most advanced bispecific antibody candidate, for the treatment of solid tumors harboring neuregulin 1 (NRG1) gene fusions and conclude our ongoing Phase 2 clinical trial for the treatment of metastatic breast cancer in combination with other therapies;
- conclude our ongoing dose-escalation portion of our Phase 1 clinical trial of MCLA-117, our bispecific antibody candidate, for the treatment of acute myeloid leukemia (AML);
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors and B-cell lymphomas, which is being co-developed with Incyte Corporation (Incyte);
- commence our Phase 1 clinical trial for MCLA-129 in collaboration with Betta Pharmaceuticals Co. Ltd. (Betta);
- continue the research and development of our other pre-clinical antibody candidates;
- expand our clinical programs to explore new potential combination therapies or indications;
- expand and enhance our technology platforms, including our Biclonics® technology platform which generates our pipeline of bispecific product candidates, our Triclonics® technology platform, which generates pre-clinical trispecific candidates and generate and develop additional multispecific antibody candidates;
- seek regulatory approvals for any antibody candidates that successfully complete clinical trials;
- potentially establish a sales, marketing and distribution infrastructure and scale-up manufacturing capabilities to commercialize any products for which we may obtain regulatory approvals;
- maintain, expand and protect our intellectual property portfolio;
- secure, maintain and/or obtain freedom to operate for our technologies and products;
- add clinical, scientific, operational, financial, information technology and management information systems and personnel, including personnel to support our product development and potential future commercialization efforts and to support our operation as a public company; and
- experience any delays or encounter any issues with any of the above, including but not limited to failed studies, complex results, manufacturing challenges, safety issues or other regulatory challenges.

We have financed our operations primarily through public offerings and private placements of our common shares and our collaboration and license agreement with Incyte and Eli Lilly. We have devoted a significant portion of our financial resources and efforts to developing our full-length bispecific antibody therapeutics, which we refer to as Biclonics®, our technology platforms, identifying potential antibody candidates, conducting pre-clinical studies of a variety of candidates, and conducting our clinical trials of zenocutuzumab, MCLA-158, and MCLA-145, concluding MCLA-117 and expected commencement of a clinical trial of MCLA-

129. We are in the early stages of development of our antibody candidates, and we have not completed development of any Biclonics® or any other drugs or biologics.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our bispecific antibody candidates, discovering and developing additional bispecific and trispecific antibody candidates, obtaining regulatory approval for any 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 (FDA), or the European Medicines Agency (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 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 could 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 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 zenocutuzumab, MCLA-158, and MCLA-145, conclude our trial of MCLA-117, commence our clinical trial for MCLA-129 and continue to research, develop and conduct pre-clinical studies of our other antibody candidates. In addition, if we obtain regulatory approval for any of our 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. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms.

Based on our current operating plan, we expect that our existing cash, cash equivalents and investments as of December 31, 2020 will be sufficient to fund our operations into at least the second half of 2024. 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 zenocutuzumab and the Phase 1 clinical trials of MCLA-117, MCLA-158, and MCLA-145;
- the success of our collaboration with Incyte to develop monospecific and bispecific antibodies candidates, including our ongoing Phase 1 clinical trial for MCLA-145;
- the cost, progress and results of our anticipated clinical trial for MCLA-129;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other bispecific and multi-specific 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 to the extent any receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any potential future claims by third parties that we are alleged to be 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 antibody candidates to the extent any 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 existing collaborations and any other future licensing or collaboration arrangements for any of our antibody candidates.

We depend heavily on the success of our antibody candidates, and we cannot give any assurance that any of our antibody candidates will receive regulatory approval, which is necessary before they can be commercialized. If we, any of our collaborators, or any other strategic partners we may enter into collaboration agreements with for the development and commercialization of our antibody candidates, are unable to commercialize our 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 and in development of multi-specific antibody candidates using our Triclonics® 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 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 and pre-clinical trispecific 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 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 antibody candidates. The success of our antibody candidates will depend on several factors, including the following:

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

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

The Biclonics® technology platform and Triclonics® technology platform are unproven, novel approaches to the production of molecules for therapeutic intervention.

We have not received regulatory approval for a therapeutic based on a full-length human bispecific or trispecific IgG approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Biclonics® and Triclonics® 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® and

Triclonics® therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our antibody candidates.

Our Biclonics® and Triclonics® technology platforms rely 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 antibody 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 antibody candidates we are developing. Through collaborations or license agreements, 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 antibody candidates, if approved. Companion diagnostics are subject to regulation by the FDA, and comparable foreign regulatory authorities as medical devices and typically require separate regulatory approval (or clearance, or certification) prior to commercialization. If needed, we intend to develop companion diagnostics in collaboration with or via license agreements 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 (or clearance, or certification) 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 (or clearance, or certification) of companion diagnostics could delay or prevent approval of our 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 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 antibody candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our 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 zenocutuzumab, MCLA-117, MCLA-158, MCLA-145, MCLA-129 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, generating and enhancing our Biclonics® technology platform, generating our Triclonics® technology platform, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for zenocutuzumab, MCLA-158, and MCLA-145, concluding the MCLA-117 trial and anticipate commencing a clinical trial for MCLA-129, we have not successfully completed any clinical trials for any 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 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 existing collaborations 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, our existing shareholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing shareholders' rights as holders 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 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 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. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. 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 antibody candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

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

- economic weakness, including inflation, or political instability, in particular, in non-U.S. economies and markets;
- differing regulatory requirements for drug approvals in non-U.S. countries;
- differing jurisdictions could present different issues for securing, maintaining and/or obtaining freedom to operate in such jurisdictions;
- potentially reduced protection for intellectual property rights;
- difficulties in compliance with non-U.S. laws and regulations;
- changes in non-U.S. regulations and customs, tariffs and trade barriers;
- changes in non-U.S. currency exchange rates of the euro and currency controls;
- changes in a specific country's or region's political or economic environment;
- trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or non-U.S. governments;
- differing reimbursement regimes and price controls in certain non-U.S. markets;
- negative consequences from changes in tax laws;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- compliance with international privacy regulations, including the General Data Protection Regulation (GDPR);
- negative consequences from the United Kingdom's withdrawal from the EU, and its potential impact on supply-chain and our personnel;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- difficulties associated with staffing and managing international operations, including differing labor relations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war, riots and terrorism, or natural disasters including earthquakes, typhoons, floods, fires, epidemics or public health emergencies and U.S. or non-U.S. governmental actions or restrictions related thereto.

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, import and export requirements, competition, 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 (FCPA) in the United States, the Bribery Act in the United Kingdom and the anti-corruption provisions of the Dutch Criminal Code in the Netherlands. Our failure to comply with anti-corruption laws applicable to us could result in penalties, which could harm our reputation and harm our business, financial condition, results of operations, cash flows or prospects. The FCPA generally prohibits companies and their intermediaries from making improper payments to foreign officials for the purpose of improperly or corruptly obtaining or keeping business, obtaining preferential treatment and/or other undue benefits or advantages. The FCPA also requires public companies to maintain accurate books and records and devise a system of sufficient internal accounting controls. We regularly review and update our policies and procedures and internal controls designed to provide reasonable assurance that we, our employees, distributors and other intermediaries comply with the anti-corruption laws to which we are subject. However, there are inherent limitations to the effectiveness of any policies, procedures and internal controls, including the possibility of human error and the circumvention or overriding of the policies, procedures and internal controls. There can be no assurance that such policies or procedures or internal controls will work effectively at all times or protect us against liability under these or other laws for actions taken by our employees, distributors and other intermediaries with respect to our business.

The Securities and Exchange Commission (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.

The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions and financial markets, which could materially affect our financial condition and results of operations.

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU on January 31, 2020 and entered into a transition period. On December 24, 2020, the United Kingdom and the EU announced that they had agreed to the terms of their future trading relationship in the EU—UK Trade and Cooperation Agreement ("TCA"), which became binding on both the EU and the United Kingdom on January 1, 2021, and awaits the final agreement of the remaining 27 EU Member States. While agreement on the terms of the TCA has avoided a "no deal" Brexit scenario, and provides in principle for quota- and tariff-free trading of goods, it is nevertheless expected that the TCA will result in the creation of non-tariff barriers (such as increased shipping and regulatory costs and complexities) to the trade in goods between the United Kingdom and the EU. Further, the TCA does not provide for the continued free movement of services between the UK and the EU and imposes additional restrictions on the free movement of people between the UK and the EU. The TCA includes provisions affecting pharmaceutical businesses (including on customs and tariffs). In addition, there are some specific provisions concerning pharmaceuticals. These include the mutual recognition of Good Manufacturing Practice (GMP) inspections of manufacturing facilities for medicinal products and GMP documents issued. The TCA does not, however, contain wholesale mutual recognition of UK and EU pharmaceutical regulations and product standards. Significant political and economic uncertainty remains about how much the relationship between the United Kingdom and EU will differ as a result of the United Kingdom's withdrawal.

The United Kingdom's withdrawal from the EU and the associated uncertainty has had and may continue to have a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Asset valuations, currency exchange rates and credit ratings may be especially subject to increased market volatility. Any of these factors could have a significant adverse effect on our business, financial condition, results of operations and prospects.

Further, the United Kingdom's withdrawal from the EU has resulted in the relocation of the EMA from the United Kingdom to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the U.K. Medicines and Healthcare products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of products in the EU and/or the United Kingdom.

The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations.

In December 2019, a strain of novel coronavirus causing the COVID-19 disease was reported to have surfaced in Wuhan, China. Since then, COVID-19 has spread throughout the world, including the Netherlands and the United States. In March 2020, the World Health Organization (WHO) characterized COVID-19 as a pandemic. To date, the COVID-19 pandemic has interfered with the normal function of businesses worldwide, including in the form of travel restrictions, shelter-in-place orders and quarantines, office and school closures, bans on public gatherings and employees being encouraged or required to work from home pursuant to guidance provided by national, state and local officials including the U.S. Center for Disease Control and Prevention (CDC) and European local health agencies, including the Dutch National Institute for Health and Environment or Het Rijksinstituut voor Volksgezondheid en Milieu (RIVM). For example, most of our employees located in the Netherlands restricted from traveling to the U.S., where certain of our collaborators and employees are located, which could have an adverse impact on our ability to conduct our business. Similarly, employees located in the U.S. are restricted from travel to the Netherlands under current guidelines. Additionally, on March 18, 2020, we temporarily suspended our laboratory research activities at our facilities in Utrecht, the Netherlands to help secure the safety of our employees and to adhere to government recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We have since re-opened our offices and laboratory in Utrecht, maintaining social distancing and imposing other requirements consistent with government guidance. Further, we have recommended our employees in the Netherlands and employees of our subsidiary Merus US, Inc., in the U.S. work from home when possible. For those employees working at our offices and laboratory in Utrecht, and offices of our subsidiary in Cambridge Ma., they are required to maintain social distancing and follow requirements consistent with the guidance provided by the CDC, Federal, state and local regulations for the U.S. and RIVM for the Netherlands. While we use reasonable business practices to mitigate the risk of exposure to COVID-19 while on Company-operated premises, we cannot guarantee that traveling to and from and visiting the office will not expose employees to infectious agents or eliminate inherent risks to our workforce and our business operations resulting from COVID-19. Given the uncertainty caused by the COVID-19 pandemic we cannot be certain that we will not suspend our laboratory research activities at our facilities or suspend use of our offices in the future.

As a result of the COVID-19 pandemic, certain of our contract research organizations (CROs) and third-party suppliers, as well as collaborators in the U.S. and China that are developing or collaborating with us to develop certain of our pre-clinical and clinical-stage antibody candidates have been affected. As a result of such impact, we may face difficulties with and delays in performance of certain chemistry manufacturing and controls associated with our clinical candidates, including as it relates to sourcing materials required for such manufacture that may be diverted for other purposes associated with COVID-19, or difficulties or delays associated with testing of our pre-clinical antibody candidates associated with our collaborations with Incyte, Eli Lilly and Simcere, which may delay or prevent their potential clinical development. Additionally, our collaborators, CROs and third-party suppliers may in the future experience closures and labor shortages, which may delay or prevent our development of our antibody candidates, including zenocutuzumab, MCLA-158 and MCLA-145 and MCLA-129. Moreover, although our collaborators based in China and elsewhere have resumed operations, we may experience labor shortages associated with these chemistry manufacturing and controls, or pre-clinical development activities due to the current restrictions on travel and work globally, which may force us to reduce related workflows until such work and travel restrictions are lifted. Also, there can be no assurances that the applicable governments will not renew or extend these closures.

With respect to our clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials and source verification of clinical data required for presentation of clinical data for zenocutuzumab, MCLA-158 and MCLA-145, and anticipated commencement of the clinical trial for MCLA-129. To date, we have observed a moderate to high impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic, particularly at sites in countries not yet open to recruitment, and to a lesser extent in countries where COVID-19 related restrictions have been eased, with adjustments made to allow remote visits for some patient follow-up, and reduced onsite monitoring by the sponsor or CRO and insufficient source verification of clinical data required for presentation of clinical data. The extent of the impact to our overall clinical development timeline is uncertain at this time and we

continue to monitor this impact on a regular basis. As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will contract COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;
- interruption of key clinical trial activities, operations, source data verification, and other clinical trial activities such as clinical trial site patient visits, patient and data monitoring, due to limitations on travel imposed or recommended by national, state or local governments, employers and others or interruption of clinical trial subject visits and study procedures (such as endoscopies that are deemed non-essential), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or EMA or comparable foreign regulatory authorities, which may impact approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns, global shipping delays or stoppages and disruptions in delivery systems;
- limitations on employee resources that would otherwise be focused on the conduct of our preclinical studies and clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- refusal of the FDA or EMA or comparable foreign regulatory authorities to accept data from clinical trials in affected geographies;
- interruption or delays in our collaborations, including with Incyte, Eli Lilly, Betta Pharma, Simcere, and our license agreements with Ono and our academic collaborators, which may experience laboratory closures causing delays in preclinical, translational and development studies that support our clinical programs and IND-enabling studies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

In addition, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common shares and any such sales may be on unfavorable terms. The COVID-19 outbreak continues to rapidly evolve. The extent to which the outbreak further impacts our business, including our preclinical studies and clinical trials, results of operations and financial condition will depend on future developments which are highly uncertain and cannot be predicted with confidence. Such factors include but are not limited to the spread of the disease, the duration of the outbreak, travel restrictions, quarantines, shelter-in-place orders and social distancing in the United States, the Netherlands and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States, the Netherlands and other countries to contain and treat the disease.

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

All of our 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 antibody candidates, particularly zenocutuzumab, MCLA-158, or MCLA-145, which we are developing with Incyte, are prolonged or delayed, we or any collaborators may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our antibody candidates on a timely basis or at all.

To obtain the requisite regulatory approvals to market and sell any of our antibody candidates, we or any collaborator for such candidates must demonstrate through extensive pre-clinical studies and clinical trials that such candidates are safe, pure and potent 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 antibody candidates may not be predictive of the results of later-stage clinical trials. 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 antibody candidates. Although we are conducting ongoing clinical trials for zenocutuzumab, MCLA-158, and MCLA-145, concluding our work on the Phase I clinical trial of MCLA-117, and anticipating commencement of the Phase I clinical trial of MCLA-129 and pre-clinical studies for other antibody candidates, we may experience delays in our ongoing clinical trials and we do not know whether planned clinical trials will begin on time, need to be redesigned, enroll patients on time or be completed on schedule, if at all. Clinical trials can be delayed, suspended, or terminated for a variety of reasons, including the following:

- delays in or failure to reach agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in or failure to recruit suitable patients to participate in a trial;
- delays in or failure to establish the appropriate dose and schedule for antibody candidates in clinical trials;
- the difficulty 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;
- investigator-sponsored studies of our product candidates, including expanded access protocols, may identify safety or efficacy concerns associated with our antibody candidates, or otherwise negatively affect patient enrollment in our ongoing and planned clinical trials;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or regulatory authorities, as applicable, to suspend or terminate a trial if we or our collaborators or regulatory authorities, find that the participants are being exposed to unacceptable health risks;
- failure to observe a meaningful clinical benefit;
- delays in or failure to obtain regulatory approval or authorizations to commence a trial;
- delays in or failure to obtain institutional review board (IRB) or Ethics Committee approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or applicable law, or to meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of antibody candidate for use in clinical trials;
- the quality or stability of an antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our antibody candidates no longer relevant;
- third party actions claiming infringement by our 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, epidemics or public health emergencies and U.S. or non-U.S. governmental actions or restrictions related thereto.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, reporting on or completing our planned and ongoing clinical trials. 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 27 EU Member States plus Iceland, Liechtenstein, Norway and the UK) 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 antibody candidates, the commercial prospects of our antibody candidates will be harmed, and our ability to generate product revenues from any of these antibody candidates, if approved, will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our 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 antibody candidates and impair our ability to commercialize our antibody candidates, if approved, 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 antibody candidates.

Clinical trials must be conducted in accordance with the FDA, EU, EEA Member States, and other applicable regulatory authorities' legal requirements, other 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 antibody candidates produced under current good manufacturing practice (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 (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 EEA 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-EEA and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EEA Competent Authorities, and different standards of diagnosis, screening and medical care.

Interim, preliminary, and "top-line" data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim, preliminary or "top-line" data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. Further, as a result of the COVID-19 or for other reasons, we may not be able to collect accurate or complete data at the time we collect such preliminary data, including as a result of the inability of sites to properly record data due to staffing limitations or the inability of patients to visit sites at scheduled times, the inability of CROs to access site data or for other reasons. In addition, we may report interim or preliminary analyses of only certain endpoints rather than all endpoints. As a result, top-line data should be viewed with caution until the final data are available.

Furthermore, the information we choose to publicly disclose regarding a particular study or clinical trial is based on more extensive information, and others may not agree with what we determine is the material or otherwise appropriate information to disclose. Any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities, or otherwise regarding a particular antibody candidate or our business. Others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions, or analyses or may interpret or weigh the importance of data differently, which could impact the value of particular programs, the approvability or commercialization of the particular antibody candidates, and our business in general. As a result, interim, preliminary or top-line data and analyses should be viewed with caution. Adverse differences between preliminary, top-line or interim data and final data or changes in what is material information regarding the results from a particular study or clinical trial could significantly harm our clinical development and business prospects and cause volatility in the price of our common shares. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Our 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 antibody candidates or following approval, if any, we may need to abandon our development of such 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 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 antibody candidate, zenocutuzumab, for the treatment of various solid tumors, which was amended to treat patients having solid tumors harboring a NRG1 gene fusion. Additionally, in January 2018 we commenced a Phase 2 clinical trial in Europe and the United States exploring zenocutuzumab, in combination with other agents, in patients with metastatic breast cancer. To date, patients treated with zenocutuzumab 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 including fever, cytokine release syndrome and chills. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors. To date, patients treated with MCLA-158 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions and skin rash associated with mAb EGFR inhibitors. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 developed in collaboration with Incyte. To date, patients treated with MCLA-145 have experienced adverse events irrespective of causality including blood alkaline phosphatase increase, anemia, and hypoalbuminemia, lymphocyte count decrease, and white blood cell count decrease. Febrile neutropenia and elevated liver enzymes have been reported as serious adverse events.

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 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 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 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 antibody candidate, if approved, 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 antibody candidates, if approved.

We depend on enrollment of patients in our clinical trials for our 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 our Phase 1/2 clinical trial of zenocutuzumab in solid tumors, we are enrolling up to 90 patients with tumors harboring NRG1 gene fusions. Solid tumors with NRG1 gene fusions occur infrequently, which could result in slow enrollment of clinical trial participants. In the Phase 1 clinical trial of MCLA-117, we announced in May 2020 we will not continue enrollment into the planned dose expansion cohorts in the trial, but plan to complete enrollment in the dose escalation phase. In the Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors or B-cell lymphoma. 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 also compete with other clinical trials for antibody candidates that are in the same therapeutic areas as our 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 antibody candidates will increase our costs, slow down our antibody candidate development and approval process, delay or potentially jeopardize our ability to commence product sales and generate revenue and harm our reputation and ability to obtain financing. In addition, some of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our antibody candidates.

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

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

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

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

Fast Track designation by the FDA for zenocutuzumab or potential future Fast Track designation of our other antibody candidates may not actually lead to a faster development or regulatory review or approval process.

We have been granted a Fast Track designation for zenocutuzumab in the United States for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy, and we may seek additional Fast Track designations for zenocutuzumab or for our other antibody candidates. The Fast Track program is intended to expedite or facilitate the process for reviewing therapeutic candidates that meet certain criteria. Specifically, new biologics are eligible for Fast Track designation if they are intended, alone or in combination with one or more drugs or biologics, 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 candidate and the specific indication for which it is being studied. With a Fast Track antibody candidate, the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

Obtaining a Fast Track designation does not change the standards for product approval, but may expedite the development or approval process. Even though the FDA has granted such designation for zenocutuzumab for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy, it may not actually result in faster clinical development or regulatory review or approval. Furthermore, such a designation does not increase the likelihood that zenocutuzumab or any other antibody candidate that may be granted Fast Track designation will receive marketing approval in the United States.

Even if our 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 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.

Any regulatory approvals that we may receive for our antibody candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a Risk Evaluation and Mitigation Strategy in order to approve our antibody candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our antibody candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates 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 on-going compliance with cGMPs, and GCPs for any clinical trials that we conduct following approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards.

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that

product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

We may not be successful in our efforts to use and expand our Biclonics® technology platform to build a pipeline of antibody candidates or to use our Triclonics® technology platform to build a pipeline of trispecific antibody candidates.

A key element of our strategy is to use and expand our Biclonics® 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 antibody candidates directed at various cancers, we may not be able to develop antibody candidates that are safe and effective.

Another important element of our strategy is to develop, use and exploit our Triclonics® technology platform to build a pipeline of trispecific antibody candidates and collaborate with third parties in potentially researching and developing these trispecific antibody candidates through pre-clinical and clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in proof of concept pre-clinical candidates, we may not be able to develop or monetize these trispecific antibody candidates or demonstrate in the clinic that they are safe and effective. Even if we are successful in continuing to build our bispecific and trispecific pipelines, 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 our bispecific antibody candidates or if we do not successfully develop, collaborate, license or begin to commercialize our trispecific 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 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 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, if any, 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 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, 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 antibody 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 antibody candidates or misread trends in the biopharmaceutical industry, in particular for our lead 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 importation, storage, 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, animal byproducts, genetically modified organisms, carcinogenic compounds, mutagenic compounds and compounds that have a toxic effect on reproduction, laboratory procedures and exposure to blood-borne pathogens. If we fail to comply with such laws and regulations, we could be subject to fines or other sanctions.

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

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

We are exposed to the risk that our employees, independent contractors, principal investigators, CROs, consultants, vendors and collaborators may engage in fraudulent conduct or other illegal activities. Misconduct by these parties could include intentional, reckless and/or negligent conduct or unauthorized activities that violate: (i) the regulations of the FDA, the EMA and other regulatory authorities, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards; (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; or (iv) laws that require the reporting of true, complete and accurate financial information and data. Specifically, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws could also involve the improper use or misrepresentation of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. Additionally, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. federal healthcare programs, individual imprisonment, other sanctions, contractual

damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

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

Certain laws and regulations require us to test our 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 Antibody Candidates

Enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our antibody candidates and may affect the prices we may set. The successful commercialization of our 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 (collectively the ACA) was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the ACA, those of greatest importance to the pharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, which is apportioned among these entities according to their market share in certain government healthcare programs;
- a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer’s outpatient drugs to be covered under Medicare Part D;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer’s Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;
- expansion of the entities eligible for discounts under the Public Health Service pharmaceutical pricing program;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services (CMS) to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (TCJA), includes a provision repealing, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case, although it is unclear when or how the Supreme Court will rule. It is also unclear how other efforts, if any, to challenge, repeal, or replace the ACA will impact the ACA or our business.

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 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 future customers and accordingly, our financial operations.

Moreover, payment methodologies, including payment for companion diagnostics, may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS began bundling the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting and, beginning in 2018, CMS began paying for clinical laboratory services based on a weighted average of reported prices that private payors, Medicare Advantage plans, and Medicaid Managed Care plans pay for laboratory services. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 21st Century Cures Act 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 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 any future 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 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 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, the 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 the 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. 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 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.

If we are required by the FDA or similar authorities to obtain approval (or clearance, or certification) of a companion diagnostic test in connection with approval of any of our antibody candidates, and we do not obtain or face delays in obtaining approval (or clearance, or certification) of a diagnostic device, we will not be able to commercialize such product candidate and our ability to generate revenue will be materially impaired.

If safe and effective use of any of our antibody candidates depends on an diagnostic that is not otherwise commercially available, then the FDA may require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves our antibody candidates, if at all. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared for that indication. If a satisfactory companion diagnostic is not commercially available, we may be required to develop or obtain one that would be subject to regulatory approval requirements. The process of obtaining or creating such diagnostics is time consuming and costly.

Companion diagnostics are developed in conjunction with clinical programs for the associated product and are subject to regulation as medical devices by the FDA and comparable regulatory authorities, and, to date, the FDA has generally required premarket approval of companion diagnostics labeled for use with cancer therapies. The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express the specific genetic alteration that the companion diagnostic was developed to detect.

If the FDA or a comparable regulatory authority requires approval (or clearance, or certification) of a companion diagnostic for any of our antibody candidates, whether before or after such candidate obtains marketing approval, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for such antibody candidate. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval (or clearance, or certification) of a companion diagnostic could delay or prevent approval or continued marketing of such antibody candidate.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process for the companion diagnostic or in transferring that process to commercial partners or negotiating insurance reimbursement plans, all of which may prevent us from completing our clinical trials or commercializing our product candidate, if approved, on a timely or profitable basis, if at all.

Approval, clearance or certification of companion diagnostics may be subject to further legislative or regulatory reforms notably in the EU. On May 25, 2017, the new In Vitro Medical Devices Regulation (2017/746 or "IVDR") entered into force. The IVDR repeals and replaces the EU In Vitro Diagnostic Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA Member States, regulations are directly applicable, i.e., without the need for adoption of EEA Member States laws implementing them, in all EEA Member States and are intended to eliminate current differences in the regulation of medical devices among EEA Member States. The IVDR, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation. The IVDR will, however, only become applicable in May 2022.

The regulation of companion diagnostics will be subject to further requirements as of the entry into force of the *in-vitro* diagnostic devices Regulation (No 2017/746) which introduces a new classification system for companion diagnostics which are now specifically defined as diagnostic tests that support the safe and effective use of a specific medicinal product, by identifying patients that are suitable or unsuitable for treatment. Companion diagnostics will have to undergo a conformity assessment by a notified body. Before it can issue a CE certificate, the notified body must seek a scientific opinion from the EMA on the suitability of the companion diagnostic to the medicinal product concerned if the medicinal product falls exclusively within the scope of the centralized procedure for the authorization of medicines, or the medicinal product is already authorized through the centralized procedure, or a marketing authorization application for the medicinal product has been submitted through the centralized procedure. For other substances, the notified body can seek the opinion from a national competent authorities or the EMA. These modifications may make it more difficult and costly for us to obtain regulatory clearances or approvals for our companion diagnostics or to manufacture, market or distribute our products after clearance or approval is obtained.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days

beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

Although we do not currently have any products on the market, if we obtain FDA approval for any of our 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 our 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 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 (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;
- the U.S. federal Food, Drug and Cosmetic Act (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), certain other health care professionals beginning in 2022, 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; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, and that require the tracking and reporting of gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

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

We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us or our collaborators, from research institutions, and 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 HIPAA, as amended by HITECH. 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. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. As such, we, our collaborators, research institutions, health care providers and other entities that provide personally identifiable information to us may be subject to state information security laws, and 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.

The United States and global data protection landscape is rapidly evolving, and we may be affected by or subject to new or amended laws and regulations in the future. For example, California recently enacted legislation, the California Consumer Privacy Act (CCPA) which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the CPRA was also recently voted into law by California residents. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of

the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

Our and our collaborators' clinical trial programs and research collaborations outside the U.S. may implicate international data protection laws, including, in Europe, the GDPR and local laws further implementing or supplementing the GDPR. The GDPR implements more stringent operational requirements for processors and controllers of personal data including requirements for such companies to be able to ensure and be able to demonstrate compliance with the GDPR. If our or our collaborators' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to €20 million 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. Further, following the withdrawal of the United Kingdom from the EU on January 31, 2020, we have to comply with the GDPR and separately the GDPR as implemented in the United Kingdom, with *each* regime having the ability to fine up to the greater of €20 million/ £17 million or 4% of global turnover. The relationship between the United Kingdom and the EU in relation to certain aspects of data protection law remains unclear, including how data transfers between EU member states and the United Kingdom will be treated. These changes may lead to additional compliance costs and could increase our overall risk.

We are also subject to EU/national laws on personal data export, as we may transfer personal data from the EU/EEA 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. In addition, in July 2020, the CJEU invalidated the Privacy Shield, under which personal data could be transferred from the EEA to US entities who had self-certified under the Privacy Shield scheme. While the CJEU upheld the adequacy of the standard contractual clauses (a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism, and potential alternative to the Privacy Shield), it made clear that reliance on them alone may not necessarily be sufficient in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. As supervisory authorities issue further guidance on personal data export mechanisms, including circumstances where the standard contractual clauses cannot be used, and/or start taking enforcement action, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, it could affect the manner in which we provide our services, the geographical location or segregation of our relevant systems and operations, and could adversely affect our financial results. We employ model clauses which remain valid according to the recent CJEU decision, but the changes and uncertainty in this area of law could require us to make operational changes and could increase costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner among jurisdictions in which we operate. 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 regardless of merit and 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.

Claims that we or any collaborators fail to comply with applicable federal, state, or local, legal or regulatory requirements, could subject us to a range of regulatory actions that could affect our or any collaborators' ability to seek to commercialize our antibody candidates, if approved. 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 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 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 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 antibody candidates or our technology obsolete, less competitive or uneconomical. Our competitors may, among other things:

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

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

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

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

If we fail to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our products, or lose such designation for zenocutuzumab in the United States, 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, 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 EU to justify investment; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of such condition authorized for marketing in the EU, or if such a method exists, the product will be of significant benefit to those affected by the condition. During this period, the EMA cannot accept another application for a MA, or grant a MA or accept an application to extend an existing MA for the same indication, in respect of a similar medicinal product. The application for orphan drug designation must be submitted before the MAA. The applicant will receive a fee reduction for the MAA if the orphan drug designation has been granted, but not if the designation is still pending at the time the MA is submitted. Orphan drug 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 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 have obtained orphan drug designation from the FDA for zenocutuzumab for the treatment of patients with pancreatic cancer and potentially may seek that or a similar designation from the EMA for zenocutuzumab, and we may seek such designation from the FDA and EMA for other clinical assets, where supported by data in the appropriate indications that meet the criteria for orphan status. Even though we obtained orphan designation in the United States for zenocutuzumab and may obtain such designation for other antibody

candidates 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 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 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 antibody candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaborators to invest in the development of our 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 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 antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our 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 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 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 any future 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 antibody candidates, if approved. 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 antibody candidates, if approved. 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 antibody candidates, if approved. We expect to experience pricing pressures in connection with the sale of any of our antibody candidates that are approved 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.

In addition, even if a pharmaceutical product obtains a marketing authorization in the EU, there can be no assurance that reimbursement for such product will be secured on a timely basis or at all.

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 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 antibody candidates that are approved 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.

Failure of our antibody candidates, if approved, to gain market acceptance 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, we will not be successful in commercializing our antibody candidates.

We currently have no marketing, sales and distribution capabilities because all of our antibody candidates are still in clinical or pre-clinical development. If any of our antibody candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our 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 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 any approved 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 an 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 an antibody candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for our antibody candidates, if approved, which we may license to others, we will rely on the assistance and guidance of those collaborators. For 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. We may rely on outside consultants to provide advice on commercialization strategies, which may fail to deliver or provide effective guidance to maximize any commercial opportunity, if any, that may arise from our antibody candidates.

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

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (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 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 2006.

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 antibody 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 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 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 antibody candidates 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 the antibody candidate 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 antibody candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our antibody candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any antibody candidates that we develop. Moreover, as a result of the COVID-19 pandemic, certain of our third-party CROs have been affected and in some instances have experienced cessation or mitigation of activity and may experience closures and labor shortages, which may negatively affect our pre-clinical and clinical development activities. 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 antibody candidates. As a result, our results of operations and the commercial prospects for our 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 (Incyte) is important to our business. If suitable monospecific or 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 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 up to 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 monospecific or bispecific antibody candidates arising from the terminated programs.

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

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

The Lilly Collaboration Agreement may be terminated:

- in its entirety or on a program-by-program basis by Eli Lilly for convenience; and
- in its entirety or on a program-by-program basis by either party due to a material breach of the Lilly Collaboration Agreement, or any one or more programs under the Lilly Collaboration Agreement, as applicable.

If the Lilly Collaboration Agreement is terminated with respect to one or more programs, depending on the stage of development, certain rights in the terminated programs revert to us.

Termination of the Lilly Collaboration Agreement could cause significant delays in our antibody candidate development and commercialization efforts, which could prevent us from commercializing our 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 Lilly Collaboration Agreement, Eli Lilly agreed to conduct certain pre-clinical and clinical development activities. If the Lilly 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 antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

Under the Lilly Collaboration Agreement, we are dependent upon Eli Lilly to successfully develop and commercialize any antibody candidates that are identified for further development under the Lilly Collaboration Agreement. We have limited ability to influence or control Eli Lilly's development and commercialization activities or the resources it allocates to development of product candidates identified under the Lilly Collaboration Agreement. Our interests and Eli Lilly's interests may differ or conflict from time to time, or we may disagree with Eli Lilly's level of effort or resource allocation. Eli Lilly 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 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.

The collaboration and license agreements with Simcere, and Betta Pharma, and the research and license agreement with Ono are important to our business. If our Biclonics® antibodies licensed in these collaboration and license agreements fail to advance or experience unacceptable safety or efficacy results if clinically developed, this could adversely impact the reputation of our platform and our ability to engage in future collaborations.

If our collaboration agreements with Simcere or Betta Pharma or our research and license agreements with Ono are terminated with respect to one or more programs, or the pre-clinical assets associated with these agreements fail to advance into the clinic, or experience negative results with respect to safety, efficacy, manufacturability, or other features of research and development, this could adversely affect the reputation of our Biclonics® technology platform and our ability to engage in future collaborations or licensing agreements. While we have certain contractual provisions in place in our collaboration agreements with Simcere and Betta Pharma that permit us to supervise development efforts associated with our pre-clinical assets with respect to Simcere, or MCLA-129, which we anticipate entering the clinic in 2021 with Betta Pharma, which have product rights in China, we cannot guarantee that these assets will be developed in China in accordance with our standards as applied to our wholly owned programs. Ono is currently pursuing at least one antibody program generated by us through use of our proprietary Biclonics® platform in an area outside oncology. To the extent this asset does not successfully advance through clinical development, this may impair our ability to leverage our platform in areas outside oncology or to engage in future license agreements to further expand the use of our platform and generate future revenue. Should any of these collaborations or license agreements fail or be terminated, any suitable alternative collaboration or license agreement would take considerable time to negotiate, if at all, and could also be on less favorable terms to us. If these agreements were to be terminated, and whether or not we identify a suitable alternative collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue

development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

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

Our product development programs and the potential commercialization of our antibody candidates will require substantial additional cash to fund expenses. Therefore, for some of our antibody candidates and with respect to our recently developed Triclonics® technology platform, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those bispecific and trispecific antibody candidates. For instance, we have license and collaboration agreements with Ono, Incyte, Eli Lilly, Simcere and Betta, under which we have licensed the development and commercialization of certain of our monospecific or 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 or trispecific 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 antibody candidates to market, further research and develop new trispecific antibody candidates, enhance our Biclonics® and Triclonics® technology platforms and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;
- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator may experience technical, clinical, intellectual property, manufacturing or other setbacks in the research or development of a product program arising from our collaboration adversely affecting the financial return of our collaboration or the reputation of our technology platform;
- 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 antibody candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our antibody candidates. Moreover, we intend to rely on third parties to produce commercial supplies of any approved antibody candidate and our commercialization of any of our antibody candidates could be stopped, delayed or made less profitable if those third parties fail to obtain approval of the FDA or comparable foreign regulatory authorities following inspection of their facilities and procedures to manufacture our antibody candidates and products, fail to provide us with sufficient quantities of 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 (CMOs) for the supply of cGMP-grade clinical trial materials and commercial quantities of our antibody candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture antibody candidates ourselves. The facilities used by our CMOs to manufacture our antibody candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP for the manufacture of our antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities or may result in delay of our ability to obtain marketing authorization, if any, of our antibody candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our 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 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 antibody candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our antibody candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

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

We rely on our CMOs to purchase from third-party suppliers the materials necessary to produce our antibody candidates for our clinical trials, and will rely on our existing and future collaborators to purchase from third-party suppliers the materials necessary to develop and produce our antibody candidates for future clinical trials and, upon approval, our products for commercialization. There are a limited number of suppliers for raw materials that we use to manufacture our antibody candidates 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 antibody candidates for our clinical trials, and if approved, ultimately for commercial sale. Apart from contractual measures, we do not have any control over the process or timing of the acquisition of these raw materials by our manufacturers or manufacturers paid by our collaborators. Moreover, we currently do not have any agreements for the commercial production of these raw materials. Although we generally do not begin a clinical trial unless we believe we have a sufficient supply of an antibody candidate to complete the clinical trial or have secured resupply capacity, any significant delay in the supply of an antibody candidate, or the raw material components thereof, for a planned or an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our antibody candidates. If our manufacturers, collaborators or we are unable to purchase these raw materials after regulatory approval has been obtained for our antibody candidates, the commercial launch of our 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 antibody candidates. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers have been affected, which could disrupt or delay their activities or ability to source materials and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our pre-clinical and clinical development activities.

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 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 antibody candidates and our Biclonics® technology platform and Triclonics® technology platform, the enforcement, defense and maintenance of which may be challenging and costly. Failure to enforce or protect these rights adequately could harm our ability to compete and impair our business.

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our Biclonics® technology platform, Triclonics® technology platform, our common light chain transgenic murine technology, our CH3 domain dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our platform technologies, and 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, or have issued and even if such patents cover our Biclonics® technology platform, Triclonics® technology platform, our common light chain transgenic murine technology, our CH3 domain dimerization technology our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, and other technologies, 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 our antibody candidates. Furthermore, if third parties have filed such patent applications on or before March 15, 2013, an interference proceeding can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. If third parties have filed such applications after March 15, 2013, a derivation proceeding can be initiated by such third parties to determine whether our invention was derived from theirs.

Issued patents covering one or more of our products or the Biclonics® technology or Triclonics® technology platforms could be found invalid or unenforceable if challenged in court.

To protect our competitive position, we may from time to time need to resort to litigation to enforce or defend any patents or other intellectual property rights owned by or licensed to us, or to determine or challenge the scope or validity of patents or other intellectual property rights of third parties. As enforcement of intellectual property rights is difficult, unpredictable and expensive, we may fail in enforcing our rights—in which case our competitors may be permitted to use our technology without being enjoined, required to pay us any license fees, or compensate us for lost profits or reasonable royalty. 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 technology covered by our patents we seek to enforce, such as those covering our antibody candidates or methods, our Biclonics® technology and Triclonics® technology platforms, our common light chain transgenic murine technology, or our CH3 domain dimerization technology, among other technologies, and then compete directly with us, without payment to us.

If we were to initiate legal proceedings against a third party to enforce a patent covering our technology, one of our products or methods, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States or in certain jurisdictions in Europe, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, for example, lack of utility, novelty, obviousness, non-enablement or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the U.S. Patent and Trademark Office (USPTO) or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the USPTO. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our technologies, products, methods or certain aspects of our Biclonics® technology and Triclonics® technology platforms. 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 antibody candidates, such that we could be required to litigate or obtain licenses from third parties in order to develop or market our antibody candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our technology platforms, methods or candidates or elements thereof, our manufacture or uses relevant to our development, or other attributes of our antibody candidates or our Biclonics® technology platform or Triclonics® technology platform. In such cases, we may not be in a position to develop or commercialize products or bispecific or trispecific antibody candidates unless we successfully

pursue litigation, opposition, inter partes, or related post-grant proceedings to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. In addition, we are aware of issued patents and/or pending patent applications held by third parties that could be alleged as covering some of our antibody candidates, irrespective of the merits. We believe that if such patents or patent applications (if issued as currently pending) were asserted against us, we would have counterclaims and defenses against such claims, including non-infringement, the affirmative defense of safe harbor designed to protect activity undertaken to obtain federal regulatory approval of a drug, including under 35 U.S.C. § 271(e) and similar foreign exceptions to infringement, and defenses concerning 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 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 antibody candidates. We could also be required to pay substantial damages. Similarly, the targets of certain of our 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 technologies could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, antibody candidates or the use of our bispecific and trispecific antibody 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 antibody candidates does not guarantee our freedom to operate and is separate from our risk of possible infringement of third parties' intellectual property rights. We may not be able to successfully settle or otherwise resolve such potential infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing any approved 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 antibody candidates that are held to be infringing or be forced to redesign antibody candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

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

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

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

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

- stop selling, incorporating, manufacturing or using our products in the United States and/or other jurisdictions that are covered by the subject intellectual property;

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

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

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

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

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

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

We currently have rights and own our intellectual property, including issued patents and pending patent applications, relating to and covering our antibody candidates and Biclonics® technology and Triclonics® technology platforms. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our antibody candidates may require specific formulations to work effectively and efficiently or companion diagnostics for safely and effective administration of our therapeutic candidates and the rights to these formulations and companion diagnostics 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 may identify as necessary for our 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.

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 an antibody candidate or program, we may have to abandon development of that antibody candidate or program and our business and financial condition could suffer.

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

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

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

Patents typically 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 antibody candidates are obtained, once the patent life has expired for a candidate, 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 antibody candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours, causing our revenue from applicable products to be reduced, possibly materially, and potentially harming our ability to recover our investment in such product or obtain a reasonable return on that investment.

Depending upon the timing, duration and conditions of FDA marketing approval of our 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) in the Netherlands. International applications under the Patent Cooperation Treaty (PCT) are usually filed within 12 months after the priority filing, where we pursue patent applications in the U.S., across the E.U., and other PCT participating jurisdictions, as based on the PCT filing, national and regional patent applications may be filed in additional jurisdictions where we believe our antibody candidates may be marketed or manufactured or our platform technologies may be utilized. 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 antibody candidate and/or technology.

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

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

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

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

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

- others may be able to make compounds that are the same as or similar to our 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 antibody candidates or technologies could use the intellectual property of others without obtaining a proper license; and
- 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 antibody candidates and technology platforms.

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

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

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

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

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

To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors, collaborators and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors, collaborators and advisers may unintentionally or willfully disclose our confidential information

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

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

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

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

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

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

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

Periodic maintenance and annuity fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we or our existing or future licensors or collaborators fail to maintain the patents and patent applications covering our antibody candidates, our competitors might be able to enter the market, which would have an adverse effect on our business.

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

We and our employees use social media to communicate internally and externally. While we have policies and procedures in place governing employee use of social media, there is risk that the use of social media by us or our employees to communicate about our antibody candidates, technologies 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, our clinical trials, or our antibody candidates, our technologies, and company generally 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 shares.

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 frequency and 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 result of the COVID-19 pandemic, we may also face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Further, as a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of the attacks described herein, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, including in the hiring of IT personnel, and improvements to IT infrastructure and controls, there can be no assurance that our efforts will prevent service interruptions or security breaches.

Any cybersecurity incident could adversely affect our business, by leading to, for example, the loss of trade secrets or other intellectual property, demands for ransom or other forms of blackmail, or the unauthorized disclosure of personal or other sensitive information of our employees, clinical trial patients, customers, and others. Although to our knowledge we have not experienced any material cybersecurity incident to date, if such an event were to occur, it could seriously harm our development programs and our business operations. We could be subject to breach notification requirements, 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.

For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a security breach or other incident were to result in the unauthorized access to or unauthorized use, disclosure, release or other processing of clinical trial data or personal data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media, and other parties pursuant to privacy and security laws. Likewise, we rely on our third-party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates and to conduct clinical trials, and similar events relating to their information technology systems could also seriously harm our business. Any security compromise affecting us, our collaborators or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures, and lead to regulatory scrutiny. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed.

Risks Related to Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel, recruiting additional qualified personnel and managing transitions among these personnel, such as the 2019-2020 transition of our former President and Chief Executive Officer, and resignation of our former Chief Medical Officer, hiring of our new Chief Medical Officer and resignation of our former Chief Scientific Officer occurring in 2020.

Our success depends upon the contributions of our senior leaders, including our board of directors, our senior management, and other key scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. The loss of key senior management, managers and senior scientists could delay our research and development and clinical trial activities or impair our ability operate the company effectively. 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, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business. Our success also depends on our ability to manage transitions among our senior management and other key personnel. In December 2019, Ton Logtenberg, Ph.D., stepped down as an executive director, a position he held since co-founding our company in 2003, and as President, Chief Executive Officer and Principal Financial Officer, and Sven "Bill" Lundberg, M.D. was appointed as an executive director and as President, Chief Executive Officer and Principal Financial Officer as of January 1, 2020. In April 2020, L. Andres Sirulnik, M.D., Ph.D. resigned as Executive Vice President, Chief Medical Officer effective April 24, 2020, and Andrew Joe, M.D., was appointed as Senior Vice President and Chief Medical Officer, effective July 27, 2020. Further, in April 2020, Mark

Throsby, Ph.D., resigned as the Executive Vice President and Chief Scientific Officer of the Company with an effective date of July 31, 2020. These changes in our senior management were disruptive to our business, and if we are unable to continue to manage orderly transitions in these cases or for other key personnel in the future, or if we are unable to recruit a suitable replacement for the Chief Scientific Officer position, or retain our existing senior management, managers and senior scientists, our business may be adversely affected.

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 continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug and clinical development, regulatory affairs and sales and marketing. To manage our 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 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

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. 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. On August 21, 2019, we filed a Registration Statement on Form F-3, as amended by Post-Effective Amendment No. 1 to Form F-3 on Form S-3, to register the shares of common stock sold to Incyte. As a result, these shares can be freely sold in the public market. In connection with entering into a settlement agreement with Regeneron Pharmaceuticals, we entered into a Share Subscription Agreement with Regeneron, pursuant to which we issued and sold to Regeneron 600,000 of our common shares. Regeneron's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. In addition, in connection with entering into the Lilly Collaboration Agreement, we entered into a Lilly Share Subscription Agreement with Eli Lilly, pursuant to which we issued and sold to Eli Lilly 706,834 of our common shares. Eli Lilly's ability to sell these common shares is subject to certain limitations, including that Eli Lilly has agreed not to transfer, sell, or otherwise dispose of the shares for a certain period of time following the closing date, subject to certain customary exceptions.

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.

As at 12 February 2021, a bill is pending in Dutch Senate which, if enacted in its current form, would introduce a statutory cooling-off period of up to 250 days during which the general meeting of shareholders would not be able to dismiss, suspend or appoint members of the board of directors (or amend the provisions in the articles of association dealing with those matters) unless those matters would be proposed by the board of directors. This cooling-off period could be invoked by the board of directors in case:

- shareholders, using either their shareholder proposal right or their right to request a general meeting of shareholders, propose an agenda item for the general meeting of shareholders to dismiss, suspend or appoint a member of the board of directors (or to amend any provision in the articles of association dealing with those matters); or

- a public offer for the company is made or announced without the company's support, provided, in each case, that the board of directors believes that such proposal or offer materially conflicts with the interests of the company and its business.

The cooling-off period, if invoked, ends at occurrence of the earliest of the following events:

- the expiration of 250 days from:
  - in case of shareholders using their shareholder proposal right, the day after the deadline for making such proposal expired;
  - in case of shareholders using their right to request a general meeting of shareholders, the day when they obtain court authorization to do so; or
  - in case of a hostile offer being made, the first following day;
- the day after the hostile offer having been declared unconditional; or
- the board of directors voluntarily terminating the cooling-off period.

In addition, shareholders representing at least 3% of our issued share capital may request the Dutch Enterprise Chamber of the Amsterdam Court of Appeals for early termination of the cooling-off period. The Dutch Enterprise Chamber of the Amsterdam Court of Appeals must rule in favor of the request if the shareholders can demonstrate that:

- the board of directors, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have come to the conclusion that the relevant shareholder proposal or hostile offer constituted a material conflict with the interests of the company and its business;
- the board of directors cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making;
- if other defensive measures have been activated during the cooling-off period and not terminated or suspended at the relevant shareholders' request within a reasonable period following the request (i.e., no 'stacking' of defensive measures).

During the cooling-off period, if invoked, the board of directors must gather all relevant information necessary for a careful decision-making process. In this context, the board of directors must at least consult with shareholders representing at least 3% of our issued share capital at the time the cooling-off period was invoked and the works council. Formal statements expressed by these stakeholders during such consultations must be published on our website to the extent these stakeholders have approved that publication.

Ultimately one week following the last day of the cooling-off period, the board of directors must publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting of shareholders. If this legislation passes, this may make it more difficult for a third party or group of third parties to acquire control of us or effect a change in 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.

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 (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.

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with the provisions of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and the rules of Nasdaq applicable to U.S. domestic issuers, which will continue to require us to incur significant expenses and expend time and resources.

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and

current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We are also no longer exempt from the requirements of Regulation FD promulgated under the Exchange Act related to selective disclosures. We are also no longer permitted to follow our home country's rules in lieu of the corporate governance obligations imposed by Nasdaq, and are required to comply with the governance practices required by U.S. domestic issuers listed on Nasdaq. We are also required to comply with all other rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders 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 and certain private placements. In addition, we are required to report our financial results under U.S. Generally Accepted Accounting Principles, including our historical financial results, which have previously been prepared in accordance with International Financial Reporting Standards. We expect to continue to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources to comply with these requirements. In addition, we may need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act and a smaller reporting company under the rules promulgated under the Exchange 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, and reduced executive compensation disclosure. 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 following the initial public offering of our common shares, 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 are also a smaller reporting company, and we will remain a smaller reporting company until the fiscal year following the determination that our voting and non-voting common shares held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common shares held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data or supplemental financial information.

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.

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

Based on the value of our assets, including goodwill, and composition of our income, assets and operations for the taxable year 2020, we do not believe we were a PFIC for U.S. federal income tax purposes for that taxable year. A non-U.S. company generally will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise. It is possible the Internal Revenue Service could determine that we were a PFIC for the taxable year 2020. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. Once treated as a PFIC, for any taxable year in which a U.S. Holder owns equity in such foreign corporation, a foreign corporation will generally continue to be treated as a PFIC for all subsequent taxable years with respect to such U.S. Holder. If we were to be a PFIC, "excess distributions" (as such term is defined in the United States Internal Revenue Code of 1986, as amended (U.S. Tax Code)) to a U.S. Holder, and any gain recognized by a U.S. Holder on a disposition of our common shares would be taxed in potentially unfavorable ways. Among other consequences, our dividends would be taxed at the regular rates applicable to ordinary income, rather than the 20% maximum rate applicable to certain dividends received by an individual from a qualified foreign corporation, and, to the extent that they constituted excess distributions, certain interest charges may apply, and gains on the sale of our shares would be treated in the same way as excess

distributions. In addition, the U.S. Holder would be subject to detailed reporting obligations. The tests for determining PFIC status are applied annually and it is difficult to make accurate predictions of future income and assets, which are relevant to the determination of any future PFIC status. As such, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. Further, we cannot provide any assurances that we will furnish to any U.S. Holder 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, including the potential availability and advisability of an election to treat us as a qualified electing fund or a mark-to-market election. A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our common shares 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;

(3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust that (a) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the U.S. Tax Code or (b) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

If a U.S. Holder 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) as such term is defined in the Tax Code. A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income, as ordinary 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 corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may extend the statute of limitations with respect to such United States shareholder's U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether we or any of our future 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 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. The risk of being subject to increased taxation may deter our current shareholders from increasing their investment in us and others from investing in us, which could impact the demand for, and value of, our common shares.

General Risk Factors

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 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 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 common shares 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.

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

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

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 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 or a smaller reporting 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 (SOX), 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 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 SOX (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 10-K. 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 our 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. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. 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.

Item 1B. Unresolved Staff Comments.

None.

Item 2. Properties.

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, which we plan to extend through at least 2022. We also entered into a lease for 7,583 square feet of additional office space in Cambridge, Massachusetts, which commenced on April 1, 2019 and has a term of seven years.

Item 3. Legal Proceedings.

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 legal proceedings, which could be deemed to be material.

Particular legal proceedings are described in Note 10 of the Consolidated Financial Statements appended to this Annual Report on Form 10-K.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information and Holders

Our common stock is traded on The Nasdaq Global Market under the symbol "MRUS." Trading of our common stock commenced on May 24, 2016, following the completion of our initial public offering.

As of February 28, 2021, the number of holders of record of our common shares was 5. This number does not include beneficial owners whose shares are held in street name.

Dividends

We have never declared or paid cash dividends on our capital stock. We intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends to our stockholders in the foreseeable future.

Purchases of Equity Securities by the Issuer or Affiliated Purchasers

We did not repurchase any of our equity securities during the quarter ended December 31, 2020.

Recent Sales of Unregistered Securities

None.

Item 6. Selected Financial Data.

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Our management's discussion and analysis of our financial condition and results of operations are based upon our Consolidated Financial Statements included in this Annual Report on Form 10-K, which have been prepared by us in accordance with accounting principles generally accepted in the United States (U.S. GAAP) and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended. This discussion and analysis should be read in conjunction with these Consolidated Financial Statements and the notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many important factors, including those factors set forth in Part I, Item 1A. "Risk Factors" of this Annual Report on Form 10-K, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

General

We are a clinical-stage oncology company developing innovative antibody therapeutics. Our pipeline of full-length human multispecific antibody candidates are generated from our proprietary technology platforms, which are able to generate a diverse array of antibody binding domains, or Fabs, against virtually any target. Each antibody binding domain consists of a target-specific heavy chain paired with a common light chain. Multiple binding domains can be combined to produce novel bispecific and trispecific antibodies that bind to a wide range of targets and display novel and innovative biology. These platforms, referred to as Biclonics® and Triclonics™, allow us to generate large numbers of diverse panels of bispecific and trispecific antibodies, respectively, which can then be functionally screened in large-scale cell-based assays to identify those unique molecules that possess novel biology, which we believe are best suited for a given therapeutic application. Further, by binding to multiple targets, Biclonics® and Triclonics™ may be designed to provide a variety of mechanisms of action, including simultaneously blocking receptors that drive tumor cell growth and survival and mobilizing the patient's immune response by engaging T cells, and/or activating various killer cells to eradicate tumors.

Our technology platforms employ an assortment of patented technologies and techniques to generate human antibodies. We utilize our patented MeMo® mouse to produce a host of antibodies with diverse heavy chains and a common light chain that are capable of binding to virtually any antigen target. We use our patented heavy chain and CH3 domain dimerization technology to generate substantially pure bispecific and trispecific antibodies. We also employ our patented Spleen to Screen® technology to efficiently screen panels of diverse heavy chains, designed to allow us to rapidly identify Biclonics® and Triclonics™ therapeutic candidates with differentiated modes of action for pre-clinical and clinical testing.

Using our Biclonics® platform we have produced, and are currently developing, the following candidates: MCLA-128 (zenocutuzumab) for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions; MCLA-158 for the potential treatment of solid tumors; and MCLA-145, developed in collaboration with Incyte Corporation, for the potential treatment of solid tumors. In 2021, we are planning to commence a clinical trial in the United States for MCLA-129, for the potential treatment of solid tumors, which is also the subject to collaboration and license agreement, which permits Betta Pharmaceuticals Co. Ltd. (Betta) to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights. Furthermore, we have a pipeline of proprietary antibody candidates in pre-clinical development and intend to further leverage our Biclonics® technology platform to identify multiple additional antibody candidates and advance them to clinical development. Further, Merus is developing its next generation Triclonics™ technology, and has pre-clinical trispecific antibody candidates capable of simultaneously binding three targets at once.

Funding Our Operations

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 antibody candidates from discovery through pre-clinical development and into clinical trials and seek regulatory approval and pursue commercialization of any approved antibody candidate. In addition, if we obtain regulatory approval for any of our antibody candidates, if appropriate, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution.

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, business development and licensing opportunities with third parties. Adequate additional financing may not be available to us on acceptable terms, or at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. See "Impact of COVID-19 Pandemic" below and "Risk Factors—The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations." in Part I, Item 1A of this Annual Report on Form 10-K. 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 marketable securities of $207.8 million as of December 31, 2020, combined with the aggregate immediate proceeds from the closing of the collaboration and license agreement and share purchase agreement with Eli Lilly and Company (Eli Lilly) in January 2021 of $60.0 million and the aggregate net proceeds from a follow-on offering of $129.7 million in January 2021, will fund our operations at least into the second half of 2024.

Clinical Programs

Zenocutuzumab, or "Zeno" (MCLA-128: HER3 x HER2 Biclonics®)
NRG1 gene fusion (NRG1+) Cancers: Phase 1/2 eNRGy trial clinical data and program update planned for Q2 2021

We continue to enroll patients in the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. We plan to present efficacy and safety data from the eNRGy trial and Early Access Program (EAP) at the 2021 American Society of Clinical Oncology Annual Meeting, with results on more than 30 patients with NRG1+ pancreatic, non-small cell lung and other cancers across the eNRGy trial and EAP with the opportunity for four or more months of follow up. At that time, we plan to also discuss details of the program and overall strategy.

Zeno is currently in the phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. We believe that Zeno continues to demonstrate encouraging single agent activity in NRG1+ cancers and has been observed to be well tolerated, consistent with previously reported safety data in the overall patient population treated with Zeno monotherapy.

In August 2020, Zeno was granted Orphan Drug Designation by the U.S. FDA for pancreatic cancer and in January 2021, Fast Track Designation for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard-of-care therapy.

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors
Phase 1 trial continues: dose expansion in patients with gastro-esophageal and head-and-neck cancers

We are developing MCLA-158 for the potential treatment of solid tumors. Our phase 1 clinical trial of MCLA-158 is ongoing in the dose expansion phase.

On January 15, 2021, we presented in a poster session interim clinical data from the phase 1 dose escalation study of MCLA-158 at the American Society of Clinical Oncology 2021 Gastrointestinal Cancers Symposium. As of a data cut-off of September 2020, MCLA-158 was administered to 33 patients over 11 dose levels (5-1500 mg, flat dose), a heavily pretreated population having received a median of four lines of prior therapy. As of the cut-off date, MCLA-158 was observed to be well tolerated, and no dose limiting toxicities occurred. The recommended phase 2 dose was established at 1500 mg administered intravenously once every two weeks. Enrollment of patients with gastro-esophageal and head-and-neck cancers continues at this dose in the expansion phase of the open-label, multicenter trial, and preliminary evidence of antitumor activity has been observed.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial advancing with clinical update planned for 2H 2021

MCLA-145 is currently being evaluated in a phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, in patients with solid tumors. MCLA-145 is the first drug candidate co-developed under our global collaboration and license agreement with Incyte Corporation (Incyte), which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from our Biclonics® platform. Merus retains full rights to develop and commercialize MCLA-145, if approved, in the United States, and Incyte is responsible for its development and commercialization outside the United States. We plan to present a clinical update at a major medical conference in the second half of 2021.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
First patient planned to be dosed in 2021

We plan to evaluate MCLA-129 in a phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, for the treatment of various solid tumors, with a plan to dose a first patient in the United States in 2021. MCLA-129 is subject to collaboration and license agreement, which permits Betta Pharmaceuticals Co. Ltd. (Betta) to exclusively develop MCLA-129 in China, while Merus retains full ex-China rights.

In January 2021, Betta announced that the Chinese National Medical Products Administration had accepted its Investigational New Drug application of MCLA-129 injection.

Impact of COVID-19 Pandemic

The current COVID-19 pandemic has presented a substantial public health and economic challenge around the world and is affecting our employees, communities, clinical trial sites and business operations, as well as the U.S. and Dutch economies and international financial markets.

While we are currently continuing our ongoing clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials and source verification of clinical data required for presentation of clinical data for zenocutuzumab, MCLA-158 and MCLA-145, our conclusion of the MCLA-117 trial, and anticipated commencement of the clinical trial for MCLA-129. We have observed a moderate to high impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic during the fourth quarter ended December 31, 2020, particularly at sites in countries not yet open to recruitment, and to a lesser extent in countries where COVID-19 related restrictions have been eased, with adjustments made to allow remote visits for some patient follow-up, and reduced onsite monitoring by the sponsor or contract research organization (CRO). As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials. The extent of the impact to our overall clinical development timeline is uncertain at this time and we continue to monitor and assess the COVID-19 pandemic on a regular basis.

As a result of the COVID-19 pandemic, certain of our CROs and third-party suppliers, as well as collaborators in the U.S. and China that are developing or collaborating with us to develop certain of our pre-clinical and clinical-stage antibody candidates have been affected. As a result of such impact, we may face difficulties with and delays in performance of certain chemistry manufacturing and controls and testing associated with our clinical candidates, including as it relates to sourcing materials required for such manufacture that may be diverted for other purposes associated with COVID-19, or difficulties or delays associated with testing of our pre-clinical antibody candidates associated with our collaborations with Incyte, Eli Lilly and Simcere, which may delay or prevent their potential clinical development. While we currently do not anticipate any interruptions in our clinical trial supply of drug candidates, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to manufacture our clinical trial supply or source materials necessary for their manufacture.

In response to the spread of COVID-19, on March 18, 2020, we temporarily suspended our laboratory research activities at our facilities in Utrecht, the Netherlands to help secure the safety of our employees and to adhere to government recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We have since re-opened our offices and laboratory in Utrecht, maintaining social distancing and imposing other requirements consistent with government guidance. Further, we have recommended our employees in the U.S. and Netherlands work from home when possible and for those employees working at our offices and laboratory in Utrecht and offices in Cambridge Ma., they are required to maintain social distancing and follow requirements consistent with the guidance provided by the CDC, Federal, state and local regulations for the U.S. and RIVM for the Netherlands. While we use reasonable business practices to mitigate the risk of exposure to COVID-19 while on company-operated premises, we cannot guarantee that traveling to and from and visiting the office will not expose employees to infectious agents or eliminate inherent risks to our workforce and our business operations resulting from COVID-19. Given the uncertainty caused by the COVID-19 pandemic we cannot be certain that we will not suspend our laboratory research activities at our facilities or suspend use of our offices in the future.

At this time, there is significant uncertainty caused by the COVID-19 pandemic and impact of related responses. The future impact of COVID-19 on our business and clinical trials will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the Netherlands, the United States and other countries, business closures or business disruptions, the ultimate impact of COVID-19 on financial markets and the global economy, and the effectiveness of actions taken in the Netherlands, the United States and other countries to contain and treat the disease. See “Risk Factors—The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations.” in Part I, Item 1A of this Annual Report on Form 10-K.

Collaborations and Other Revenue Generating Agreements

Refer to Item 1, “Business—Our Collaborations” and Note 12, “Collaborations,” of the notes to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K for a description of the key terms of our arrangements.

Results of Operations for the Years Ended December 31, 2020 and 2019

Revenue

The following is a comparison of collaboration revenue for the years ended December 31, 2020 and 2019:

	Year Ended December 31,			
	2020	2019	Change	%
	(In thousands)			
Incyte	$ 26,580	$ 25,831	$ 749	2.9%
Ono	200	4,437	(4,237)	-95.5%
Other	3,163	1,080	2,083	192.9%
Total collaboration revenue	$ 29,943	$ 31,348	$ (1,405)	-4.5%
Grant revenue	—	(215)	215	-100.0%
Total revenue	$ 29,943	$ 31,133	$ (1,190)	-3.8%

Our revenue from each collaboration partner consists of revenue recognized from the amortization of deferred revenue related to upfront payments for licenses or options to obtain licenses in the future, research and development services reimbursement revenue earned and milestone payments earned under collaboration and license agreements with our collaboration partners.

Collaboration revenue for the year ended December 31, 2020 decreased $1.4 million as compared to the year ended December 31, 2019, primarily as a result of a decrease of $4.1 million in Ono milestone revenue due to the achievement of milestones in 2019 that did not recur in 2020, partially offset by an increase in Betta milestone revenue due to a $2.0 million earned in the fourth quarter. The change in exchange rates did not materially impact collaboration revenue.

As of December 31, 2020, we have total deferred revenue of $99.9 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and is expected to be recognized over the next five years.

Operating Expenses

The following is a comparison of operating expenses for the years ended December 31, 2020 and 2019:

	Year Ended December 31,			
	2020	2019	Change	%
	(In thousands)			
Research and development	$ 70,040	$ 55,680	$ 14,360	25.8%
General and administrative	35,781	34,110	1,671	4.9%
Total operating expenses	$ 105,821	$ 89,790	$ 16,031	17.9%

Research and Development Expense

Research and development costs consist principally of the costs associated with our research and development activities, conducting pre-clinical 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 (CROs) contract manufacturing organizations, and consultants that conduct and support clinical trials and pre-clinical studies;
- costs to develop product candidates, including raw materials and supplies, product testing, and facility related expenses; and
- amortization and depreciation of tangible and intangible fixed assets used to develop our product candidates.

Note that 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 expense for the year ended December 31, 2020 increased $14.4 million as compared to the year ended December 31, 2019, primarily as a result of an increase in manufacturing related costs, and higher pre-clinical research and development-related costs related to our programs, particularly increases in costs for zenocutuzumab, and a $2.0 million milestone earned by Betta incurred in the fourth quarter, offset by decreases in costs for MCLA-145.

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 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 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.

General and Administrative Expense

General and administrative expenses consist primarily of salaries and related benefits, including stock-based compensation, related to our executive, finance, intellectual property, business development and support functions. Other general and administrative expenses include allocated facility-related costs not otherwise included in research and development expenses, travel expenses and professional fees for auditing, tax and legal services, including intellectual property and general legal services.

General and administrative expense for the year ended December 31, 2020 increased $1.7 million as compared to the year ended December 31, 2019, primarily as a result increases in stock-based compensation, insurance, facilities, intellectual property related costs and other items, partially offset by a decrease in consulting and personnel costs.

We expect general and administrative expenses to increase as we grow as a company, driven by the need to support a growing workforce, engaging in financing transactions, establishing and maintaining our intellectual property rights, fulfilling our compliance requirements as a public company and related legal costs.

Other Income, Net

The following is a comparison of other income, net, for the years ended December 31, 2020 and 2019:

	Year Ended December 31,			
	2020	2019	Change	%
	(In thousands)			
Interest income, net	$ 300	$ 1,889	$ (1,589)	-84.1%
Foreign exchange (losses) gains	(9,432)	1,615	(11,047)	-684.0%
Miscellaneous income and gains	—	196	(196)	-100.0%
Total other income, net	$ (9,132)	$ 3,700	$ (12,832)	-346.8%

Other income, net consists of interest earned on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange gains or losses on our foreign denominated cash, cash equivalents and marketable securities.

Income Tax Expense

The following is a comparison of income tax expense for the years ended December 31, 2020 and 2019:

	Year Ended December 31,			
	2020	2019	Change	%
	(In thousands)			
Current	$ 625	$ 283	$ 342	120.8%
Deferred	(122)	(89)	(33)	37.1%
Income tax expense	$ 503	$ 194	$ 309	159.3%

We are subject to income taxes in the Netherlands and the U.S. Our current and deferred tax provision represents taxable income attributed to our U.S. operations as a consequence of allocating income to that jurisdiction. No current or deferred provision for income taxes has been made for income taxes in the Netherlands due to losses for tax purposes. Further, given a history of losses in the Netherlands, no deferred tax assets in excess of deferred tax liabilities are recognized as it is not more likely than not that they will be recovered.

Net Loss

Net loss for the year ended December 31, 2020 was $85.5 million, compared to $55.2 million for the year ended December 31, 2019. The increase in net loss was primarily due to the decrease in collaboration revenue and increases in research and development and general and administrative expenses discussed above.

Liquidity and Capital Resources

Cash requirements

We require external sources of financing to fund our operations. Since inception through December 31, 2020, we have raised an aggregate of $566.9 million, of which $125.4 million was non-equity funding through our collaboration agreements, $330.8 million was from the sale of common shares and $110.7 million was from private funding sources prior to our initial public offering. As of December 31, 2020, we had $207.8 million in cash, cash equivalents and marketable securities that are available to fund our current and future operations.

In addition to our existing cash, cash equivalents and marketable securities, we may receive research and development co-funding and are eligible to earn a significant amount of milestone payments under our collaboration agreements. Our ability to earn these payments and the timing of earning these payments is dependent upon the outcome of our research and development activities and is uncertain at this time. Our collaboration and license agreements may require payment of milestones to third parties contingent on future events.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity or debt financings, collaboration arrangements and government grants. Except for any obligations of our collaborators to make license, milestone or royalty payments under our agreements with them, and government grants, we do not have any committed external sources of liquidity.

To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our shareholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common shareholders. 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. If we raise additional funds through collaboration arrangements in the future, we may have to relinquish valuable rights to our technologies, future revenue streams or product candidates or grant licenses on terms that may not be favorable to us.

If we are unable to raise any additional funds that may be needed through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product candidate development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our primary uses of capital are: clinical trial costs, third-party research and development services, personnel, laboratory and related supplies, legal and other regulatory expenses and general overhead costs. Because our product candidates are in various stages of clinical and pre-clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. In addition, our expenditures as reported in our financial statements may be expected to be variable due to that uncertainty. We enter into contracts in the normal course of business with CROs for clinical and pre-clinical research studies, external manufacturers for product candidates for use in our clinical trials, and other research supplies and other services as part of our operations. These contracts generally provide for termination on notice, and therefore are cancelable contracts and are not contractual obligations. Our material contractual obligations, if any, are described elsewhere in this Annual Report on Form 10-K, including Notes 9 and 10 of the attached Consolidated Financial Statements.

Based on our current operating plan, research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash, cash equivalents and marketable securities as of December 31, 2020, combined with the aggregate immediate proceeds from the closing of the collaboration and license agreement and share purchase agreement with Eli Lilly in January 2021 of $60.0 million and the aggregate net proceeds from the January 2021 follow-on offering of $129.7 million will be sufficient to fund our planned operating expenses and capital expenditure requirements into at least the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, particularly as the process of testing product candidates in clinical trials is costly and the timing of progress in these trials is uncertain. As a result, we could use our capital resources sooner than we expect.

Sources and uses of cash

The following is a summary of cash flows for the years ended December 31, 2020 and 2019:

	Year Ended December 31,			
	2020	2019	Change	%
	(In thousands)			
Net cash used in operating activities	$ (79,901)	$ (63,048)	$ (16,853)	27%
Net cash provided by (used in) investing activities	(1,486)	24,172	(25,658)	-106%
Net cash provided by financing activities	39,520	74,232	(34,712)	-47%

Operating Activities

Net cash used in operating cash activities for the year ended December 31, 2020 increased $16.9 million as compared to the year ended December 31, 2019 primarily as a result of operating cash receipts related to collaboration arrangements (upfront payments, milestones, and research and development reimbursements) decreased $1.9 million, operating cash out flows related to operating expenses and taxes increased $12.7 million, and cash out flows related to other income increased $2.2 million.

Investing Activities

Net cash used in investing activities for the year ended December 31, 2020 decreased $25.7 million as compared to the year ended December 31, 2019, primarily as a result of the decrease in net cash inflows from the maturity of debt securities used to fund current operations of $27.0 million offset by the decrease in purchases of property, equipment and intangibles of $1.3 million.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2020 decreased $34.7 million as compared to the year ended December 31, 2019, primarily as a result of the decrease in receipt of proceeds from our equity issuances of $36.1 million offset by increases in proceeds received from option exercises of $1.4 million.

Cash Management

Our objective in managing our cash resources (cash, cash equivalents, and marketable securities) is to safeguard Merus' ability to continue as a going concern and to minimize the cost of capital to provide returns for shareholders and benefits for other stakeholders.

Once we receive a source of financing, our cash resources are invested to preserve capital as a primary goal, and to derive some return as a secondary consideration. Cash and cash equivalents include deposits and investments held with financial institutions with an original maturity date of less than three months. Marketable securities include commercial paper, securities issued by several public corporations and the U.S. Treasury with a maturity date of greater than three months at the date of settlement. Cash and cash equivalents are held at banks and financial institutions with credit ratings varying between A and AAA, while investments are in highly rated vehicles with identical credit ratings.

Our invested cash resources are deployed to achieve our operating objectives in furthering our programs.

Critical Accounting Policies and Estimates

Our accounting policies are more fully described in Note 2 to our Consolidated Financial Statements included elsewhere in the Annual Report on Form 10-K. As disclosed in Note 2, the preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions about future events that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ significantly from those estimates. We believe that the following discussion addresses our most critical accounting policies, which are those that are most important to the portrayal of our financial condition and results of operations and require management's most difficult, subjective and complex judgments on material matters.

Revenue Recognition

Significant judgement is required in applying our accounting policies concerning revenue recognition. Our collaboration arrangements may be subject to the scope of many accounting standards in addition to the standards applicable to revenue from contracts with customers, including whether all or part of the arrangement may be a collaboration arrangement as defined in the accounting standards or whether financial instruments exchanged in the same arrangement may be subject to other guidance. Such matters may impact the initial recognition, subsequent accounting and disclosures concerning the arrangement.

Our collaboration arrangements typically include a license to our intellectual property and significant judgement is applied in determining whether the particular license is distinct from other performance obligations in the arrangement. We consider whether the counterparty may be able to utilize the license in the absence of the provision of other performance obligations by us. Each collaboration features unique terms to a license and the provision of other performance obligations also varies. Such considerations impact the timing of recognition of consideration allocated to performance obligations.

A key estimate in the application of our revenue recognition policy concerns the method of recognition of revenue over time as performance obligations are completed. Methods may include an input-based, output-based or other rational allocation method. Such estimates are often derived from expectations on the outcome of research and development activities which are subject to uncertainty. Changes in these estimates impact the timing of revenue recognition. These estimates have not materially changed in the periods presented in our Consolidated Financial Statements. For example, with respect to the license and related activities performance obligation of the Incyte collaboration arrangement recognized as revenue over time as access to the platform for the generation of potential product candidates is provided to the customer, an increase of one year in the estimate as of January 1, 2020 would have decreased revenue recognized for the year ended December 31, 2020 by approximately $2.5 million, excluding the effects of foreign exchange translation.

Stock-Based Compensation

The expense for stock-based compensation for options granted to employees is typically determined based on the grant-date fair value of those options. The grant date fair value is derived from the use of valuation models which are commonly used. These valuation models use inputs which require estimates that are reflective of future expectations including the forward expected risk-free interest rate, volatility of our shares, and the expected exercise behavior of employees. We employed the Black Scholes option pricing model to value its stock options for the year-ended December 31, 2020, and a Hull-White option pricing model in prior years. While historical averages may be indicative of future expectations, such assumptions may or may not be accurate. Significant judgement must be employed to derive reasonable estimates in determining the grant-date fair value.

The estimates involved in the valuation of stock-based compensation have not materially changed in the periods presented in our Consolidated Financial Statements, as disclosed in Note 13 under the subheading of "*Stock Option Valuation*".

The actual weighted-average grant-date fair value of options granted for the year ended December 31, 2020 was $11.75. While valuation inputs in the valuation models employed may be interdependent, as an example, an increase of one year in the expected exercise behavior of employees would have increased the weighted-average grant-date fair value of options granted for the year ended December 31, 2020 to $12.34. Similarly, an increase of 1% in the estimated volatility of our shares would increase the weighted-average grant-date fair value of options granted for the year ended December 31, 2020 to $11.84. We granted 1,258,341 options for the year ended December 31, 2020, and we recognize compensation expense based on the grant-date fair value on a straight-line basis over the requisite service period of the awards, generally from the date of grant through each vesting date. Options granted generally vest over four years.

Going Concern

Our evaluation of our ability to continue as a going concern requires us to evaluate our future sources and uses of cash sufficient to fund our currently expected operations in conducting research and development activities one year from the date our financial statements are issued. We evaluate the probability associated with each source and use of cash resources in making our going concern determination. The research and development of pharmaceutical products is inherently subject to uncertainty.

Recent Accounting Pronouncements

For a discussion of pending and recently adopted accounting pronouncements, see Note 2 to our Consolidated Financial Statements included elsewhere in this Annual Report on Form 10-K.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements and do not have any holdings in variable interest entities.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable as a Smaller Reporting Company.

Item 8. Financial Statements and Supplementary Data.

The financial statements required to be filed pursuant to this Item 8 are appended to this Annual Report on Form 10-K. An index of those financial statements is found in Item 15 of Part IV of this Annual Report on Form 10-K.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive and financial officer, has evaluated, as of the end of the period covered by this Annual Report on Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-

15(e) and 15d-15(e) under the Exchange Act). Based on such evaluation, our principal executive and principal financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2020.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our management conducted an assessment of the effectiveness of our internal control over financial reporting based on the criteria set forth in "Internal Control - Integrated Framework (2013)" issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, our management concluded that, as of December 31, 2020, our internal control over financial reporting was effective.

Attestation Report of the Independent Registered Public Accounting Firm

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to an exemption established by the JOBS Act for "emerging growth companies."

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) identified in management's evaluation pursuant to Rules 13a-15(d) or 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2020 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Director Biographical Information

Anand Mehra, M.D., age 45, has served as a non-executive director of our board since August 2015 and as Chairman of our board of directors effective since June 2020. Dr. Mehra held various positions at Sofinnova Investments (f.k.a. Sofinnova Ventures) from 2007 to January 2020, most recently holding the position of a managing general partner, where he focused on working with entrepreneurs to build drug development companies. He led the firm's investments in Vicept Therapeutics (acquired by Allergan), Aerie Pharmaceuticals, Inc., Aclaris Therapeutics, Inc. ("Aclaris"), and Spark Therapeutics. Prior to joining Sofinnova, Dr. Mehra worked in J.P. Morgan's private equity and venture capital group and as a consultant at McKinsey & Company. He currently serves as a member of the board of directors of the publicly held Aclaris. Within the past five years, he also served on the boards of directors of the publicly held pharmaceutical companies Marinus Pharmaceuticals, Inc., Spark Therapeutics, Inc. and Aerie Pharmaceuticals. Dr. Mehra received a B.A. degree in political philosophy from the University of Virginia and an M.D. degree from Columbia University's College of Physicians and Surgeons. We believe that Dr. Mehra's extensive experience in the life science industry, his service on the board of directors of other public life science companies and his extensive leadership experience qualify him to serve on our board of directors.

Mark Iwicki, age 54, has served as a non-executive director 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 currently serves as the Chairman and Chief Executive Officer of Kala Pharmaceuticals, Inc., a pharmaceutical company, where he has been employed since April 2015. From February 2014 to November 2014 Mr. Iwicki served as President and Chief Executive Officer of Civitas Therapeutics. 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 served in several roles, including Chief Commercial Officer, President and Chief Operating Officer and Director and Chief Executive Officer at Sunovion Pharmaceuticals, Inc., formerly Sepracor, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Iwicki held executive positions, including Vice President and Business Unit Head, at Novartis Pharmaceuticals Corporation, a pharmaceutical company. Mr. Iwicki currently serves on the board of directors of Akero Therapeutics, Inc., Pulmatrix, Inc., Kala Pharmaceuticals, Inc. Within the past five years, he also served on the board of directors of the publicly held pharmaceutical company Aimmune Therapeutics Inc. Mr. Iwicki received a B.A. in business administration from Ball State University and an M.B.A. from Loyola University. We believe that Mr. Iwicki is qualified to serve on our board of directors due to his leadership, commercial and business experience in the biotechnology industry and breadth and knowledge about our business as well as his tenure as CEO and independent director in several publicly traded biotechnology companies.

Len Kanavy, age 59, has served as a non-executive director of our board of directors since July 2018. Mr. Kanavy most recently served as Senior Vice President, Commercial Business Operations at Genentech, a biotechnology company, from September 2006 to September 2016, where he was responsible for strategic decisions for the U.S. commercial business, including product launches, valuation of business development opportunities, clinical development plan options and pricing. From 2014 to 2016, 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. Mr. Kanavy holds a B.S. in Business Administration and an M.B.A. with a specialization in Finance from the University of Scranton. We believe that Mr. Kanavy is qualified to serve on our board of directors due to his leadership, business development and commercial experience in the biotechnology industry.

Bill Lundberg, M.D., age 57, has served on our board of directors since June 2019 and as an executive director since December 2019. Since December 2019, Dr. Lundberg has served as our President, Chief Executive Officer and Principal Financial Officer. From January 2015 to February 2018, Dr. Lundberg was Chief Scientific Officer of CRISPR Therapeutics AG ("CRISPR"), a biotechnology company, where he was responsible for establishing and growing research and development in the United States and oversaw CRISPR's first CRISPR-based product from inception to regulatory filing for clinical trials. From February 2011 to January 2015, Dr. Lundberg was Vice President and Head of Translational Medicine at Alexion Pharmaceuticals, Inc. ("Alexion"), where he oversaw research and development from discovery through early-stage development, and prior to that, he was Director and Chief Medical Officer of Taligen Therapeutics, Inc. ("Taligen"), a biotechnology company, which was acquired by Alexion in 2011. Prior to Taligen, he held roles of increasing responsibility in clinical drug development and medical affairs at Xanthus/Antisoma, Wyeth (now Pfizer), and Genzyme. Dr. Lundberg currently serves on the board of directors of Vor Biopharma. Dr. Lundberg received an M.D. from Stanford University and M.B.A. from the University of Massachusetts. He completed post-doctoral training at the Whitehead Institute/MIT, and clinical training in Medicine and Medical Oncology from Harvard and the Dana-Farber Cancer Institute. We believe that Dr. Lundberg is qualified to serve on our board of directors due to his experience in the field of medicine, clinical drug development, scientific experience, leadership and business experience.

Gregory D. Perry, age 60, has served as a non-executive director of our board of directors since May 2016 and Vice Chairman of our board of directors since August 2018. Mr. Perry has served as the Chief Financial Officer at Finch Therapeutics Group, a microbiome therapeutics company, since May 2018. Mr. Perry served as the Chief Financial and Administrative Officer of Novelion Therapeutics Inc., a biopharmaceutical company ("Novelion"), from November 2016 to December 2017. Prior to Novelion, Mr. Perry was Chief Financial Officer of Aegerion Pharmaceuticals Inc., a biopharmaceutical 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., now Sensen Bio, a fusion-protein therapeutics company, from January 2014 to June 2015. Prior to that, Mr. Perry served as the Interim Chief Financial Officer of InVivo Therapeutics Holdings Corp. , a biomaterials and biotechnology company, from September 2013 to December 2013, and prior to that he served as Senior Vice President and Chief Financial Officer of ImmunoGen, Inc., a biotechnology 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 he was the Chief Financial Officer of Elixir Pharmaceuticals and, prior to that 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, 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. We believe that Mr. Perry is qualified to sit on our board of directors based on his financial experience, leadership and business experience and breadth and knowledge about our business.

Paolo Pucci, age 59, has served as a non-executive director of our board of directors since June 2020. Mr. Pucci served as the Chief Executive Officer of ArQule, Inc., a biopharmaceutical oncology company engaged in the research and development of targeted therapeutics, from June 2008 until its acquisition by Merck in January 2020. Prior to joining ArQule, Mr. Pucci worked at Bayer AG from 2001 to 2008, where he served in a number of leadership capacities including President of the Oncology & Global Specialty Medicines Business Units and was a member of the Bayer Pharmaceuticals Global Management Committee. Before Bayer, Mr. Pucci held positions of increasing responsibility with Eli Lilly and Company from July 1991 to April 2001, culminating with his appointment as Managing Director, Eli Lilly Sweden AB. Mr. Pucci earned an MS in economics and accounting from Università degli Study di Napoli Federico II and an MBA in marketing and finance from the University of Chicago. Within the past five years, Mr. Pucci previously served on the boards of directors of Algeta ASA, until its acquisition by Bayer AG, and Dyax Inc., until its acquisition by Shire Plc (which was subsequently acquired by Takeda Pharmaceutical Company Ltd.), New Link Genetics Inc and ArQule Inc., until its acquisition by Merck Inc. He currently serves on the boards of directors of publicly held life sciences companies West Pharmaceuticals Services, Inc., Replimmune Group Inc., and Trillium Therapeutics Inc. We believe that Mr. Pucci is qualified to serve on our board of directors due to his leadership, international business and biotechnology experience in large multinational pharmaceutical corporations as well as his tenure as CEO and independent director in several publicly traded biotechnology companies.

Victor Sandor, M.D.C.M., age 54, has served as a non-executive director of our board of directors since June 2019. From September 2014 to December 2019, Dr. Sandor was the Chief Medical Officer at Array BioPharma ("Array"), a pharmaceutical company, where he oversaw clinical development through regulatory approval of Braftovi and Mektovi for the treatment of BRAFV600E/K mutant melanoma and Braftovi for the treatment of BRAFV600E mutant colorectal cancer. Prior to joining Array, from February 2010 to September 2014, he was Senior Vice President for Global Clinical Development at Incyte Corporation ("Incyte"), a pharmaceutical company, where he oversaw clinical development through regulatory approval of Jakafi for the treatment of myelofibrosis and polycythemia vera. Prior to joining Incyte, Dr. Sandor was Vice President and Chief Medical Officer for oncology at Biogen Idec and, prior to that held positions of increasing responsibility in oncology product development at AstraZeneca, where he played a lead role in the registration of Arimidex(r) (anastrozole) for adjuvant use and the development of early stage programs through proof-of-concept. Dr. Sandor received his M.D.C.M. from McGill University in Montreal, Canada, and completed his Fellowship in Medical Oncology at the National Institutes of Health in Bethesda, Maryland. He currently serves on the boards of directors of publicly held life sciences companies ADC Therapeutics and Prelude Therapeutics. We believe that Dr. Sandor is qualified to serve on our board of directors due to his experience in the field of medicine, clinical drug development and scientific experience.

Information About Our Executive Officers

Andrew Joe, M.D., age 55, has served as our Chief Medical Officer since July 2020. His responsibilities include overseeing clinical and regulatory strategy and activities at Merus. He brings over 20 years of experience in clinical drug development and translational research within industry and academic medicine. Dr. Joe most recently led the immuno-oncology program at Sanofi, which included co-development of LIBTAYO® (cemiplimab-rwlc) with Regeneron in skin, lung and other cancers. Previously at Merck Sharp & Dohme Corp., he led the KEYTRUDA® (pembrolizumab) New Indications Development Team in obtaining the first tumor/histology-agnostic drug approval in Microsatellite Instability-High (MSI-H) cancer, and the first immuno-oncology drug approval in a gynecological malignancy (cervical cancer). Dr. Joe also played key roles at Novartis in the global approval of Zykadia® (ceritinib) in ALK-positive lung cancer and at Roche in the global approval of ZELBORAF® (vemurafenib) in BRAF-mutant metastatic melanoma.

Dr. Joe is an Assistant Professor of Medicine at Columbia University Irving Medical Center. He received B.S. degrees in chemistry and biology from the Massachusetts Institute of Technology and an M.D. from the Mount Sinai School of Medicine.

Alexander ("Lex") Berthold Hendrik Bakker, Ph.D., age 54, has served as our Chief Development Officer since October 2010. His responsibilities include strategic scientific leadership, management of pre-clinical and clinical development and manufacturing, business development support, external collaboration and partnership management. Prior to joining Merus, Mr. Bakker directed pre-clinical 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.

Cornelis Adriaan ("John") de Kruif, Ph.D., age 57, 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 platform technology development, 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. Mr. de Kruif holds a Ph.D., in Antibody Engineering from Utrecht University.

Hui Liu, Ph.D., age 48, has served as our Chief Business Officer since December 2015 and Head of Merus U.S. since October 2018. His responsibilities include business development, alliance management, product strategy, finance and Merus operations in the U.S. Prior to joining Merus, Dr. Liu served as Vice President and Global Head, Business Development & Licensing, Oncology, from 2013 to 2015, and as Vice President and Global Head, Business Development & Licensing, Vaccines & Diagnostics, from 2009 to 2012, at Novartis AG. Prior to Novartis, Dr. Liu held positions of increasing responsibilities in business development at Pfizer, Inc. from 2004 to 2009 and in the R&D organization at Pfizer 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.

Peter B. Silverman, J.D., age 43, has served the Company since 2014, first as outside counsel, Head of Utrecht since April 2020, General Counsel since February 2018 and our Chief Intellectual Property Officer and Head of US Legal since February 2017. His responsibilities include all aspects of the Company's legal and intellectual property matters, and he provides significant contributions to the Company's management and operations of the headquarters in Utrecht. 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 and technologies. Mr. Silverman was an associate at Kaye Scholer LLP (now Arnold & Porter Kaye Scholer LLP), and prior to that 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, graduating magna cum laude and Order of the Coif. He is admitted to practice law in New York. Mr. Silverman also holds a B.A. in biology from the University of Rochester.

Code of Ethics

We have adopted a Code of Business Conduct and Ethics for all of our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted a current copy of our Code of Business Conduct and Ethics on our website at www.merus.nl in the "Investors & Media" section under "Corporate Governance." We intend to satisfy the disclosure requirement under Item 5.05 of Form 8-K regarding amendment to, or waiver from, a provision of our Code of Business Conduct and Ethics, as well as Nasdaq's requirement to disclose waivers with respect to directors and executive officers, by posting such information on our website at the address and location specified above. The information contained on our website is not incorporated by reference into this Annual Report on Form 10-K.

Other

The remaining information required by this Item 10 will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this Item 12 will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this Item 13 will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders.

Item 14. Principal Accounting Fees and Services.

The information required by this Item 14 will be included in our definitive Proxy Statement for the 2021 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits, and Financial Statement Schedules.

(a)

1. Financial Statements.

The following Report and Consolidated Financial Statements of the Company are included in this Annual Report on Form 10-K:

Index to Consolidated Financial Statements

2. Financial Statements and Schedules.

All financial statement schedules have been omitted because the required information is either presented in the consolidated financial statements or the notes thereto or is not applicable or required.

3. Exhibits.

The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed/ Furnished
			File No.	Exhibit No.	Filing Date	
	Articles of Association and By-Laws					
3.1	Articles of Association of Merus N.V., as amended on December 5, 2019	6-K	001-37773	3	12/6/19	
	Instruments Defining the Rights of Security Holders					
4.1	Description of Securities					*
4.2	Registration Rights Agreement, dated May 24, 2016, by and among the Registrant and the shareholders party thereto	6-K	001-37773	4.1	5/27/16	
4.3	Registration Rights Agreement, dated February 13, 2018, by and among the registrant and the Investors identified on Exhibit A attached thereto	6-K	0001-37773	99.2	2/15/18	
4.4	Securities Purchase Agreement, dated February 13, 2018, by an among the registrant and the Investors identified on Exhibit A attached thereto	6-K	0001-37773	99.1	2/15/18	
	Material Contracts – Management Contracts and Compensation Plans					
10.1.1	Merus N.V. 2010 Employee Option Plan, as amended	20-F	001-37773	4.1	4/30/18	
10.1.2	Merus N.V. 2016 Incentive Award Plan and forms of award agreements thereunder, as amended	20-F	001-37773	4.2	4/30/18	
10.1.3	Merus N.V. Non-Executive Director Compensation Program	10-Q	001-37773	10.1	8/6/20	
10.1.4	Form of Board of Directors Indemnification Agreement	F-1/A	333-207490	10.4	5/9/16	
10.1.5	Employment Agreement, dated July 2, 2020, by and among Merus US, Inc., the Registrant and Andrew Joe	10-Q	001-37773	10.4	8/6/20	
10.1.6	Employment Agreement, dated December 16, 2015, by and among Merus US, Inc., the Registrant and Hui Liu, as amended on March 2, 2016	20-F	001-37773	4.7	4/30/18	
10.1.7	Employment Agreement, dated August 20, 2020 between Peter Silverman and Merus N.V.	10-Q	001-37773	10.3	11/5/20	
10.1.8	Employment Agreement, dated January 1, 2019, by and among Merus US, Inc., the Registrant and Sven A. Lundberg	10-K	001-37773	10.1.13	3/16/20	
10.1.9	English language translation of Employment Agreement, dated as of August 5, 2010, by and between the Registrant and Alexander Bakker	20-F	001-37773	4.10	4/30/18	
10.1.10	Settlement Agreement, dated April 16, 2020, by and between the Registrant and Mark Throsby	10-Q	001-37773	10.2	5/11/20	
10.1.11	Consultancy Agreement, dated April 13, 2020, by and between the Registrant and Victor Sandor	10-Q	001-37773	10.3	8/6/20	

Exhibit Number	Exhibit Description	Form	Incorporated by Reference to Filings Indicated			Filed/ Furnished
			File No.	Exhibit No.	Filing Date	
10.1.12	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	20-F	001-37773	4.9	4/30/18	
10.1.13	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	20-F	001-37773	4.11	4/30/18	
	Material Contracts – Banking and Financing					
10.2.1	English language translation of Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A., dated December 29, 2005	F-1	333-207490	10.8	10/19/15	
10.2.2	English language translation of letter amendment, dated October 21, 2015, to Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A.	F-1/A	333-207490	10.9	1/21/16	
10.2.3	English language translation of letter amendment, dated March 15, 2016, to Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A.	F-1/A	333-207490	10.9.1	5/9/16	
10.2.4	English language translation of letter amendment, dated March 15, 2016, to Loan Agreement between the Registrant and Coöperatieve Rabobank Utrechtse Heuvelrug U.A.	F-1/A	333-207490	10.9.2	5/9/16	
	Material Contracts – Leases					
10.3.1	English language translation of Lease Agreement between the Registrant and Stichting Incubator Utrecht, dated April 22, 2016	F-1/A	333-207490	10.12	5/9/16	
10.3.2	English language translation of Amendment to Lease Agreement, dated as of November 1, 2016 by and between the Registrant and Stichting Incubator Utrecht	20-F	001-37773	4.15.1	4/30/18	
10.3.3	English language translation of the Lease, dated May 1, 2018, by and between the Registrant and Stichting Incubator Utrecht	6-K	001-37773	99.3	8/10/18	
	Material Contracts – Collaboration and License Agreements					
10.4.1†	Collaboration and License Agreement, dated December 20, 2016, by and between the Registrant and Incyte Corporation	20-F	001-37773	4.12	4/28/17	
10.4.2†	Share Subscription Agreement, dated December 20, 2016, by and between the Registrant and Incyte Corporation	20-F	001-37773	4.13	4/28/17	

Exhibit Number	Exhibit Description	Incorporated by Reference to Filings Indicated				Filed/ Furnished
		Form	File No.	Exhibit No.	Filing Date	
10.4.3†	Contract Research and License Agreement and Addendum between the Registrant and ONO Pharmaceutical Co., Ltd., dated April 8, 2014	F-1	333-207490	10.9	10/19/15	
10.4.4†	Contract Research and License Agreement by and between the Registrant and Ono Pharmaceuticals Co., Ltd., dated March 14, 2018	20-F	001-37773	4.19	4/30/18	
10.4.5††	Collaboration and License Agreement, dated January 18, 2021, by and between the Registrant and Eli Lilly and Company					*
	Other Exhibits					
21.1	List of Subsidiaries	F-1/A	333-207490	21.1	4/8/16	
23.1	Consent of Independent Registered Public Accounting firm					*
31.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to rules 13a-14(a) and 15d-14(a) under the Securities and Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002					*
32.1	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002					*
101.INS	Inline XBRL Instance Document - the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document					*
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					*
101.LAB	Inline XBRL Taxonomy Label Linkbase Document					*
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).					*

* Filed herewith.
** Furnished herewith.
† Confidential treatment granted as to portions of the exhibit. Confidential materials omitted and filed separately with the Securities and Exchange Commission.
†† Portions of the exhibit have been omitted. Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

Item 16. Form 10-K Summary.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized**.**

MERUS N.V.

Date: March 16, 2021

By: /s/ Sven A. Lundberg
Sven (Bill) Ante Lundberg
President, Chief Executive Officer and
Principal Financial Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ Sven A. Lundberg **Sven (Bill) Ante Lundberg**	President, Chief Executive Officer, Principal Financial Officer and Director	March 16, 2021
/s/ Harry Shuman **Harry Shuman**	Principal Accounting Officer	March 16, 2021
/s/ Anand Mehra **Anand Mehra**	Chairman of the Board of Directors	March 16, 2021
/s/ Mark T. Iwicki **Mark T. Iwicki**	Director	March 16, 2021
/s/ Len Kenavy **Len Kenavy**	Director	March 16, 2021
/s/ Greg D. Perry **Greg D. Perry**	Director	March 16, 2021
/s/ Paolo Pucci **Paolo Pucci**	Director	March 16, 2021
/s/ Victor Sandor **Victor Sandor**	Director	March 16, 2021

MERUS N.V.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Merus N.V.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Merus N.V. and subsidiary (together, 'the Company') as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years in the two year period ended December 31, 2020, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG Accountants N.V.

We have served as the Company's auditor since 2009.

Rotterdam, The Netherlands
March 16, 2021

MERUS N.V.
CONSOLIDATED BALANCE SHEETS
(Amounts in thousands except per share data)

	2020	2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 163,082	$ 197,612
Marketable securities	44,673	42,153
Accounts receivable	46	941
Accounts receivable (related party)	1,623	1,711
Prepaid expenses and other current assets	8,569	4,951
Total current assets	217,993	247,368
Marketable securities	—	2,009
Property and equipment, net	4,115	3,715
Operating lease right-of-use assets	3,907	5,215
Intangible assets, net	2,843	2,876
Deferred tax assets	410	288
Other assets	1,949	1,905
Total assets	$ 231,217	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 3,126	$ 3,029
Accrued expenses	21,803	13,536
Income taxes payable	206	—
Current portion of lease obligation	1,432	1,380
Current portion of deferred revenue	625	941
Current portion of deferred revenue (related party)	19,554	17,901
Total current liabilities	46,746	36,787
Lease obligation	2,521	3,872
Deferred revenue, net of current portion	237	780
Deferred revenue, net of current portion (related party)	79,450	90,637
Total liabilities	128,954	132,076
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 31,602,953 and 28,882,217 shares issued and outstanding as at December 31, 2020 and 2019, respectively	$ 3,211	$ 2,918
Additional paid-in capital	490,093	441,395
Accumulated other comprehensive income	9,071	1,586
Accumulated deficit	(400,112)	(314,599)
Total stockholders' equity	102,263	131,300
Total liabilities and stockholders' equity	$ 231,217	$ 263,376

See notes to consolidated financial statements.

MERUS N.V.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Amounts in thousands except per share data)

	Year Ended December 31,	
	2020	2019
Collaboration revenue	$ 3,363	$ 5,517
Collaboration revenue (related party)	26,580	25,831
Grant revenue	—	(215)
Total revenue	29,943	31,133
Operating expenses:		
Research and development	70,040	55,680
General and administrative	35,781	34,110
Total operating expenses	105,821	89,790
Operating loss	(75,878)	(58,657)
Other income, net:		
Interest income, net	300	1,889
Foreign exchange (losses) gains	(9,432)	1,615
Miscellaneous income and gains	—	196
Other income, net	(9,132)	3,700
Loss before income tax expense	(85,010)	(54,957)
Income tax expense	503	194
Net loss	$ (85,513)	$ (55,151)
Other comprehensive loss:		
Currency translation adjustment	7,485	(1,308)
Comprehensive loss	$ (78,028)	$ (56,459)
Loss per share allocable to common stockholders:		
Basic and diluted	$ (2.92)	$ (2.28)
Weighted average shares outstanding:		
Basic and diluted	29,256,203	24,218,083

See notes to consolidated financial statements.

MERUS N.V.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Amounts in thousands)

	Year Ended December 31,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (85,513)	$ (55,151)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	1,165	902
Amortization of intangible assets	279	236
Foreign exchange losses (gains)	8,957	(1,068)
Stock-based compensation expense	9,372	7,834
Amortization of discount on investments	40	(531)
Deferred tax benefit	(122)	(89)
Changes in operating assets and liabilities:		
Accounts receivable	1,149	633
Operating lease right-of-use assets and lease obligations	—	(112)
Prepaid expenses and other current assets	(2,895)	(1,029)
Accounts payable	(110)	22
Accrued expenses	7,023	3,317
Deferred revenue	(19,246)	(18,012)
Net cash used in operating activities	**(79,901)**	**(63,048)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	(66,845)	(60,413)
Proceeds from maturities of marketable securities	66,646	87,183
Purchases of intangible assets	—	(375)
Purchases of property and equipment	(1,287)	(2,223)
Net cash provided by (used in) investing activities	**(1,486)**	**24,172**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from issuance of common stock, net of issuance costs	38,072	74,184
Proceeds from stock options exercised	1,448	48
Net cash provided by financing activities	**39,520**	**74,232**
Foreign exchange impact on cash, cash equivalents and restricted cash	7,337	(2,273)
Net increase (decrease) in cash, cash equivalents and restricted cash	(34,530)	33,083
Cash, cash equivalents, and restricted cash, beginning of period	197,813	164,730
Cash, cash equivalents, and restricted cash, end of period	**$ 163,283**	**$ 197,813**
SUPPLEMENTAL DISCLOSURES:		
Non-cash lease obligations acquired from operating lease right-of-use assets	$ —	$ 3,875
Non-cash purchases of property, equipment and intangibles	$ 36	$ 187
Non-cash financing costs	$ 71	$ 164
Income taxes paid	$ (322)	$ (320)
Income tax refunds received	$ 24	$ —
CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 163,082	$ 197,612
Restricted cash included in other assets	201	201
	$ 163,283	$ 197,813

See notes to consolidated financial statements.

MERUS N.V.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(Amounts in thousands except share data)

	Common Shares		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income	Equity
Balance at December 31, 2018	23,358,977	$ 2,366	$ 360,045	$ (259,448)	$ 2,894	$ 105,857
Issuance of common stock, net	5,462,500	546	73,474	—	—	74,020
Exercise of stock options and vesting of restricted stock units	60,740	6	42	—	—	48
Stock-based compensation	—	—	7,834	—	—	7,834
Currency translation adjustment	—	—	—	—	(1,308)	(1,308)
Net loss	—	—	—	(55,151)	—	(55,151)
Balance at December 31, 2019	28,882,217	$ 2,918	$ 441,395	$ (314,599)	$ 1,586	$ 131,300
Issuance of common stock, net	2,451,281	265	37,906	—	—	38,171
Exercise of stock options and vesting of restricted stock units	269,455	28	1,420	—	—	1,448
Stock-based compensation	—	—	9,372	—	—	9,372
Currency translation adjustment	—	—	—	—	7,485	7,485
Net loss	—	—	—	(85,513)	—	(85,513)
Balance at December 31, 2020	31,602,953	$ 3,211	$ 490,093	$ (400,112)	$ 9,071	$ 102,263

See notes to consolidated financial statements.

1. The Company

Merus N.V. is a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics, headquartered in Utrecht, the Netherlands. Merus US, Inc. is a wholly-owned subsidiary of Merus N.V. located at 139 Main Street, Cambridge, Massachusetts, United States (collectively, the “Company”).

Since inception, the Company has generated an accumulated loss of $400.1 million as of December 31, 2020. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its bispecific antibody candidates advance through discovery, pre-clinical development and clinical trials and as it seeks regulatory approval and pursues commercialization of any approved bispecific antibody candidate.

As a result, the Company may need additional financing to support its continuing operations. Until the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through public equity offerings, debt financings, or other sources, which may include collaborations with third parties and business development opportunities. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company’s inability to raise capital as and when needed would have a negative impact on its financial condition and ability to pursue its business strategy. The Company will need to generate significant revenues to achieve profitability and may never do so.

Based on our current operating plan, the Company expects that its existing cash, cash equivalents and marketable securities of $207.8 million as of December 31, 2020, combined with the aggregate immediate proceeds from the closing of the collaboration and share purchase agreements with Eli Lilly & Co (Eli Lilly) in January 2021 of $60.0 million and the aggregate net proceeds from the January 2021 follow-on offering of $129.7 million in January 2021, will fund the Company’s operations at least into the second half of 2024.

2. Summary of Significant Accounting Policies

Basis of Preparation

The Company prepared its consolidated financial statements in compliance with generally accepted accounting principles in the U.S. ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of Consolidation

Subsidiaries are entities controlled by the Company, consisting of Merus N.V.’s wholly owned subsidiary Merus US, Inc. The Company controls an entity when it is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The financial statements of subsidiaries are included in the consolidated financial statements from the date on which control commences until the date on which control ceases. All significant intercompany balances and transactions have been eliminated in consolidation.

Functional and Presentation Currency

Items recorded in each of the Company’s entities are measured using the currency of the primary economic environment in which the entity operates (the "functional currency"). Merus US, Inc.’s functional currency is the U.S. dollar. The functional currency of Merus N.V. is the euro. After measuring foreign currency denominated transactions into an entity’s functional currency, to the extent that a subsidiary’s functional currency differs from its parent, a subsidiary’s financial position and results of operations are translated into its parent’s functional currency. The Company’s consolidated financial position and results of operations are translated into the U.S. dollar as the Company’s reporting currency.

Use of Estimates

The preparation of these consolidated financial statements in accordance with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities, as of the date of the consolidated financial statements, and the reported amounts of collaboration revenue and expenses during the reporting period. Actual results and outcomes may differ materially from management’s estimates, judgments and assumptions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk include cash, cash equivalents, marketable securities and accounts receivable. The Company attempts to minimize the risks related to cash, cash equivalents and marketable securities by working with highly rated financial institutions that invest in a broad and diverse range of financial instruments as defined by the Company. The Company has established guidelines relative to credit ratings and maturities intended to safeguard principal balances and maintain liquidity. The Company maintains its funds in accordance with its investment policy, which defines allowable investments, specifies credit quality standards and is designed to limit the Company's credit exposure to any single issuer.

Accounts receivable represent amounts due from collaboration partners. The Company monitors economic conditions to identify facts or circumstances that may indicate that any of its accounts receivable are at risk of collection.

Subsequent Events

The Company considers events or transactions that occur after the balance sheet date but before the consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The Company evaluated all events and transactions through the date these financial statements were filed with the Securities and Exchange Commission.

Fair Value Measurements

Fair value is defined as an exit price, representing the amount that would be received upon the sale of an asset or payment to transfer a liability in an orderly transaction between market participants. Fair value is a market-based measurement that is determined based on assumptions that market participants would use in pricing an asset or liability. A three-tier fair value hierarchy is used to prioritize the inputs in measuring fair value as follows:

- Level 1 – Quoted market prices (unadjusted) in active markets for identical assets or liabilities that the reporting entity has the ability to access at the measurement date.
- Level 2 – Quoted market prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, or other inputs that are observable, either directly or indirectly. Fair value determined through the use of models or other valuation methodologies.
- Level 3 – Significant unobservable inputs for assets or liabilities that cannot be corroborated by market data. Fair value is determined by the reporting entity's own assumptions utilizing the best information available and includes situations where there is little market activity for the asset or liability.

The asset's or liability's fair value measurement within the fair value hierarchy is based upon the lowest level of any input that is significant to the fair value measurement.

The Company considers its cash, cash equivalents, accounts receivable, marketable securities due with maturities 12 months or less, and accounts payable financial instruments to reflect their fair value given their short maturity and risk profile of the counterparty.

Going Concern

At each reporting period, the Company evaluates whether there are conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that the financial statements are issued. The Company is required to make certain additional disclosures if it concludes substantial doubt exists and it is not alleviated by the Company's plans or when its plans alleviate substantial doubt about the Company's ability to continue as a going concern.

The Company's evaluation entails analyzing prospective operating budgets and forecasts for expectations of the Company's cash needs, and comparing those needs to the current cash, cash equivalent and marketable security balances. After considering the Company's current research and development plans and the timing expectations related to the progress of its programs, and after considering its existing cash, cash equivalents and marketable securities as of December 31, 2020, the Company did not identify conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements were issued.

Cash and Cash Equivalents

The Company considers all highly liquid debt securities with original final maturities of three months or less from the date of purchase to be cash equivalents. Instruments subject to restrictions are not included in cash and cash equivalents.

Marketable Securities

The Company classifies marketable securities that are debt securities with a remaining maturity when purchased of greater than three months as held-to-maturity as the Company has the positive intent and ability to hold such debt securities through maturity.

Debt securities that are classified as held-to-maturity are initially recognized and measured at fair value. Subsequent to initial recognition, they are measured at amortized cost using the effective interest rate method. Interest income from these debt securities is included in interest income. Marketable securities are classified as current if their expected maturity is within one year or less of the balance sheet date and non-current if their maturity is beyond one year of the balance sheet date.

Accounts Receivable

Accounts receivable are amounts due from collaboration partners as a result of research and development services provided or milestones achieved but not yet paid.

Allowance for Credit Losses

The Company evaluates its cash equivalents, accounts receivable and held-to-maturity marketable securities financial assets for expected credit losses. Expected credit losses represent the portion of the amortized cost basis of a financial asset that an entity does not expect to collect. An allowance for expected credit losses is meant to reflect a risk of loss even if remote, irrespective of the expectation of collection from a particular issuer or debt security. The Company has not historically experienced any credit losses on any of its financial assets.

With respect to cash equivalents and accounts receivable, given consideration of their short maturity, historical losses and the current environment, the Company concluded there is generally no expected credit losses for these financial assets. With respect to held-to-maturity marketable securities which are comprised of debt securities, the Company evaluates expected credit losses on a pooled basis based on issuer-type which have similar credit risk characteristics. The allowance for credit losses is immaterial for all periods presented.

Property and Equipment

The Company records property and equipment at cost. The Company calculates depreciation and amortization using the straight-line method over the following estimated useful lives:

Asset Category	Useful Lives
Laboratory equipment	5 years
Office furniture and equipment	5 years
Leasehold improvements	Shorter of useful life or term of lease

The Company capitalizes expenditures for new property and equipment and improvements to existing facilities and charges the cost of maintenance to expense. The Company eliminates the cost of property retired or otherwise disposed of, along with the corresponding accumulated depreciation or amortization, from the related accounts, and the resulting gain or loss is reflected in the results of operations.

Intangible Assets

Intangible assets are identifiable non-monetary assets without physical substance. An asset is a resource that is controlled by the enterprise as a result of past events (for example, purchase or self-creation) and from which future economic benefits (inflows of cash or other assets) are expected. The useful lives of intangible assets are assessed to be definite-lived and amortized over the useful economic life. The Company’s intangible assets are comprised of purchased licenses to intellectual property and software licenses.

Impairment of Long-Lived Assets

The Company reviews long-lived assets to be held and used, including property and equipment, operating lease right-of-use assets and definite-lived intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets or asset group may not be recoverable.

Evaluation of recoverability is first based on an estimate of undiscounted future cash flows resulting from the use of the asset or asset group and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset or asset group, the assets are written down to their estimated fair values. No such impairments were recorded in 2020 or 2019.

Leases

The Company determines if an arrangement is or contains a lease at inception. For leases with a term of 12 months or less, the Company does not recognize a right-of-use asset or lease liability. The Company does not have any finance leases.

Right-of-use assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease, and excludes non-lease payments. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

Operating lease right-of-use assets also include the effect of any lease payments made and excludes lease incentives. The lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term.

The Company has real estate operating lease agreements with lease and non-lease components, which are generally accounted for separately as operating lease costs and variable lease costs. Non-lease components in real estate leases refer to services provided by the lessor related to the premises. Fixed and variable lease payments are both allocated to lease and non-lease components. The allocation is determined on a relative fair value basis of the services provided relative to the operating lease of premises. With respect to equipment leases, the Company has elected not to allocate payments amongst lease and non-lease components as a practical expedient as afforded under ASC 842, *Leases*.

Income Taxes

Deferred Taxes

The Company records deferred taxes to recognize the future effects of temporary differences between the tax basis and financial statement carrying amount of assets and liabilities. The Company measures the deferred taxes using enacted tax rates expected to apply when the temporary differences are realized and records a valuation allowance to reduce deferred tax assets if it is determined that it is more likely than not that all or a portion of the deferred tax asset will not be realized. The Company considers many factors when assessing the likelihood of future realization of deferred tax assets, including recent earnings results, expectations of future taxable income, carryforward periods available, reversing taxable temporary differences and other relevant factors. The Company records changes in the required valuation allowance in the period that the determination is made.

Unrecognized Tax Benefits

The Company assesses its income tax positions and records tax benefits for all years subject to examination based upon management's evaluation of the technical merits, facts, circumstances and information available as of the reporting date. For those tax positions where it is more likely than not that a tax benefit will be sustained, the Company records the largest amount of tax benefit with a greater than 50.0% likelihood of being realized upon settlement with a taxing authority having full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will be sustained, the Company does not recognize a tax benefit in the financial statements. The Company records interest and penalties related to an underpayment of income taxes, if applicable, as a component of income tax expense.

Revenue Recognition

The Company recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for an arrangement, the Company performs the following five step analysis:

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 a performance obligation.

The Company has entered into collaboration and license agreements, which are within the scope of ASC 606, *Revenue from Contracts with Customers*, to discover, develop, manufacture and commercialize product candidates. The terms of these agreements typically contain multiple promises or obligations, which may include: (i) licenses, or options to obtain licenses, to product candidates or future product candidates directed to specific targets (referred to as "exclusive licenses") and (ii) research and development activities to be

performed on behalf of the collaboration partner related to the licensed targets. The Company also derives revenue from government grants.

As part of the accounting for these arrangements, the Company must use judgment to determine:

a) the number of performance obligations based on the determination under step (ii) above and whether those performance obligations are distinct from other performance obligations in the contract;

b) the transaction price under step (iii) above; and

c) the stand-alone selling price for each performance obligation identified in the contract for the allocation of transaction price in step (iv) above.

The Company uses judgment to determine whether milestones or other variable consideration, except for sales-based royalties, should be included in the transaction price as described further below. The transaction price is allocated to each performance obligation on a relative stand-alone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. In validating its estimated stand-alone selling price, the Company evaluates whether changes in the key assumptions used to determine its estimated stand-alone selling price will have a significant effect on the allocation of arrangement consideration between performance obligations.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying consolidated balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion. Amounts recognized as revenue, but not yet received or invoiced are generally recognized as unbilled receivables.

Exclusive Licenses

If the license to the Company's intellectual property is determined to be distinct from the other promises or performance obligations identified in the arrangement, which generally include research and development services, the Company recognizes revenue from non-refundable, upfront 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.

In assessing whether a license is distinct from the other promises, the Company considers relevant facts and circumstances of each arrangement, including the rights and obligations set out in the contract, the research and development capabilities of the collaboration partner and the availability of the associated expertise in the general marketplace. In addition, the Company considers whether the collaboration partner can benefit from the license for its intended purpose without the receipt of the remaining promises, whether the value of the license is dependent on the unsatisfied promises, whether there are other vendors that could provide the remaining promises, and whether it is separately identifiable from the remaining promises.

For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue.

The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition. The measure of progress, and thereby periods over which revenue should be recognized, are subject to estimates by management and may change over the course of the research and development and licensing agreement.

The Company's arrangements may provide the collaboration partner with the right to select a target for licensing either at the inception of the arrangement or in the future. Under these arrangements, fees may be due to the Company (i) at the inception of the arrangement as an upfront fee or payment, (ii) upon the exercise of an option to acquire a license or (iii) upon extending the selection period as an extension fee or payment. If an arrangement is determined to contain customer options that allow the customer to acquire additional goods or services, the goods and services underlying the customer options are not considered to be performance obligations at the outset of the arrangement, as they are contingent upon option exercise. The Company evaluates the customer options for material rights, or options to acquire additional goods or services for free or at a discount. If the customer options are determined to represent a material right, the material right is recognized as a separate performance obligation at the inception of the arrangement. The Company allocates the transaction price to material rights based on the relative stand-alone selling price, which is determined based on the identified discount and the probability that the customer will exercise the option. Amounts allocated to a material right are not recognized as revenue until, at the earliest, the option is exercised or expires.

For arrangements that include sales-based milestones and royalties, 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 sales-based milestones or royalty revenue resulting from any of its arrangements.

Research and Development Services

The promises under the Company's collaboration and license agreements generally include research and development services to be performed by the Company on behalf of the collaboration partner. For performance obligations that include research and development services, the Company recognizes revenue allocated to such performance obligations based on an appropriate measure of progress. The Company utilizes judgment to determine the appropriate method of measuring progress for purposes of recognizing revenue, which is generally an input measure such as costs incurred. The Company evaluates the measure of progress each reporting period as described under *Exclusive Licenses* above.

Reimbursements from the partner are evaluated as to whether the Company acts as a principal or an agent in such relationships. The Company evaluates whether control over the underlying goods or services were obtained prior to transferring these goods or services to the collaboration partner. Where the Company does not control the goods or services prior to transferring these goods or services to the collaboration partner, such reimbursements are presented net of costs.

At the inception of each arrangement that includes development milestone payments in respect of development efforts, the Company evaluates whether the development milestones are considered probable of being achieved and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated development milestone value is included in the transaction price. Development milestone payments that are not within the control of the Company or the licensee, such as regulatory approvals, are not considered probable of being achieved until those approvals are received. The Company evaluates factors such as the scientific, clinical, regulatory, commercial, and other risks that must be overcome to achieve the particular development milestone in making this assessment. There is judgment involved in determining whether it is probable that a significant revenue reversal would not occur.

At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of all development milestones subject to constraint and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. If a milestone or other variable consideration relates specifically to the Company's efforts to satisfy a single performance obligation or to a specific outcome from satisfying the performance obligation, the Company generally allocates the milestone amount entirely to that performance obligation once it is probable that a significant revenue reversal would not occur.

Government Grants

The Company receives certain government and regional grants, which support its research efforts in defined projects, and include contributions towards the R&D cost. When there is reasonable assurance that the Company will comply with the conditions attached to a received grant, and when there is reasonable assurance that the grant will be received, government grants are recognized as revenue on a gross basis in the consolidated statement of profit or loss and comprehensive loss on a systematic basis over the periods in which the Company recognizes expenses for the related costs for which the grants are intended to compensate. In the case of grants related to assets, the received grant will be deducted from the carrying amount of the asset. Government grant revenue may be subject to review by a government authority in periods subsequent to their recognition and may result in the reversal of grant revenue previously recognized. Reversals of grant revenue are presented as contra revenue in the consolidated statement of operations.

Research and Development Expenses

Research and development expenses are expensed as incurred. Research and development expenses are comprised of costs incurred in providing research and development activities, including salaries and benefits, facilities costs, overhead costs, contract research and development services, and other outside costs. Nonrefundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

When third-party service providers' billing terms do not coincide with the Company's period-end, the Company is required to make estimates of its obligations to those third parties, including clinical trial and pharmaceutical development costs, contractual services costs and costs for supply of its product candidates incurred in a given accounting period and record accruals at the end of the period. The Company bases its estimates on its knowledge of the research and development programs, services performed for the period, past history in conducting similar activities and the expected duration of the third-party service contract, among other considerations.

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 vendors will exceed the level of services provided and result in a prepayment of research and development expenses.

The WBSO (*afdrachtvermindering speur- en ontwikkelingswerk*) is a Dutch fiscal facility that provides subsidies to companies, knowledge centers and self-employed people who perform research and development activities (as defined in the WBSO Act). Under

this act, a contribution is paid towards the labor costs of employees directly involved in research and development. For the year ended December 31, 2020 and 2019, the Company recognized $6.0 million and $4.5 million as a reduction of research and development expenses, respectively.

Share-Based Payments

The Company measures employee share-based compensation based on the grant date fair value of the share-based compensation award. The Company grants stock options at exercise prices equal to the fair value of the Company's common stock on the date of grant, based on observable market prices.

For share-based payments subject time-based vesting, the Company recognizes employee stock-based compensation expense on a straight-line basis over the requisite service period of the awards, generally from the date of grant through each vesting date. The Company recognizes forfeitures at the time they occur. The actual expense recognized over the vesting period will only represent those options that vest; the effect of forfeitures in the recognition of periodic compensation expense are not estimated prior to their occurrence.

Earnings (Loss) per Share

The Company computes basic earnings (loss) per share by dividing income (loss) allocable to common stockholders by the weighted average number of shares of common stock outstanding. During periods of income, the Company allocates participating securities a proportional share of income determined by dividing total weighted average participating securities by the sum of the total weighted average common shares and participating securities. During periods of loss, the Company allocates no loss to participating securities because they have no contractual obligation to share in the losses of the Company. The Company computes diluted earnings (loss) per share after giving consideration to the dilutive effect of stock options and restricted stock units ("RSU") that are outstanding during the period, except where such non-participating securities would be anti-dilutive.

Segment Information

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

Pending Accounting Pronouncements

In August 2018, the FASB issued ASU 2018-15, *Intangibles-Goodwill and Other-Internal-Use Software (Subtopic 350-40): Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement That Is a Service Contract.* The new guidance aligns the requirements for capitalizing implementation costs incurred in a cloud-based hosting arrangement that is a service contract with the requirements for capitalizing implementation costs incurred to develop or obtain internal-use software (and hosting arrangements that include an internal-use software license). This ASU is effective for the Company at the beginning of 2021, including interim periods within that reporting period, although early adoption is permitted. The Company does not expect the impact of adoption to be significant.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808),* which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The ASU will be effective for the Company in the first quarter of fiscal 2021, with early adoption permitted. As of December 31, 2020, none of the Company's arrangements fall within the scope of ASC 808. However, as the Company may engage in future collaborative arrangements in the future, this ASU may apply to those new arrangements.

3. Investments in Debt Securities

Debt securities are classified in the consolidated balance sheet as follows:

	December 31,	
	2020	2019
	Balance	Balance
	(in thousands)	
Cash equivalents	$ 17,654	$ 34,053
Current marketable securities	44,673	42,153
Non-current marketable securities	—	2,009
Total	$ 62,327	$ 78,215

The following table summarizes debt securities by maturity at December 31, 2020 (in thousands):

Maturity	Amortized Cost
Within one year	$ 62,327
After one year through five years	—
Total	$ 62,327

The following table summarizes debt securities by credit-quality indicator:

	Credit Quality Indicator as of December 31, 2020			
	AAA	AA- to AA+	A- to A+	Total
	(In thousands)			
Money market funds	$ 10,156	$ —	$ —	$ 10,156
U.S. treasuries	—	15,043	—	15,043
U.S. government agency securities	—	9,150	—	9,150
Corporate paper and notes	7,498	—	20,480	27,978
Total	$ 17,654	$ 24,193	$ 20,480	$ 62,327

The credit quality indicator was derived from publicly available ratings published by Moody's or a comparable credit rating agency, last updated as of December 31, 2020.

The following table summarizes the fair value of debt securities by major security type held at December 31, 2020 (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 10,156	$ —	$ —	$ 10,156
U.S. treasuries	15,043	1	—	15,044
U.S. government agency securities	9,150	—	—	9,150
Corporate paper and notes	27,978	2	(2)	27,978
Total	$ 62,327	$ 3	$ (2)	$ 62,328

The following table summarizes the fair value of debt securities by major security type held at December 31, 2019 (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 34,053	$ —	$ —	$ 34,053
U.S. treasuries	1,496	2	—	1,498
U.S. government agency securities	3,987	7	—	3,994
Corporate paper and notes	38,679	32	(2)	38,709
Total	$ 78,215	$ 41	$ (2)	$ 78,254

The allowance for credit losses applicable to debt securities was immaterial in all periods presented.

Fair Value

The fair value of money market funds is determined based on publicly available market price for these funds (Level 1). The fair value of other debt securities is determined based on the publicly available inputs which includes a market price for the same or similar instruments adjusted for estimates in interest yield (Level 2).

4. Prepaid Expenses and Other Assets

Prepaid expenses and other current assets consisted of the following:

	December 31,	
	2020	2019
	(In thousands)	
Prepaid clinical and manufacturing costs	$ 4,971	$ 2,779
Prepaid general and administrative costs	2,460	789
Interest receivable	80	259
Other	1,058	1,124
Total	$ 8,569	$ 4,951

Restricted cash included in other assets totaled $0.2 million and $0.2 million as of December 31, 2020 and 2019, respectively. The nature of the restriction relates to amounts held as collateral for a credit card borrowing arrangement.

5. Property and Equipment, net

Property and equipment, net consists of the following:

	December 31,	
	2020	2019
	(In thousands)	
Laboratory equipment	$ 5,695	$ 4,538
Office equipment and furniture	1,300	1,186
Leasehold improvements	117	79
Construction in progress	496	—
Property and equipment	7,608	5,803
Less: accumulated depreciation and amortization	(3,493)	(2,088)
Property and equipment, net	$ 4,115	$ 3,715

Depreciation and amortization expense was $1.2 million and $0.9 million for the years ended December 31, 2020, and 2019, respectively. Property and equipment are predominantly located in the Netherlands.

6. Intangible assets, net

Intangible assets, net consists of the following:

	December 31,	
	2020	2019
	(In thousands)	
Licenses of intellectual property	$ 3,898	$ 3,568
Software licenses	288	264
Intangible assets	4,186	3,832
Less: accumulated amortization	(1,343)	(956)
Intangible assets, net	$ 2,843	$ 2,876

Amortization expense was $0.3 million and $0.2 million for the years ended December 31, 2020, and 2019, respectively. Intangible assets are predominantly located in the Netherlands.

Amortization expense over the next five years are expected to be as follows (in thousands):

Year	Expected amortization
2021	$ 300
2022	300
2023	230
2024	196
2025	166
Thereafter	1,651
Total remaining value	$ 2,843

7. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2020	2019
	(In thousands)	
Accrued research and development expenses	$ 15,372	$ 6,618
Accrued personnel costs	4,854	4,495
Accrued general and administrative expenses	1,566	2,402
Other	11	21
Accrued expenses	$ 21,803	$ 13,536

8. Income Taxes

The components of loss from operations before income tax expense are as follows:

	Year ended December 31,	
	2020	2019
	(In thousands)	
United States	$ (3,832)	$ (1,363)
Netherlands	(81,178)	(53,594)
Total loss before income taxes	$ (85,010)	$ (54,957)

The components of income tax expense (benefit) from continuing operations are as follows:

	December 31,	
	2020	2019
	(In thousands)	
U.S. federal	$ 391	$ 243
U.S. state	234	40
Total current tax expense	$ 625	$ 283
U.S. federal	$ (86)	$ (63)
U.S. state	(36)	(26)
Total deferred tax benefit	$ (122)	$ (89)
Total income tax expense	$ 503	$ 194

The parent company is subject to income tax in the Netherlands where a greater proportion of economic activity is attributed. A reconciliation of the Netherlands statutory income tax rate to the Company's effective income tax rate is as follows:

	Year Ended December 31,	
	2020	2019
Netherlands statutory income tax rate	25.0%	25.0%
Changes in tax rates	10.6	1.5
Non-deductible expenses	(2.4)	(3.7)
Change in valuation allowance	(33.5)	(23.3)
Other	(0.3)	0.1
Effective income tax rate	(0.6)%	(0.4)%

In 2018 and 2020, Dutch tax authorities enacted new tax rates applicable to future periods which impact the measurement of deferred income taxes. The effect of the change in the valuation allowance each year reflects the increase or decrease in the valuation allowance against deferred tax assets attributable to the Netherlands.

The components of the Company's deferred tax assets (liabilities) consist of the following:

	December 31,	
	2020	2019
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 66,572	$ 33,917
Deferred revenue	24,966	23,926
Excess interest carryforward	2,080	—
Lease obligation	1,058	1,333
Accrued expenses and other	494	319
Total deferred tax assets	95,170	59,495
Deferred tax asset valuation allowance	(93,645)	(57,876)
Total deferred tax assets, net of valuation allowance	1,525	1,619
Deferred tax liabilities:		
Operating lease right-of-use assets	$ 1,048	$ 1,331
Other	67	—
Total deferred tax liabilities	1,115	1,331
Net deferred tax asset	$ 410	$ 288

After consideration of all positive and negative evidence, the Company believes that it is more-likely-than-not that our Netherlands deferred tax assets that are not supported by reversing temporary differences will not be realized. As a result, the Company established a valuation allowance of $93.6 million and $57.9 million as of December 31, 2020 and 2019, respectively. The increase in the valuation allowance of $35.8 million and $13.2 million for the years ended December 31, 2020 and 2019, respectively, is primarily attributable to the increase in net operating loss carryforward deferred tax assets for which a full valuation allowance applies and change in tax rates. As of December 31, 2020, the portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits would be credited directly to contributed capital totaled $2.1 million.

As of December 31, 2020, the Company did not have any net operating losses for U.S. federal or state income tax purposes. The Company had net operating loss carryforwards for Dutch income tax purposes, the amount and expiry are as follows (in thousands):

Expiry Year	Netherlands Tax Loss Carryforward
2024	$ 23,129
2025	110,165
2026	95,568
2027	37,426
Total	$ 266,288

As of December 31, 2020, the Company had no unrecognized tax benefits. As of December 31, 2020, the Company had no accrued interest or penalties related to underpayments of income taxes and no amounts have been recognized in the consolidated statements of operations. The Company will recognize interest and penalties related to an underpayment of income taxes in income tax expense.

The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions as well as in the Netherlands. The statute of limitations for assessment by the Internal Revenue Service (IRS), and Massachusetts tax authorities is closed for tax years prior to 2017. The statute of limitations for assessment by the Netherlands tax authorities is closed for tax years prior to 2015. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

9. Operating Leases

Merus N.V. leases its corporate headquarters under an agreement term of five years, which expires in the fourth quarter of 2021. On May 1, 2018, Merus N.V. 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 also expires in the fourth quarter of 2021. Given the Company's current plans, the renewal term has not been included in the estimate of the lease term. Fixed lease payments increase annually and include an

increase based on an inflationary measure. Variable payments include amounts due to the lessor for additional services and cost reimbursements.

In March 2019, Merus US, Inc. entered into a lease agreement for office space in Cambridge, Massachusetts. The lease commenced in the second quarter of 2019 and has a term of seven years, and may be extended for another five years. Given the Company's current plans, the renewal term has not been included in the estimate of the lease term. Fixed lease payments increase annually and include an increase on an inflationary measure. Variable payments include amounts due to the lessor for additional services and cost reimbursements.

The Company's operating leases relate to its real estate leases that are not classified as finance leases.

In July 2019, the Company entered into a lease with Kadans Science Partner XII B.V. ("Kadans"), pursuant to which the Company agreed to lease approximately 5,070 square meters of office and laboratory space in a new multi-tenant office building that is to be constructed in Utrecht, the Netherlands. The initial term of the lease is ten years from the date that the premises are completed in accordance with certain specifications provided in a development agreement (described below), which is expected to occur in mid-2022. The lease will renew for two 5-year terms following the initial term, unless earlier terminated by the Company or Kadans, except that the earliest Kadans may terminate the lease is 20 years from the completion date. The lease provides for an estimated initial rent of approximately €1.3 million per annum. The rent amount is subject to adjustment based on the consumer price index (the "CPI") beginning on January 1, 2019 through the completion date and then annually thereafter, subject to certain limitations if the CPI is greater than 3.0%. The final initial rent amount is contingent upon, among other things, the parameters of the final constructed premises, the final floor area, and the CPI adjustment described above, and will be determined upon the completion date and recorded in a first rider, signed by the Company and Kadans, to the lease. The Company is also responsible for certain fit-out costs and service fees related to the premises.

In July 2019, the Company also entered into a development agreement with Kadans and another party, Genmab B.V., which provides for the design, development and construction of the new multi-tenant office building of which the premises is a part.

The components of lease cost recorded in the Company's consolidated statement of operations and statement of cash flows were as follows:

	For the Year Ended December 31,	
	2020	2019
	(In thousands)	
Operating lease cost	$ 1,611	$ 1,386
Variable lease cost	375	297
Total lease cost included in operating expenses	$ 1,986	$ 1,683
Cash paid to lessors included in operating cash outflows	$ 2,478	$ 2,273

The Company's non-lease cost and other costs paid to the lessor are primarily related to services provided by the lessor in operating the premises that includes fees, operating costs, taxes and insurance related to the leased premises.

Maturities of the Company's operating lease obligations as of December 31, 2020 were as follows (in thousands):

Year	Operating Leases
2021	$ 1,577
2022	614
2023	630
2024	645
2025	662
Thereafter	222
Total lease payments	4,350
Less: amount representing interest	(397)
Total lease obligations	$ 3,953

The weighted-average remaining lease terms and discount rates related to the Company's leases were as follows:

	As of December 31,	
	2020	2019
Weighted-average remaining operating lease term (in years)	4.2	4.8
Weighted-average discount rate for operating leases	4.9%	5.0%

10. Commitments and Contingencies

Indemnities

The Company indemnifies its officers and directors for certain events or occurrences while the officer or director is, or was, serving at the Company's request in such capacity. The maximum potential amount of future payments the Company could be required to make is unlimited; however, the Company has directors' and officers' insurance coverage that is intended to limit its exposure and enable it to recover a portion of any future amounts paid.

The Company enters into certain agreements with other parties in the ordinary course of business that contain indemnification provisions. These typically include agreements with directors and officers, business partners, contractors, landlords, clinical sites and customers. Under these provisions, the Company may indemnify and hold harmless the indemnified party for losses suffered or incurred by the indemnified party as a result of the Company's activities, such as gross negligence, willful misconduct or at times, other activities. These indemnification provisions may survive termination of the underlying agreements. The maximum potential amount of future payments the Company could be required to make under these indemnification provisions may be unlimited. However, to date the Company has not incurred material costs to defend lawsuits or settle claims related to these indemnification provisions. As a result, the estimated fair value of these obligations is minimal. Accordingly, the Company did not have any liabilities recorded for these obligations as of December 31, 2020.

Litigation

On April 5, 2018, an unnamed third party and Regeneron Pharmaceuticals Inc., or Regeneron filed notices of opposition against the Company's EP 2604625 patent, entitled "Generation of Binding Molecules," in the European Opposition Division of the European Patent Office (the "EPO"). The notices asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. Regeneron withdrew its opposition pursuant to a global December 20, 2018 settlement with the Company. On August 20, 2018, the Company timely responded to these submissions with respect to the unnamed third party. An opposition hearing was held in June 2019, wherein the EPO revoked the EP 2604625 patent in its entirety under Art. 123(2) EPC. The Company timely appealed that decision in December 2019 before the Technical Board of Appeals for the EPO seeking reinstatement of the patent and proposing auxiliary requests for certain amended claims, with further proceedings to be scheduled in the future. As this opposition proceeding continues, the Company cannot be certain that it will ultimately prevail.

From time to time, the Company may be involved in various other claims and legal proceedings relating to claims arising out of the Company's operations.

11. Stockholders' Equity

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to dividends when and if declared by the board of directors.

Share Issuances

On November 7, 2019, the Company completed an underwritten public offering in which the Company sold 5,462,500 common shares, including 715,500 common shares pursuant to the underwriters' option to purchase additional shares, at a price to the public of $14.50 for aggregate net proceeds of $74.0 million.

On November 23, 2020, the Company sold 766,666 common shares, at a price of $15.00 for aggregate proceeds of $11.5 million.

On November 24, 2020, the Company sold 384,615 common shares, at a price of $15.60 for aggregate proceeds of $6.0 million.

On December 3, 2020, the Company sold 1,300,000 common shares, at a price of $16.90 for aggregate proceeds of $22.0 million.

Equity Compensation Plan

As of January 1, 2021, a total of 2,336,997 shares of common stock were reserved for additional grants of stock awards under the Company's 2016 Incentive Award Plan. Stock-based compensation expense related to the equity compensation plan is more fully described in Note 13, *Employee Benefit Plans*.

12. Collaborations

Incyte

In December 2016, pending regulatory clearance, Incyte agreed to pay the Company a $120.0 million, non-refundable upfront payment, and purchased 3.2 million common shares at a stated price per share of $25.00, for an aggregate purchase price of $80.0 million. In exchange, the Company granted Incyte with a license to certain of its intellectual property and committed to collaborate with Incyte to research, discover and develop monospecific or bispecific antibodies utilizing the Company's proprietary bispecific technology platform. The collaboration is managed by a joint steering committee in which both parties are represented and is tasked with overseeing the activities which significantly contributes to the collaboration. The collaboration may encompass up to 11 product candidates that result from the Company's application of its proprietary Biclonics® technology platform. During the course of the initial research term, Merus proposes product candidates to Incyte, which evaluates whether to designate proposed product candidates from the Company to make a selection for further research. Proposed product candidates begin at a pre-clinical stage of development. Incyte has certain rights to replace product candidates, including the right to substitute a product candidate after initial selection. The Company would be entitled to future consideration in the form of cost reimbursements for research services, development milestones, commercialization milestones and royalties related to the programs under the arrangement.

At inception of the collaboration, two potential bispecific product candidates were under preliminary evaluation. After further research, a lead candidate was ultimately selected for the first product candidate, designated MCLA-145, and the other potential product candidate was not pursued. For the designated product candidate (MCLA-145), the Company retains 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, the parties will conduct and share equally the costs of mutually agreed global development activities and will be solely responsible for independent development activities in each party's respective territories. For all other programs under the arrangement to be selected by Incyte, Incyte will be responsible for all research, development and commercialization costs. The Company may elect to co-fund the development of certain of the other programs in the future, in which case costs and benefits would be shared. The Company has not elected to co-fund any programs to date.

At inception of the arrangement, the Company identified a performance obligation comprised of a combined delivery of a license and related activities, including the activities of the joint steering committee, to which to allocate consideration. The arrangement also allowed for optional future research services to advance selected product candidates through discovery and research. The transaction price was comprised of fixed consideration of an upfront payment of $120.0 million and proceeds from the sale of shares of $80.0 million. All other consideration under the arrangement was determined to be variable consideration and fully constrained at inception. $152.6 million of the transaction price was allocated to the license and related activities performance obligation after accounting for the purchase of common shares by Incyte.

On January 23, 2017, the Company completed the sale of shares and exchange of the license. The Company initially deferred the transaction price allocated to the license and related activities performance obligation as deferred revenue, to be recognized as revenue over time as the primary benefit of the license to Incyte is access to the platform for the generation of potential product candidates. Development milestones, commercialization milestones and royalties are variable consideration, fully constrained, to be recognized in future periods in accordance with the Company's revenue recognition policy. Cost reimbursements for research services are recognized as they are performed over time as these are considered a separate performance obligation.

At December 31, 2020, the Company is currently engaged in research and development activities for MCLA-145 and developing candidates for the other programs. No development or commercialization milestones have been achieved to date.

ONO

On March 14, 2018, 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 Biclonics® technology platform against two undisclosed targets directed to a particular undisclosed target combination. ONO is responsible for identifying lead candidates and 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. In addition, the Company was entitled to €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 is entitled to research and development milestones in addition to royalties on future sales. The Company identified performance obligations for: (1) provision of a license for the target combination, and (2) research and development services. The Company concluded that Ono would be able to develop and benefit from the license, independent of the research and development services. The research and development services are capable of being performed by third parties with an appropriate sub-license, and are recognized over time as these services are delivered. Milestone payments are fully constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

On March 3, 2016, the Company was engaged to perform manufacturing services for Ono in support of their clinical trials that was the subject of a prior arrangement with Ono initiated in 2014. The Company was entitled to compensation to oversee and support a manufacturing process with the use of an outside third-party and to deliver quantities of manufactured product. The Company identified one performance obligation to provide manufacturing supervision services involving the transfer of know-how and the development of a manufacturing process with the third-party and three performance obligations related to the services provided in connection with the delivery of product each having separate and distinct requirements. The Company acts as an agent for Ono with respect to the third-party manufacturing costs incurred for the underlying product and presents the recovery of such costs net in research and development expense in the consolidated statement of operations.

The Company received €3.7 million (approximately $4.1 million) for the year ended December 31, 2019 for development milestones received from Ono based on their progress. The amounts are recognized as revenue in the consolidated statement of operations for the year ended December 31, 2019. No comparable development milestones were received in the year ended December 31, 2020. Research and development services were completed in 2018.

Simcere

In January 2018, the Company granted Simcere an exclusive license to develop and commercialize up to three bispecific antibodies to be produced by Merus utilizing the Company's Biclonics® technology platform in China. The Company will retain all rights outside of China. The Company has agreed to lead research and discovery activities, while Simcere has agreed to be responsible for the Investigational New Drug ("IND") enabling studies, clinical development, regulatory filings and commercialization of these potential product candidates in China. The Company received an upfront, non-refundable payment of $2.75 million, relating to three separate research programs. The Company may be entitled to future development milestone payments.

At inception of the arrangement, the Company identified three performance obligations comprised of the combined delivery of a license and performance of research and development activities with respect to each program. The Company performs research and development activities to achieve candidate nomination. The Company concluded that these activities were not distinct from the underlying license for each program as Simcere would not be able to benefit from the license apart from research and development activities at this phase of development.

The transaction price under the arrangement comprised fixed consideration of $2.75 million. The transaction price was allocated to each separate performance obligation on a relative standalone fair value basis. The Company deferred the portion of the upfront payment allocated to the three performance obligations as deferred revenue, to be recognized over time. Compensation for research and development services prior to candidate nomination are allocated to each program performance obligation and also recognized over time. Development milestone payments allocated to each of the program performance obligations are constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

To date, the Company has achieved two milestones under this agreement and has received an aggregate of $1.3 million in milestone payments, including a milestone payment of $0.5 million for the quarter ended September 30, 2020, concerning the generation of functional data associated with the second bispecific antibody research program. At December 31, 2020, research and development for one of the three programs is on-going.

Betta

On December 10, 2018, the Company granted Betta an exclusive license to develop and commercialize in China MCLA-129, a proprietary Biclonics® produced by its Biclonics® technology platform. The Company retains all rights outside of China. Betta has agreed to retain a contract manufacturing organization with experience in filing IND applications with U.S. regulatory authorities and CTAs with European regulatory authorities in order to produce clinical trial materials for the Chinese market and rest of the world. As a key strategic component of the collaboration, Betta will be responsible for IND enabling studies and manufacturing of clinical trial

materials in China, which the Company intends to use to assist regulatory filing and early stage clinical development in the rest of the world.

In addition to a non-refundable upfront payment of $1.0 million, Betta and the Company will share equally the cost of the transfer of the manufacturing technology to a contract manufacturing organization. The Company is also eligible to receive an aggregate of $12.0 million in milestone payments contingent upon Betta achieving certain specified development and commercial goals as well as tiered royalty payments of net sales of any products resulting from the collaboration in China. In turn, Betta is also entitled to milestone payments based on the Company's progress.

The Company identified a single combined performance obligation, being the delivery of the MCLA-129 license including activities necessary to complete the technology transfer. The Company had no other commitments. The transaction price is comprised of fixed consideration of $1.0 million and fully allocated to the single performance obligation which would be fulfilled at a point in time. The technology transfer to deliver the license was completed in 2018 and Company recognized the revenue related to this performance obligation of $1.0 million as revenue for the year ended December 31, 2018. Development milestone payments allocated to the performance obligation are constrained as variable consideration to be recognized in future periods in accordance with the Company's revenue recognition policy.

In the quarter ended December 31, 2020, both the Company and Betta achieved a development milestone both valued at $2.0 million. The amounts are recognized as milestone revenue of $2.0 million and research and development cost of $2.0 million in the Company's statement of operations for the year ended December 31, 2020.

Contract Assets, Liabilities, Revenues and Expenses

The following tables provide amounts by year indicated and by line item included in the Company's accompanying consolidated financial statements attributable to transactions arising from its collaboration arrangements. The dollar amounts in the tables below are in thousands.

	Related Party	Third Party		
	Incyte	Ono	Other	Total
Contract assets				
Accounts receivable				
Balance at January 1, 2020	**$ —**	$ 786	$ —	**$ 786**
Billings	**6,546**	—	644	**644**
Cash receipts	**(6,587)**	(772)	(607)	**(1,379)**
Adjustments	**—**	—	(11)	**(11)**
Foreign exchange	**41**	(14)	20	**6**
Balance at December 31, 2020	**—**	—	46	**46**
Unbilled receivables				
Balance at January 1, 2020	**$ 1,711**	$ —	$ 155	**$ 155**
Accrued receivables	**6,354**	—	581	**581**
Billings	**(6,546)**	—	(644)	**(644)**
Adjustments	**—**		(94)	**(94)**
Foreign exchange	**104**	—	2	**2**
Balance at December 31, 2020	**1,623**	—	—	**—**
Contract liabilities				
Deferred revenue				
Balance at January 1, 2020	**$ 108,538**	$ 336	$ 1,385	**$ 1,721**
Revenue recognized in the period	**(18,194)**	(200)	(743)	**(943)**
Foreign exchange	**8,660**	15	69	**84**
Balance at December 31, 2020	**99,004**	151	711	**862**
Less: current portion	**(19,554)**	(151)	(474)	**(625)**
Non-current balance at December 31, 2020	**79,450**	—	237	**237**

The balance of unbilled receivables predominantly represents reimbursement revenue under the Company's collaboration arrangements earned in the period to be billed and collected in the next period, generally quarterly. Incyte is a related party as a shareholder, as more fully described in Note 15.

	For the Year Ended December 31, 2020			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 18,193**	$ 200	$ 695	**$ 895**
Reimbursement revenue	**8,387**	—	(12)	**(12)**
Milestones	**—**	—	2,480	**2,480**
Total collaboration revenue	**$ 26,580**	$ 200	$ 3,163	**$ 3,363**
Operating expenses:				
Research and development expense	**$ 2,036**	$ —	$ 1,944	**$ 1,944**
General and administrative expense	**—**	—	—	**—**
Total operating expenses from collaborations	**$ 2,036**	$ —	$ 1,944	**$ 1,944**
Revenue recognized that was included in deferred revenue at the beginning of the period	**$ 18,193**	$ 200	$ 738	**$ 938**

	For the Year Ended December 31, 2019			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 17,839**	$ 196	$ 643	**$ 839**
Reimbursement revenue	**7,992**	99	153	**252**
Milestones	**—**	4,142	284	**4,426**
Total collaboration revenue	**$ 25,831**	$ 4,437	$ 1,080	**$ 5,517**
Operating expenses:				
Research and development expense	**$ 680**	$ —	$ —	**$ —**
General and administrative expense	**—**	—	—	**—**
Total operating expenses from collaborations	**$ 680**	$ —	$ —	**$ —**
Revenue recognized that was included in deferred revenue at the beginning of the period	**$ 17,839**	$ 196	$ 945	**$ 1,141**

13. Employee Benefit Plans

Share-Based Payments

2010 Plan

In 2010, the Company established the Merus B.V. 2010 Employee Option Plan (the "2010 Plan") that entitled key management personnel, staff and consultants providing similar services to purchase shares in the Company. Under the 2010 Plan, holders of vested options were entitled to purchase depositary receipts for common shares at the exercise price determined at the date of grant. Upon exercise of the option, common shares were issued to a foundation established to facilitate administration of share-based compensation awards and pool the voting interests of the underlying shares, and depositary receipts were issued by the foundation to the individual holders. In connection with the IPO, the 2010 Plan was amended to cancel the depositary receipts and allow individual holders to directly hold the common shares obtained upon exercise of their options.

Options granted under the 2010 Plan generally vest in installments over a four-year period from the grant date: 25% percent 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 thereafter. Options expire after 8 years from the date of grant. The last grant of options pursuant to the 2010 Plan occurred in 2016, with no further grants expected.

2016 Plan

In 2016, the Company established the 2016 Incentive Award Plan (the "2016 Plan"). All incentive award grants since 2016 are being made under the 2016 Plan.

Options granted to employees under the 2016 Plan generally vest in installments over a four-year period from the grant date: 25% percent 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 thereafter. Certain options may vest dependent on the attainment of performance criteria. Options expire after 10 years from the date of grant.

Options granted to non-executive directors consist of initial option grants as well as subsequent annual awards. The initial award of options granted vest in installments over a three-year period: 33% of the options vest on the first anniversary of the vesting commencement date, and 67% of the options vest in 24 monthly installments thereafter. Each subsequent award vests over a one-year period in 12 monthly installments. The Company measures the fair value of an option through the application of an option pricing model, as more fully described below.

The RSUs granted to employees under the 2016 Plan vest in installments over a four-year period from the grant date. Certain RSUs may vest dependent on the attainment of performance criteria. Each RSU represents the right to receive one common share. The fair value of an RSU is determined by reference to the price of the underlying common share.

The number of common shares authorized for issuance for future grants under the 2016 Plan as of January 1, 2021 totaled 2,336,997.

Share-Based Compensation Expense

Share-based compensation expense is classified in the consolidated statements of operations and comprehensive loss as follows:

	Year Ended December 31,	
	2020	2019
	(In thousands)	
Research and development	$ 2,969	$ 3,186
General and administrative	6,403	4,648
Total	$ 9,372	$ 7,834

As of December 31, 2020, there was $8.0 million in unrecognized stock-based compensation that are expected to vest. These costs are expected to be recognized over a weighted average remaining vesting period of 1.3 years.

Stock Option Valuation

The Company uses the Black-Scholes option-pricing model to measure the fair value of stock option awards. In prior years, a Hull-White option-pricing model was used. Key weighted average assumptions used in this pricing model on the date of grant for options granted to employees are as follows:

	Year Ended December 31,	
	2020	2019
Risk-free interest rate	1.3%	2.5%
Contractual life of options (years)	10.0	10.0
Expected term of options (years)	6.3	N/A
Expected volatility of underlying stock	86.1%	87.0%
Expected dividend yield	0.0%	0.0%

The risk-free interest rate is based upon the U.S. Treasury yield curve in effect at the time of grant, with a term that approximates the expected life of the option. The Company determines the expected volatility using a blended approach encompassing its historical experience and the historical volatility of a peer group of comparable publicly traded companies with product candidates in similar stages of development to the Company's product candidates. A simplified method using a weighted-average mid-point between an award's vesting date and expiry is used to estimate the expected life of options in all periods presented as a sufficient history of participant exercise behavior is not readily observable. The Company has applied an expected dividend yield of 0.0% as the Company has not historically declared a dividend and does not anticipate declaring a dividend during the expected life of the options.

Stock Option Activity

The following is a summary of stock option activity for the year ended December 31, 2020:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2020	3,314,871	$ 14.67		
Granted	1,258,341	16.16		
Exercised	(202,207)	7.16		
Forfeited or expired	(622,094)	16.62		
Outstanding at December 31, 2020	3,748,911	$ 15.59	5.9	$ 11,454
Exercisable at December 31, 2020	2,140,953	$ 15.85	4.1	$ 7,122

	Year Ended December 31,	
	2020	2019
Weighted-average fair value of options granted	$ 11.75	$ 7.54

RSU Activity

The following is a summary of RSU activity for the year ended December 31, 2020:

	Number of RSUs	Weighted Average Grant-date Fair Value
Non-vested at January 1, 2020	82,642	$ 19.68
Granted	46,474	16.00
Vested	(67,248)	19.94
Forfeited	(2,093)	21.11
Non-vested at December 31, 2020	59,775	$ 16.48

Intrinsic Value of Stock Options Exercised and Vested RSUs

	Year Ended December 31, (In thousands)	
	2020	2019
Total fair value of RSUs vested	$ 961	$ 726
Aggregate intrinsic value of options exercised	1,750	112

Post-Employment Benefit Plan

The Company has established a post-employment benefit plan for employees of the Netherlands that entitles executive officers and other staff members to retire at the age of 67 and receive annual payments based upon the average salary earned during the service period. The Company has insured the benefit liabilities through purchased non-participating annuities from an insurance company and has no other obligation other than to pay the annual insurance premiums to the insurance company. After purchasing the insurance, the Company has no further obligation (legal or constructive) to pay further amounts if the insurance fund has insufficient assets to pay all employee benefits relating to current and prior service. Contributions to purchase non-participating annuities are expensed as incurred as service costs. Company contributions to the post-employment benefit plan totaled $2.0 million and $1.3 million in the years ended December 31, 2020 and 2019, respectively.

401(k) Savings Plan

The Company has a defined contribution 401(k) savings plan (the “401(k) Plan”). The 401(k) Plan covers substantially all U.S. employees, and allows participants to defer a portion of their annual compensation on a pretax basis. The Company matches contributions to the 401(k) Plan, matching 50% of an employee’s contribution up to a maximum of 3% of the participant’s compensation. Company contributions to the 401(k) Plan totaled $0.1 million and $0.1 million in the years ended December 31, 2020 and 2019, respectively.

Executive Settlement

In December 2019, in connection with the departure of the Chief Executive Officer of the Company, the Company awarded benefits, including the following: cash compensation of $0.9 million, a grant of 30,000 RSUs, extended vesting of his equity incentive awards through June 30, 2021 and extended exercisability of his equity incentive awards through December 31, 2021. The cash compensation is to be paid by the Company by January 31, 2020. There were no substantive service conditions associated with the benefits awarded other than the passage of time. The Company incrementally recognized $1.8 million in general and administrative expense associated with these benefits in the consolidated statement of operations for the year ended December 31, 2019.

14. Loss per Share

The two-class method was not applied for the years ended December 31, 2020 and 2019 due to the net loss recognized in each of those periods.

Basic and diluted loss per share allocable to common stockholders are computed as follows:

	Year Ended December 31,	
	2020	2019
	(In thousands except per share data)	
Net loss	$ (85,513)	$ (55,151)
Weighted average shares outstanding	29,256,203	24,218,083
Basic and diluted loss per share allocable to common stockholders	$ (2.92)	$ (2.28)

15. Related Party Transactions

The Company has entered into the Incyte collaboration and license agreement and the Incyte share subscription agreement in which the terms and transactional amounts incurred between Incyte and the Company are more fully described in Note 12. Incyte is a shareholder with holdings representing approximately 10.1% of the outstanding shares of the Company as of December 31, 2020, and 11.1% as of December 31, 2019.

16. Subsequent Events

On January 18, 2021, the Company entered into a Collaboration and License Agreement (the “Collaboration Agreement”) and Share Subscription Agreement (the “Subscription Agreement”) with Eli Lilly and Company, an Indiana corporation (“Eli Lilly”). Eli Lilly has agreed to pay an upfront, non-refundable payment of $40 million for the rights granted under the Collaboration Agreement within 30 days following the Effective Date. Eli Lilly will fund the research and development activities to be conducted by the Company for each program under an agreed research plan and budget. With respect to each product arising from each program, the Company is eligible to receive up to $290 million in future contingent development and regulatory milestones and up to $250 million in commercial sales milestones, for a total of up to approximately $1.6 billion for a single product generated from all three programs. The Company is further eligible to receive, on a product-by-product and country-by-country basis, tiered royalties based on the level of worldwide aggregate annual net sales at percentages ranging from the mid-single digits to low double digits until the royalty term expires. In connection with entering into the Collaboration Agreement, pursuant to the Subscription Agreement, on January 18, 2021, Eli Lilly agreed to purchase 706,834 common shares of the Company at a price per share of $28.295 for aggregate gross proceeds to the Company of approximately $20 million. Eli Lilly agreed not to transfer, sell, or otherwise dispose of the Shares for a period of time following the Closing Date, subject to certain customary exceptions.

On January 21, 2021, the Company entered into an underwriting agreement with Jefferies LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (collectively, the “Underwriters”), in connection with the issuance and sale by the Company in a public offering of 4,848,485 common shares of the Company, nominal value €0.09 per share, at a public offering price of $24.75 per share, less underwriting discounts and commissions. The Company also granted the Underwriters an option exercisable for 30 days to purchase up to an additional 727,272 common shares at the public offering price, less underwriting discounts and commissions. On January 21, 2021, the Underwriters exercised this option in full. The closing of the offering occurred on January 25, 2021, resulting in aggregate net proceeds to the Company of $129.7 million.

**DESCRIPTION OF THE REGISTRANT'S SECURITIES
REGISTERED PURSUANT TO SECTION 12 OF THE
SECURITIES EXCHANGE ACT OF 1934, AS AMENDED**

As of December 31, 2020, Merus N.V. (the "Company," "we," "us," and "our") had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended: our common shares. Set forth below is a summary of certain information concerning our share capital as well as a summary of certain material provisions of our articles of association (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 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 has been publicly filed with the Securities and Exchange Commission.

DESCRIPTION OF SHARE CAPITAL AND ARTICLES OF ASSOCIATION

General

We were incorporated on June 16, 2003 as a private company with limited liability (*besloten vennootschap met beperkte aansprakelijkheid*) under Dutch law. 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

Our authorized share capital is €8,100,000, comprised of 45,000,000 common shares and 45,000,000 preferred shares, nominal value €0.09 per share.

Preferred Shares

On May 24, 2016, we entered into a call option agreement (the "call option agreement") with an independent foundation (*stichting*) under Dutch law called Stichting Continuïteit Merus (the "Protective Foundation") which agreement was most recently amended on August 27, 2018, pursuant to which the Protective Foundation would be allowed to acquire a number of preferred shares, which number is equal to the lesser of the following numbers: (i) the total number of shares (of whichever class) of our issued capital held by third parties immediately prior to the issuance of such preferred shares less the number of preferred shares already held by the Protective Foundation at that time (if any) and less one; or (ii) the maximum number of preferred shares that may be issued under our authorized capital as included in the Articles of Association, without approval by our general meeting of shareholders or our board of directors. There are 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.

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

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.

Subject to any provision of mandatory Dutch law and any higher quorum requirement stipulated in our Articles of Association, if and for as long as the Company is subject to the rules and requirements of a securities exchange and such securities exchange requires the Company to have a quorum for the general meeting of shareholders, then the general meeting of shareholders can only pass resolutions if at least one third of our issued and outstanding shares are present or represented at such general meeting.

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 (the "Enterprise Chamber"). The Enterprise Chamber may grant the claim for squeeze out in relation to all minority shareholders and will determine the price to be paid for the shares, if necessary after appointment of one or three experts who will offer an opinion to the Enterprise

Chamber on the value to be paid for the shares of the minority shareholders. Once the order to transfer becomes final before the Enterprise Chamber, the 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 the call option agreement. The 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, a number of preferred shares, which number is equal to the lesser of the following numbers: (i) the total number of shares (of whichever class) of our issued capital held by third parties immediately prior to the issuance of such preferred shares less the number of preferred shares already held by the Protective Foundation at that time (if any) and less one; or (ii) the maximum number of preferred shares that may be issued under our authorized capital as included in the Articles of Association, 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 have implemented staggered terms of our directors, as a result of which our directors are not all subject to election in any one year.

Dutch cooling-off period in face of shareholder activism or hostile take-over

As at 12 February 2021, a bill is pending in Dutch Senate which, if enacted in its current form, would introduce a statutory cooling-off period of up to 250 days during which the general meeting of shareholders would not be able to dismiss, suspend or appoint members of the board of

directors (or amend the provisions in the Articles of Association dealing with those matters) unless those matters would be proposed by the board of directors. This cooling-off period could be invoked by the board of directors in case:

a. shareholders, using either their shareholder proposal right or their right to request a general meeting of shareholders, propose an agenda item for the general meeting of shareholders to dismiss, suspend or appoint a member of the board of directors (or to amend any provision in the Articles of Association dealing with those matters); or

b. a public offer for the Company is made or announced without the Company's support, provided, in each case, that the board of directors believes that such proposal or offer materially conflicts with the interests of the Company and its business.

The cooling-off period, if invoked, ends at occurrence of the earliest of the following events:

a. the expiration of 250 days from:

i. in case of shareholders using their shareholder proposal right, the day after the deadline for making such proposal expired;

ii. in case of Shareholders using their right to request a general meeting of shareholders, the day when they obtain court authorization to do so; or

iii. in case of a hostile offer being made, the first following day;

b. the day after the hostile offer having been declared unconditional; or

c. the board of directors voluntarily terminating the cooling-off period.

In addition, shareholders representing at least 3% of the Company's issued share capital may request the Dutch Enterprise Chamber of the Amsterdam Court of Appeals for early termination of the cooling-off period. The Enterprise Chamber must rule in favour of the request if the shareholders can demonstrate that:

a. the board of directors, in light of the circumstances at hand when the cooling-off period was invoked, could not reasonably have come to the conclusion that the relevant shareholder proposal or hostile offer constituted a material conflict with the interests of the Company and its business;

b. the board of directors cannot reasonably believe that a continuation of the cooling-off period would contribute to careful policy-making;

c. if other defensive measures have been activated during the cooling-off period and not terminated or suspended at the relevant shareholders' request within a reasonable period following the request (i.e., no 'stacking' of defensive measures).

During the cooling-off period, if invoked, the board of directors must gather all relevant information necessary for a careful decision-making process. In this context, the board of directors must at least consult with shareholders representing at least 3% of the Company's issued share capital at the time the cooling-off period was invoked and the Company's works council. Formal statements expressed by these stakeholders during such consultations must be published on the Company's website to the extent these stakeholders have approved that publication.

Ultimately one week following the last day of the cooling-off period, the board of directors must publish a report in respect of its policy and conduct of affairs during the cooling-off period on the Company's website. This report must remain available for inspection by shareholders and others with meeting rights under Dutch law at the Company's office and must be tabled for discussion at the next general meeting of shareholders.

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.

Exhibit 10.4.5
EXECUTION VERSION

COLLABORATION AND LICENSE AGREEMENT

between

ELI LILLY AND COMPANY

and

MERUS N.V.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

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COLLABORATION AND LICENSE AGREEMENT

This **Collaboration and License Agreement** ("***Agreement***") is entered into as of January 18, 2021 (the "***Effective Date***") by and between **Merus N.V.,** a corporation organized and existing under the laws of the Netherlands and having an address at Yalelaan 62, 3584 CM Utrecht, The Netherlands ("***Merus***"), and **Eli Lilly and Company**, a corporation organized and existing under the laws of Indiana, with its principal business office located at Lilly Corporate Center, Indianapolis, Indiana 46285, U.S.A. ("***Lilly***"). Lilly and Merus are each hereafter referred to individually as a "***Party***" and together as the "***Parties***."

Whereas, Merus is a biotechnology company engaged in the research and development of bispecific antibody therapeutics in immuno-oncology;

Whereas, Lilly is a pharmaceutical company engaged in the research, development, manufacturing, marketing and distribution of pharmaceutical products, including therapeutic products;

Whereas, Merus and Lilly desire to collaborate to research, discover and develop certain Compounds or Products using the Merus Know-How and Merus Patents (each as defined below);

Whereas, Lilly desires to obtain from Merus, and Merus desires to grant to Lilly, certain exclusive license rights to research, discover, develop, manufacture, and commercialize such Compounds or Products, subject to the terms and conditions of this Agreement; and

Whereas, in connection with the above and the Parties entering into this Agreement, Lilly is making an equity investment in Merus through an acquisition of common shares of Merus stock pursuant to that certain Share Subscription Agreement, dated as of the Effective Date, between the Parties ("***Purchase Agreement***").

Now, Therefore, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties hereby agree as follows:

ARTICLE 1

DEFINITIONS

Capitalized terms used in this Agreement and the Exhibits hereto shall have the following meanings (or as defined elsewhere in this Agreement):

1.1 "***1st Extension Term***" has the meaning set forth in Section 4.3.

1.2 "***2nd Extension Term***" has the meaning set forth in Section 4.3.

1.3 "***Acquirer***" has the meaning set forth in the definition of "Change of Control."

1.4 "***Acquisition Transaction***" has the meaning set forth in Section 15.8.6.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

1.5 "***ADC***" means a monospecific antibody that is conjugated to a payload with a linker.

1.6 "***Additional Target***" has the meaning set forth in Section 3.2.

1.7 "***Affiliate***" means, with respect to either Party, any entity that, at the relevant time (whether as of the Effective Date or thereafter), directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such Party, for so long as such control exists. As used in this Section 1.7, "control" means: (a) to possess, directly or indirectly, the power to direct or cause the direction of the management or policies of an entity, whether through ownership of voting securities or by contract relating to voting rights or corporate governance; or (b) direct or indirect ownership of [*] or more of the voting share capital or other equity interest in such entity.

1.8 "***Agreement***" has the meaning set forth in the Preamble.

1.9 "***Alliance Manager***" has the meaning set forth in Section 2.1.

1.10 "***Applicable Laws***" means the applicable provisions of any and all federal, national, supranational, regional, state and local laws, treaties, statutes, rules, regulations, guidelines or requirements, administrative codes, guidance, ordinances, judgments, decrees, directives, injunctions, orders, or permits of or from any court, arbitrator, Regulatory Authority, Governmental Authority, taxing authority, national securities exchange or exchange listing organization having jurisdiction over or related to the relevant subject item that may be in effect from time to time during the Term. For the avoidance of doubt, Applicable Laws include all applicable data protection and privacy laws.

1.11 "***Background Know-How***" means Lilly Background Know-How or Merus Background Know-How.

1.12 "***Biclonics® Antibody***" means any bivalent mono- or bispecific bivalent antibody (a) the rights to which are Controlled by Merus or its Affiliates as of the Effective Date or during the Research Term; or (b) that is discovered or generated under the Agreement; that in each case of (a) and (b), contains at least one (1) Target Binder either: [*].

1.13 "***Biosimilar Product***" means, with respect to a Product, and on a Product-by- Product and country-by-country basis, any product (including a "generic product," "biogeneric," "follow-on biologic," "follow-on biological product," "follow-on protein product," "similar biological medicinal product," or "biosimilar product") approved by way of: (a) a Regulatory Approval process governing approval of interchangeable or biosimilar biologics as described in 42 U.S.C. § 262, or is the subject of a notice with respect to such Product under 42 U.S.C. § 262(l)(2); or (b) an abbreviated regulatory mechanism or equivalent process for Regulatory Approval to those set forth in subclause (a) by the relevant Regulatory Authority in a country, where such approval referred to or relied on (1) the Marketing Authorization for such Product held by Lilly or its Affiliate or Sublicensee in such jurisdiction or (2) the data contained or incorporated by reference in the Marketing Authorization for such Product held by Lilly or its Affiliate or Sublicensee in such jurisdiction, and that in each case: (i) is sold in the same country (or is commercially available in the same country) as such Product by any Third Party that is not a Sublicensee of Lilly or its Affiliates and that did not purchase such product in a chain of distribution that included any of Lilly or any of its Affiliates or its Sublicensees; and (ii) either (A) contains an active ingredient that is "highly similar" to such Product (as the phrase

"highly similar" is used in 42 U.S.C. § 262(i)(2), and subject to the factors set forth in FDA's Guidance for Industry, "Quality Considerations in Demonstrating Biosimilarity of a Therapeutic Protein Product to a Reference Product," (April 2015), at Section V, and any successor FDA guidance thereto), or (B) meets the equivalency determination by the applicable Regulatory Authority in any country or jurisdiction outside the United States (including a determination that the product is "comparable," "interchangeable," "bioequivalent," "biosimilar" or other term of similar meaning, with respect to the Product), in each case, as is necessary to permit substitution of such product for the Product under Applicable Law in such country.

1.14 "***Bona Fide Financing Transaction***" means a transaction or series of transactions resulting in a Change of Control of Merus where: (a) such Change of Control is a result of a *bona fide* transaction [*]; and (b) the Acquirer in the resulting Change of Control is not [*]. For the purpose of this definition, [*], *mutatis mutandis*.

1.15 "***Business Day***" means any day, other than any Saturday, Sunday, or any day that banks are authorized or required to be closed in: (a) Indianapolis, Indiana, (b) Boston, Massachusetts, or (c) the Netherlands.

1.16 "***Calendar Quarter***" means each respective period of three (3) consecutive months ending on March 31, June 30, September 30, and December 31 of any Calendar Year.

1.17 "***Calendar Year***" means each respective period of twelve (12) consecutive months commencing on January 1 and ending on December 31.

1.18 "***Change of Control***" means:

(a) with respect to either Party: (i) the acquisition by a Third Party, in one transaction or a series of related transactions, of direct or indirect beneficial ownership of more than [*] of the outstanding voting equity securities of such Party; (ii) a merger or consolidation involving such Party, as a result of which a Third Party acquires direct or indirect beneficial ownership of more than [*] of the voting power of the surviving entity immediately after such merger, reorganization or consolidation; or (iii) a sale of all or substantially all of the assets of such Party in one transaction or a series of related transactions to a Third Party. The acquiring or combining Third Party in any of (i), (ii) or (iii), and any of such Third Party's Affiliates (whether in existence as of or any time following the applicable transaction, but other than the acquired Party and its Affiliates as in existence prior to the applicable transaction or Affiliates it controls after the applicable transaction) are referred to collectively herein as the "***Acquirer***"; or

(b) with respect to the acquisition of Merus by a Lilly Competitor, whether in one transaction or a series of related transactions, in addition to the items in Section 1.18(a), the acquisition of: (i) majority control of the board of directors or equivalent governing body of Merus; (ii) direct or indirect beneficial ownership of more than [*] of the outstanding voting equity securities of Merus; (iii) the ability to cause the direction of the management or allocation of corporate resources of Merus; or (iv) all or substantially all of the assets of Merus related to the transactions contemplated by this Agreement; in which case such Lilly Competitor and its Affiliates (other than Merus and its Affiliates in existence prior to the applicable transaction) shall also be considered an Acquirer.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

1.19 "***Cell Line Generation***" means, with respect to a given Lilly Target or Lilly Target Pair that is the subject of a Research Program, that a cell line for the GMP manufacturing of a Collaboration Compound, Monospecific Compound or Modified Compound or Product directed to such Lilly Target or Lilly Target Pair has been generated.

1.20 "***Change of Control Notice***" has the meaning set forth in Section 15.8.1.

1.21 "***Claim***" has the meaning set forth in Section 11.1.1.

1.22 "***Clinical Trial***" means a Phase I Clinical Trial, Phase II Clinical Trial or Phase III Clinical Trial, or any post-Marketing Authorization human clinical trial, as applicable.

1.23 "***Code***" has the meaning set forth in Section 13.7.

1.24 "***Collaboration Compound***" means, with respect to each Research Program any Research Compound that satisfies the Success Criteria [*].

1.25 "***Combination Product***" has the meaning set forth in the definition of "Net Sales".

1.26 "***Commercial Milestone Event***" has the meaning set forth in Section 8.3.

1.27 "***Commercial Milestone Payment***" has the meaning set forth in Section 8.3.

1.28 "***Commercialization***" means any and all activities directed to the offering for sale and sale of a Product (or other compound, product or therapy, as the context requires) including: (a) activities directed to storing, marketing, promoting, detailing, distributing, importing, exporting, selling and offering to sell that Product or other compound, product or therapy; (b) conducting Clinical Trials after Marketing Authorization of a Product, or other product or therapy; (c) interacting with Regulatory Authorities regarding the foregoing; and (d) seeking Regulatory Approvals (as applicable) for and registration of that Product, or other product or therapy (*i.e.*, other than Marketing Authorization, which is addressed within "Development") in the Field in the Territory. When used as a verb, "**to Commercialize**" and "**Commercializing**" means to engage in Commercialization and "**Commercialized**" has a corresponding meaning.

1.29 "***Commercially Reasonable Efforts***" of a Party means, with respect to the performance of Research, Development, Manufacturing, and Commercialization activities with respect to a Compound or Product, the carrying out of such activities with that level of efforts and resources commonly applied by such Party to carry out such a task or obligation, consistent with the general practice followed by such Party relating to other pharmaceutical compounds, products or therapies owned by it, or to which it has exclusive rights, which are of similar market potential at a similar stage in their development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of Third Party products in development and in the marketplace, supply chain management considerations, [*] the compound, product or therapy (including with respect to patent or regulatory exclusivity), the regulatory structure involved, the profitability of the applicable compound, product or therapy [*], and other relevant technical, legal, scientific or medical factors.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

1.30 "***Compassionate Use Product***" means any unit of Product that is transferred, sold or otherwise disposed of under a treatment IND, as named patient sales, under any expanded access program, as test marketing, as emergency use sales, or as compassionate use sales.

1.31 "***Competing Program***" has the meaning set forth in Section 7.3.1.

1.32 ***Compound***" means a: (a) Research Compound, (b) Collaboration Compound, (c) Monospecific Compound, or (d) Modified Compound, as the context dictates. For clarity, [*].

1.33 "***Confidential Proprietary Information***" has the meaning set forth in Section 12.1.1.

1.34 "***Confidentiality Agreement***" means that certain Mutual Confidentiality Agreement between the Parties having an effective date of May 28, 2020, including the First Amendment with an effective date of May 28, 2020, and the Second Amendment with an effective date of May 28, 2020.

1.35 "***Control***" or "***Controlled***" means, with respect to any Know-How, Patents, or other intellectual property rights, that a Party has the legal authority or right (whether by ownership, license, or otherwise) to grant to the other Party a license, covenant not to sue, sublicense, access, or right to use (as applicable) under such Know-How, Patents, or other intellectual property rights, on the terms and conditions set forth herein; provided that in respect of any rights that the granting Party controls pursuant to a Third Party agreement, such rights shall not be considered to be Controlled by the granting Party hereunder: [*].

1.36 "***Cover***" means, with respect to a particular subject matter at issue and a relevant Patent, that one or more claims of such Patent would be infringed, absent ownership of or a license under such Patent, by the Exploitation of such subject matter (considering claims of patent applications to be issued as then pending).

1.37 "***Development***" or "***Develop***" means any and all activities directed to the non-clinical and clinical drug development activities that are necessary or useful to obtain Marketing Authorization for a Compound or Product (or other compound, product or therapy, as the context requires) including design and conduct of Clinical Trials and the preparation and filing of Regulatory Filings and all regulatory affairs related to the foregoing. When used as a verb, "***Developing***" means to engage in Development and "***Developed***" has a corresponding meaning. For clarity, "***Development***" shall not include any Commercialization activities.

1.38 "***Development/Regulatory Milestone Event***" has the meaning set forth in Section 8.3.

1.39 "***Development/Regulatory Milestone Payment***" has the meaning set forth in Section 8.3.

1.40 "***Disclosing Party***" has the meaning set forth in Section 12.1.1.

1.41 "***Dispute***" has the meaning set forth in Section 14.2.

1.42 "***Divestiture***" has the meaning set forth in Section 7.3.1.

1.43 "***Dollar***" means a U.S. dollar, and "$" is to be interpreted accordingly.

1.44 "***Effective Date***" has the meaning set forth in the introductory paragraph of this Agreement.

1.45 "***Eli Lilly and Company Animal Care and Use Requirement for Animal Researchers and Suppliers***" has the meaning set forth in Section 4.7.

1.46 "***Eli Lilly and Company Good Research Practices***" has the meaning set forth in Section 4.7.

1.47 "***E.U.***" means the European Union, as comprised as of the date of inquiry, provided that solely for the purposes of this Agreement, E.U shall be deemed to include the United Kingdom.

1.48 "***EU5 Market***" means individually each of the United Kingdom, Germany, France, Spain and Italy.

1.49 "***Executive Officers***" means (a) with respect to Merus, [*], and with respect to Lilly, [*]; or any other person that such person in the foregoing (a) or (b) designates from time to time having no less decision-making authority than the officer listed here for the respective Party.

1.50 "***Existing Patents***" has the meaning set forth in Section 10.2.4.

1.51 "***Existing Third Party Agreements***" means the agreements entered into between Merus and a Third Party prior to the Effective Date, whereby the Third Party is licensed by Merus (including any option to take a license) to develop and commercialize a monospecific antibody directed against a target selected from within a target pair combination researched or developed by Merus, where such target is also a Lilly Target hereunder.

1.52 "***Exploit***" or "***Exploitation***" means, as applicable, to do any or all of Researching, Developing, Manufacturing, having Manufactured, using, having used, Commercializing or otherwise exploiting.

1.53 "***Extension Fee***" has the meaning set forth in Section 4.3.

1.54 "***Extension Terms***" has the meaning set forth in Section 4.3.

1.55 "***FDA***" means the United States Food and Drug Administration or any successor agency thereto.

1.56 "***Field***" means all uses including, without limitation, any and all uses for the diagnosis, prevention, amelioration, and treatment of any disease or medical condition in humans and animals.

1.57 "***Final Research Deliverables***" means, on a Research Program-by-Research Program basis, those deliverables required to be provided by Merus to Lilly during the course of or at the completion of all activities under each Research Plan, in order for such Research Program to be considered fully performed prior to the expiry of the Research Term, such deliverables being those as set forth on Schedule 1.57.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

1.58 "***Firewall Period***" means, in the case of a Change of Control of Merus in which the Acquirer of Merus has a Competing Program, the period commencing on the effective date of the Change of Control and ending on the earlier of [*].

1.59 "***Firewalls***" means effective walls and screens established between Merus, on the one hand, and on the other hand an Acquirer of Merus that has a Competing Program, to ensure that no [*] are accessible [*]. For purposes of this definition, "Firewalls" shall include [*]. For clarity, where senior management personnel review and evaluate plans and information regarding the activities under this Agreement solely in connection with making portfolio decisions among product opportunities, including such other product or product candidates, such senior management personnel shall not be deemed to be working on the Competing Program under this Agreement so long as they do not pass information from one program to another.

1.60 "***First Commercial Sale***" means, with respect to a Product and a country, the first sale of such Product by Lilly (or its Affiliates or their Sublicensees) to a Third Party for end use or consumption of such Product in such country after Regulatory Approval required to market and sell the Product has been granted with respect to such Product in such country. [*].

1.61 "***Force Majeure Event***" has the meaning set forth in Section 15.10.

1.62 "***FTE***" means the equivalent of a full-time Merus employee's work performing activities under a Research Plan, which is at least [*] work hours per Calendar Year. If any such individual works partially on work under a Research Plan for a Research Program and partially on other work in a Calendar Quarter, then the "FTE" to be attributed to such individual's work hereunder shall be calculated based upon the percentage of such individual's total work time in such Calendar Quarter that such individual spent working under a Research Plan for such Research Program based on [*] working hours per Calendar Year, applied consistently throughout the Calendar Year. [*]. For clarity, no individual person can ever constitute more than a single FTE.

1.63 "***FTE Rate***" means the rate of FTE costs actually incurred by Merus and agreed upon in advance by the Parties pursuant to the Research Budget, which shall not exceed [*] per FTE per Calendar Year. The FTE Rate includes costs of salaries, benefits, other human resources-related costs associated with the employment of employees, supplies [*].

1.64 "***Gatekeeper***" has the meaning set forth in Section 3.5.1.

1.65 "***Good Laboratory Practices***" or "***GLPs***" means the applicable then-current standards for laboratory activities for pharmaceuticals, as set forth in the FDA's Good Laboratory Practice regulations as defined in 21 C.F.R. Part 58, the Council Directive 87/18/EEC, as amended, the principles for Good Laboratory Practice and/or the Good Laboratory Practice principles of the Organization for Economic Co-Operation and Development ("OECD"), and such standards of good laboratory practice as are required by the European Union and other organizations and governmental agencies in countries in which a Product is Developed, to the extent such standards are not less stringent than United States Good Laboratory Practice.

1.66 "***Good Manufacturing Practices***" or "***GMPs***" means all applicable current Good Manufacturing Practices including, as applicable: (a) the principles detailed in the US Current Good Manufacturing Practices, 21 C.F.R. Parts 4, 210, 211, 601, 610 and 820; (b) European Directive

2003/94/EC and Eudralex 4; (c) the principles detailed in the WHO TRS 986 Annex 2, TRS 961 Annex 6, TRS 957 Annex 2, and TRS 999 Annex 2; (d) ICH Q7 guidelines; and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.67 "***Good Research Practices***" or "***GRP***" means all applicable current Good Research Practices including, as applicable: (a) the research quality standards defining how Lilly's research laboratories conduct good science for non-regulated work as set forth in Exhibit 4.7 Part A of this Agreement; (b) the Research Quality Association (RQA) 2014 Quality in Research Guidelines for Working in Non-Regulated Research; (c) the WHO Quality Practices in Basic Biomedical Research Guidelines, and (d) the equivalent Applicable Laws if any, in any relevant country, each as may be amended and applicable from time to time.

1.68 "***Government Official***" has the meaning set forth in Section 10.4.5.

1.69 "***Governmental Authority***" means any national, international, federal, state, provincial or local government, or political subdivision thereof, or any multinational organization or any authority, agency or commission entitled to exercise any administrative, executive, judicial, legislative, police, regulatory or taxing authority or power, and any court or tribunal (or any department, bureau or division thereof, or any governmental arbitrator or arbitral body).

1.70 "***HCDR3***" means the third heavy chain complementarity-determinant region determined by the amino acid sequence of the variable (V) domain [*].

1.71 "***Homology Exclusivity Period***" means, on a Research Program-by-Research Program basis, the period commencing on the earlier of: (a) the date that Merus provides Lilly with the Final Research Deliverables for such Research Program, or (b) the date the Research Term for such Research Program expires, and in each case of (a) or (b), ending [*] following such date.

1.72 "***IND***" means an investigational new drug application filed with the FDA or any similar application filed with a Regulatory Authority in a country outside the U.S. required to commence Clinical Trials of a pharmaceutical product in such country.

1.73 "***Indemnitee***" has the meaning set forth in Section 11.1.3.

1.74 "***Indemnitor***" has the meaning set forth in Section 11.1.3.

1.75 "***Indication***" means any intended use of a Product (a) for any therapeutic treatment, prevention, mitigation, cure, or diagnosis of a recognized disease or condition, (b) of a manifestation of a recognized disease or condition, or (c) for the relief of symptoms associated with a recognized disease or condition, in each case (a), (b) and (c), as provided for in the U.S. Code of Federal Regulations (CFR) labeling requirements in 21 CFR Part 201 (or an equivalent requirement in any country outside the United States) and for which a separate application for Marketing Authorization, or a supplement to an existing application for Marketing Authorization (in each case, such application or supplement to be based on the results of a novel pivotal clinical study), is required for the purpose of obtaining Marketing Authorization in a country. [*].

1.76 "***Infringement***" has the meaning set forth in Section 9.3.1.

1.77 "***Initial Research Plan***" has the meaning set forth in Section 4.4.

1.78 "***Initial Research Term***" has the meaning set forth in Section 4.3.

1.79 "***Initial Target***" means [*].

1.80 "***Initiation***" means, with respect to a Clinical Trial, the first dosing in the first human subject in such Clinical Trial.

1.81 "***Internal Compliance Codes***" has the meaning set forth in Section 10.4.3.

1.82 "***Internal Merus Program***" means a *bona fide* internal program of research and development activities directed to a Target that [*] is (a) being conducted by Merus or its Affiliates, or (b) the subject of [*].

1.83 "***Inventions***" means all discoveries, developments, processes, methods, formulations, compositions of matter, articles of manufacture, materials, and inventions, whether or not patentable, that are created, conceived of, or discovered by or on behalf of a Party (whether solely or jointly by the Parties) in the course of performing activities under this Agreement, together with all intellectual property rights therein.

1.84 "**[*] *Know-How***" has the meaning set forth in [*].

1.85 "**[*] *Patents***" has the meaning set forth in [*].

1.86 "***Joint Patent***" has the meaning set forth in Section 9.1.2(c).

1.87 "***Joint Research Program Know-How***" means any: (a) Research Program Know-How created, conceived of, or discovered jointly by the Parties (whether by employees of the Parties or their Affiliates or Third Parties acting on their behalf); (b) or improvements made by either Party under this Agreement to [*]; or (c) any [*].

1.88 "***Joint Research Program Patent***" means any Patent that Covers any Joint Research Program Know-How [*].

1.89 "***JSC***" has the meaning set forth in Section 2.3.

1.90 "***Know-How***" means any non-public proprietary scientific or technical information, inventions, discoveries, results and data of any type whatsoever, in any tangible or intangible form, including non-public inventions, discoveries, databases, safety information, practices, methods, instructions, techniques, processes, drawings, documentation, specifications, formulations, formulae, knowledge, know-how, trade secrets, materials, skill, experience, test data and other non-public information and technology applicable to formulations, compositions or products or to their Exploitation or to methods of assaying or testing them, including pharmacological, pharmaceutical, medicinal chemistry, biological, chemical, biochemical, toxicological and clinical test data, Personal Information, physical and analytical, safety, quality control data, manufacturing, and stability data, materials, studies and procedures, and manufacturing process and development information, results and data.

1.91 "***Lilly***" has the meaning set forth in the Preamble.

1.92 "***Lilly Background Know-How***" means: any and all Know-How that Lilly or any of its Affiliates: (a) Controls as of the Effective Date; or (b) discovers, creates or acquires outside the scope of the Research Program, in each case of (a) and (b) that is necessary or reasonably useful for the Exploitation of a Compound or Product.

1.93 "***Lilly Background Patent***" means any Patent: (a) that solely Covers any Lilly Background Know-How; and (b) that Lilly or any of its Affiliates (i) Controls as of the Effective Date or (ii) acquires outside the scope of the Research Program.

1.94 "***Lilly Competitor***" means a company that: [*] has a [*] program [*] expected or intended to have application for [*]; and [*] either (i) has a market capitalization of [*], or (ii) during the Calendar Year [*], had reported [*] sales of [*].

1.95 "***Lilly De-Novo Sequence***" means a [*] sequence that binds a Lilly Target and is: (a) discovered, created or generated by or on behalf of Lilly or its Affiliates (but not by Merus, its Affiliates or any of their respective subcontractors, in each case, pursuant to this Agreement) in connection with the exercise of its rights or the performance of its activities under this Agreement, (b) included in a Modified Compound or Product derived from such Modified Compound, and (c) not (i) [*], or (ii) [*]. For clarity, any Lilly De-Novo Sequence would be included within the Lilly Sole IP.

1.96 "***Lilly Indemnitee***" has the meaning set forth in Section 11.1.1.

1.97 "***Lilly Know-How***" means all Know-How Controlled by Lilly or any of its Affiliates as of the Effective Date or during the Term, in each case, that is mutually and specifically agreed by the JSC in writing to be necessary or reasonably useful for Merus to conduct activities under any Research Plan.

1.98 "***Lilly Patent***" means any Patent Controlled by Lilly or any of its Affiliates as of the Effective Date or during the Term, that Covers any Lilly Know-How.

1.99 "***Lilly Prosecuted Patents***" has the meaning set forth in Section 9.2.2(a).

1.100 "***Lilly Research Program Know-How***" means any Research Program Know-How created, conceived of, or discovered solely by or on behalf of Lilly or any of its Affiliates (other than by Merus or its Affiliates).

1.101 "***Lilly Research Program Patent***" means any Patent that Covers any Lilly Research Program Know-How and that does not Cover any Merus Platform IP or Lilly Target Binder IP.

1.102 "***Lilly Sole Arising IP***" has the meaning set forth in Section 9.1.2(a).

1.103 "***Lilly Sole IP***" has the meaning set forth in Section 9.2.3.

1.104 "***Lilly Target Binder***" means a Target Binder [*] for potential use in a Collaboration Compound [*] in accordance with the process set forth in Section 4.2. [*].

1.105 "***Lilly Target Binder IP***" means any Know-How that: (a) is generated in the performance of activities under this Agreement by or on behalf of either Party either alone or jointly (including jointly with the other Party); and (b) is [*] to any Lilly Target Binder [*].

1.106 "***Lilly Target Binder Patents***" means any Patent that: (a) Lilly or any of its Affiliates Control as of the Effective Date or during the Term; and (b) Covers any Invention within the Lilly Target Binder IP.

1.107 "***Lilly Target Pair***" means any Lilly Target together with CD3, but not any additional Target.

1.108 "***Lilly Targets***" means, individually or collectively, the Initial Target, the Additional Targets, and any Replacement Targets, but in each case excluding any and all Replaced Targets.

1.109 "***Losses***" has the meaning set forth in Section 11.1.1.

1.110 "***Manufacture***" and "***Manufacturing***" means any and all activities related to the production, manufacture, formulation, finishing, packaging, labeling, shipping and holding of any Compound or Product, or other compound, product or therapy, or any component, intermediary or precursor thereof (including, for clarity, expression vectors, cell lines, culture media and feeds), and including process development, process qualification and validation, scale-up, pre-clinical, clinical and commercial manufacture, quality assurance and quality control (including testing).

1.111 "***Marketing Authorization***" means, collectively, all Regulatory Approvals (including any Pricing and Reimbursement Approval) from the relevant Regulatory Authority necessary to initiate marketing and selling a Product in a country or jurisdiction.

1.112 "***Materials Transfer Record***" has the meaning set forth in Section 4.9.

1.113 "***Merus***" has the meaning set forth in the Preamble.

1.114 "***Merus Background Know-How***" means any and all Know-How that Merus or any of its Affiliates Controls, and: (a) that exists as of the Effective Date; or (b) that is discovered, created or acquired outside the scope of the Research Program after the Effective Date, in each case ((a) and (b)), [*] for the Exploitation of a Compound or Product. For clarity, any Manufacturing-related Know-How disclosed to Lilly pursuant to Section 5.1 shall be deemed Merus Background Know-How for all purposes hereunder.

1.115 "***Merus Background Patent***" means any Patent: (a) that Covers any Merus Background Know-How; and (b) that Merus or any of its Affiliates Controls (i) as of the Effective Date or (ii) that is acquired outside the scope of the Research Program. For clarity, each of the Patents set forth on Exhibit 10.2.4 as of the Effective Date are Merus Background Patents.

1.116 "***Merus External Costs***" means costs, expenses, and charges [*] in the performance of Research under the applicable Research Plan.

1.117 "***Merus Indemnitee***" has the meaning set forth in Section 11.1.2.

1.118 "***Merus Internal Costs***" means [*] in the performance of the Research under the applicable Research Plan.

1.119 "***Merus Know-How***" means, individually or collectively, the Merus Background Know-How, the Merus Platform IP, the Merus Research Program Know-How and Merus's share in the Joint Research Program Know-How, in each case, [*] for, the Exploitation of Compounds or Products.

1.120 "***Merus Materials***" has the meaning set forth in Section 4.10.

1.121 "***Merus Patent***" means any Patent that is a Merus Background Patent, Merus Platform Patent or Merus Research Program Patent and Merus's share in each Joint Patent (subject to Section 9.1.4), but specifically excluding any Patent that is assigned to Lilly pursuant to Section 9.1.2(d), from and after the date of such assignment.

1.122 "***Merus Platform IP***" means all Inventions and Know-How that: (a) (i) Merus or any of its Affiliates Controls as of the Effective Date or during the Term, or (ii) is generated in the performance of activities under this Agreement by or on behalf of either Party either alone or jointly (including jointly with the other Party) including any of their Affiliates, employees, independent contractors or consultants in the course of conducting activities under this Agreement; and (b) relates to the Merus Platform Technology or any component of the Merus Platform Technology [*].

1.123 "***Merus Platform Patent***" means any Patent that (a) Merus or any of its Affiliates Control as of the Effective Date or during the Term and (b) Covers any subject matter within the Merus Platform IP.

1.124 "***Merus Platform Technology***" means Merus's proprietary: (a) Biclonics® [*] technology [*]; (b) [*] binding domains or variants thereof; (c) technology for [*] into bi-specific constructs; (d) [*]; and (e) [*], that in each case of (a) through (e), [*] are not [*] publicly available (*i.e.*, [*]).

1.125 "***Merus Prosecuted Patents***" has the meaning set forth in Section 9.2.2(b).

1.126 "***Merus Research Program Know-How***" means any Research Program Know-How created, conceived of, or discovered solely by or on behalf of Merus or any of its Affiliates.

1.127 "***Merus Research Program Patent***" means any Patent that Covers any Invention within the Merus Research Program Know-How, and that does not Cover any Merus Platform IP or Lilly Target Binder IP.

1.128 "***Merus Sole Arising IP***" has the meaning set forth in Section 9.1.2(b).

1.129 "***Merus Sole IP***" has the meaning set forth in Section 9.2.3.

1.130 "***Milestone Events***" has the meaning set forth in Section 8.3.

1.131 "***Milestone Payments***" has the meaning set forth in Section 8.3.

1.132 "***Modified Compound***" means any analog, derivative, or modified version of a Collaboration Compound that is generated by or on behalf of Lilly or any of its Affiliates (other than by Merus or its Affiliates during the Research Term), in each case that is directed against the applicable Lilly Target Pair, but excluding such Lilly Target Pair together with a third Target (and, for clarity, Lilly is not licensed under the terms of this Agreement to generate any such multi-specific compound), and excluding any analog, derivative, or modified version of a Collaboration Compound where the modification is [*]. For clarity, where a Modified Compound generated by or on behalf of Lilly or any of its Affiliates is [*], such compound shall be considered a Modified Compound for all purposes hereunder.

1.133 "***Monospecific Compound***" means any compound directed against a Lilly Target alone (as a monospecific or as an ADC), wherein the compound incorporates, is derived from, or is a modification to [*] of a Collaboration Compound or a Modified Compound.

1.134 "***Net Sales***" means, with respect to a particular Product, the gross amount invoiced by Lilly, its Affiliates, or any Sublicensee thereof to unrelated Third Parties (excluding any Sublicensee) for such Product in the Territory, less:

[*]

Such amounts shall be determined from the books and records of Lilly or the applicable Sublicensee, maintained in accordance with U.S. GAAP or, in the case of Sublicensees, U.S. GAAP or IFRS, as consistently applied across Lilly's product portfolio. [*]. [*], Net Sales of the Product shall be deemed to be the cash value of such other payment.

In the event that the Product is sold as part of a Combination Product (where "***Combination Product***" means any pharmaceutical product which comprises the Product and other active compound(s) and/or ingredient(s)), the Net Sales of the Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product (as defined in the standard Net Sales definition) by the fraction, A / (A+B) where A is [*] in the same period of time and in the same country of sale as the Combination Product, and B is [*] in the same period of time and in the same country of sale as the Combination Product. For clarity, a Product that is an ADC would not be considered a Combination Product [*].

In the event that the weighted average sale price of the Product can be determined but the weighted average sale price of the other compound(s) or ingredient(s) cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the fraction A / C where A is [*] in the same period of time and in the same country of sale as the Combination Product and C is [*] of the Combination Product.

In the event that the weighted average sale price of the other compound(s) or ingredient(s) can be determined but the weighted average sale price of the Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the following formula: one (1) minus (B / C) where B is [*] in the same quantity as contained in the Combination Product in the same period of time and in the same country of sale as the Combination Product and C is [*] of the Combination Product.

In the event that the weighted average sale price of both the Product and the other compound(s) or ingredient(s) in the Combination Product cannot be determined, the Net Sales of the Product shall be deemed to be equal to [*] of the Net Sales of the Combination Product.

The weighted average sale price for a Product, other compound(s) or ingredient(s), or Combination Product shall be calculated on a Combination Product-by-Combination Product and country-by-country basis once each Calendar Year and such price shall be used during all applicable royalty-reporting periods for such Combination Product in such country for the entire following Calendar Year. When determining the weighted average sale price of a Product, other compound(s) or ingredient(s), or Combination Product, the weighted average sale price shall be calculated by dividing the sales dollars (translated into Dollars) by the units of active ingredient sold during the twelve (12) months (or the number of months sold in a partial Calendar Year) of the preceding Calendar Year for the respective Product, other compound(s) or ingredient(s), or Combination Product. In the initial Calendar Year, a forecasted weighted average sale price will be used for the Product, other compound(s) or ingredient(s), or Combination Product. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be [*] the following Calendar Year.

[*]

1.135 "***Parallel Program***" means a Lilly program outside of the scope of this Agreement that: (a) is directed to [*]; (b) includes at [*]; and (c) [*], has not been terminated or [*]. For clarity: [*].

1.136 "***Party***" and "***Parties***" has the meaning set forth in the Preamble.

1.137 "***Party Specific Regulations***" has the meaning set forth in Section 10.4.2.

1.138 "***Patent Working Group***" has the meaning set forth in Section 9.2.

1.139 "***Patents***" means: (a) pending patent applications including provisional or non-provisional applications, issued patents, utility models and designs; (b) reissues, substitutions, confirmations, registrations, validations, re-examinations, additions, continuations, continued prosecution applications, continuations-in-part, or divisions of or to any of the foregoing; and (c) extensions, renewals or restorations of any of the foregoing by existing or future extension, renewal or restoration mechanisms, including supplementary protection certificates or the equivalent thereof, including in any country of the world.

1.140 "***Patent Challenge***" has the meaning set forth in Section 13.2.4(c).

1.141 "***Payment***" has the meaning set forth in Section 8.8.2.

1.142 "***Person***" means any corporation, limited or general partnership, limited liability company, joint venture, trust, unincorporated association, governmental body, authority, bureau or agency, any other entity or body, or an individual.

1.143 "***Personal Information***" means, in addition to any definition for any similar term (*e.g.*, "personal data" or "personally identifiable information" or "PII") provided by Applicable Laws, or

by either Party in any of its own privacy policies, notices or contracts, all information that identifies, could be used to identify, or is otherwise associated with an individual person, whether or not such information is associated with an identified individual person.

1.144 "***Phase I Clinical Trial***" means a clinical trial of a Product generally consistent with 21 C.F.R. § 312.21(a) (or the non-United States equivalent thereof).

1.145 "***Phase II Clinical Trial***" means a clinical trial of a Product generally consistent with 21 C.F.R. § 312.21(b) (or the non-United States equivalent thereof).

1.146 "***Phase III Clinical Trial***" means a clinical trial of a Product generally consistent with 21 C.F.R. § 312.21(c) (or the non-United States equivalent thereof).

1.147 "***Pricing and Reimbursement Approval***" means, with respect to a Product, the approval, agreement, determination or decision of any Regulatory Authority establishing the price or level of reimbursement for such Product, as required in a given country or jurisdiction prior to sale of such Product in such country or jurisdiction.

1.148 "***Product***" means any pharmaceutical product, in any preparations and presentations, in any dosage strengths, compositions, formulations, and routes of administration, in each case, that incorporates, contains or comprises a Compound other than a Research Compound. For clarity: (a) Products shall not include any compound or product that is directed to a Lilly Target Pair together with any other Target, and Lilly is not licensed by Merus to generate any such multi-specific product under the terms of this Agreement; and (b) where the same Compound is Developed or Commercialized as a monotherapy or as part of a combination therapy in multiple preparations, presentations, dosage strengths, compositions, formulations, or routes of administration, each of the foregoing shall constitute the same "Product" for all purposes hereunder.

1.149 "***Product Patent***" means any Patent within the Merus Patents (excluding any Merus Platform Patents) or Lilly Patents (excluding any Lilly Target Binder Patent), in each case, that Covers the composition of matter, or method of using or making, a specific Collaboration Compound, Modified Compound, Monospecific Compound or Product, including [*] (and for clarity, excluding any such Patent that only Covers [*]. [*]; provided however that where the [*] of any specific Collaboration Compound, or any Modified Compound or Monospecific Compound for which [*].

1.150 "***Project Manager***" has the meaning set forth in Section 2.2.

1.151 "***Prosecute and Maintain***" or "***Prosecution and Maintenance***" with respect to a particular Patent, means all activities associated with the preparation, filing, prosecution and maintenance of such Patent, together with the conduct of interferences, derivation proceedings, inter partes review and post-grant review, the defense of oppositions and other similar proceedings with respect to that Patent, including any activities associated with claims, including as a claim, counterclaim or declaratory judgment action, of unpatentability, invalidity or unenforceability of such Patent that are brought by a Third Party in connection with an Infringement under Section 9.3.

1.152 "***Prosecuting Party***" has the meaning set forth in Section 9.2.1.

1.153 "***Purchase Agreement***" has the meaning set forth in the Recitals.

1.154 "***Receiving Party***" has the meaning set forth in Section 12.1.1.

1.155 "***Reduced Payment Product***" means any Product that: (a) is a Monospecific Compound comprising any Target Binder of a Collaboration Compound or a Modified Compound that [*]; or (b) a Collaboration Compound or Modified Compound that [*]. For clarity, [*].

1.156 "***Regulatory Approvals***" means, collectively, any and all approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations) or waivers of any Regulatory Authority that are necessary for the Exploitation of a pharmaceutical product (including any Product) in any country or jurisdiction, including Pricing and Reimbursement Approval, as applicable.

1.157 "***Regulatory Authority***" means any Governmental Authority that has responsibility in its applicable jurisdiction over the Exploitation of pharmaceutical products (including any Product) in a given jurisdiction. For countries where governmental approval is required for pricing or reimbursement for a pharmaceutical product (including any Product) to be reimbursed by national health insurance (or its local equivalent), Regulatory Authority includes any Governmental Authority whose review or approval of pricing or reimbursement of such product is required.

1.158 "***Regulatory Filings***" means, collectively, any and all applications, filings, submissions, approvals (including supplements, amendments, pre- and post-approvals, pricing and reimbursement approvals), licenses, registrations, permits, notifications, and authorizations (including marketing and labeling authorizations) or waivers with respect to the Exploitation of a Product made to or received from any Regulatory Authority in a given country, including INDs.

1.159 "***Relevant Third Party IP***" has the meaning set forth in Section 6.8.

1.160 "***Replaced Target***" has the meaning set forth in Section 3.3.

1.161 "***Replacement Period***" has the meaning set forth in Section 3.3.

1.162 "***Replacement Target***" has the meaning set forth in Section 3.3.

1.163 "***Research***" means any and all activities directed to the discovery, identification, generation, screening, testing, validation, functional testing, assessment and optimization of a Compound or Product (or other compound, product or therapy, as the context requires) in advance of Development, including the selection, discovery, generation, optimization or identification of Target Binders. When used as a verb, "***Researching***" means to engage in Research, and "***Researched***" has a corresponding meaning.

1.164 "***Research Budget***" has the meaning set forth in Section 4.4.

1.165 "***Research Compound***" means, with respect to each Research Program, each compound that is created, conceived of, discovered or delivered by or on behalf of Merus or its Affiliates under the applicable Research Plan that: [*]

1.166 "**[*] *Know-How***" means any Know-How comprising any panel of [*] antibody constructs [*] to identify or select the Collaboration Compounds associated with such Research Program [*], but specifically excluding: [*], and (b) any [*], including in each case, the sequences thereof (including, for clarity, [*]).

1.167 "**[*] *Patents***" means any Patent containing claims that Cover any [*].

1.168 "***Research Continuance Scenario***" has the meaning set forth in Section 15.8.2(b).

1.169 "***Research Expenditures***" has the meaning set forth in Section 4.6.1.

1.170 "***Research Plan***" has the meaning set forth in Section 4.4.

1.171 "***Research Program***" has the meaning set forth in Section 4.1

1.172 "***Research Program Know-How***" means all Know-How created, conceived of, or discovered by or on behalf of either Party, either alone or jointly (including jointly with the other Party), during the Research Term in the performance of the Research Program that is not Merus Platform IP or Lilly Target Binder IP.

1.173 "***Research Program Patent***" means any Patent that Covers Research Program Know-How and that does not Cover any Merus Platform IP or Lilly Target Binder IP, but excluding any [*].

1.174 "***Research Term***" has the meaning set forth in Section 4.3.

1.175 "***Research Transfer***" has the meaning set forth in Section 15.8.2(a)(i).

1.176 "***Research Transfer Scenario***" has the meaning set forth in Section 15.8.2(a).

1.177 "***Reserved Target***" has the meaning set forth in Section 3.4.

1.178 "***Review Period***" has the meaning set forth in Section 4.6.3(d).

1.179 "***Residuals***" has the meaning set forth in Section 12.1.5.

1.180 "***Royalty***" has the meaning set forth in Section 8.4.2.

1.181 "***Royalty Term***" has the meaning set forth in Section 8.4.1.

1.182 "***Royalty-Bearing Claim***" means with respect to a [*] Product, any Valid Claim in any: (a) Product Patent that Covers [*] the composition of matter of such Product, or [*] a method of use of such Product [*], or (b) Merus Patent [*] that Covers the [*] composition of matter of such Product, [*], or [*] a method of use of such Product [*], in each case of (a) and (b), [*].

1.183 "***Sublicensee***" means a Third Party that is granted a license or sublicense to Exploit Products in the Field in the Territory, beyond the mere right to purchase Products from Lilly and its Affiliates and resell such Products, and excludes Lilly's Affiliates or Third Party subcontractors that act solely for Lilly or its Affiliates in the supply chain or that perform discrete services (as opposed to being granted broad rights or responsibilities) on behalf of Lilly or its Affiliates.

1.184 "***Success Criteria***" means, on a Research Program-by-Research Program basis, those specific requirements set forth in the applicable Research Plan qualifying a Research Compound to be designated as [*] Collaboration Compounds, subject to the number of lead and back-up Collaboration Compounds for each such Research Program [*].

1.185 "***Target***" means a tumor-associated antigen.

1.186 "***Target Binder***" means one or more: [*] that is sufficient to confer specific antigen binding to CD3 or a Lilly Target.

1.187 "***Term***" has the meaning set forth in Section 13.1.

1.188 "***Terminated Compound***" has the meaning set forth in Section 13.4.3.

1.189 "***Terminated Product***" has the meaning set forth in Section 13.4.3.

1.190 "***Terminated Target***" has the meaning set forth in Section 13.4.3.

1.191 "***Territory***" means worldwide.

1.192 "***Third Party***" means any Person other than Lilly or Merus (or their respective Affiliates).

1.193 "***U.S.***" means the United States of America.

1.194 "***Unavailable Target***" means, with respect to a Target, that, at the relevant time, such Target is the subject of: (a) (i) at least [*], or (ii) an [*], in each case ((i) and (ii)) for use of such Target [*], or that grants (or is intended to grant) rights for such Target that [*], or (b) an [*].

1.195 "***Valid Claim***" means a claim contained in: (a) an issued and unexpired Patent that has not been revoked or held unenforceable, unpatentable or invalid by a judgment of a court or other governmental agency of competent jurisdiction, such judgment being final and unappealable (or judgment from which no appeal was taken within the allowable time period) or (b) a Patent application that has been pending [*] or less from the filing date and that has not been abandoned (without the possibility of refiling) or finally rejected by a judgment of a court or other governmental agency of competent jurisdiction, such judgment being final and unappealable (or judgment from which no appeal was taken within the allowable time period).

1.196 "***Withholding Tax Action***" has the meaning set forth in Section 8.8.2.

1.197 "***Working Group***" has the meaning set forth in Section 2.4.

ARTICLE 2

GOVERNANCE AND JOINT STEERING COMMITTEE

2.1 **Alliance Managers**

. Within [*] following the Effective Date, each Party shall appoint one (1) individual to act as the Alliance Manager for such Party (each, an "***Alliance Manager***"). Without limiting the responsibilities and authorities of Project Managers or the JSC (as expressly set

forth herein), the Alliance Managers shall each be the primary point of contact for the Parties regarding the collaboration and related activities contemplated by this Agreement and shall help facilitate all such activities hereunder. Each Alliance Manager shall be permitted to attend meetings of the JSC and any sub-committee as a nonvoting observer. Either Party, upon prior written notice to the other Party, may change its Alliance Manager. For clarity, the same employee may, but need not, be both the Alliance Manager and a Project Manager.

2.2 **Project Managers**

. Lilly and Merus shall each assign one (1) employee to serve as the primary point of contact between the Parties with respect to each Lilly Target being Researched under the Research Programs (each, a "***Project Manager***"). Each Project Manager shall have appropriate technical expertise in connection with the subject matter of the applicable Research Program. The Project Managers shall regularly communicate with each other to address Research Program-related issues, needs and updates and facilitate communications and organization of Working Groups associated with the Research Plan. Either Party, upon reasonable prior notice to the other Party, may change its Project Manager. For clarity, the same employee may, but need not, be the Project Manager for multiple Lilly Targets.

2.3 **Joint Steering Committee**

. Within [*] after the Effective Date, the Parties shall establish a cross-functional, joint steering committee (the "***JSC***") composed of up to [*] senior representatives from each Party (provided that each Party has an equal number of representatives) that will oversee and manage the collaboration between the Parties with respect to each Research Program. The JSC may, from time to time, establish subcommittees and Working Groups as it deems necessary to further the purposes of this Agreement. Each Party shall appoint its respective representatives to the JSC from time to time, and may change its representatives, in its sole discretion, effective upon written notice to the other Party designating such change. The representatives from each Party shall have appropriate technical credentials, experience and knowledge pertaining to, and ongoing familiarity, with the Research and applicable Research Programs. [*]

2.4 **Working Groups**

. The Parties may establish working groups consisting of members from both Merus and Lilly (each, a "***Working Group***") to oversee aspects of the activities of each Research Program. From time to time, the Parties may establish additional Working Groups as needed to oversee particular activities and/or projects. Each Working Group shall undertake the activities delegated to it by the JSC (excluding the Patent Working Group, which shall be separately constituted hereunder and shall not report to, or accept delegation from, the JSC). During the process of establishing each Working Group, and subject to the foregoing, such Working Group and the JSC shall agree regarding which matters such Working Group will resolve on its own and which matters such Working Group will advise the JSC and/or the Project Managers regarding (and with respect to which such advice-specific matters the JSC will resolve).

2.5 **Function and Powers of the JSC**

. The JSC will:

(a) (i) approve the Initial Research Plan attached hereto as Exhibit 4.4.1 within [*] of the Effective Date, (ii) prepare, discuss, and approve each subsequent Research Plan for each Research Program, and (iii) prepare, review, discuss, and approve any amendments that may be necessary or desired to the Research Plans;

(b) oversee the implementation of the Research Plans, including the activities, timing and deliverables thereunder, and coordination of such activities and timing across Research Programs and mutually agree [*], as described in Section 4.1;

(c) discuss the progress of the Research and the Research Programs generally, and the discovery, identification, selection and validation of the Compounds and Products;

(d) provide a forum for the Parties to share and discuss information relating to the research and validation of the Lilly Targets, Compounds and Products, including the results of the activities being carried out under the Research Plans;

(e) address issues arising in the performance of the Research Plans, including specifically [*]

(f) direct and oversee any operating Working Groups on all significant issues, and resolve disputed matters that may arise at the Working Groups;

(g) facilitate the exchange of Know-How or materials (pursuant to Section 4.9 or Section 4.10, as applicable) as required hereunder, including by establishing a recordation process for, [*] the Final Research Deliverables;

(h) agree and specifically identify any information or materials Lilly provided to Merus for the conduct of activities under any Research Plan and that are non-public and proprietary to Lilly as Lilly Know-How, not otherwise documented or addressed under Section 2.5(e)(iii); and

(i) perform any and all tasks and responsibilities that are expressly attributed to the JSC under this Agreement or as otherwise agreed by the Parties in writing.

2.6 **Meetings**

. The JSC will meet at least [*] during the Research Term. The JSC may conduct such meetings by telephone, videoconference, or in person. Each Alliance Manager may call special meetings of the JSC with at least [*] prior written notice, or a shorter time period in exigent circumstances, to resolve particular matters requested by such Party that are within the purview of the JSC, the resolution of which cannot be reasonably postponed until the next regularly scheduled JSC meeting. Meetings of the JSC are effective only if at least [*] of each Party participates in such meeting, not including the Alliance Manager. Each Alliance Manager shall be permitted to attend meetings of the JSC, and any Working Group, as a non-voting observer. Each Alliance Manager may invite a reasonable number of other participants, in addition to its representatives, to attend JSC meetings in a non-voting capacity; provided that if either Alliance Manager intends to have any Third Party (including any consultant) attend such a meeting, such Alliance Manager shall provide prior written notice to the other Alliance Manager. Such Alliance Manager shall ensure that each such Third Party is bound by confidentiality and non-use obligations consistent with the terms of this Agreement. Each Party is responsible for its own expenses incurred in connection with participating in and attending all such meetings. The [*] Alliance Manager or his/her designee shall keep minutes of each JSC meeting that records in writing all decisions made, action items assigned or completed and other appropriate matters. The [*] Alliance Manager shall send meeting minutes to all members of the JSC promptly after a meeting for review. Each JSC member shall have [*] from receipt in which to comment on and to approve the minutes (such approval not to be unreasonably withheld,

conditioned or delayed). If a JSC member, within such time period, does not notify the [*] Alliance Manager that s/he does not approve of the minutes, the minutes shall be deemed to have been approved by such member. The Parties acknowledge and agree that, notwithstanding the requirements of this Section 2.6 for the JSC to meet [*], the Parties shall communicate and meet (as appropriate, including via the Project Managers) on a more informal basis as needed to discuss the progress of the Research Programs.

2.7 **Decisions**

. In conducting themselves on the JSC or any Working Group, and in exercising their rights under this Article 2, all representatives of both Parties shall consider diligently, reasonably and in good faith all input received from the other Party. The JSC will use reasonable efforts to make decisions on all matters by consensus, with the representatives of each Party having, collectively, one (1) vote on behalf of that Party. If the JSC cannot reach consensus or a dispute arises that cannot be resolved within the JSC, either Party may refer such dispute to the Executive Officers for resolution. If consensus cannot be reached with respect to a decision within [*] after attempted resolution by the Executive Officers, then:

2.7.1 Merus shall have final decision-making authority with respect to: [*]; provided that Merus, in exercising its final decision-making authority with respect to subclause (b), shall not resolve any such a matter in a manner that: (i) excuses, reduces, or materially delays Merus's obligations under this Agreement; (ii) amends, modifies, or waives compliance with the terms of this Agreement or any Research Plan; or (iii) materially increases Lilly's obligations (including payment obligations) as a result, and in the case of the foregoing subclauses (i) through (iii), the status quo shall persist unless and until the Parties mutually agree; and

2.7.2 Lilly shall have the final decision-making authority with respect to: [*]; provided that Lilly, in exercising its final decision-making authority, shall not resolve any such a matter in a manner that: (i) excuses, reduces, or materially delays its obligations under this Agreement; or (ii) amends, modifies, or waives compliances with the terms of this Agreement; and provided further that Lilly shall not have the right to exercise its final decision-making authority to: [*] in a manner that would require Merus to incur costs [*] that Lilly does not agree to reimburse, or [*] require Merus to violate or take any action in conflict with any agreement Merus may have with any Third Party, or [*]. In the case of the foregoing subclauses [*], the status quo shall persist unless and until the Parties mutually agree.

2.7.3 **Limitations on Final Decision Right**. Notwithstanding the final decision making rights of a Party set forth in Sections 2.7.1 and 2.7.2, neither Party shall exercise its right to finally resolve a dispute in connection with matters under this Article 2: [*]

2.8 **Authority**

. The Alliance Managers, Project Managers, JSC, and each Working Group have only the powers assigned expressly to them in this Article 2 and elsewhere in this Agreement (or in the case of Working Groups, as expressly assigned to them by the JSC). Each Party retains the rights, powers, and discretion granted to it under this Agreement and neither Party may delegate or vest such rights, powers, or discretion in the Alliance Manager, a Project Manager, the JSC, or any Working Group, unless expressly provided for in this Agreement or the Parties expressly so agree in writing. The JSC shall not have the power to amend, waive or modify any term of this Agreement, and no decision of the JSC shall be in contravention of any terms and conditions of this Agreement. It is understood and agreed that issues to be formally decided by the JSC are limited to those specific issues that are expressly provided in this Agreement to be decided by the JSC.

2.8.1 **Discontinuation of JSC**. The JSC will automatically disband upon the expiration of the Research Term. Once disbanded, all approval rights of the JSC, or final decision making authority granted to a Party pursuant to this Agreement, shall become approval rights of the corresponding Party (*i.e.*, mutual agreement by the Parties or final decision making authority by a Party).

ARTICLE 3

TARGET SELECTION AND REPLACEMENT

3.1 Lilly Targets

. During the Research Term, Lilly will have the right to select up to three (3) Targets to be included as Lilly Targets for Research. As of the Effective Date, the Parties have identified the Initial Target to be the subject of Research under this Agreement. During the Research Term, Lilly may (a) select up to [*] as Lilly Targets for Research and (b) until the expiration of the [*] replace any Lilly Targets (pursuant to Section 3.3) for Research, provided that there may be no more than [*] under this Agreement.

3.2 Additional Targets

. During the Research Term, Lilly shall have the right to name up to [*] to be included as Lilly Targets for Research under this Agreement ("***Additional Targets***"). Lilly may exercise such right [*] during the Research Term by providing written notice to Merus, through the JSC, of the identity of the Additional Target, provided that Lilly may not name any Unavailable Target as an Additional Target. [*]

3.3 Replacement Targets

. Until the expiration of [*] (the "***Replacement Period***"), Lilly shall have the right to replace [*] with a replacement Target (each, a "***Replacement Target***"); provided that Unavailable Targets shall not be eligible to be selected by Lilly as Replacement Targets. Lilly may exercise such right [*] by providing written notice to Merus, through the JSC, of the identity of the Replacement Target as well as the Lilly Target to be replaced (such target, the "***Replaced Target***"). [*] For clarity, (a) Lilly may at its discretion and subject to the process set forth in this Section 3.3, [*], subject to the [*] limit in the aggregate across all Research Programs, (b) all rights in Replaced Targets shall revert to Merus, and the licenses to Lilly with respect to Collaboration Compounds arising from such Research Program shall not include any rights with respect to such Replaced Targets, and (c) a Replacement Target that replaces an Initial Target or Additional Target may itself be eligible to be replaced by a Replacement Target at any time during the Replacement Period, provided that [*].

3.4 Reserved Targets

. Promptly following the Effective Date, by and through the Gatekeeper process described in Section 3.5 below, the Parties shall identify up to [*] as Targets to be reserved under this Agreement (the "***Reserved Targets***"). Lilly may maintain a maximum of [*]. During [*], unless otherwise agreed by Lilly in writing, Merus may not, directly or indirectly, either alone or with or through one (1) or more Third Parties (a) engage in [*] subject to any rights granted under any Existing Third Party Agreement that have been notified to Lilly in accordance with Section 6.2, [*]; or (b) collaborate or enter into any arrangement with, or work for the benefit of, any Third Party in connection with [*] any Reserved Target in combination with CD3 (alone or with another Target, *i.e.*, a multispecific) or subject to any rights granted under any Existing Third Party Agreement [*]. Upon the earlier of the expiration of [*], any Reserved Target that has not been selected by Lilly

as a Lilly Target pursuant to the terms of this Article 3 will cease to be a Reserved Target and shall cease to be subject to the terms of this Agreement.

3.5 **Gatekeeper Process**

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3.5.1 The Parties have agreed on an independent third party to act as an information gatekeeper (the "***Gatekeeper***") through which (a) the Parties have worked, prior to the Effective Date, to identify the Initial Target, and (b) during the Research Term: [*] The costs of the Gatekeeper shall be shared equally by the Parties.

3.5.2 As of the Effective Date, Merus has provided to the Gatekeeper the list of Unavailable Targets, and from time to time thereafter in response to Lilly notifying the Gatekeeper that it wishes to inquire whether a Target is Unavailable so long as Lilly has not yet designated [*] Lilly Targets during the Research Term, (a) Merus will provide the Gatekeeper [*] with a then-current list of all Unavailable Targets (such list of Unavailable Targets, as updated from time to time as set forth in this Section 3.5.2, the "***Unavailable Target List***") and (b) [*]. Upon receipt of an inquiry, the Gatekeeper will notify Merus of its receipt of an inquiry from Lilly without disclosing the subject Target, after which Merus will [*] provide the Gatekeeper with any updates to the Unavailable Target List. The Gatekeeper will inform Lilly in writing whether the subject Target is an Unavailable Target within [*] of receipt of Merus's updated Unavailable Target List and, if the Target is a not an Unavailable Target, the Gatekeeper will inform Lilly of the availability of such Target. If the Gatekeeper notifies Lilly in response to an inquiry that a Target is an Unavailable Target, Lilly will not have exhausted any of its rights to identify Targets as a result of the inquiry. If, during the Research Term, [*].

[*], unless, as of such date, [*].

3.5.3 During the Research Term, [*].

ARTICLE 4

RESEARCH PROGRAM

4.1 **Research Program Overview and Responsibilities**

. Merus and Lilly will collaborate in a program, on a Lilly Target-by-Lilly Target basis, to Research Compounds and Products directed against such Lilly Target Pair (each such program, a "***Research Program***"). During the Research Term, each Party will be responsible for conducting all Research specifically allocated to such Party in the applicable Research Plan. Under each Research Plan, the Parties will endeavor to [*] based on the scientific facts and circumstances, prior to commencing the applicable Research Plan. For clarity: (a) the target [*]; and (b) Merus shall not, without Merus's prior written consent, be obligated to [*] for each Research Program. Merus's performance of its respective Research obligations shall be funded as set forth in Section 4.6.

4.2 **Diligence Efforts**

. Each Party shall use Commercially Reasonable Efforts to execute and to perform, or cause to be performed, in a good scientific manner and in compliance with Applicable Law, the Research activities assigned to it in each Research Plan with respect to each Lilly Target and Lilly Target Pair. With respect to each Research Program, Merus's obligations under a Research Plan shall cease upon the earlier of (a) the expiration of the Research Term and (b) Merus's

fulfillment of its obligations under the applicable Research Program and delivery to Lilly of the Final Research Deliverables. [*] Lilly may provide Lilly Target Binders to be engineered into a Research Compound by Merus pursuant to any such Research Program for the generation of [*] under the applicable Research Program; provided that: (i) such Collaboration Compounds incorporating a Lilly Target Binder (where such Lilly Target Binder is incorporated prior to the delivery to Lilly of the Final Research Deliverables) [*]; and (ii) Lilly otherwise retains all rights in and to such Lilly Target Binders as are contributed to any given Research Program, including, for the avoidance of doubt, all rights to Exploit monospecific, bispecific or multispecific compounds, any components thereof, and all products incorporating the foregoing (outside the scope of this Agreement), that in each case utilize such Lilly Target Binder (and that are not developed or generated utilizing the Merus Platform Technology [*], in each case, Merus has disclosed to Lilly hereunder), and such compounds and products shall not be subject to the payment of any consideration to Merus hereunder by reason of such Lilly Target Binder being so used.

4.3 **Research Term**

. The period of time in which the Research Programs shall be conducted will commence on the Effective Date and continue until the earlier of (a) the date upon which a total of three Research Programs have delivered at least [*] and (b) the [*] of the Effective Date (the "***Initial Research Term***"). At least [*] in advance of the expiration of such Initial Research Term, Lilly may [*], by written notice to Merus, elect to further extend the term of such Research Program by an additional six (6) months (such extension, the "***1st Extension Term***") and, at least [*] in advance of the expiration of such 1st Extension Term, may further elect to extend the term of such Research Program by another additional six (6) months (such further extended term, the "***2nd Extension Term***", and with the 1st Extension Term, the "***Extension Terms***"), provided that (a) the 2nd Extension Term shall be solely for [*], (b) [*], and (c) as consideration for [*], Lilly shall pay to Merus [*] "***Extension Fee***"). [*] Extension Fee shall be payable by Lilly no later than the date of expiration of [*]. The Initial Research Term, together with any Extension Term, and any further extensions as may be mutually agreed by the Parties (in each case, solely to extent such extensions occur), shall be deemed the "***Research Term***."

4.4 **Research Plans**

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4.4.1 **Content**. The Parties shall conduct the Research Program for each Lilly Target Pair pursuant to a comprehensive written research plan (each, a "***Research Plan***") that sets forth, for each such Research Program: (a) the objective of the applicable Research Plan and the Research activities to be conducted by each of the Parties, and the allocation of activities and responsibilities between the Parties; (b) [*]; (c) the [*] of such activities; (d) the applicable Success Criteria; and (e) [*]. The Research Plan for the Initial Target is attached hereto as Exhibit 4.4.1 (the "***Initial Research Plan***"). The Research Plan(s) for Additional Targets and any Replacement Targets shall be drafted by Merus promptly following the selection of the applicable Lilly Target, and Merus shall thereafter: (i) provide a draft of such Research Plan to the JSC [*], and (ii) provided that [*], in each case following the date on which Lilly names an Additional Target or Replacement Target as a Lilly Target for inclusion in the Lilly Target Pair in accordance with Article 3. Each Research Plan shall substantially follow, in form and substance, the form of the Initial Research Plan, except to the extent the Parties agree to any deviations from such form with respect to any particular Additional Target or Replacement Target.

4.4.2 **Approval and Amendments**. The JSC shall regularly review the Research Plans (including the coordination of the activities across Research Programs and to account for the

number of active Research Plans at any given time) and the progress of activities being conducted under the Research Plans, in no event less frequently than [*]. Either Party may propose amendments to the Research Plan for a particular Research Program from time to time as appropriate, to take into account completion, commencement, or cessation of activities contemplated in the then-current Research Plan for such Research Program or any newly available information related to such Research Program. Such amendments shall be effective upon JSC approval and subject to the decision making in accordance with Section 2.7. The Parties understand and agree that [*].

4.5 **Records; Reports**

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4.5.1 **Records**. Merus shall maintain, or cause to be maintained, during the Research Term and for a reasonable period of time thereafter that is consistent with industry standards, complete and accurate records (paper and electronic) of its Research data and results for each Research Program in sufficient detail and in a good scientific manner appropriate for scientific, patent, and regulatory purposes, which records will reasonably reflect all work performed by or on behalf of Merus under the Research Plan for each Research Program. Lilly may request a copy of any such records of Merus, except that Merus may redact any portion of such records that Merus reasonably determines to constitute Confidential Proprietary Information that is not licensed to Lilly hereunder, or to which Lilly does not otherwise have a right hereunder.

4.5.2 **Reports and Data Package**. Each Party shall regularly report to the other Party through the JSC (or its designated Working Group) its results in conducting Research under the Research Plan for each Research Program. For each Research Program, Merus shall provide the JSC with: (a) the Final Research Deliverables set forth in the Research Plan for such Research Program, [*] after the completion of Merus's Research for such Research Program; and (b) at each regularly-scheduled JSC meeting, for any then ongoing Research Program during the Research Term, a reasonably detailed summary of [*] for such Research Program under this Agreement.

4.5.3 **Modified Compound Notice**. On a Research Program-by-Research Program basis, where Lilly has generated a Modified Compound or Monospecific Compound that it intends to Develop as a Product, [*], a "***Modified Compound Notice***"), provided that [*] and shall in any event treat it as Lilly's Confidential Proprietary Information [*]; further provided [*].

4.6 **Research Program Funding**

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4.6.1 **Merus Research Costs**. Lilly will fund (in accordance with Section 4.6.3) all Merus Internal Costs and Merus External Costs (collectively, "***Research Expenditures***") in accordance with the Research Budget set forth in the applicable Research Plan. [*] On at least an annual basis for each Research Program, no later than July 31 in each Calendar Year, the Parties shall discuss through the JSC the Research Expenditures incurred during the prior [*], and the Research Expenditures expected to be incurred during the following [*]. Following such discussion, the JSC shall amend (if applicable) and approve the Research Budget for the applicable Research Program for the following Calendar Year.

4.6.2 **Compliance with Research Budget**. Merus shall promptly notify Lilly once its Research Expenditures [*]. Following such notice by Merus, the Parties shall discuss in good faith whether to amend the Research Budget; provided that Merus shall use Commercially Reasonable Efforts to manage the Research Expenditures to avoid exceeding the Research Budget absent any change in the Research Plan or any scientific or regulatory reasons beyond the reasonable control of

Merus (taking into account matters of objectively reasonable calculation and efficiency of application of Research Expenditures).

4.6.3 **Calculations of Research Expenditures; Reimbursement by Lilly**. The Research Expenditures shall be calculated and reimbursed in accordance with this Section 4.6.3 as follows:

(a) Lilly shall only be obligated to reimburse Merus to the extent that the nature and scope of the work performed by Merus: (i) [*]; or (ii) has otherwise been approved in advance in writing by Lilly via the JSC;

(b) Merus shall invoice Lilly for reimbursement of Merus Internal Costs for each Research Plan on a [*]. Lilly shall then have [*] after its receipt of such invoice to review such invoice and raise any amounts disputed in good faith to Merus. For any amounts payable under an applicable invoice during such period that are not subject to a reasonable dispute by Lilly, Lilly shall pay the undisputed amounts under any such invoice [*]. Merus shall submit with [*] for such applicable invoiced period, including [*];

(c) Merus shall invoice Lilly for reimbursement of Merus External Costs for each Research Plan [*]. Irrespective of whether such payments are made in advance or in arrears, Lilly shall then have [*] after its receipt of such invoice to review such invoice and raise any amounts disputed in good faith to Merus. For any amounts payable under an applicable invoice not disputed by Lilly in good faith, during such [*]; provided that if Lilly reimburses Merus for advance payments made by Merus [*];

(d) For the duration of Lilly's funding commitment with respect to such Research Program, and for a period of [*] thereafter (the "***Review Period***"), Merus shall maintain complete and accurate books and records regarding the Research Expenditures invoiced to Lilly. [*] *mutatis mutandis* (subject only to replacing references to "Lilly" with references to "Merus," and vice versa, and other analogous changes, including changes related to the subject matter of the audit); and

(e) Without prejudice to Lilly's right to recoup any improperly paid amounts identified after an invoiced amount has been paid (including where such amounts are identified as a result of an audit pursuant to Section 8.6), any payment dispute shall be resolved in accordance with the procedures set forth in Section 14.2, provided that the existence of any such dispute shall not relieve Lilly of its obligations to make payment on any non-disputed invoiced amounts or entitle Lilly to any reduction or offset with respect to any amounts otherwise payable under this Agreement.

4.7 **Certain Standards Applicable to Work**

. All Research conducted by either Party for non-regulated work under this Agreement will be conducted in accordance with the Research Plans, Eli Lilly and Company Good Research Practices, Eli Lilly and Company Animal Care and Use Requirement for Animal Researchers and Suppliers and all Applicable Laws, including those regarding data privacy and data security laws and regulations. For purposes of this Agreement, "***Eli Lilly and Company Good Research Practices***" means the compiled set of shared research quality standards defining how Lilly's research laboratories conduct good science for non-regulated work as set forth in Exhibit 4.7 Part A. For purposes of this Agreement, "***Eli Lilly and Company Animal Care and Use Requirement for Animal Researchers and Suppliers***" means the guidelines relating

to animal care and use for research done on behalf of Lilly as set forth in Exhibit 4.7 Part B. If Lilly reasonably requests, [*]. If Merus [*]. Merus maintains all rights to redact information and shield from such audit any confidential information of a Third Party, to the extent Merus deems such measures necessary to protect Merus's obligations to any such Third Party. Additionally, Lilly may [*], in each case provided that Lilly has requested [*] does not unreasonably interfere with Merus's operations. Lilly may also request that Merus exercise its rights, upon reasonable notice, to conduct a compliance audit under Merus's agreements with Third Party subcontractors engaged in performing activities under this Agreement, if any, provided that such request may be made no more than [*]. All such audits shall be done at Lilly's cost and expense and the parties shall cooperate in good faith with respect to the exercise of any such audit right.

4.8 **Subcontracting**

. Each Party may engage its Affiliates or Third Party subcontractors (including contract research organizations and contract manufacturing organizations) to perform such portions of its research obligations under the Research Program that it customarily engages for its other similar research activities. The activities of any such Third Party subcontractors will be considered activities of such subcontracting Party under this Agreement. The subcontracting Party shall ensure compliance by such Third Party subcontractors with the terms of this Agreement, including any applicable Research Plans. The subcontracting Party shall ensure, prior to engaging any Third Party subcontractor, that such Third Party subcontractor is subject to written agreements containing terms and conditions that: (a) protect the rights of the Parties under this Agreement, including by imposing obligations of confidentiality on each such Third Party subcontractor that are no less than the obligations of confidentiality on each Party under this Agreement; (b) do not under any circumstance impose any payment obligations or liability on the non-subcontracting Party; and (c) are otherwise consistent with the relevant terms of this Agreement, including with respect to each Party's obligations [*].

4.9 **Lilly Materials**

. In connection with the execution of the Research Plan, Lilly may need to transfer certain Lilly materials to Merus that are not otherwise delivered under a supply or other separate agreement between the Parties or their Affiliates. In each such case, the Parties will mutually agree on the terms of such material transfer. Any such materials provided to Merus shall be accompanied by a materials transfer record substantially in the form of Exhibit 4.9 (each a "***Materials Transfer Record***") or as otherwise agreed through the JSC pursuant to Section 2.5(e) or 2.5(g). In the event of such transfer, unless otherwise mutually agreed by the Parties in writing, Lilly shall be responsible for obtaining all necessary approvals and/or filings as required under Applicable Laws for the exportation of any such materials to Merus and Merus shall be responsible for obtaining all necessary approvals and/or filings as required under Applicable Laws for their importation and use by Merus.

4.10 **Merus Materials**

. In order to execute the Research Plan, Merus may need to transfer certain materials to Lilly that are not otherwise delivered under a supply or other separate agreement between the Parties or their Affiliates ("***Merus Materials***"). On a Research-Program-by-Research Program basis, Lilly may use any Merus Materials that [*]; provided, however, that all other Merus Materials may only be used by Lilly for activities under the Research Plan, or such other activities [*]. Unless otherwise mutually agreed by the Parties in writing, Merus shall be responsible for obtaining all necessary approvals and/or filings as required under Applicable Laws for the exportation of Merus Materials to Lilly and Lilly shall be responsible for obtaining all necessary approvals and/or filings as required under Applicable Laws for their importation and use by Lilly. All Merus Materials

will at all times remain the property of Merus and will be held confidential in respect to Third Parties and will not be transferred to a Third Party without prior written permission of Merus, unless the Third Party agrees to terms and use limitations at least as restrictive as those set forth in this Agreement and such transfer is documented by a materials transfer record similar to the Material Transfer Records used under this Agreement. Upon the termination of this Agreement, Lilly will, at Merus's sole discretion and Lilly's cost, either (a) dispose of any residual Merus Materials not consumed by Lilly in the performance of this Agreement in accordance with Applicable Laws, or (b) upon request, return such Merus Materials to Merus. Any Merus Materials provided to Lilly by Merus or by Lilly to any Third Party (to the extent permitted herein) shall be accompanied by a Materials Transfer Record. Without limiting the foregoing, following the completion of a given Research Program with respect to a Lilly Target Pair, at Lilly's request, Merus may transfer or cause to be transferred to Lilly any Manufacturing-related Merus Know-How reasonably necessary or useful for the Exploitation by Lilly of a Compound or Product and licensed to Lilly under Section 6.1.

ARTICLE 5

DEVELOPMENT, REGULATORY AND COMMERCIAL MATTERS

5.1 Responsibilities; Parallel Target Pair Programs

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5.1.1 **General Development Responsibilities**. Except with respect to Research activities to be conducted by Merus pursuant to a Research Plan, Lilly shall be solely responsible for the Exploitation of Compounds and Products with respect to Lilly Target Pairs (or in the event Lilly pursues a Monospecific Compound, directed to each applicable Lilly Target as a monospecific or ADC), including all Manufacturing and Commercialization activities, in all cases, in accordance with the terms of this Agreement. With respect to each Lilly Target Pair for which Merus has delivered to Lilly a lead Collaboration Compound and the JSC-specified number of back-up Collaboration Compounds arising under the applicable Research Plan for such Research Program: (a) until [*], Lilly shall use Commercially Reasonable Efforts, at its own expense, to Develop and obtain Marketing Authorization [*] Product directed to each such Lilly Target Pair [*] in each of the United States, Japan, and at least two (2) of the EU5 Markets, and (b) following [*] arising from activities under this Agreement, Lilly shall use Commercially Reasonable Efforts to Commercialize such Product in each [*]. Subject to the terms and conditions of this Agreement, including the foregoing sentence, all decisions concerning the Exploitation of Compounds and Products, including the clinical and regulatory strategy of Compounds and Products, the marketing and sales of Products, and the design, price, and promotion of Products, shall be at the sole discretion of Lilly.

5.1.2 **[*] Programs** [*****].

5.2 Cooperation

. If Lilly reasonably requests assistance or input from Merus with respect to activities related to seeking, obtaining or maintaining Regulatory Approval or Marketing Authorization or with respect to Commercialization in the United States, Japan or E.U. being undertaken by Lilly in respect of a Compound or Product, Merus shall (at Lilly's expense), use its Commercially Reasonable Efforts to cooperate in good faith with Lilly in response to such request (*e.g.*, by responding to regulatory inquiries relating to the Research of a Compound by Merus, intellectual property matters with respect to Merus Know-How, Merus Patents, etc.), provided that Merus shall not be required to generate any additional data or other Know-How in connection with

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

such requests unless (a) the relevant applicable data or Know-How is not reasonably capable of being produced or generated by Lilly or a Third Party contractor, and (b) Lilly agrees in writing to reimburse Merus for its reasonably incurred internal costs and out-of-pocket expenses in connection with the generation of such additional data or other Know-How.

5.3 **Reports**

. Lilly shall keep Merus reasonably informed as to the progress and results of its and its Affiliates' and Sublicensees' Development activities under this Agreement, and shall provide Merus with a high-level written report summarizing its Development activities and the results thereof with respect to each Product and Lilly Target on at least [*] basis, including, by way of example, the Initiation and completion of Clinical Trials, submission of applications for, and receipt of, any Marketing Authorizations, and shall include in such report in respect of each such Product, the anticipated dates of commercial launch in each of the U.S., Japan, and the EU5 Markets as well as any required report [*]. Each such report shall also include a list of any safety issues or adverse events associated with the administration of the Products during such Development or any subsequent Commercialization of such Product. With respect to any material safety issue or material adverse event arising in connection with: (a) in respect of Lilly, the Exploitation of any Compound or Product, or (b) in respect of Merus, [*], solely where such material safety issue or material adverse event under this subclause is attributable to [*], the applicable Party shall notify the other Party directly (as well as the JSC) within [*] following such adverse event, and the Parties shall cooperate in good faith to address any issues arising from such adverse event. Upon the notified Party's request, the notifying Party shall make appropriate personnel reasonably available to answer any reasonable questions the notified Party has in relation to any such report. The notifying Party's obligations under this Section 5.3 shall cease with respect to a Product upon the First Commercial Sale of a Product in the U.S., provided that each Party shall continue to provide the other Party with information regarding safety issues or adverse events that relate to (i) with respect to Lilly [*] in a Product, and (ii) with respect to Merus [*] as in a Lilly Product, as long as Lilly is Exploiting such Product(s) hereunder.

5.4 **Regulatory Responsibilities**

. As between the Parties, Lilly shall be responsible for the preparation, submission, and maintenance of all Regulatory Filings and obtaining Regulatory Approvals (including the preparation and submission of the IND filing and for seeking IND approval) with respect to Compounds and Products and shall have sole control over all interactions with the applicable Regulatory Authority. Merus shall reasonably cooperate with Lilly, at Lilly's reasonable request and expense, with respect to any regulatory matters related to Compounds or Products related to seeking, obtaining or maintaining Regulatory Approval or Marketing Authorization or with respect to Commercialization in the United States, Japan or E.U., provided that such cooperation relates to the work Merus conducted pursuant to the applicable Research Plan, and provided further that nothing in this Section 5.4 shall require Merus to generate any additional data or other Know-How. Lilly will own all right, title and interest in and to any and all Regulatory Filings and Regulatory Approvals for Compounds and Products and, as between the Parties, all such Regulatory Filings and Regulatory Approvals will be held in the name of Lilly, and Merus shall execute all documents and take all actions as are necessary [*] to vest such title in Lilly.

5.5 **Adverse Event Reporting**

. Lilly shall establish, hold, and maintain the global safety database for Collaboration Compounds, Monospecific Compounds, Modified Compounds and Products with respect to information on adverse events concerning the Collaboration Compounds, Monospecific Compounds, Modified Compounds and Products, as and to the extent required by Applicable Law.

ARTICLE 6

LICENSE RIGHTS

6.1 License Grant to Lilly

. Subject to the terms and conditions of this Agreement, and on a Research Program-by-Research Program basis, Merus (on behalf of itself and each of its Affiliates) hereby grants to Lilly and each of its Affiliates an exclusive (even as to Merus and its Affiliates, but subject to Section 6.2), worldwide, royalty-bearing license, with the right to grant sublicenses (through multiple tiers, as provided in Section 6.4), under all Merus Know-How, Merus Patents and Merus Sole Arising IP in connection with any and all Compounds or Products directed against: (a) any Lilly Target (solely where such Compound or Product is a Monospecific Compound); or (b) any Lilly Target Pair (but excluding any multi-specific compounds or products directed against the Lilly Target Pair together with one or more additional Targets); [*] subject to the terms and conditions of this Agreement, including Sections 8.3 and 8.4. [*].

6.2 Existing Third Party Agreements

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(a) The Parties acknowledge and agree that the exclusive license granted to Lilly in Section 6.1 in respect of Monospecific Compounds developed by Lilly may be subject to one or more Existing Third Party Agreement(s), in which case, Lilly's rights may be non-exclusive in respect of any compounds or products generated by such Third Party pursuant to such agreement that are directed to such Lilly Target. [*]

(b) [*]

(c) [*]

6.3 License Grant to Merus

. Subject to the terms and conditions of this Agreement, Lilly (on behalf of itself and each of its Affiliates) hereby grants to Merus and each of its Affiliates a worldwide, fully paid, royalty-free, non-sub-licensable (except to Third Party subcontractors acting on its behalf, as permitted by Section 4.8), non-exclusive license under any Lilly Know-How, Lilly Patents and Lilly Sole Arising IP (but solely such Lilly Know-How, Lilly Patents and Lilly Sole Arising IP as Lilly discloses to Merus, by and through and as approved in writing by the JSC on a Research Plan-by-Research Plan basis, for use under and in accordance with a Research Plan), solely as directed by the JSC in its written approval for such use. The foregoing license shall expire at the end of the applicable the Research Term.

6.4 Third-Party Sublicenses

. Lilly and its Affiliates may grant one or more sublicenses under the rights and licenses granted to it solely under license scope of Section 6.1, in full or in part, to Third Parties (with the right to sublicense through multiple tiers); provided that: (a) any such permitted sublicense is consistent with and subject to the terms and conditions of this Agreement; and (b) Lilly shall remain responsible for performance of such Party's obligations under this Agreement and shall be responsible for all actions of each such Sublicensee as if such Sublicensee were the Party hereunder. As soon as reasonably practicable (but in any case within [*]) after the execution of any such sublicense agreement that grants rights to a Third Party to conduct clinical Development and Commercialization of Products in the United States, Japan or an EU5 Market (but excluding, for clarity, sublicenses granted solely for the purposes of a party carrying out promotional, marketing or

distribution activities on behalf of Lilly), Lilly shall provide Merus with written notice thereof, including the identity of the sublicensee and the scope of the license granted.

6.5 **No Implied Rights**

. Except as expressly set forth in this Agreement, neither Party shall be granted, by implication or otherwise, any license or right to or under any other intellectual property interest, including any trademarks, Know-How, or Patents, of the other Party.

6.6 **Retained Rights**

. Notwithstanding the exclusive license granted to Lilly pursuant to Section 6.1 during the Term, Merus shall retain all rights under the Merus Know-How and Merus Patents (a) to perform, and to subcontract pursuant to Section 4.8, its obligations under this Agreement, and (b) for any purpose outside the scope of the license granted under Section 6.1, subject in each case of (a) and (b) to Merus's obligations under Article 7. For clarity, nothing herein shall limit Merus's ability to use its panel of CD3 antibodies included within the Merus Platform Technology or Merus Platform IP or that is otherwise Covered by a Merus Patent for Exploitation of internal programs or with a Third Party for any bispecific or multispecific compound or product that is not directed to (i) a Lilly Target Pair, or (ii) a Reserved Target in combination with CD3 during the period such Target constitutes a Reserved Target. On a Lilly Target-by-Lilly Target basis, subject to Merus's exclusivity obligations pursuant to Section 7.1 (if applicable), Merus retains all rights to use and commercialize any [*] against such Lilly Target that Merus discovers, identifies or generates without use of or reference to [*] generated with respect to such Lilly Target, provided that subject to the terms of the Existing Third Party Agreements, such retained use is not with respect to development or commercialization of (A) a Monospecific Compound, or (B) a bispecific compound against the Lilly Target Pair, or multispecific compounds including a Lilly Target Pair (excluding any Replaced Target or a Terminated Target), but in each case of (A) and (B), excluding any Terminated Product or Terminated Compound. For clarity, subject to Merus's exclusivity obligations under Section 7.1 (if applicable), Merus's rights set out in this Section 6.6 shall apply if Merus discovers, identified or generates a [*] sequence directed against a Lilly Target that is identical to (1) any sequence [*], or (2) any [*] sequence directed against a Lilly Target used in a Research Program, provided such [*] sequence is discovered, identified or generated without use of or reference to the [*] generated with respect to such Lilly Target.

6.7 **Safe Harbor Research**

. Subject to Merus's exclusive grant of rights in Section 6.1 and its obligations under Article 7, but otherwise notwithstanding anything to the contrary in this Agreement, by entering into this Agreement, neither Party is forfeiting any rights that such Party may have to perform research activities in compliance with 35 U.S.C. § 271(e)(1) or any experimental or research use exemption that may apply under Applicable Law or in any country.

6.8 **Inclusion of Third Party IP**

. If Merus, in its sole discretion, enters into an agreement with a Third Party after the Effective Date pursuant to which Merus in-licenses any Know-How, Patents, or other intellectual property rights, that would constitute Merus Know-How or Merus Patents if Controlled by Merus, (any such Know-How, Patents or other intellectual property rights, collectively, "***Relevant Third Party IP***") then Merus shall, [*] following the execution of such agreement, provide Lilly with a written summary of [*]; and (b) a proposed allocation of [*] that would arise as a result of Lilly's or any of its Affiliate's or Sublicensee's use or practice of such Relevant Third Party IP in connection with the Exploitation of Products under this Agreement. Within [*] following Lilly's receipt of the written summary described above, the Parties (through the JSC) shall meet and determine in good faith (i) an allocation of [*] payment made in respect of

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

obtaining rights to the Relevant Third Party IP (based on the relative value of any sublicense that would be granted under such Relevant Third Party IP to Lilly (as compared to the value of the rights retained by Merus or granted to its other sublicensees)), and (ii) those payments (or portions thereof) that may become due under the applicable Third Party agreement by reason of exercise by Lilly or any of its Affiliate's or Sublicensee's exercise of any sublicense of rights to such Relevant Third Party IP. Within [*] following the final determination of (i) and (ii) above, which determination would not be subject to either Party's final decision making authority at the JSC and would instead be subject to resolution in accordance with Section 14.2, Lilly shall elect, in its sole discretion on written notice to Merus, to either (A) agree in writing to reimburse Merus for those allocable amounts paid or payable by Merus (as such amounts become due) under such Third Party agreement in accordance with final determination of such allocation described in (i) and (ii) above, in which case the relevant Know-How, Patents, or other intellectual property rights that were licensed by Merus shall be "Controlled" by Merus and included within the Merus Know-How or Merus Patents and licensed to Lilly under this Agreement, or (B) notify Merus that it does not desire a sublicense under such Relevant Third Party IP, in which case the Relevant Third Party IP would not be "Controlled" by Merus for the purposes of this Agreement, and Lilly would have no responsibility for any payments under the Third Party Agreement under which Merus acquired rights to the Relevant Third Party IP. [*].

ARTICLE 7

EXCLUSIVITY

7.1 Merus Exclusivity Obligations

. On a Lilly Target-by-Lilly Target basis, during the Term of this Agreement, and other than in connection with its obligations under this Agreement, neither Merus, nor any of its Affiliates (subject, in the case of Affiliates that control Merus in the future, to Section 15.8), shall, directly or indirectly, either alone or with or through one (1) or more Third Parties:

(a) engage in (i) any Exploitation activities with respect to any of the Collaboration Compounds, or any Modified Compounds or Monospecific Compounds of which Merus has received notice under Section 4.5.3 (subject to Section 6.2 in respect of existing Third Party rights, and subject to Section 7.1(a)(ii)(B) [*], (ii) any Exploitation activities with respect to any compound or product that includes the same [*] that binds the Lilly Target in (A) any Collaboration Compound, or (B) Modified Compound or Monospecific Compound for which Merus has received a Modified Compound Notice under Section 4.5.3, provided that at the time Merus receives such Modified Compound Notice, such sequence was not [*], and further provided that the total number of [*] sequences binding the Lilly Target on which Merus is restricted shall in no event exceed [*] per Research Program at any given point in time (and in the event Lilly issues a Modified Compound Notice at a time which there are already a number of sequences in the aggregate that reach such cap, [*]), (iii) Research (other than with respect to the practice of any rights expressly reserved by Merus pursuant to Section 6.6), Development or Commercialization of any monospecific antibody (including an ADC) directed against a Lilly Target (excluding any Replaced Target or a Terminated Target), but excluding any Terminated Product or Terminated Compound, subject to any Existing Third Party Agreements for which Merus has provided Lilly written notice pursuant to Section 6.2, or (iv) Exploitation of any [*] absent a license from Lilly in respect of Lilly's joint interest in such rights, as further described in Section 9.1.4;

(b) engage in any Exploitation activities with respect to any compound or product directed against any Lilly Target Pair (a "***Restricted Product***"), including for clarity, any Restricted Product that also binds one or more other Target(s) in addition to the Lilly Target Pair (*i.e.*, a multispecific product);

(c) collaborate or enter into any arrangement with, or work for the benefit of, any Third Party involving any of activities in subclauses (a) or (b), or enter into any agreement to do any of such activities in subclauses (a) or (b); or

(d) grant any Third Party any license, sublicense, covenant not to assert or other rights (including to or under any Merus Know-How or Merus Patents) to or otherwise enable such Third Party to (or assign, convey, transfer or sell any rights to a Third Party to) conduct any activities falling within subclauses (a), (b) or (c), provided that subject to Section 15.8, the foregoing shall not prevent, or place any restrictions on Merus's ability to enter into any Change of Control transaction.

Subject to the obligations of this Article 7, Merus will otherwise be free to Exploit itself, or to grant rights to any Third Party with respect to (1) any Target (that, where not in combination with another Target, is not a Lilly Target) and (2) any Target combination that is not a combination of a Lilly Target and CD3 (with or without any other Target(s)). For clarity, Merus does not exclusively license rights to any CD3 antibody under this Agreement to Lilly for any Lilly Target Pair, and any and all CD3 antibodies Controlled by Merus or its Affiliates are and will remain available to Merus or its Affiliates for use in any Internal Merus Program or with any Third Party.

7.2 **Certain Sequence Exclusivity**

. On a Research Program-by-Research Program basis, during the Homology Exclusivity Period for such Research Program, [*] binds the Lilly Target in the designated lead Collaboration Compound included in the Final Research Deliverables for such Research Program. If Lilly elects, [*] that binds the Lilly Target in such lead Collaboration Compound, and Lilly notifies Merus (at its sole discretion) of the sequence of such [*] by delivering a Modified Compound Notice with respect thereto: [*]. For clarity, if Lilly generates such a Modified Compound and elects not to notify Merus of the sequence thereof, the rights granted to Lilly with respect to such sequence shall remain non-exclusive in accordance with Section 6.1(b)(ii).

7.3 **Transactions Involving Competing Programs**

.

7.3.1 **Acquisition of Existing Competing Program**. Notwithstanding the exclusivity obligations set forth in Section 7.1, if, after the Effective Date, any Third Party becomes an Affiliate of Merus that Merus controls (as such term is defined in the definition of "Affiliate") as a result of a merger, acquisition, consolidation, asset sale, or other similar transaction (whether in a single transaction or series of related transactions), and, as of the closing date of such transaction, such Third Party is engaged in: (a) the Exploitation of a compound or product; or (b) the licensing, conveyance, sublicensing or other grant of rights in Patents and Know-How with respect to such a compound or product, in each case of (a) and (b) that would cause Merus to breach its exclusivity obligations set forth in Section 7.1 (such activities in (a) and (b), a "***Competing Program***"), then Merus shall provide Lilly with written notice of such transaction promptly[*], and Merus shall (or shall cause such Affiliate to), within [*] after the closing of such transaction, either: (i) complete a Divestiture of such Competing Program; or (ii) wind down and terminate the Competing Program. "***Divestiture***," means, [*]. "Divestiture" does not mean that following the sale or transfer of rights to

the Competing Program by such Party to a Third Party that such Party waives any right to receive a continuing share of profit, royalty payment, or other economic interest in the success of such Competing Program so long as such Party does not undertake or support any diligence or performance obligation with respect to such Competing Program.

7.3.2 **Existing Competing Program of a Merus Acquirer**. If after the Effective Date any Third Party becomes an Acquirer of Merus as a result of a Change of Control of Merus, and, as of the closing date of such transaction, such Acquirer is engaged in a Competing Program, then the provisions of Section 15.8 shall apply.

ARTICLE 8

FEES, ROYALTIES, & PAYMENTS

8.1 **Upfront Payment**

. As partial consideration for the rights granted by Merus to Lilly pursuant to the terms of this Agreement, Lilly shall pay to Merus a one-time, non-refundable, non-creditable license fee payment equal to Forty Million Dollars ($40,000,000) within thirty (30) days following the Effective Date.

8.2 **Equity Investment**

. Lilly will make an equity investment to acquire common shares of Merus pursuant to the terms of the Purchase Agreement.

8.3 **Milestone Payments**

.

8.3.1 On a Product-by-Product basis, Lilly shall pay to Merus certain non-refundable, non-creditable milestone payments, as follows (subject to Section 8.3.3): (a) within [*] following any Product achieving a development or regulatory milestone event set forth in Table 8.3 below, by or on behalf of Lilly or its Affiliates (including by and through a Sublicensee acting within the scope of the license granted in Section 6.1) (each, a "***Development/Regulatory Milestone Event***"), Lilly shall pay to Merus the corresponding Milestone Payment indicated in Table 8.3 (each such Milestone Payment, a "***Development/Regulatory Milestone Payment***"); and (b) within [*] following the end of the Calendar Quarter in which any Product achieves a commercial milestone event set forth in Table 8.3, by or on behalf of Lilly or its Affiliates (including by and through a Sublicensee acting within the scope of the license granted in Section 6.1) (each, a "***Commercial Milestone Event***"), Lilly shall pay to Merus the corresponding Milestone Payment indicated in Table 8.3 (each such Milestone Payment, a "***Commercial Milestone Payment***"). The Development/Regulatory Milestone Events and Commercial Milestone Events may be referred to individually or collectively as "***Milestone Events***," and Development/Regulatory Milestone Payments and Commercial Milestone Payments may be referred to individually or collectively as "***Milestone Payments***". For clarity, each Milestone Payment shall be payable only once per Product (recognizing that the Milestone Events for the "first Indication for a Product" and "second Indication for a Product" will be separately payable once for each Product), no Milestone Payment shall be payable for subsequent or repeated achievements of the same Milestone Event with respect to the same Product.

8.3.2 The Development/Regulatory Milestone Events for the Initiation of a Clinical Trial are intended to be sequential, and achievement of a Development/Regulatory Milestone Event

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

for Initiation of a Clinical Trial shall result in deemed achievement of all earlier Development/Regulatory Milestone Events. The Development/Regulatory Milestone Events for the First Commercial Sale of a Product for a first or second Indication are intended to be sequential to the Development/Regulatory Milestone Events applicable to the Initiation of a Clinical Trial for such Indication, and achievement of a Development/Regulatory Milestone Event for the First Commercial Sale of a Product for a particular Indication shall result in deemed achievement of the following Development/Regulatory Milestone Events (in each case, solely to the extent not already achieved once for such Product): Initiation of the first Phase I Clinical Trial; Initiation of the first Phase II Clinical Trial; and, as applicable, either: (a) the Initiation of the first Phase III Clinical Trial for the first Indication for a Product or (b) the Initiation of the first Phase III Clinical Trial for the second Indication for a Product. Similarly, achievement of each Commercial Milestone Event measured by annual Net Sales shall result in achievement of all Commercial Milestone Events measured by a lower amount of annual Net Sales.

8.3.3 Notwithstanding the foregoing, Lilly will only be required to pay Merus [*] of each Milestone Payment for any Reduced Payment Product that achieves the applicable Milestone Event. For clarity, a Product that incorporates, contains or comprises a Modified Compound is not a Reduced Payment Product, unless such Product otherwise meets the definition of a Reduced Payment Product.

Table 8.3 – Milestone Payments [

Development/Regulatory Milestone Event	**Milestone Payment**
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]
Total Development/Regulatory Milestone Payments Per Product:	**USD $290 Million**
Commercial Milestone Event	**Milestone Payment**
[*]	[*]
[*]	[*]

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

[*]	[*]
[*]	[*]
Total Commercial Milestone Payments Per Product:	**USD $250 Million**

8.4 **Royalties on Products**

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8.4.1 **Royalty Term**. Lilly shall pay Merus royalties as set forth in this Section 8.4 on a Product-by-Product and country-by-country basis in the Territory during the period of time beginning on the date of the First Commercial Sale of such Product in such country and continuing until the later of: (a) the expiration or abandonment of the last-to-expire Royalty-Bearing Claim in such country; (b) the expiration of any period of data, regulatory, or market exclusivity, or supplemental protection certificates (other than Patent rights) covering the Product in such country ("***Regulatory Exclusivity***"); or (c) [*] years after the First Commercial Sale of such Product in such country (the "***Royalty Term***"). Upon the expiration of the Royalty Term for a Product in a particular country, then subject to Section 8.4.4, the licenses granted by Merus to Lilly under Section 6.1 with respect to such Product and such country shall survive and become perpetual, fully-paid, and royalty-free, and shall remain exclusive (even as to Merus and its Affiliates).

8.4.2 **Royalty Rates**. On a Product-by-Product and country-by-country basis, during the Royalty Term, Lilly shall pay to Merus a tiered royalty equal to the percentages of annual Net Sales of such Product, as set forth in Table 8.4.2 below (the "***Royalty***"), calculated by multiplying the applicable royalty rate percentage by the corresponding portion of aggregate Net Sales for such Product in such Calendar Year. Notwithstanding the foregoing, Lilly will only be required to pay Merus: [*] of the applicable royalty percentage set forth below for Net Sales of any Reduced Payment Product. For clarity, a Product that incorporates, contains or comprises a Modified Compound is not a Reduced Payment Product, unless such Product otherwise meets the definition of a Reduced Payment Product.

Annual Net Sales Per Product	**Royalty Rate**
[*]	[*]
[*]	[*]
[*]	[*]
[*]	[*]

8.4.3 **Valid Claim**. From the first full Calendar Quarter during the Royalty Term for a Product for which there is no Royalty-Bearing Claim that Covers such Product in such country, the Royalty rates provided in Section 8.4.2 for the Product will be reduced in such country by (a) [*], after which, the foregoing reduction shall increase to [*] (in addition to any reductions in Section 8.4.4 and Section 8.4.5, but subject to Section 8.4.6).

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

8.4.4 **Biosimilar Products**. On a country-by-country and Product-by-Product basis, following the first commercial sale of one (1) or more Biosimilar Products with respect to a Product in any country in the Territory during the Royalty Term, the Royalty rates provided in Section 8.4.2 for such Product will: be (a) permanently reduced in such country by [*] percent in such country during the Royalty Term once such Biosimilar Product(s) has or have a combined market share of [*] or more in such country; or (b) by [*] percent in such country during the Royalty Term once such Biosimilar Product(s) has or have a combined market share of [*] or more in such country, in which case, [*]. The determination of market share for the purpose of this Section 8.4.4, shall be measured in local currency, over the Calendar Quarter, as reported by IQVIA or other customary market intelligence service used by Lilly and reasonably acceptable to Merus.

8.4.5 **Third Party Payments**. On a Product-by-Product and country-by-country basis, Lilly may deduct from any Royalty payments to Merus under this Section 8.4: (a) for each Product that is not a Reduced Payment Product, an amount equal to [*] of [*] made by Lilly to a Third Party in connection with sales of such Products in such country under this Agreement in consideration for a right or license under such Third Party's interest in any Patents that would, absent such a right or license, be infringed [*] in the applicable country in the Territory ("***Necessary Third Party IP***"), and (b) for each Reduced Payment Product, an amount equal to [*] of [*] made by Lilly to a Third Party in connection with sales of such Reduced Payment Product in a given country in the Territory under this Agreement in consideration for a right or license under such Third Party's interest in any Patents that would, absent such a right or license, be infringed [*] (i) [*], or (ii) any [*], in each case, in such Reduced Payment Product in the Field in the applicable country in the Territory. For clarity, such deduction shall not apply where any payments made by Lilly to a Third Party in connection with sales of such Reduced Payment Products in such country under this Agreement in consideration for a right or license under such Third Party's interest in any Patents that would, absent such a right or license, be infringed in whole or in part by [*] of said Reduced Payment Product.

8.4.6 **Royalty Floor**. Notwithstanding the foregoing Sections 8.4.3, 8.4.4(a), 8.4.5 and 15.8.2(a)(iv) with respect to any Product in any Calendar Quarter, except in the case of a reduction under Section 8.4.4(b), the Royalty that would otherwise have been due under Section 8.4.2 with respect to Net Sales of such Product in the applicable country(ies) during such Calendar Quarter shall not be reduced by more than [*] as a result of all such reductions. For clarity, the foregoing [*] floor shall not apply to the reduction in royalties taken pursuant to Section 8.4.4(b).

8.4.7 **Payment; Reports**. Royalty payments due by Lilly to Merus under this Section 8.4 will be calculated and reported for each Calendar Quarter. All Royalty payments due under this Section 8.4 shall be paid within [*] after the end of each Calendar Quarter and shall be accompanied by a report setting forth Net Sales and Royalties for each Product sold by Lilly and its Affiliates and Sublicensees in the Territory and providing notice of any Commercial Milestone Event that have been achieved in such Calendar Quarter.

8.5 **Method of Payment; Currency Conversion**

. Unless otherwise agreed by the Parties, all payments due under this Agreement shall be paid in Dollars by wire transfer or electronic funds transfer of immediately available funds to an account designated by the payee; provided however, that Lilly shall only be required to disburse funds to the payee's jurisdiction of incorporation or to a jurisdiction in which the payee has a significant business presence. When conversion of payments from any currency other than Dollars is required, Lilly's then-current standard exchange rate

methodology will be employed for the translation of foreign currency sales into Dollars; provided that this methodology is used by Lilly in the translation of its foreign currency operating results, is consistent with U.S. GAAP [*].

8.6 **Records and Audits**

. Lilly shall keep, and shall cause its Affiliates and Sublicensees to keep, complete and accurate records which may be necessary to ascertain properly and to verify the Royalties and Milestone Payments due hereunder. Such records shall be kept for such period of time required by Applicable Laws, but no less than [*] following the end of the Calendar Quarter to which they pertain. Merus shall have the right, but not more than [*] during the Term, to [*] have an independent, certified public accountant [*] inspect Lilly's records for the purpose of determining the accuracy of Royalties and Milestone Payments [*]. No period will be audited more than once and each audit must be reasonable in scope. [*]. The independent, certified public accountant selected shall keep confidential any information obtained during such inspection and shall report to Merus and Lilly only the amounts of Net Sales and Royalties and/or Milestone Payments due and payable. Such audits may be exercised during normal business hours upon reasonable prior written notice to Lilly. Merus shall bear the full cost of such audit unless such audit discloses an underpayment by Lilly of more than [*], of the amount of Royalties or other payments due under this Agreement for the audited period, in which case, Lilly shall bear the cost of such audit and shall remit to Merus the amount of any underpayment within [*] of the date the auditor's written report is received. Any overpayment by Lilly revealed by an audit shall be [*] within [*] of the receipt of the request).

8.7 **Late Payments**

. If any payment properly due under this Agreement and not subject to a good faith dispute is not paid when due in accordance with the applicable provisions of this Agreement, the payment shall accrue interest from the date due at the rate of prime (as reported in *The Wall Street Journal* (Eastern U.S. edition)) plus [*] or the maximum rate allowable by Applicable Law, whichever is less. The payment of such interest shall not limit the Party entitled to receive payment from exercising any other rights it may have as a consequence of the lateness of any payment.

8.8 **Taxes**

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8.8.1 **Cooperation and Coordination**. The Parties acknowledge and agree that it is their mutual objective and intent to minimize, to the extent feasible and in compliance with Applicable Laws, taxes payable with respect to their collaborative efforts under this Agreement and that they shall use reasonable efforts to cooperate and coordinate with each other to achieve such objective. Where any payment due to Merus hereunder is subject to any withholding or similar tax, the Parties shall use their commercially reasonable efforts to take all such actions as shall enable them to take advantage of any applicable double taxation agreement or treaty.

8.8.2 **Payment of Tax**. The upfront, milestones, royalties and other amounts payable by Lilly to Merus to this Agreement (each, a "***Payment***") shall be paid free and clear of any and all taxes, except for any withholding taxes required by Applicable Law. Except as provided in this Section 8.8.2. Merus shall be solely responsible for paying any and all taxes (other than withholding taxes required by Applicable Law to be deducted from Payments and remitted by Lilly) levied on account of, or measured in whole or in part by reference to, any Payments it receives. Lilly shall deduct or withhold from the Payments any taxes that it is required by Applicable Law to deduct or withhold. Notwithstanding the foregoing, if Merus is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, applicable withholding tax, it may deliver to Lilly or the

appropriate Governmental Authority (with the assistance of Lilly to the extent that this is reasonably required and is expressly requested in writing) the prescribed forms necessary to reduce the applicable rate of withholding or to relieve Lilly of its obligation to withhold such tax and Lilly shall apply the reduced rate of withholding or dispense with withholding as the case may be; provided that Lilly has received evidence, in a form satisfactory to Lilly, of Merus's delivery of all applicable forms (and, if necessary, its receipt of appropriate governmental authorization) at least [*] prior to the time Payments are due. If in accordance with the foregoing, Lilly withholds any amounts of tax, it shall pay to Merus the balance when due, make timely payment to the proper tax authority of the withheld amount and send to Merus proof of such payment within [*] following such payments. Notwithstanding the foregoing, the Parties acknowledge and agree that if Lilly (or its Affiliates or successors) is required to make a payment to Merus subject to a deduction or withholding of tax, and if such deduction or withholding of tax arises or is increased solely as a result any action taken by Lilly or its Affiliates or successor or assignee, including without limitation the assignment or transfer of all or a portion of this Agreement by the payor pursuant to Section 15.7 or otherwise, or there is a change, whether by corporate continuance, merger or other means, in the tax residency of Lilly, or payments arise or are deemed to arise through a branch of the payor (each a "***Withholding Tax Action***"), then notwithstanding anything to the contrary herein, the payment by Lilly (in respect of which such deduction and withholding of tax is required to be made) shall be increased by the amount necessary to ensure that Merus receives an amount equal to the same amount that it would have received had no Withholding Tax Action occurred.

ARTICLE 9

INTELLECTUAL PROPERTY

9.1 Ownership of Intellectual Property

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9.1.1 **Background IP**. As between the Parties, and subject to the licenses granted under this Agreement and the requirements of this Section 9.1: (a) Lilly shall solely own (or retain ownership of) all rights, title and interests in and to the Lilly Background Know-How and Lilly Background Patents; and (b) Merus shall solely own (or retain ownership of) all rights, title and interests in and to the Merus Background Know-How and Merus Background Patents.

9.1.2 **Ownership of Arising IP.**

(a) **Lilly Ownership**. Subject to Section 9.1.2(d), as between the Parties, and subject to the licenses and obligations of exclusivity granted hereunder, Lilly shall solely own (or retain ownership of) all rights, title and interests in and to: (i) all [*] and [*]; (ii) any [*] and [*]; and (iii) except as expressly set forth in Section 9.1.2(b)(i), all Inventions and Know-How made following the completion of activities under the applicable Research Plan (or the expiration of the Research Term, if earlier) solely by or on behalf of Lilly or its Affiliates ((other than by Merus or its Affiliates)) in connection with the exercise of its rights or the performance of its activities under this Agreement (collectively (i) through (iii) the "***Lilly Sole Arising IP***"). Notwithstanding the foregoing, [*].

(b) **Merus Ownership**. Subject to Section 9.1.2(d), as between the Parties, and subject to the licenses and obligations of exclusivity granted hereunder, Merus shall solely own (or retain ownership of) all rights, title and interests in and to all: (i) Merus Platform IP and Merus

Platform Patents; (ii) all [*] and [*]; and (iii) except as expressly set forth in Section 9.1.2(a)(i), all Inventions and Know-How made following the completion of activities under the applicable Research Plan (or the expiration of the Research Term, if earlier) solely by or on behalf of Merus or its Affiliates in connection with the exercise of its rights or the performance of its activities under this Agreement (collectively (i) through (iii) the "***Merus Sole Arising IP***"). Notwithstanding the foregoing, [*].

(c) **Joint Ownership.** Subject to Section 9.1.2(d), as between the Parties, each Party shall own an equal, undivided interest in and to: (i) any Joint Research Program Know-How and Joint Research Program Patents; and (ii) except as expressly set forth in Section 9.1.2(a)(i), or 9.1.2(b)(i), any other Inventions and Know-How that are made following the completion of activities under the applicable Research Plan (or the expiration of the Research Term, if earlier) jointly by or behalf of the Parties or their Affiliates in connection with the performance of the Parties' activities under this Agreement ((i) and (ii), collectively, the "***Joint Know-How***" and any Patents Covering such Joint Know-How (including all Joint Research Program Patents), the "***Joint Patents***"), [*]. Each Party shall promptly disclose to the other Party in writing, and shall cause its Affiliates, licensees and sublicensees to so disclose, the conception, discovery, development, making, or reduction to practice of any Joint Know-How.

(d) **Assigned [*] Patents**. Notwithstanding Sections 9.1.2(a), 9.1.2(b) or 9.1.2(c), as between the Parties, Lilly shall own [*], (B) a specific [*] disclosed by [*], or (C) on a Research Program-by-Research Program basis, [*] provided that [*] of such Compound that binds [*]; and (ii) does not include claims that [*]. For the avoidance of doubt, all Patents and Patent applications [*].

9.1.3 **Inventorship**. Inventorship as between the Parties will be determined in accordance with U.S patent laws. All such determinations shall be documented to ensure that the Patent claims in any divisional or continuation patent applications reflect appropriate inventorship.

9.1.4 **Rights of Joint Owners**. Subject to the express licenses and obligations of exclusivity granted hereunder, and the obligations of the Parties with respect to any Joint Know-How and Joint Patents, each Party shall have full rights to exploit, license and transfer any Joint Know-How and Joint Patents, in each case, without any obligation or requirement of an accounting to the other Party, so long as such use, sale, license, or transfer is subject to and consistent with the terms of this Agreement, including exclusivity obligations; provided, that neither Party may Exploit, license or transfer [*], without the express consent of the other Party, where such consent may be conditioned on [*]; provided, however, that each Party may, [*], and the other Party is deemed to have consented to such enforcement action by operation of this section.

9.1.5 **Independent Development**. Subject to the licenses and obligations of exclusivity granted hereunder, nothing in this Agreement shall be construed as limiting either Lilly's or Merus's right to research, develop, improve and in-license technology, including technology related to the Lilly Background Know-How (in the case of Lilly) or Merus Background Know-How (in the case of Merus), outside the scope of this Agreement in its ordinary course of business.

9.1.6 **Contribution of [*] Know-How**. [*] shall inform [*] in writing, prior to contributing to any Research to be conducted under any Research Plan, any portion of the [*] Know-How or [*] Patents that are in-licensed from a Third Party, together with any material conditions or

restrictions associated with such contribution, including any conflict with the ownership and use rights with respect to Patents and Know-How contemplated by this Agreement. [*] shall not so contribute any such [*] Know-How or [*] Patents without [*] prior written consent therefor.

9.1.7 **Assignment Obligations**. Each Party shall cause all employees, independent contractors, consultants, and others who perform activities for such Party under this Agreement to be under an obligation to assign (or, if such Party is unable to cause such person or entity to agree to such assignment obligation despite such Party using reasonable efforts to negotiate such assignment obligation, provide a license, preferably exclusive, under) to such Party their rights in and to any Inventions and all intellectual property rights therein, except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a Party shall obtain a suitable license, preferably exclusive, or right to obtain such a license, provided that this exception shall not apply to Research Program Know-How). Each Party shall use reasonable efforts to promptly disclose to the other Party all Inventions that are [*] to the Parties' activities under this Agreement or to any obligation to assign hereunder, including any invention disclosures, or other similar documents, submitted to it by its employees, agents or independent contractors describing such Inventions, and all information relating to such Inventions [*] for the preparation, filing and maintenance of any Patent with respect to such Invention in accordance with the terms of this Agreement.

9.1.8 **Assignment of Arising IP**. The assignments by each Party necessary to accomplish the ownership provisions set forth in Section 9.1.2 are hereby made, and each Party shall execute such further documentation as may be necessary or appropriate, and provide reasonable assistance and cooperation, to implement the provisions of Section 9.1.2. Without limiting the foregoing, [*] Each inventing Party shall take (and cause its employees, agents, contractors and sublicensees (if applicable) to take) such further actions reasonably requested by the other Party to evidence any such assignment set forth in this Section 9.1.8, and to reasonably support the other Party's efforts to Patent or obtain other intellectual property rights in connection with any assigned Inventions or Know-How in accordance with the terms of this Agreement.

9.2 **Patent Prosecution and Maintenance**

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9.2.1 **Patent Representatives; Patent Working Group**. Promptly following the Effective Date, the Parties shall establish a working group to oversee the strategy for Prosecution and Maintenance of any Patents hereunder (the "***Patent Working Group***"). Each Party shall designate to the other Party in writing a patent Prosecution and Maintenance representative to liaise with the other Party's Prosecution and Maintenance representative with respect to the Prosecution and Maintenance of Patents under this Section 9.2 as soon as practicable following the Effective Date (but in no event more than [*] following the Effective Date). Each Party may update its patent Prosecution and Maintenance representative at any time upon written notice to the other Party. The [*] patent Prosecution and Maintenance representatives, and any additional members designated by the Parties (in such numbers as the Parties mutually agree), will serve as members of the Patent Working Group. The Patent Working Group shall serve as a forum for the exchange of information between the Parties pursuant to which each Party responsible for handling the Prosecution and Maintenance of Patents in accordance with this Section 9.2 (the "***Prosecuting Party***") may keep the other Party reasonably informed of the status of the any applicable Patent and to make decisions regarding the filing, Prosecution and Maintenance, as set forth in this Section 9.2.

9.2.2 **Rights to Prosecute and Maintain Patents**. As between the Parties, subject to the provisions of this Section 9.2:

(a) **Lilly as the Prosecuting Party**: Lilly has (i) the sole right (at Lilly's sole cost and expense), but not the obligation, to Prosecute and Maintain each Lilly Background Patent and Lilly Target Binder Patent, (ii) the first right, but not the obligation, to Prosecute and Maintain all (A) Product Patents [*], (B) [*] and (C) [*], in each case, at Lilly's sole cost and expense, (provided, in each case of (i) and (ii), that Lilly shall [*] in a manner reasonably likely to [*], and Merus shall have the secondary right (at its sole cost and expense) to Prosecute and Maintain any Patent described in (ii), as provided in Section 9.2.5, and (iii) the sole right (at Lilly's sole cost and expense), but not the obligation, to Prosecute and Maintain each Patent owned or Controlled by Lilly that is not covered by Section 9.2.2(a)(i)-(ii) or 9.2.2(b), but that Covers any Invention or subject matter within the Lilly Sole Arising IP (collectively, the "***Lilly Prosecuted Patents***").

(b) **Merus as the Prosecuting Party**. Merus has (i) the sole right (at Merus's sole cost and expense), but not the obligation, to Prosecute and Maintain each Merus Background Patent and Merus Platform Patent, and (ii) the first right to, but not the obligation, to Prosecute and Maintain each [*], each [*] (provided, in each case of (i) and (ii), that Merus shall [*] in a manner reasonably likely to [*], and Lilly shall have the secondary right (at its sole cost and expense) to Prosecute and Maintain any such Patent described in (ii) in each case, as provided in Section 9.2.5, and (iii) the sole right (at Merus's sole cost and expense), but not the obligation, to Prosecute and Maintain each Patent owned or Controlled by Merus that is not covered by Section 9.2.2(a) or 9.2.2(b)(i)-(ii), but that Covers any Invention or subject matter within the Merus Sole Arising IP (collectively, the "***Merus Prosecuted Patents***").

9.2.3 **Cooperation of the Parties; Coordination of Filings; Step-In Rights**.

(a) **General Information Rights**. With respect to each of the Merus Prosecuted Patents and the Lilly Prosecuted Patents, the Prosecuting Party shall (i) keep the other Party (through the Patent Working Group) reasonably informed of the status of any applicable Patent or application, including by promptly providing the Patent Working Group with all material correspondence received from any Patent authority in connection therewith (including with respect to any office actions); (ii) promptly [*], provided that, subject to Section 9.2.3(b) and without limiting Section 9.2.4 with respect to [*], the Parties shall discuss such Prosecution and Maintenance only with respect to claims that specifically relate to any Collaboration Compound, Monospecific Compound, Modified Compound or Product, (B) [*] shall discuss such Prosecution and Maintenance only with respect to claims that [*] (C) all decisions relating to any [*]; and (D) all decisions relating to any [*]: (x) Lilly shall have final-decision making authority in respect thereto solely with respect to [*]; and (z) Merus shall otherwise have final-decision making authority in respect to all [*]; provided that Merus shall not exercise such final-decision making authority in a manner reasonably likely to [*].

(b) **Cooperation**. Each Party shall cooperate fully with the other Party in the Prosecution and Maintenance of Patents under this Section 9.2 at its own cost (except as expressly set forth otherwise in this Article 9), including by executing all papers and instruments, or requiring its employees or contractors, to execute such papers and instruments, to enable the other Party to apply for and to Prosecute and Maintain such Patents in any country as permitted by this Section 9.2.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

Each Party and the Patent Working Group shall consider in good faith the interests of the other Party and shall strive to maximize the benefit of any Inventions (and associated Patents) contemplated under this Agreement for both Parties; provided that where [*] asserts the subject-matter of an Invention to be novel and inventive or otherwise patentable subject matter, [*] will not (either itself or through an Affiliate or Third Party or in support of an assertion by such Affiliate or Third Party) make any assertion to the contrary or act in a manner reasonably likely to have a detrimental effect on such Invention or any associated Patents, except to the extent reasonably required [*] to comply with 37 C.F.R. § 1.56, in which case, [*] shall provide [*] with reasonable advance notice of its proposed assertion or activity and shall discuss with [*] in good faith prior to making such assertion or undertaking such activity.

9.2.4 **Separation of Patent Claims; Identification of Assigned Product Patents**. If a Party determines that an application for a Patent filed, or sought to be filed, by the other Party claims, (a) on the one hand, any Merus Background Know-How, Merus Platform IP, [*] (the "***Merus Sole IP***"), and (b) on the other hand, any Lilly Background Know-How, Lilly Target Binder IP, [*] (the "***Lilly Sole IP***"), then the Parties agree that, to the extent practicable, such application shall be divided into two (2) or more Patent applications, so that each application shall contain claims that cover only one of Merus Sole IP (as applicable), on the one hand, or the Lilly Sole IP, on the other hand, so as to more effectively enable the distinct ownership rights and Prosecution and Maintenance of such Patent applications by the Parties. Similarly, an attempt shall be made to divide Patent applications into those that claim [*]. Without limiting the foregoing, on a Research Program-by-Research Program basis, upon delivery of the Final Research Deliverables in respect of each Collaboration Compound and in respect of any Modified Compound, that includes a [*], Merus shall, working through the Patent Working Group, seek to identify any Patents [*] that disclose or include claims that specifically recites [*]: (i) such [*] or (ii) the [*] and, in each case of (i) or (ii), if any such Patents exist, [*], provided that Merus will, in any case, consider any such request in good faith. All such efforts pursuant to this Section 9.2.4 shall be coordinated through the Patent Working Group.

9.2.5 **Step-in Rights**. The applicable Prosecuting Party for any Patent for which it has the first (but not sole) right to Prosecute and Maintain shall notify the Patent Working Group in writing of its intention to suspend or cease any Prosecution and Maintenance of any such Patent at least [*] prior to any filing or payment due date, or any other due date that requires action, in connection with the ongoing Prosecution and Maintenance of such Patent. In such event, the Prosecuting Party shall permit the other Party, at the other Party's discretion and at its sole expense, to continue Prosecution and Maintenance of such Patent, and will take all actions and execute all documents reasonably necessary for the other Party to assume such Prosecution and Maintenance as the Prosecuting Party for such Patent. Without limiting the foregoing, if a Party is the Prosecuting Party of any Joint Patent that it intends to abandon, then the other Party shall have the option to elect by providing written notice to the Patent Working Group to [*] continue Prosecution and Maintenance of such Joint Patent [*], as contemplated above [*]. Upon receipt of such request, the Prosecuting Party [*]. Following any [*], subject in all cases to the rights and licenses granted by the Parties hereunder.

9.3 **Infringement and Misappropriation by Third Parties**

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9.3.1 **Notice**. Each Party shall notify the other within [*] of becoming aware of any alleged or threatened infringement by a Third Party of any of the Merus Patents, Lilly Patents, or

Joint Patents, which infringing activity involves the Exploitation by a Third Party of any compound or product that is directed to the same Lilly Target or Lilly Target Pair to which a Product under this Agreement is also directed, in each case, in the Field in the Territory, and any related declaratory judgment, opposition, or similar action alleging the invalidity, unenforceability or non-infringement of any of the Merus Patents, Lilly Patents, or Joint Patents with respect to any such Third Party compound or product (collectively "***Infringement***").

9.3.2 **Lilly Sole Enforcement Rights**. Subject to Section 9.3.8, as between the Parties, Lilly has the sole right to initiate any proceedings or take other appropriate actions against: (a) misappropriation or violation of any Lilly Background Know-How, or any Know-How within the Lilly Sole IP [*]; or (b) Infringement of any Lilly Background Patent, or any Lilly Target Binder Patent, or any Patent within the Lilly Sole IP [*] or to defend against any challenge to any of the foregoing. Lilly shall keep Merus reasonably informed of the status of such enforcement efforts and shall consider in good faith Merus's comments thereon, to the extent such actions are relevant to Merus's rights under such Patents and Know-How pursuant to this Agreement, including under Section 8.4.

9.3.3 **Merus Sole Enforcement Rights**. Subject to Section 9.3.6 and 9.3.8, as between the Parties, Merus has the sole right to initiate any proceedings or take other appropriate actions against: (a) misappropriation or violation of any Merus Sole IP (other than those Patents and claims for which Lilly has the first right pursuant to Section 9.3.4) and [*], or (b) Infringement of any Merus Background Patent, Merus Platform Patent or any Patent within the Merus Sole IP (other than those Patents and claims for which Lilly has the first right pursuant to Section 9.3.4) or to defend against any challenge to any of the foregoing. Merus shall keep Lilly reasonably informed of the status of such enforcement efforts and shall consider in good faith Lilly's comments thereon, to the extent such actions are relevant to Lilly's rights under such Patents and Know-How pursuant to this Agreement.

9.3.4 **Product IP, Joint Product IP, Research Program IP**. Subject to Section 9.3.8, as between the Parties, Lilly has the first right, but not the obligation, to bring and control any legal action in connection with: (a) any misappropriation or violation of any (i) Joint Know-How excluding [*], or (ii) any other Research Program Know-How that [*], (b) an Infringement of any (i) Joint Patent (other than [*]), (ii) Product Patent, (iii) any claim of any [*] Patent that Covers and recites [*], (c) any defense against any challenge to (i) any Joint Know-How or Joint Patent (other than [*]), (ii) any Product Patent, (iii) any claim of any [*] Patent that Covers and recites [*]. Lilly shall keep Merus reasonably informed of the status of such enforcement efforts and shall consider in good faith Merus's comments thereon. Lilly shall provide Merus with drafts of all material papers to be filed with the court and shall in good faith consider all reasonable comments thereto by Merus before filing such papers. Merus may, at its own expense, be represented in any such action by counsel of its own choice. If Lilly does not bring such legal action within [*] after the notice provided pursuant to Section 9.3.1, Merus may bring and control any legal action in connection with the events set forth in subclauses (a) through (c) above, in each case, at Merus's sole cost and expense as it reasonably determines appropriate. In connection with any obligation described in this Section 9.3 to keep the other Party reasonably informed of any enforcement efforts, the Parties will discuss in good faith the commencement of any action prior to the initiation thereof (through the Patent Working Group or otherwise) and discuss in good faith the strategy for any enforcement any such Know-How

or Patents contemplated in this Section 9.3. Without limiting the foregoing, where Lilly is the enforcing party under this Section 9.3.4 or under Section 9.3.2, Lilly will not [*].

9.3.5 **[*] Know How; Patents.** Subject to Section 9.3.8, as between the Parties, either Merus or Lilly may initiate proceedings or take other appropriate actions against: (a) misappropriation or violation of any [*]; or (b) Infringement of any [*], or to defend against any challenge to any of the foregoing. For a period of not less than [*], the Parties will discuss in good faith the commencement of any action prior to the initiation thereof (through the Patent Working Group or otherwise) and discuss in good faith the strategy for any enforcement of any such Know-How or Patents contemplated in this Section 9.3. Without limiting the foregoing, the Party that initiates any such action shall keep the other Party reasonably informed of the status of such enforcement efforts and shall consider in good faith such other Party's comments thereon, to the extent such actions are relevant to such other Party's rights under such Patents and Know-How pursuant to this Agreement.

9.3.6 **Request to Enable Enforcement Against Other Third Party Infringers.** Where Lilly identifies [*], Lilly may by written notice request that Merus [*]. The Parties shall discuss any such requests made by Lilly in good faith, including by and through the Patent Working Group. Merus shall promptly respond to such request [*].

9.3.7 **Allocation of Recoveries**. Any recoveries resulting from enforcement action relating to a claim of misappropriation, violation or Infringement (including any defense) shall be first applied against payment of each Party's costs and expenses in connection therewith (which amounts shall be allocated pro rata if insufficient to cover the totality of such expenses). [*] will retain [*]; provided that [*].

9.3.8 **Cooperation**. At the request and expense of the Party bringing an action under this Section 9.3, the other Party shall provide reasonable assistance in connection therewith, including by executing reasonably appropriate documents, cooperating in discovery and joining as a party to the action if required by Applicable Law to pursue such action. In connection with any such enforcement action, the Party bringing the action shall not enter into any settlement admitting the invalidity or non-infringement of, or otherwise impairing the other Party's rights in, the applicable Patents, or imposing any material cost or liability on, or admission by, the other Party, in each case without the prior written consent of the other Party. If there is more than one controlling Party with respect to a misappropriation, violation or Infringement, the Parties shall negotiate in good faith to determine control over the handling of the action.

9.4 **Defense and Settlement of Third Party Claims**

. Each Party shall promptly notify the other in writing of any allegation by a Third Party that the activity of either of the Parties pursuant to this Agreement infringes or may infringe the intellectual property rights of such Third Party. Merus has the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Merus's activities at its own expense and by counsel of its own choice, and Lilly may, at its own expense, to be represented in any such action by counsel of its own choice. Lilly has the sole right to control any defense of any such claim involving alleged infringement of Third Party rights by Lilly's activities at its own expense and by counsel of its own choice, and Merus may, at its own expense, to be represented in any such action by counsel of its own choice. Neither Party may

settle any patent infringement litigation under this Section 9.4 [*]. This Section 9.4 shall also govern [*].

9.5 **Patent Extensions; Patent Linkage**

. [*] Patent claiming or covering a Collaboration Compound, Monospecific Compound, Modified Compound or Product should be extended, and thereafter [*] in obtaining patent term restorations, supplemental protection certificates or their equivalents, and other forms of patent term extensions for a given Collaboration Compound, Monospecific Compound, Modified Compound or Product with respect to any applicable [*] in any country or region where applicable. The Parties shall also cooperate in addressing all issues relating to patent linkage in any country or region where applicable. [*] shall have final decision making authority with respect to all decisions regarding such patent term extensions or regarding issues of patent linkage.

9.6 **CREATE Act**

. It is the Parties' intention that this Agreement is a "joint research agreement" as that phrase is defined in 35 U.S.C. § 102(c) as amended by the Cooperative Research and Technology Enhancement (CREATE) Act, including the provisions of 35 U.S.C. § 102(b)(2)(c). The Parties agree to cooperate and to take reasonable actions to maximize the protections available for the Compounds and Products under such safe harbor provisions.

9.7 **Trademarks**

. Lilly shall have the right to select, and will be free, in its sole discretion, to use and to register in any trademark office in the Territory, any trademark that specifically relates to a Product or service-mark associated with use of a Product. As between the Parties, Lilly shall own all right, title and interest in and to any such trademarks or service-marks adopted by Lilly, and is responsible for the registration, filing, maintenance and enforcement thereof.

ARTICLE 10

REPRESENTATIONS, WARRANTIES AND COVENANTS

10.1 **Mutual Representations and Warranties**

. Each of Lilly and Merus represent and warrant, as of the Effective Date, that:

10.1.1 it is duly organized and validly existing under in the Applicable Laws of the jurisdiction of its incorporation or formation, as applicable, has full corporate, limited liability company or other power and authority, as applicable, to enter into this Agreement and to carry out the provisions hereof, and has sufficient facilities, experienced personnel or other capabilities (including via Affiliates and/or Third Parties) to enable it to perform its obligations under this Agreement;

10.1.2 it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and the individual executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate, limited liability company or other action, as applicable; and

10.1.3 this Agreement is legally binding upon it and enforceable in accordance with its terms (except as the enforceability thereof may be limited by bankruptcy, bank moratorium or similar laws affecting creditors' rights generally and laws restricting the availability of equitable remedies and may be subject to general principles of equity whether or not such enforceability is

considered in a proceeding at law or in equity) and the execution, delivery and performance of this Agreement by it have been duly authorized by all necessary corporate action and do not and will not: (a) conflict with, or constitute a default or result in a breach under, any agreement, instrument or understanding, oral or written, to which it is a party or by which it may be bound, or violate any Applicable Law; or (b) require any consent or approval of its stockholders or similar.

10.2 **Merus Representations and Warranties**

. Merus, on behalf of itself and its Affiliates, represents and warrants to Lilly that, as of the Effective Date:

10.2.1 **No Targets Encumbered**. The Initial Target is not an Unavailable Target.

10.2.2 **No Grants that Conflict with this Agreement**. Merus and its Affiliates have not granted, and will not grant during the Term, any rights (or other encumbrances) to any Third Party to Merus Know-How that prevent or conflict with the rights granted to Lilly hereunder.

10.2.3 **Control over Know-How and Patents**. Merus has Control over all Know-How and Patent rights owned by it or its Affiliates that are [*] Exploitation of Compounds with respect to the Lilly Target identified as of the Effective Date.

10.2.4 **Existing Patents**.

(a) All Patent rights contained in the Merus Patents existing as of the Effective Date that are issued or subject to a pending application for issuance (the "***Existing Patents***") are listed on Exhibit 10.2.4 and all such Existing Patents are: (i) to the extent issued (unless otherwise indicated on Exhibit 10.2.4), subsisting and to Merus's knowledge, not invalid or unenforceable, in whole or in part, or confer a valid right to claim priority thereto; (ii) solely and exclusively owned or exclusively licensed to Merus, free of any encumbrance, lien or claim of ownership by any Third Party that would conflict with the rights granted to Lilly under this Agreement; (iii) to the extent subject to a pending application for issuance, being diligently prosecuted in the respective patent offices in which such applications have been filed in accordance with Applicable Law and, for pending applications, to Merus's knowledge, Merus and its Affiliates have presented all information material to patentability to the relevant patent examiner at the relevant patent office of the U.S. Patent and Trademark Office in compliance with 37 CFR § 1.56; and (iv) filed and maintained properly and correctly, and all applicable fees applicable thereto have been paid on or before the due date for payment.

(b) To Merus's knowledge, neither Merus nor any of its Affiliates have taken any action that would render any invention claimed in the Existing Patents unpatentable.

(c) The Existing Patents represent all Merus Patents that relate to the Merus Know-How or the exploitation thereof under this Agreement, as such activities are contemplated as of the Effective Date.

10.2.5 **No Third Party Agreements**. Subject to Section 6.2, there are no license or other agreements with Third Parties to which Merus or its Affiliate is a party regarding the exploitation of (a) any Merus Know-How or (b) other materials, in each case, contemplated to be provided by Merus to Lilly hereunder, under which license or other agreements Merus contemplates granting Lilly a sublicense or covenant not to sue, as to which the absence of rights under such license

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

or agreement may impair Lilly's ability to Exploit Compounds or Products hereunder, or which license or other agreement otherwise conflicts with the rights granted to Lilly hereunder.

10.2.6 **Litigation and Actions Relating to Intellectual Property**. Merus: (a) has not received any written notice of any threatened claims or litigation seeking to invalidate or otherwise challenge the Merus Know-How or Merus Patents, or Merus's or its Affiliates' rights therein; (b) is not aware of any pending or threatened action, suit, proceeding or claim by a Third Party asserting that Merus or any of its Affiliates is infringing or has misappropriated or otherwise is violating any Patent right, trade secret or other proprietary right of any Third Party as would reasonably be expected to impair the ability of Merus to fulfill any of its obligations under this Agreement; and (c) is not aware of any Patent right, trade secret or other proprietary right of any Third Party that Merus reasonably believes would be infringed, misappropriated or otherwise violated [*].

10.2.7 **Other Material Claims and Actions**. There are no claims, actions, or proceedings pending or, to Merus's knowledge, threatened by any Third Party; nor, to Merus's knowledge, are there any formal inquiries initiated or written notices received that may lead to the institution of any such legal proceedings, in each case (or in aggregate) against Merus or its properties, assets or business, which if adversely decided, would, individually or in the aggregate, have a material adverse effect on, or prevent Merus's ability to conduct the Research or to grant the licenses or rights granted to Lilly under this Agreement.

10.2.8 **Assignment by Employees, Agents and Consultants**. Merus has obtained from each of its current employees, consultants and contractors who are expected to perform research or development activities pursuant to this Agreement, written agreements containing industry standard obligations of confidentiality and non-use and an assignment to Merus of all inventions (and all of such Person's rights thereto) generated in the course of their engagement or employment, as applicable.

10.2.9 **No Government Funding**. The inventions claimed or covered by the Merus Patents: (a) were not conceived, discovered, developed or otherwise made in connection with any research activities funded, in whole or in part, by the federal government of the United States of America or any agency thereof; (b) are not a "subject invention" as that term is described in 35 U.S.C. Section 201(e) and (c) are not otherwise subject to the provisions of the Patent and Trademark Law Amendments Act of 1980, as amended, codified at 35 U.S.C. §§ 200-212, as amended, as well as any regulations promulgated pursuant thereto, including in 37 C.F.R. Part 401.

10.3 **Mutual Covenants**

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10.3.1 **Employees, Consultants and Contractors**. Each Party covenants that it has obtained or will obtain written agreements from each of its employees, consultants and contractors who perform Research or Development activities pursuant to this Agreement, which agreements will obligate such persons to obligations of confidentiality and non-use and to assign inventions in a manner consistent with the provisions of this Agreement.

10.3.2 **Debarment**. Each Party represents, warrants and covenants to the other Party that neither it nor its officers, employees, agents, consultants or any other person used by such Party in the performance of the respective Research and Development activities under this Agreement is: (a) debarred or disqualified under the U.S. Federal Food, Drug and Cosmetic Act; (b) listed by any

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government or regulatory agencies as ineligible to participate in any government healthcare programs or government procurement or non-procurement programs (as that term is defined in 42 U.S.C. §1320a-7b(f)), or excluded, debarred, suspended or otherwise made ineligible to participate in any such program; or (c) convicted of a criminal offense related to the provision of healthcare items or services, or is subject to any such pending action. Each Party will not during the Term knowingly, employ or use, directly or indirectly, including through Affiliates the services of any such person. In the event that either Party becomes aware of the debarment or disqualification or threatened debarment or disqualification of any person providing services to such Party, directly or indirectly, including through Affiliates or, in the case of Lilly, Sublicensees, which directly or indirectly relate to activities contemplated by this Agreement, such Party shall promptly notify the other Party in writing and such Party shall cease employing, contracting with, or retaining any such person to perform any such services.

10.3.3 **Protection of Information**. Each Party agrees that during the Term of this Agreement, and without limiting its obligations hereunder, each Party shall implement technical and organizational measures to protect all confidential information under the Agreement that are appropriate and that provide no less protection than [*].

10.4 **Compliance**

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10.4.1 **Compliance with Agreement; Applicable Laws**. Each Party covenants to the other that in the performance of its obligations under this Agreement, such Party shall comply with, and shall cause its Affiliates and its and its Affiliates' employees and contractors to comply, with all Applicable Laws and in all material respects with the terms of this Agreement. No Party shall, or shall be required to, undertake any activity under or in connection with this Agreement which violates, or which it believes, in good faith, may violate, any Applicable Laws. Without limiting the foregoing, each Party represents that it has not and will not use in any capacity the services of any person or entity who is:

(a) debarred or has been convicted of a crime for which a person or entity can be debarred under any governmental statute (including 21 USC Section 335a, as amended ("***Section 335a***")) or, to such Party's knowledge, threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person or entity can be debarred under any governmental statute, including Section 335a;

(b) disqualified under 21 CFR 312.70 or, to such Party's knowledge, threatened to be disqualified thereunder;

(c) suspended by the Office for Protection of Research Risks under 45 CFR Part 46 or, to such Party's knowledge, threatened to be suspended thereunder;

(d) excluded by the federal government from participation in federal healthcare programs as set forth by the Department of Health and Human Services Office of Inspector General at http://exclusions.oig.hhs.gov and the Excluded Parties List System at http://www.sam.gov, which includes the General Services Administration or, to such Party's knowledge, threatened to be disqualified or indicted for a crime for which a person can be so excluded; or

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

(e) to such Party's knowledge, the subject of any past or pending governmental or regulatory investigation, inquiry, warning or enforcement action, including a government-mandated corporate integrity agreement, or has violated any applicable anti-kickback or false claims laws or regulations related to their conduct of research.

10.4.2 **Compliance with Party Specific Regulations**. In carrying out their respective obligations under this Agreement, the Parties agree that each Party will meet its obligations with respect to all judgments, decrees, orders or similar decisions issued by any Governmental Authority specific to a Party, and all consent decrees, corporate integrity agreements, or other agreements or undertakings of any kind by a Party with any Governmental Authority, in each case as the same may be in effect from time to time and applicable to a Party's activities contemplated by this Agreement (the "***Party Specific Regulations***"). Neither Party shall be obligated to pursue any course of conduct that would result in such Party being in material breach of any Party Specific Regulation applicable to it; provided that in the event that a Party refuses to fulfill its obligations under this Agreement in any material respect on such basis, it shall provide written notice thereof to the other Party and such other Party shall have the right to terminate this Agreement in accordance with Section 13.2; however, under such circumstances, such termination shall be the sole remedy for such terminating Party and such terminating Party shall not be entitled to any other remedy under law or equity. All Party Specific Regulations are binding only in accordance with their terms and only upon the Party to which they relate.

10.4.3 **Compliance with Internal Compliance Codes**. All Internal Compliance Codes shall apply only to the Party to which they relate. The Parties agree that each Party shall operate in a manner consistent with its Internal Compliance Codes applicable to its performance under this Agreement. "***Internal Compliance Codes***," as used in this Section 10.4.3, means a Party's internal policies and procedures intended to ensure that a Party complies with Applicable Laws, Party Specific Regulations, and such Party's internal ethical, medical and similar standards.

10.4.4 **Compliance with Anti-Corruption Laws**. In connection with this Agreement, each Party shall comply with all Applicable Laws applicable to the performance of its obligations or exercise of its rights, including, where applicable, all local, national, and international laws, regulations, and industry codes dealing with government procurement, conflicts of interest, corruption or bribery, including, if applicable, the U.S. Foreign Corrupt Practices Act of 1977, as amended, and any laws enacted to implement the Organisation of Economic Cooperation and Development Convention on Combating Bribery of Foreign Officials in International Business Transactions.

10.4.5 **Prohibited Conduct**. Without limiting the other obligations of the Parties set forth in this Section 10.4, each Party covenants to the other that, as of the Effective Date and in the performance of its obligations under this Agreement through the expiration and termination of this Agreement, such Party and, to its knowledge, its Affiliates and its and its Affiliates' employees and contractors, in connection with the performance of their respective obligations under this Agreement, have not made, offered, given, promised to give, or authorized, and will not make, offer, give, promise to give, or authorize, any bribe, kickback, payment or transfer of anything of value, directly or indirectly through Third Parties, to any Government Official for the purpose of: (a) improperly influencing any act or decision of the Person or Government Official; (b) inducing the Person or Government Official to do or omit to do an act in violation of a lawful or otherwise required duty; (c)

securing any improper advantage; or (d) inducing the Person or Government Official to improperly influence the act or decision of any organization, including any government or government instrumentality, to assist any Party in obtaining or retaining business. For the purpose of this Section 10.4.5, "***Government Official***" means: (x) any officer, employee (including physicians, hospital administrators, or other healthcare professionals), agent, representative, department, agency, de facto official, representative, corporate entity, instrumentality or subdivision of any government, military or international organization, including any ministry or department of health or any state-owned or affiliated company or hospital; (y) any candidate for political office, any political party or any official of a political party, in each case for the purpose of obtaining or retaining business for or with, or directing business to, any Person, including either Party; or (z) any Person acting in an official capacity on behalf of any of the foregoing.

10.4.6 **Compliance with Data Protection and Privacy Laws.** In connection with this Agreement, the Parties shall comply with all Applicable Laws with respect to the receipt, collection, compilation, use, storage, processing, sharing, safeguarding, security (technical, physical and administrative), disposal, destruction, disclosure, or transfer (including cross-border) of Personal Information, including providing any notice, obtaining any consent or prior authorization, and conducting any assessment required under Applicable Laws.

10.5 **Disclaimer**

. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS Article 10, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF PATENT CLAIMS. NOTHING IN THIS AGREEMENT SHALL BE CONSTRUED AS A REPRESENTATION MADE OR WARRANTY GIVEN BY EITHER PARTY THAT EITHER PARTY WILL BE SUCCESSFUL IN OBTAINING ANY PATENTS OR THAT ANY PATENTS WILL ISSUE BASED ON A PENDING APPLICATION. WITHOUT LIMITING THE RESPECTIVE RIGHTS AND OBLIGATIONS OF THE PARTIES EXPRESSLY SET FORTH HEREIN, EACH PARTY SPECIFICALLY DISCLAIMS ANY GUARANTEE THAT ANY RESEARCH PROGRAM WILL BE SUCCESSFUL, IN WHOLE OR IN PART.

ARTICLE 11

INDEMNIFICATION

11.1 **Indemnity**

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11.1.1 **By Merus**. Subject to Section 11.1.3, Merus shall defend, indemnify and hold harmless Lilly and its Affiliates, and their respective directors, officers, employees, and agents (each, a "***Lilly Indemnitee***") from and against any and all costs, fees, expenses, losses, liabilities, and damages, including reasonable legal expenses and attorneys' fees (collectively, "***Losses***") to which any Lilly Indemnitee may become subject as a result of any claim, demand, action or other proceeding by any Third Party (a "***Claim***") to the extent such Losses arise out of: [*]; except, in each case, to the extent such Losses result from matters subject to subclauses (a), (b), or (c) of Section 11.1.2.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

11.1.2 **By Lilly**. Subject to Section 11.1.3, Lilly shall defend, indemnify and hold harmless Merus, its Affiliates, and their respective directors, officers, employees and agents (each, an "***Merus Indemnitee***") from and against any and all Losses to which any Merus Indemnitee may become subject as a result of any Claim to the extent such Losses arise out of: [*]; except, in each case, to the extent such Losses result from matters subject to subclauses (a), (b) or (c) of Section 11.1.1.

11.1.3 **Procedure**. A Party that intends to claim indemnification under this Article 11 (the "***Indemnitee***") shall promptly notify the Indemnitor (the "***Indemnitor***") in writing of any Claim in respect of which the Indemnitee intends to claim such indemnification. The failure to deliver written notice to the Indemnitor within a reasonable time after the commencement of any action with respect to a Claim shall only relieve the Indemnitor of its indemnification obligations under this Article 11 if and to the extent the Indemnitor is actually and materially prejudiced thereby. The Indemnitor has sole control of the defense or settlement thereof. The Indemnitee shall cooperate fully with the Indemnitor and its legal representatives in the investigation of any action with respect to a Claim covered by this indemnification, at the Indemnitor's expense. The Indemnitee may participate at its expense in the Indemnitor's defense of and settlement negotiations for any Claim with counsel of the Indemnitee's own selection at its own expense. The Indemnitor shall not settle any Claim without [*]. So long as the Indemnitor is actively defending the Claim in good faith, the Indemnitee shall not [*]. If the Indemnitor does not assume and conduct the defense of the Claim as provided above: (a) the Indemnitee may defend against, consent to the entry of any judgment, or enter into any settlement with respect to such Claim in any manner the Indemnitee may deem reasonably appropriate [*]; and (b) the Indemnitor shall remain responsible to indemnify the Indemnitee as provided in this Article 11.

11.2 **Insurance**

. During the Term, each Party shall maintain such types and amounts of liability insurance (including self-insurance) as is normal and customary in the industry generally for similarly situated parties and adequate to cover its obligations under this Agreement, and Merus will upon request provide Lilly with a certificate of insurance in that regard, along with any amendments and revisions thereto.

ARTICLE 12

CONFIDENTIALITY

12.1 **Confidential Proprietary Information**

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12.1.1 **Confidential Proprietary Information**. In connection with this Agreement, Lilly may disclose certain confidential information that is Lilly Know-How to Merus and Merus may disclose certain confidential information that is Merus Know-How to Lilly (such confidential information, "***Confidential Proprietary Information***"). Without limiting the foregoing, the terms of this Agreement are the Confidential Proprietary Information of both Parties and shall be treated confidentially by each of the Parties, subject to the exceptions set forth in Section 12.1.5. Information exchanged by the Parties pursuant to the Confidentiality Agreement shall be deemed Confidential Proprietary Information disclosed under this Agreement, and shall be subject to the terms of this Agreement from and after the Effective Date. All Confidential Proprietary Information containing

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

Personal Information shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such Party.

12.1.2 **Restrictions**. A Party (the "***Receiving Party***") that has received or receives Confidential Proprietary Information from the other Party (the "***Disclosing Party***") shall keep all the Disclosing Party's Confidential Proprietary Information in confidence with the same degree of care with which the Receiving Party holds its own confidential information (but in no event less than a commercially reasonable degree of care). A Receiving Party shall not use the Disclosing Party's Confidential Proprietary Information except in connection with the performance of its obligations and exercise of its rights under this Agreement.

12.1.3 **Exceptions**. The obligations of confidentiality and restriction on use of Confidential Proprietary Information under Section 12.1.2 do not apply to any information that the Receiving Party can prove by competent written evidence: (a) is now, or hereafter becomes, through no act or failure to act on the part of the Receiving Party, generally known or available to the public; (b) is known by the Receiving Party at the time of receiving such information, other than by previous disclosure of the Disclosing Party, or its Affiliates, employees, agents, consultants, or contractors; (c) is hereafter furnished to the Receiving Party without restriction by a Third Party who has no obligation of confidentiality or limitations on use with respect thereto, as a matter of right; or (d) is independently discovered or developed by the Receiving Party without the direct or indirect use, reference or reliance upon of Confidential Proprietary Information belonging to the Disclosing Party. Specific information shall not be deemed to be within any of the foregoing exclusions merely because it is embraced by more general information falling within those exclusions.

12.1.4 **Permitted Disclosures**. The Receiving Party may disclose Confidential Proprietary Information belonging to the Disclosing Party as expressly permitted by this Agreement or if and to the extent such disclosure is reasonably necessary in the following instances:

(a) Prosecution and Maintenance of Patents as permitted by this Agreement, provided that [*] (not to be unreasonably withheld, conditioned or delayed);

(b) Regulatory Filings for Product that such Party has a license or right to develop hereunder in a given country or jurisdiction, provided that [*];

(c) prosecuting or defending litigation as permitted by this Agreement;

(d) complying with applicable court orders or governmental regulations, including mutually recognized security laws;

(e) in response to a valid request by a U.S., state, foreign, provincial, or local tax authority, in which case either Party may disclose [*];

(f) disclosure to its and its Affiliates' employees, consultants, contractors and agents, and to Sublicensees (in the case of Lilly), in each case on a need-to-know basis in connection with the Exploitation of Products in the Field in the Territory, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; and

(g) disclosure to potential and actual investors, acquirers, licensees and other financial or commercial partners solely for the purpose of evaluating or carrying out an actual

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

or potential investment, acquisition, or collaboration, in each case under written obligations of confidentiality and non-use at least as stringent as those herein; provided [*].

Notwithstanding the foregoing, if a Party is required to make a disclosure of the other Party's Confidential Proprietary Information pursuant to Section 12.1.4(c), or Section 12.1.4(d), or a copy of this Agreement pursuant to Section 12.1.4(a), it shall give reasonable advance notice to the other Party of such disclosure and use efforts to secure confidential treatment of such Confidential Proprietary Information at least as diligent as such Party would use to protect its own Confidential Proprietary Information, but in no event less than reasonable efforts. Subject to the foregoing, any information disclosed pursuant to this Section 12.1.4 remains Confidential Proprietary Information and subject to the restrictions set forth in this Agreement, including the foregoing provisions of this Article 12.

12.1.5 **Public Domain Information [*]**. Nothing in this Agreement shall prevent a Party from using any Know-How that is in the public domain. A Party shall also not be restricted under, and shall not be in breach of, this Agreement from [*] on an "as is, where is" basis, with all faults and all representations and warranties disclaimed and at such Party's sole risk.

12.1.6 **Disclosure of Agreement**. Notwithstanding the foregoing, either Party or its Affiliates may disclose the relevant terms of this Agreement: (a) to the extent required or advisable to comply with the rules and regulations promulgated by the U.S. Securities and Exchange Commission or any equivalent governmental agency in any country in the Territory, provided that such Party shall submit a confidential treatment request in connection with such disclosure and shall submit with such confidential treatment request only such redacted form of this Agreement as may be mutually agreed in writing by the Parties; (b) upon request from a Governmental Authority (such as a tax authority), provided that the disclosing Party uses reasonable efforts to ensure the Governmental Authority maintains such terms as confidential; [*], provided that any sublicensee, collaborator or potential sublicensee or collaborator agree in writing to be bound by obligations of confidentiality and non-use no less protective of the Disclosing Party than those set forth in this Agreement.

12.1.7 **Survival**. Each Party's obligations under this Section 12.1 apply during the Term and continue for [*] thereafter with respect to Confidential Proprietary Information.

12.2 **Publicity**

. Following the Effective Date, the Parties shall issue a joint press release in a mutually agreed upon form. Thereafter, either Party may make subsequent public disclosure of the contents of such press release and, except as permitted under Section 12.1.4 and this Section 12.2, neither Party shall issue any subsequent press release or public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof without the prior written consent of the other Party, not to be unreasonably withheld, conditioned, or delayed; provided that neither Party will be prevented from complying with: (a) any duty of disclosure it may have pursuant to Applicable Laws or pursuant to the rules of any recognized stock exchange or quotation system subject to the restrictions set forth in Sections 12.1.4 and 12.1.5; or (b) any valid request received from a U.S., state, foreign, provincial, or local tax authority. If either Party desires to issue a press release or other public statement disclosing information relating to this Agreement or the transactions contemplated hereby or the terms hereof, [*], the issuing Party will provide the other Party with a copy of the proposed press release or public statement. The issuing Party shall specify

with each such proposed press release or public statement, taking into account the urgency of the matter being disclosed and time periods for disclosure mandated by Applicable Law, a reasonable period of time within which the Receiving Party may provide any comments on such proposed press release or public statement. If the reviewing Party provides any comments, the Parties shall consult with one another on such proposed press release or public statement and work in good faith to prepare a mutually acceptable press release or public statement, provided that nothing in this Section 12.2 shall prohibit a Party from making a disclosure as it determines, based on advice of counsel, is reasonably necessary to comply with Applicable Laws or for appropriate market disclosure. Each Party may repeat any information relating to this Agreement that has already been publicly disclosed in accordance with this Section 12.2, provided that such information continues as of such time to be accurate, and is disclosed in substantially the same context as the previously approved disclosure.

12.3 **Publication**

. Lilly shall be entitled to issue scientific publications and make presentations with respect to any of the Research Programs, Lilly Targets, Compounds, Products, and their testing in accordance with Lilly's internal guidelines [*]. Merus shall not issue any scientific publications regarding any of the foregoing without Lilly's prior written consent. Notwithstanding the foregoing, (a) Merus shall not be restricted, and shall have the first right, in Merus's sole discretion, to publish or present any information relating to [*], provided that any such publication does not [*]; (b) Lilly shall not publish or present any information relating to [*] without Merus's prior written consent and (c) nothing in this Section 12.3 shall be construed to limit any right of either Party to make any publications in relation to its activities performed outside of the scope of this Agreement, provided that such publications are made in accordance with any obligations such Party may have hereunder regarding the non-use and non-disclosure of any Confidential Proprietary Information of the other Party.

ARTICLE 13

TERM & TERMINATION

13.1 **Term**. This Agreement commences on the Effective Date and, unless terminated earlier as provided in this Article 13, shall continue on a Product-by-Product basis until the expiration of the last Royalty Term in the Territory for such Product (the "***Term***").

13.2 **Termination for Material Breach**

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13.2.1 **Termination**. Either Party may terminate this Agreement, in whole or on a Research Program-by-Research Program or Target-by-Target basis, upon written notice to the other Party if such other Party materially breaches its obligations under this Agreement and, after receiving written notice from the non-breaching Party identifying such material breach in reasonable detail, fails to cure such material breach within [*] from the date of such notice; provided that if such non-payment related breach is not reasonably capable of cure within such [*], the breaching Party may submit, prior to the end of such [*], a reasonable plan to cure the breach within an additional [*], in which case the other Party may not terminate this Agreement for so long as the breaching Party is [*] to implement such cure plan within such additional [*].

13.2.2 **Dispute**. If the alleged breaching Party disputes in good faith the existence or materiality of a breach specified in a notice provided by the other Party in accordance with Section

13.2.1, and such alleged breaching Party provides the other Party notice of such dispute within such [*] period, then the non-breaching Party may not terminate this Agreement under Section 13.2.1 unless and [*].

13.2.3 **Lilly Option to Continue Agreement**. Notwithstanding anything to the contrary under this Agreement, if Merus materially breaches this Agreement, as finally determined under Article 14, during the Research Term such that Lilly would otherwise have the right to terminate this Agreement under Section 13.2, Lilly shall have the option to cause the Research Transfer Scenario to occur by written notice to Merus. [*]. For clarity, the Agreement shall continue in accordance with its terms, save as expressly set forth in this Section 13.2.3.

13.2.4 **Termination for Patent Challenge**. Except to the extent the following is unenforceable under the laws of a particular jurisdiction:

(a) Merus may immediately terminate this Agreement with respect to any Product that is Covered by any licensed Merus Patent(s) the subject any Patent Challenge commenced by Lilly or its Affiliates or sublicensees, individually or in association with any other Person, in respect of any Merus Patent anywhere in the world. For clarity, the foregoing right of termination shall not apply with respect to any Patent Challenge where the Patent Challenge is [*]. For clarity, if a Third Party that is not a sublicensee of Lilly commences a legal action challenging the validity, enforceability or scope of any Merus Patent anywhere in the world, and Lilly's sole involvement in such action is to respond to a subpoena or take another action that is otherwise compelled by Applicable Law, then such involvement shall not be deemed to be a Patent Challenge.

(b) Lilly may immediately terminate the license granted in Section 6.3 in respect of any licensed Lilly Patent(s) the subject of the Patent Challenge, if Merus or its Affiliates or sublicensees, individually or in association with any other Person, commences a Patent Challenge in respect of any Lilly Patent anywhere in the world. For clarity, the foregoing right of termination shall not apply with respect to any Patent Challenge where the Patent Challenge is [*]. For clarity, if a Third Party that is not a sublicensee of Merus commences a legal action challenging the validity, enforceability or scope of any Lilly Patent anywhere in the world, and Merus's sole involvement in such action is to respond to a subpoena or take another action that is otherwise compelled by Applicable Law, then such involvement shall not be deemed to be a Patent Challenge.

(c) For the purposes of this Section 13.2.4, a "***Patent Challenge***" shall mean any declaratory judgment action, *inter* partes review, post-grant review, opposition or similar proceeding or other legal action challenging the validity, enforceability or scope of any Merus Patent or Lilly Patent (as applicable) anywhere in the world.

13.2.5 **Termination of Program Exclusivity**. If Lilly or any Person within Lilly charged with making such decisions in accordance with its usual internal business practices, [*]. In addition, if Lilly has ceased material Development and Commercialization activities under this Agreement with respect to any Research Program (including all Collaboration Compounds, Modified Compounds, or Products within such Research Program and directed to the applicable Lilly Target or Lilly Target Pair) for a continuous period of [*].

13.3 **Termination by Lilly**

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13.3.1 **Partial Termination**. Lilly may, at any time in its sole discretion and without cause, terminate this Agreement in whole or on a Research Program-by-Research Program (which termination would apply with respect to the Lilly Target and Lilly Target Pair to which such Research Program relates) or country-by-country basis upon [*] prior written notice to Merus.

13.3.2 **Entire Agreement**. Lilly may, in its sole discretion, terminate this Agreement in its entirety at any time and without cause upon [*] prior written notice to Merus.

13.4 **Effects of Termination**

. The following shall apply upon termination of this Agreement made in accordance with this Article 13:

13.4.1 **Termination of Licenses**. All licenses granted under Article 6 shall terminate automatically as of the termination effective date; provided that if Lilly (or its Affiliates or Sublicensees) has inventory of usable Product(s) as of the effective date of termination, then Lilly (and its Affiliates and Sublicensees) may continue to sell off such inventory of Products in the Field in the Territory (and fulfill customer orders therefor) until [*] and shall pay Merus any applicable royalties due based on such sales in accordance with Section 8.4. Any permitted sublicense granted by Lilly or its Affiliate to a Third Party under the licenses granted to Lilly under this Agreement [*].

13.4.2 **Destruction of Confidential Proprietary Information**. Each Receiving Party shall destroy (at the Disclosing Party's written request) all such Confidential Proprietary Information of the Receiving Party in its possession as of the effective date of expiration or termination [*], provided that each Receiving Party may retain and continue to use such Confidential Proprietary Information of the Disclosing Party to the extent necessary to exercise any surviving rights, licenses or obligations under this Agreement. Notwithstanding the foregoing, a Receiving Party shall not be required to destroy any computer files created during automatic system back up that are subsequently stored securely by it and not readily accessible to its employees, consultants, or others who received the Disclosing Party's Confidential Proprietary Information under this Agreement.

13.4.3 **Terminated Targets**. In the event this Agreement is terminated with respect to a particular Research Program, then the Lilly Target and Lilly Target Pair that is the subject of each such Research Program shall be "***Terminated Target(s)***", and each Product and any Compound contained in such Product that was directed against such Terminated Target(s) shall be designated a "***Terminated Product***" or "***Terminated Compound***" (as the case may be). If this Agreement is terminated in its entirety, all Lilly Targets and Lilly Target Pairs shall be Terminated Targets and all Products shall be Terminated Products and all Compounds shall be Terminated Compounds. Upon designation of a Target as a Terminated Target: (a) the Target shall cease to be a Lilly Target and the Parties shall conclude the Research Program with respect to such Terminated Target (if not already concluded) in an orderly manner (as determined by the JSC and at the cost of Lilly); (b) Lilly's obligations to pay Milestone Payments or Royalties on Products in respect of that Terminated Target shall cease (except to the extent payable prior to the date thereto); (c) Lilly shall cease all its activities under this Agreement in relation to all Terminated Compounds and Terminated Products, and (d) all licenses granted by Merus to Lilly under this Agreement shall terminate. In addition, if this

Agreement is terminated by Lilly under Section 13.3 or by Merus under Sections 13.2.1 or 13.2.4, [*].

13.5 **Reversion of Product Rights**

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13.5.1 **Early Termination [*]**. If this Agreement is terminated by Lilly under Section 13.3 or by Merus under Sections 13.2.1 or 13.2.4, with respect to one or more Lilly Targets (including termination of given Research Program that is directed to such Lilly Target) [*].

13.5.2 **Other Termination [*]**. In the event of any termination of this Agreement by Lilly under Section 13.3 or by Merus under Sections 13.2.1 or 13.2.4 (or any partial termination of this Agreement with respect to any Terminated Target (and all associated Terminated Products and Terminated Compounds)) that is not a termination described in Section 13.5.1, then, in addition to those general effects set forth in Section 13.4, as applicable and which will apply only with respect to the applicable Terminated Target (and all associated Terminated Products and Terminated Compounds), on the request of Merus, [*].

13.6 **Survival**

. Expiration or termination of this Agreement shall not relieve the Parties of any obligation or right accruing prior to such expiration or termination. Except as set forth in this Section 13.6 or elsewhere in this Agreement, the obligations and rights of the Parties under the following provisions of this Agreement shall survive expiration or termination of this Agreement: Article 1 (to the extent such definitions are used in surviving provisions), Sections 2.7 (solely with respect to decisions made prior to expiration or termination and subject to the limitations in Section 2.8), 4.3 (solely with respect to amounts accrued prior to termination or expiration), 4.5.1 (as applicable to retention of record following the Research Term), 4.6 (solely with respect to costs incurred prior to the expiration or termination of this Agreement), 4.7 (with respect to Research conducted prior to such expiration or termination), 4.8 (with respect to responsibility and compliance), 4.10, 8.3 (solely in respect to Milestone Events reached prior to such expiration or termination), 8.5 to 8.8 (in each case solely to the extent required to make final reimbursements, reconciliations or other payments owed following termination or expiration), Sections 9.1 (other than 9.1.2(d) or 9.1.6), 9.2 (solely in respect of Joint Patents, Joint Know-How, Research Compound Panel Know-How and Research Compound Panel Patents), 9.3 (solely in respect of Joint Patents, Joint Know-How, Research Compound Panel Know-How and Research Compound Panel Patents), 9.4, Article 11, Article 12 (for [*] period in Section 12.1.7 except that Section 12.1.5 shall survive in perpetuity), Sections 13.4 through 13.7, Article 14, and Sections 15.1, 15.2 to 15.7, 15.9, 15.10 to 15.17 and 15.18 (with respect to responsibility for Affiliates).

13.7 **Bankruptcy Code**

. If this Agreement is rejected by a Party as a debtor under Section 365 of the United States Bankruptcy Code or similar provision in the bankruptcy laws of another jurisdiction (the "***Code***"), then, notwithstanding anything else in this Agreement to the contrary, all licenses and rights to licenses granted under or pursuant to this Agreement by the Party in bankruptcy to the other Party are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the Code (or similar provision in the bankruptcy laws of the jurisdiction), licenses of rights to "intellectual property" as defined under Section 101(35A) of the Code (or similar provision in the bankruptcy laws of another applicable jurisdiction). The Parties agree that a Party that is a licensee of rights under this Agreement shall retain and may fully exercise all of its rights and elections under the Code, and that upon commencement of a bankruptcy proceeding by or against a Party under the Code, the other Party

shall be entitled to a complete duplicate of, or complete access to (as such other Party deems appropriate), any such intellectual property and all embodiments of such intellectual property, if not already in such other Party's possession, shall be promptly delivered to such other Party: (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by such other Party, unless the bankrupt Party elects to continue to perform all of its obligations under this Agreement; or (b) if not delivered under the foregoing subclause (a), upon the rejection of this Agreement by or on behalf of the bankrupt Party upon written request therefor by the other Party. The foregoing provisions of this Section 13.7 are without prejudice to any rights a Party may have arising under the Code.

ARTICLE 14

GOVERNING LAW; DISPUTE RESOLUTION

14.1 Governing Law

. This Agreement is governed by and will be construed in accordance with the laws of the State of New York, without reference to its conflict of laws principles. The United Nations Convention of International Contracts on the Sale of Goods (the Vienna Convention) does not apply to this Agreement.

14.2 Disputes

. The Parties recognize that controversies or claims arising out of, relating to, or in connection with this Agreement may arise from time to time. It is the objective of the Parties to establish procedures to facilitate the resolution of disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties shall follow the procedures set forth in this Section 14.1 to resolve any dispute. If any dispute, claim or controversy of any nature arising out of or relating to this Agreement, including any action or claim based on tort, contract or statute, or concerning the interpretation, effect, termination, validity, performance or breach of this Agreement (each, a "***Dispute***"), arises between the Parties, such Dispute shall, following any discussion and attempted resolution through the JSC, if applicable, first be referred to the Executive Officers of each Party for resolution. Either Party, may make such referral by written notice to the other Party, and within [*] after receipt of such written request, the Parties shall exchange the names of the respective Executive Officers to whom such Dispute is referred. The Executive Officers shall have an additional [*] following such exchange of names to attempt to resolve the Dispute (*i.e.*, [*] from the date of notice of referral of the Dispute). If, following such period, the Executive Officers have not succeeded in negotiating a resolution of the Dispute, and a Party wishes to pursue the matter, the Parties, the Dispute shall be subject to final resolution in any federal court having jurisdiction thereof located in New York, New York as further described in Section 14.3.

14.3 Litigation; Equitable Relief

. The Federal courts located in New York, New York shall have exclusive jurisdiction over, and shall be the exclusive venue for resolution of, any Dispute not resolved through the informal Dispute-resolution procedures described above. Either Party may, at any time and without waiving any remedy under this Agreement, seek from any court having jurisdiction any temporary injunctive or provisional relief necessary to protect the rights or property of that Party. Any final judgment resolving a Dispute may be enforced by either Party in any court having appropriate jurisdiction.

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

ARTICLE 15

MISCELLANEOUS

15.1 **Entire Agreement; Amendment**

. This Agreement, including the Exhibits hereto, sets forth the complete, final and exclusive agreement and all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and supersedes, as of the Effective Date, all prior and contemporaneous agreements and understandings between the Parties with respect to the subject matter hereof, including the Confidentiality Agreement. The foregoing may not be interpreted as a waiver of any remedies available to either Party as a result of any breach, prior to the Effective Date, by the other Party of its obligations under the Confidentiality Agreement. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

15.2 **Limitation of Liability**

. NEITHER PARTY MAY RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT, REGARDLESS OF ANY NOTICE OF THE POSSIBILITY OF SUCH DAMAGES; ***PROVIDED, HOWEVER***, THAT THIS SECTION 15.2 SHALL NOT BE CONSTRUED TO LIMIT EITHER PARTY'S INDEMNIFICATION OBLIGATIONS UNDER ARTICLE 11, [*] OR CONFIDENTIALITY OBLIGATIONS UNDER ARTICLE 12 OR A PARTY'S GROSS NEGLIGENCE OR WILFUL MISCONDUCT.

15.3 **Independent Contractors**

. The relationship between Lilly and Merus created by this Agreement is solely that of independent contractors. This Agreement does not create any agency, distributorship, employee-employer, partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative of the other Party, and neither Party can assume or create any obligation, representation, warranty, or guarantee, express or implied, on behalf of the other Party. The Parties (and any successor, assignee, transferee, or Affiliate of a Party) shall not treat or report the relationship between the Parties arising under this Agreement as a partnership for United States tax purposes, without the prior written consent of the other Party unless required by Applicable Laws.

15.4 **Notice**

. Any notice required or permitted to be given by this Agreement must be in writing, in English. Any and all notices or other communications or deliveries required or permitted to be provided hereunder must be in writing and will be deemed given and effective if: (a) delivered by hand or by overnight courier with tracking capabilities; (b) mailed postage prepaid by first class, registered, or certified mail; or (c) delivered by facsimile or electronic mail followed by delivery via either of the methods set forth in clauses (a) and (b) of this Section 15.4, in each case, addressed as set forth below unless changed by notice so given:

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

If to Merus:

Merus N.V.
Yalelaan 62,
3584 CM Utrecht,
The Netherlands
Attn: General Counsel
Telephone: 31 85 016 2557
E-mail: p.silverman@merus.nl

with a copy (which shall not constitute notice) to:

Cooley LLP
3175 Hanover Street
Palo Alto, CA 94304

USA
Attn: Kate Hillier
Email: khillier@cooley.com

If to Lilly:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46285
Attn: Vice President, Corporate Business Development
Fax: (317) 651-3051

with a copy (which shall not constitute notice) to:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, IN 46285
Attn: General Counsel
Fax: (317) 433-3000

Merus shall also provide a copy of any notice (via e-mail if available) to Lilly's Alliance Manager.

15.5 **Severability**

. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable, or illegal by a court of competent jurisdiction, such adjudication shall not, to the extent feasible, affect or impair, in whole or in part, the validity, enforceability, or legality of any remaining portions of this Agreement. All remaining portions will remain in full force and effect and in such event, the Parties shall negotiate in good faith to promptly replace the invalid, unenforceable, or illegal provision with a valid, enforceable, and legal provision that most closely effectuates the original intent of the Parties.

15.6 **Non-Use of Names**

. Merus shall not use the name, trademark, logo, or physical likeness of Lilly or its respective officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Lilly's prior written consent. Merus shall require its Affiliates to comply with the foregoing. Lilly shall not use the name, trademark, logo, or

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

physical likeness of Merus or its officers, directors or employees, or any adaptation of any of them, in any advertising, promotional or sales literature, without Merus's prior written consent. Lilly shall require its Affiliates and Sublicensees to comply with the foregoing.

15.7 **Assignment**

. Neither Party may assign or transfer this Agreement or any rights or obligations hereunder without the prior written consent of the other, except that a Party may make such an assignment or transfer without the other Party's consent to: (a) its Affiliate, provided that such Party shall remain primarily liable for any acts or omissions of such Affiliate; or (b) to an Acquirer in connection with a Change of Control, subject to Section 15.8. Any permitted assignee shall, in writing to the non-assigning Party, expressly assume performance of such assigning Party's rights and obligations. Any permitted assignment is binding on the successors of the assigning Party. Any assignment or attempted assignment by either Party in violation of the terms of this Section 15.7 is null, void and of no legal effect.

15.8 **Merus Change of Control**

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15.8.1 **Notification of Change of Control**. Merus shall provide Lilly with written notice of any Change of Control of Merus promptly, but no later than the earlier of: (a) [*] following the (i) first public announcement of such Change of Control or, (ii) if earlier and not prohibited by the terms of any written agreement between Merus and such any Third Party, the execution of a definitive agreement relating to such Change of Control, or (b) unless prohibited under Applicable Law or by the terms of any written agreement between such Party and any Third Party, at least [*] prior to the earlier of: (i) the first public announcement of, or (ii) the execution of any agreement pertaining to, such transaction, which notice in each case of (a) or (b) shall summarize the nature of the transaction and the identity of the Acquirer (a "***Change of Control Notice***"). If Merus undergoes a Change of Control that is not [*], then Section 15.8.2 shall apply. For avoidance of doubt, (a) a Change of Control of Merus [*].

15.8.2 **Effects of Change of Control**. If there is a Change of Control of Merus during the Research Term, then Merus shall continue to conduct the Research Program, in accordance with the terms of this Agreement, and the Research Continuance Scenario set forth in Section 15.8.2(b) shall apply. Notwithstanding the foregoing, solely where (1) such Change of Control occurs following [*], (2) at such time, Merus has generated at [*] for such Research Program, and (3) the Acquirer is [*], Lilly may elect, by written notice to Merus, which notice shall be delivered, if at all, within [*] following the applicable notice of such Change of Control delivered to Lilly pursuant to Section 15.8.1, to either continue with the Research Continuance Scenario set forth in Section 15.8.2(b), or to step in to assume responsibility for the conduct of the remaining activities pursuant to each Research Plan (the "***Research Activities***"), in which case the Research Transfer Scenario set forth in Section 15.8.2(a) shall apply.

(a) **Research Transfer Scenario**. The "***Research Transfer Scenario***" means [*], the following shall apply:

(i) within [*] following receipt of Lilly's written notice, Merus shall disclose or deliver to Lilly, to the extent not previously provided, the Merus Know-How solely consisting of [*] which in each case, [*] for Lilly to complete each applicable Research Plan (as constituted at the time of such Change of Control) and for Lilly's Exploitation of each Compound or

Product (including for regulatory purposes). In addition, upon Lilly's reasonable request and expense, Merus will: (A) provide [*]; and (B) [*] (the "***Research Transfer***"). The Research Transfer to be undertaken under the foregoing shall be overseen by a Working Group established for such purposes, which Working Group may put in place a technology transfer plan expressly identifying [*]. For clarity [*], whether or not at the date of such transfer, [*], and to enable Lilly with respect to the licenses granted in Section 6.1, provided that in no event will Merus be required to transfer to Lilly (1) any Merus Platform Technology, or (2) more than [*] Research Compounds that have met the Success Criteria. Promptly following the conclusion or termination of any Research Program that has been the subject of a Research Transfer, Lilly shall return to Merus all Research Compounds and other components of the Research Transfer (in each case, solely to the extent such materials would not have otherwise constituted part of the Final Research Deliverables that Merus would have delivered to Lilly pursuant to such Research Plan) and on Merus's request, certify such complete return in writing.

(ii) the JSC shall be immediately disbanded, and all approval rights of the JSC, or final decision making authority granted to a Party pursuant to this Agreement, shall become approval rights of the corresponding Party (*i.e.*, mutual agreement by the Parties or final decision making authority by a Party);

(iii) [*];

(iv) Any documented internal and out-of-pocket expenses Lilly incurs in performance of such Research or take over from Merus, that were not otherwise to be borne by Lilly, shall [*];

(v) With respect to Prosecution and Maintenance of Merus Research Program Patents that are [*], Lilly shall have sole control over Prosecution and Maintenance of such Patents, without the need to provide information to, consult with, or consider the comments of, Merus, the JSC or the Patent Working Group]; and

(vi) Solely in the event of a Change of Control to a Lilly Competitor, Merus shall thereafter have no right to: (A) [*] to the extent prosecuted by Lilly in accordance with this Agreement; (B) [*]; (C) [*]; (D) to take over Prosecution and Maintenance of [*]; or (E) to have the final say over any [*].

(b) **Research Continuance Scenario**. The "***Research Continuance Scenario***" means that Merus shall continue the Research Activities, if any, being conducted under any Research Plan, and the Research Program and this Agreement shall continue in the same manner as prior to the Change of Control, and in which case:

(i) Lilly will maintain its rights under this Agreement;

(ii) Merus shall continue to perform the Research Activities hereunder, with the same level of diligence applied to such activities after the consummation of such Change of Control when compared with those that were in place prior to the consummation of such Change of Control, where the "same level of diligence" shall require that Merus dedicates at least the same level of effort, including by dedicating the same number of FTEs and other resources to such Research Program as it was applying prior to such Change of Control or as were committed to be

applied pursuant to the then applicable Research Plan (including as described in any timelines, schedules, Gantt charts, plans or protocols set forth therein) for the remainder of the Research Term; and the Research Term shall be automatically extended without any requirement for Lilly to pay additional consideration, until the later of [*], provided that in each case, it is reasonably likely that the remaining Research Activities under the then current Research Plan can be completed within such timeframe.

15.8.3 **Acquirer Engaged in Competing Program.** If Merus undergoes a Change of Control and, as of the closing date of such Change of Control transaction, such Acquirer is engaged in a Competing Program or is a Lilly Competitor, then regardless of any other elections Lilly may make hereunder, Merus shall implement (as of the closing of such transaction) and enforce Firewalls for the duration of the Firewall Period.

15.8.4 **Covenant Not to Sue [*]**. Following any Change of Control of Merus to [*].

15.8.5 **Firewall Audits**. Lilly shall have the right, through a designated Third Party auditor, to monitor and audit Merus's (and, as applicable, its Affiliates') compliance with its obligations under this Agreement to implement and enforce Firewalls under this Section 15.8, and to require Merus (or its Affiliates) to promptly remediate any non-compliance identified by such audit. In connection with such audit, duly authorized representatives of Lilly's designated auditor may make an on-site visit to Merus (or its Affiliate) for the purpose of conducting such audit. Lilly may conduct such audits from time to time as reasonably necessary to confirm Merus's compliance with such Firewall requirements, no more than [*] per Calendar Year, or more frequently if [*]. Such audits shall be conducted during Merus's regular business hours, for a duration only as reasonably necessary to confirm Merus's compliance with the applicable Firewall requirements, and shall not unreasonably interfere with or impede Merus's business operations. Lilly shall provide Merus with written notice of such audit at least [*] prior to such requested audit (or such shorter period as may be designated by Lilly if Lilly reasonably believes at any time that Merus is not in compliance with such Firewall requirements). All such audits shall be conducted at Lilly's cost and expense. The auditor shall only be permitted to disclose to Lilly the existence of any non-compliance with Merus's obligations under this Agreement to implement and enforce Firewalls under this Section 15.8, but may not disclose the substance of such findings.

15.8.6 **Acquiror IP**. Notwithstanding anything to the contrary in this Agreement, and without limiting any obligations with respect to the implementation of any Firewalls hereunder [*], in the event of a Change of Control of Merus where (a) the Acquirer merges with, consolidates with or acquires Merus or an Affiliate of Merus, or (b) Merus or an Affiliate of Merus transfers to an Acquirer all or substantially all of its assets to which this Agreement relates (each of (a) or (b), an "***Acquisition Transaction***"), then any technology or intellectual property right owned or controlled by any Acquirer (and not Controlled by Merus or its Affiliates) immediately prior to the effective date of such Acquisition Transaction shall not be deemed be 'Controlled' by Merus or its Affiliates after the effective date of such Acquisition Transaction for purposes of this Agreement. [*] and [*] in the Field and in the Territory.

15.9 **Waivers**

. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement shall neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance

or in any other instance. Any waiver by a Party of a particular provision or right shall be in writing, shall be as to a particular matter and, if applicable, for a particular period of time and shall be signed by such Party.

15.10 **Force Majeure**

. Neither Party shall be in breach of this Agreement or otherwise liable to the other for any failure or delay in performing any of its obligations under this Agreement or for other nonperformance hereunder (excluding, in each case, the obligation to make payments when due) during any period in which such delay or failure is caused by a Force Majeure Event. In such event, the affected Party shall notify the other Party of the Force Majeure Event, and use Commercially Reasonable Efforts to overcome such Force Majeure Event and resume performance of its obligations under this Agreement as soon as and to the extent practicable, provided that in no event shall any Party be required to prevent or settle any labor disturbance or dispute. All delivery dates under this Agreement that have been affected by a Force Majeure Event shall be tolled for the duration of such Force Majeure Event. "***Force Majeure Event***" means an event, act, occurrence, condition or state of facts, in each case outside the reasonable control of a Party, including: (a) acts of God (b) fires, floods, earthquakes or other natural disasters; (c) war (threats), riots, armed conflicts, terrorist attacks or bombings; (d) sanctions, embargo, import and export restrictions, quota or prohibitions and license restrictions; (e) any law or action taken by a government or public authority, including without limitation laws or action related to public safety or public health; (f) any "lockdown", quarantine or other similar restrictions imposed by any Governmental Authority in connection with any applicable epidemic or pandemic; (g) labor or trade disputes, strikes, industrial action or lookouts; (h) fire, explosions or damages to the necessary facilities; or (i) non-performance by suppliers or subcontractors due to a Force Majeure Event in each case that interfere with the normal business operations of such Party.

15.11 **Interpretation**

. The captions and headings to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement. Unless specified to the contrary, references to Articles, Sections, Appendices or Exhibits mean the particular Articles, Sections, Appendices or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. In the event of any conflict between the main body of this Agreement and any Exhibit hereto, the main body of this Agreement shall prevail. Unless context otherwise clearly requires, whenever used in this Agreement: (a) the words "include" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation"; (b) the word "day" or "year" means a calendar day or year unless otherwise specified; (c) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (d) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement as a whole and not merely to the particular provision in which such words appear; (e) the words "shall" and "will" have interchangeable meanings for purposes of this Agreement; (f) provisions that require that a Party, the Parties or a committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (g) words of any gender include the other gender; (h) words using the singular or plural number also include the plural or singular number, respectively; (i) references to any specific law, rule or regulation, or article, section or other division thereof, shall be deemed to include the then-current amendments thereto or any replacement law, rule or regulation thereof; (j) the phrases "non-refundable" and "non-creditable" shall not prohibit, limit or restrict either Party's right to obtain damages in connection with a breach of this Agreement; (k) the word "or" means

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

"and/or" unless the context dictates otherwise because the subjects of the conjunction are mutually exclusive; and (l) neither Party shall be deemed to be acting on behalf of the other Party.

15.12 **Counterparts; Electronic Signatures**

. This Agreement may be executed in any number of counterparts, each of which is deemed an original, but all of which together constitute one instrument. This Agreement may be executed and delivered electronically and upon such delivery such electronic signature will be deemed to have the same effect as if the original signature had been delivered to the other Party.

15.13 **Expenses**

. Each Party shall pay its own costs, charges and expenses incurred in connection with the negotiation, preparation and execution of this Agreement.

15.14 **Further Assurances**

. Lilly and Merus hereby covenant and agree without the necessity of any further consideration, to execute, acknowledge and deliver any and all documents and take any action as may be reasonably necessary to carry out the intent and purposes of this Agreement.

15.15 **No Third Party Beneficiary Rights**

. This Agreement is not intended to and shall not be construed to give any Third Party any interest or rights (including any Third Party beneficiary rights) with respect to or in connection with any agreement or provision contained herein or contemplated hereby, except as otherwise expressly provided for in this Agreement.

15.16 **Construction**

. The Parties hereto acknowledge and agree that: (a) each Party and its counsel reviewed and negotiated the terms and provisions of this Agreement and have contributed to its revision; (b) the rule of construction to the effect that any ambiguities are resolved against the drafting Party shall not be employed in the interpretation of this Agreement; and (c) the terms and provisions of this Agreement shall be construed fairly as to all Parties hereto and not in a favor of or against any Party, regardless of which Party was generally responsible for the preparation of this Agreement.

15.17 **Cumulative Remedies**

. No remedy referred to in this Agreement is intended to be exclusive unless explicitly stated to be so, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law.

15.18 **Extension to Affiliates**

. Except as expressly set forth otherwise in this Agreement, each Party shall have the right to extend the rights and immunities granted in this Agreement to one or more of its Affiliates. All applicable terms and provisions of this Agreement, except this right to extend, shall apply to any such Affiliate to which this Agreement has been extended to the same extent as such terms and provisions apply to the Party extending such rights and immunities. For clarity, Lilly extending the rights and immunities granted hereunder shall remain primarily liable for any acts or omissions of its Affiliates.

[signature page follows]

[*] Certain information in this document has been omitted as the information is not material and would be competitively harmful if publicly disclosed.

In Witness Whereof, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives.

Merus N.V.

By: /s/ Bill Lundberg
Name: Bill Lundberg
Title: CEO

Eli Lilly and Company

By:/s/ David A. Ricks
Name: David A. Ricks
Title: Chairman and Chief Executive Officer

Schedule 1.57

Final Research Deliverables

[*]

Exhibit 4.4.1

[*]

Exhibit 4.7 – Part A

[*]

Exhibit 4.7

Exhibit 4.7 – Part B

[*]

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Exhibit 4.7

Exhibit 4.9

Form of Materials Transfer Record

The Material(s) described below is/are supplied by one Party to the other Party subject to the terms and conditions of the Collaboration and License Agreement between Merus and Lilly effective ____ ("Agreement"). For clarity, defined terms used herein and not defined herein have the meanings ascribed to such terms in the Agreement. This Exhibit may be executed in one or more counterparts, including by facsimile or "PDF" exchange, each of which shall be deemed to be an original as against any party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.

Direction of Transfer:

☐ To Lilly, from Merus

☐ To Merus, from Lilly

Description of Material(s):

In signing below, the Merus scientist and Lilly scientist acknowledge that they understand and will abide by the terms and conditions under which the Material(s) is/are provided.

Lilly Representative Signature Merus Representative Signature

Lilly Representative Name Merus Representative Name

Date Date

Exhibit 10.2.4

Existing Patents

[*]

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Merus N.V.:

We consent to the incorporation by reference in the registration statements (File Nos. 333-211497 and No. 333-230708) on Form S-8 and registration statement (File No. 333-233383) on Form S-3 of Merus N.V. of our report dated March 16, 2021, with respect to the consolidated balance sheets of Merus N.V. as of December 31, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2020, and the related notes, which report appears in the December 31, 2020 Annual Report on Form 10-K of Merus N.V.

/s/ KPMG Accountants N.V.

Rotterdam, The Netherlands
March 16, 2021

Exhibit 31.1

CERTIFICATION

I, Sven (Bill) Ante Lundberg, certify that:

1. I have reviewed this Annual Report on Form 10-K of Merus N.V.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 16, 2021

By: /s/ Sven A. Lundberg

Sven (Bill) Ante Lundberg
President, Chief Executive Officer and
Principal Financial Officer
(Principal Executive Officer and
Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Merus N.V. (the "Company") for the period ended December 31, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: March 16, 2021

By: /s/ Sven A. Lundberg

Sven (Bill) Ante Lundberg
President, Chief Executive Officer and
Principal Financial Officer
(Principal Executive Officer and
Principal Financial Officer)