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, 2021

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	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	(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, 2021, was approximately $730.3 million.

The number of shares of registrant's Common Shares outstanding as of February 21, 2022 was 43,477,052.

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 2022 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.

Auditor Firm Id	1012	Auditor name: KPMG Accountants N.V.	Auditor Location: Rotterdam, The Netherlands

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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 “Summary Risk Factors,” “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 our inception and we expect to continue to incur significant expenses and operating 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 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 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 and proprietary technologies, 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 is 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 multispecific 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 or Zeno) for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions; MCLA-158 (petosemtamab) for the potential treatment of solid tumors; MCLA-145 for the potential treatment of solid tumors; and MCLA-129, for the potential treatment of lung and other solid tumors. 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 (NRG1+) 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 June 2021, we presented interim data from our phase 1/2 NRG1 fusion-positive solid tumor trial, eNRGy and the Early Access Program (EAP), at the American Society of Clinical Oncology (ASCO) Annual Meeting. As of the April 13, 2021 efficacy data cutoff date, 61 patients with NRG1+ cancer were enrolled, including 45 patients evaluable for response. Confirmed partial responses were observed by investigator review (RECIST v1.1) in 42% (5 of 12) patients with pancreatic cancer and in 29% (13 of 45) patients across all NRG1+ tumor types treated. One additional partial response was confirmed after the data cutoff date, which if included in the interim efficacy analysis, would increase the percentage of confirmed partial responses across all NRG1+ tumor types treated to 31% (14 of 45 patients). In November 2021, we announced that we met with the U.S. Food and Drug Administration (FDA) in an end-of-phase Type B meeting to discuss interim results from the ongoing phase 1/2 eNRGy trial and EAP in NRG1+ cancers, and to discuss the development plan for zenocutuzumab. Based on feedback received from the FDA, Merus believes that the trial design and planned enrollment will be appropriate to potentially support a Biologics License Application (BLA) submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers. Merus believes that, if the rate of enrollment and efficacy results remain consistent, a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, that could provide a potential registrational data set. In July 2020, the 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. We plan to provide a clinical update in the first half of 2022.

- ***Successfully develop our bispecific antibody candidate MCLA-158, petosemtamab.*** We are developing petosemtamab for a potential dual EGFR/LRG5 blockade for the treatment of solid tumors. Our phase 1 clinical trial of petosemtamab is ongoing in the dose expansion phase. In October 2021, we presented interim clinical data in patients with advanced head and neck squamous cell carcinoma (HNSCC) at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. As of the safety and efficacy data cutoff date of August 9, 2021, 10 patients with advanced HNSCC were enrolled and seven were evaluable for an interim efficacy analysis by investigator assessment. Three of seven patients achieved partial responses, with one of these three achieving complete response after the data cutoff date. Tumor reduction was observed in all seven patients. Enrollment of patients continues at this dose in the expansion phase of the open-label, multicenter trial. We plan to provide a clinical update in the second half of 2022.

- ***Successfully develop our bispecific antibody candidate MCLA-145.*** We are developing MCLA-145 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. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. In December 2021, we presented interim clinical data on MCLA-145 from the phase 1 trial dose escalation study in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021. As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors had been treated at eight dose levels ranging from 0.4-75mg every two weeks. Preliminary evidence of antitumor activity was observed at doses ≥25 mg biweekly. Merus is also planning to evaluate the combination of MCLA-145 with a PD-1 blocking antibody.

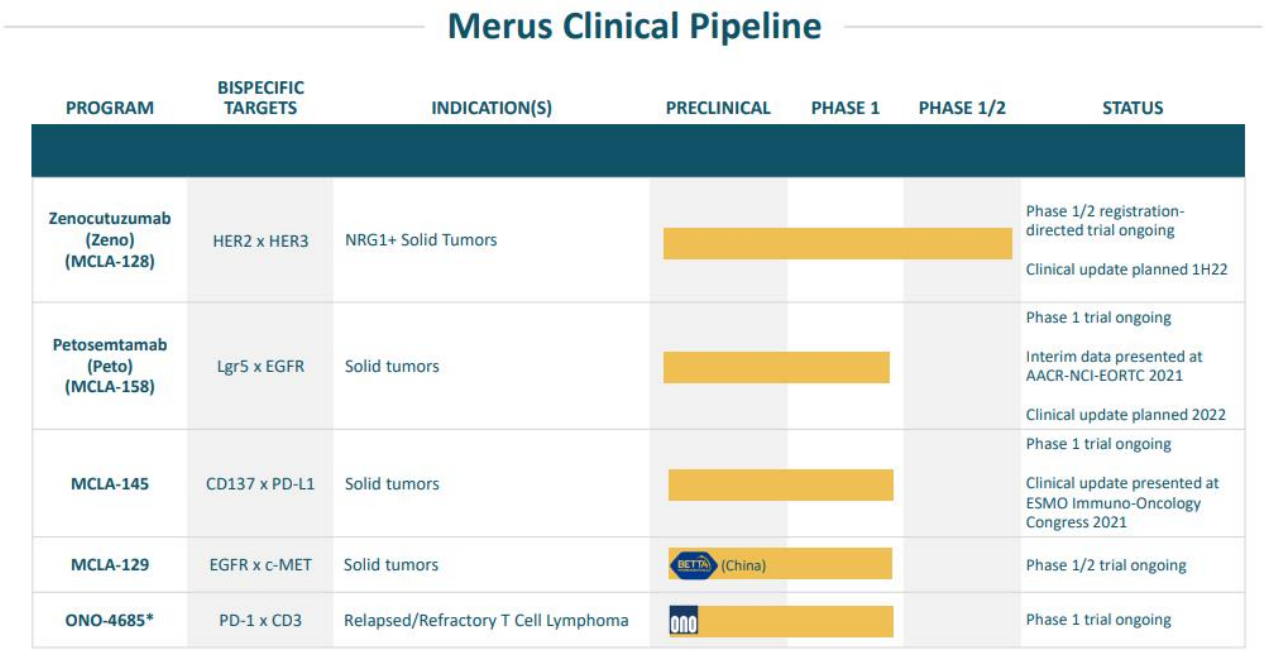
- ***Successfully develop our bispecific antibody candidate MCLA-129.*** We are developing MCLA-129 as a potential treatment for solid tumors, including non-small cell lung cancer (NSCLC). In May 2021, we announced that the first patient was treated in the phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced NSCLC and other solid tumors. At the American Association for Cancer Research 2021 Annual Meeting, we presented data that demonstrate in preclinical models MCLA-129 blocks EGF and HGF binding to their respective receptors EGFR and c-MET and MCLA-129's enhanced Fc is capable of potent promotion of antibody-dependent cellular cytotoxicity and antibody-dependent cellular phagocytosis. The data also show MCLA-129 potently inhibits NSCLC tumor growth as monotherapy and in combination with an EGFR TKI and overcomes HGF-mediated EGFR-TKI resistance in preclinical models. MCLA-129 is the subject to a collaboration and license agreement between Merus and Betta Pharmaceuticals Co. Ltd. (Betta), whereby Merus exclusively licensed Betta to develop MCLA-129 in China, while Merus retains full ex-China rights. We plan to provide a clinical update in the second half of 2022.

- ***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) 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, 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, including for indications in and 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:



*If commercialized, Merus to receive royalties.

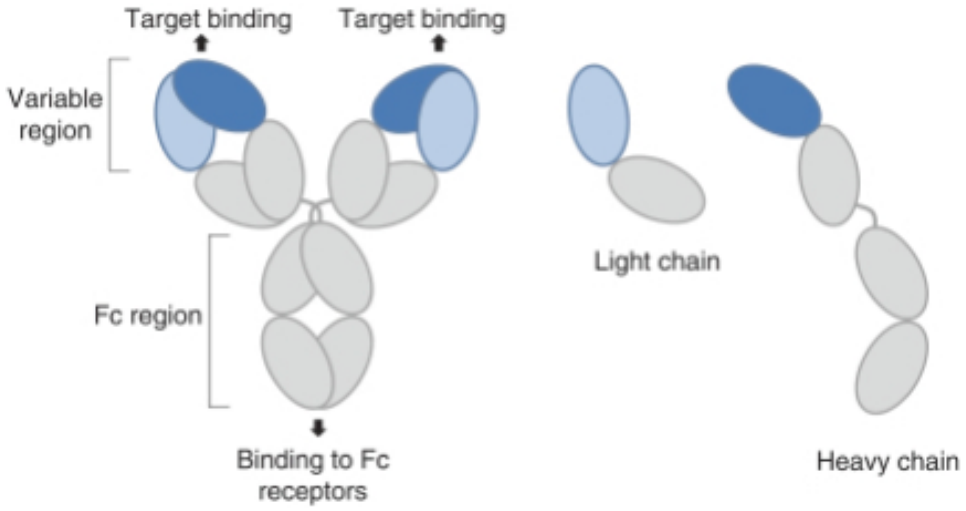
Cancer Immunotherapeutics

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 multispecific 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 multispecific antibodies, the two or more variable regions bind to two or more different targets. To achieve this in the full-length IgG format, different heavy chain variable regions that can 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 multispecific 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.

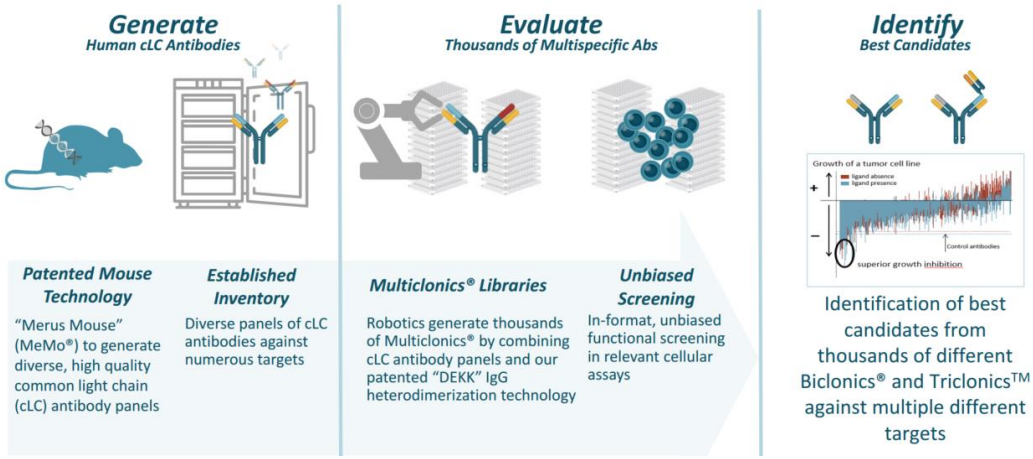
- ***Engaging the innate immune response through multiple mechanisms.*** We can produce enhanced ADCC modifications in the Fc region of our Biclonics® or Triclonics® designed to facilitate the recruitment of immune effector cells, such as natural killer cells, or NK cells, and macrophages, to directly 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® , heterodimerization technology, 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:

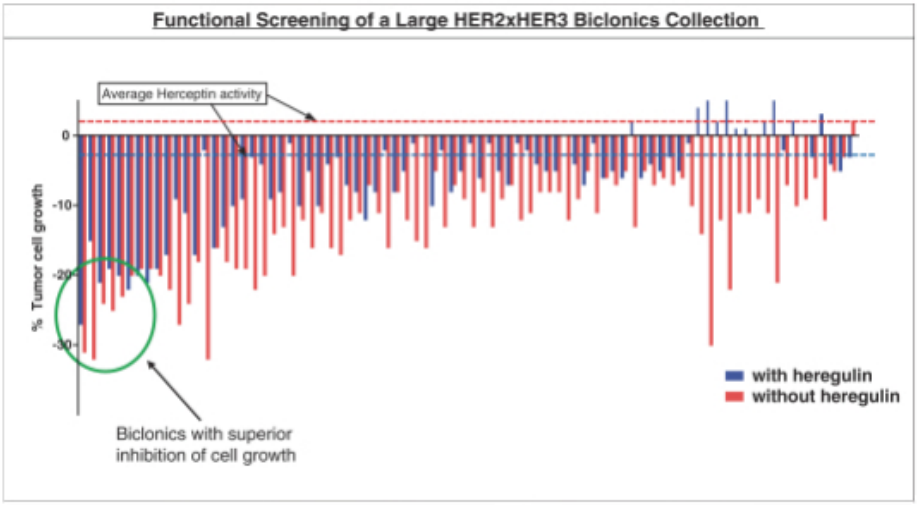
Human antibody generation. Our platform for generating human antibodies employs our patented transgenic common light chain technology, which we refer to as MeMo®, which harbors human heavy chain variable regions and a human common light chain in its germline. MeMo® harnesses the power of the *in vivo* 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 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 (petosemtamab) 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, and is designed to block 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 that can cause stability or developability obstacles, and instead allow us to create Biclonics® with more predictable behavior during development.

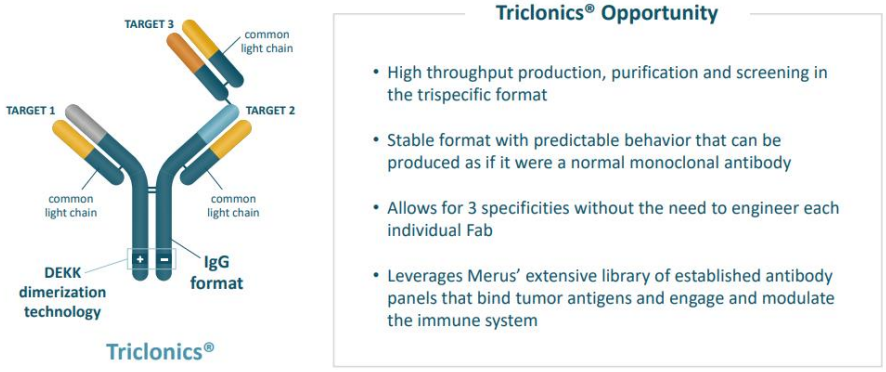
- ***Our Biclonics® technology platform allows for functional evaluation of Biclonics® in the relevant therapeutic format leading to the discovery of therapeutic candidates with novel and innovative properties.*** Our Biclonics® technology platform permits rapid functional screening of large collections 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.

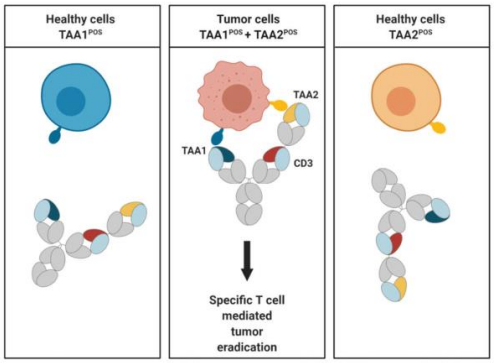
- ***Biclonics® can be reliably manufactured with high yields.*** Because our Biclonics® retain the IgG format of antibodies, our Biclonics® are manufactured using the large-scale industry-standard processes that are also used for the production of conventional mAbs, and the yields of Biclonics® we obtain are comparable to those of normal IgG antibodies. In stable cell lines, and using our IgG-based purification process can result in up to greater than 98% purity for our Biclonics®.

Our Triclonics® Platform

Our Triclonics® technology is covered by existing Merus patents and other pending applications. This 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 significant specificity and potency in 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 and potentially having greater potency and a larger therapeutic window.



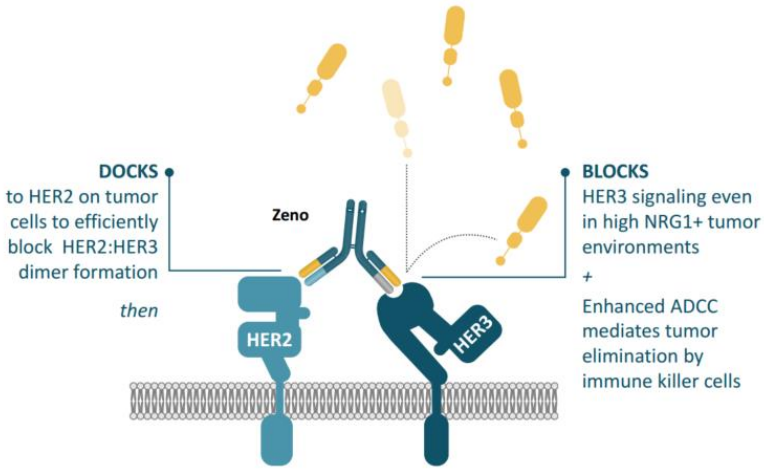
Our process to select lead Triclonics® leverages our patented MeMo® and Spleen to Screen® human antibody generation and heterodimerization technologies, along with our proprietary linkers based on natural structures to undertake high throughput unbiased functional screening of Triclonics®. With this 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®)

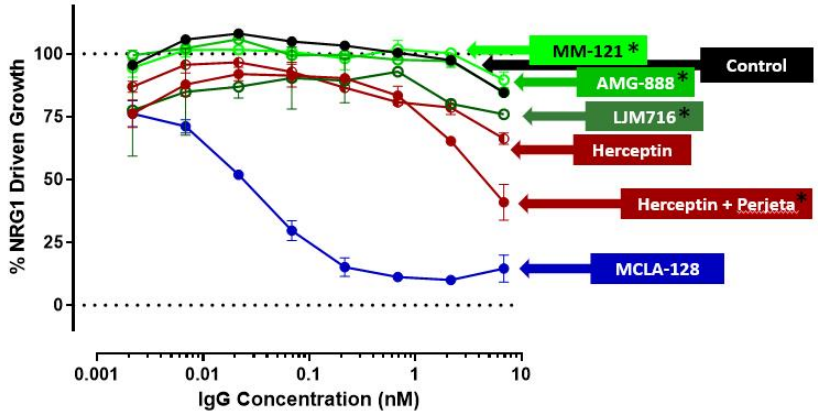
Zenocutuzumab is an antibody-dependent cell-mediated cytotoxicity (ADCC) -enhanced Biclonics® that utilizes Merus' Dock & Block® mechanism to bind to HER2, and bind to and disrupt the interaction between HER3 and ligand, NRG1 or mutated form NRG1 fusion, in solid tumors. HER2, or human epidermal growth 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 solid tumors, and are associated with activation of HER2/HER3 signaling and growth of cancer cells. The NRG1 fusion is a powerful driver of cancer cell growth. We believe that pre-clinical studies and clinical evaluation indicate 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+)

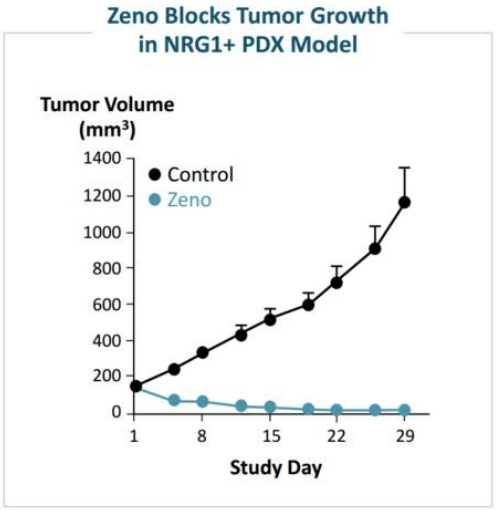
Development

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.

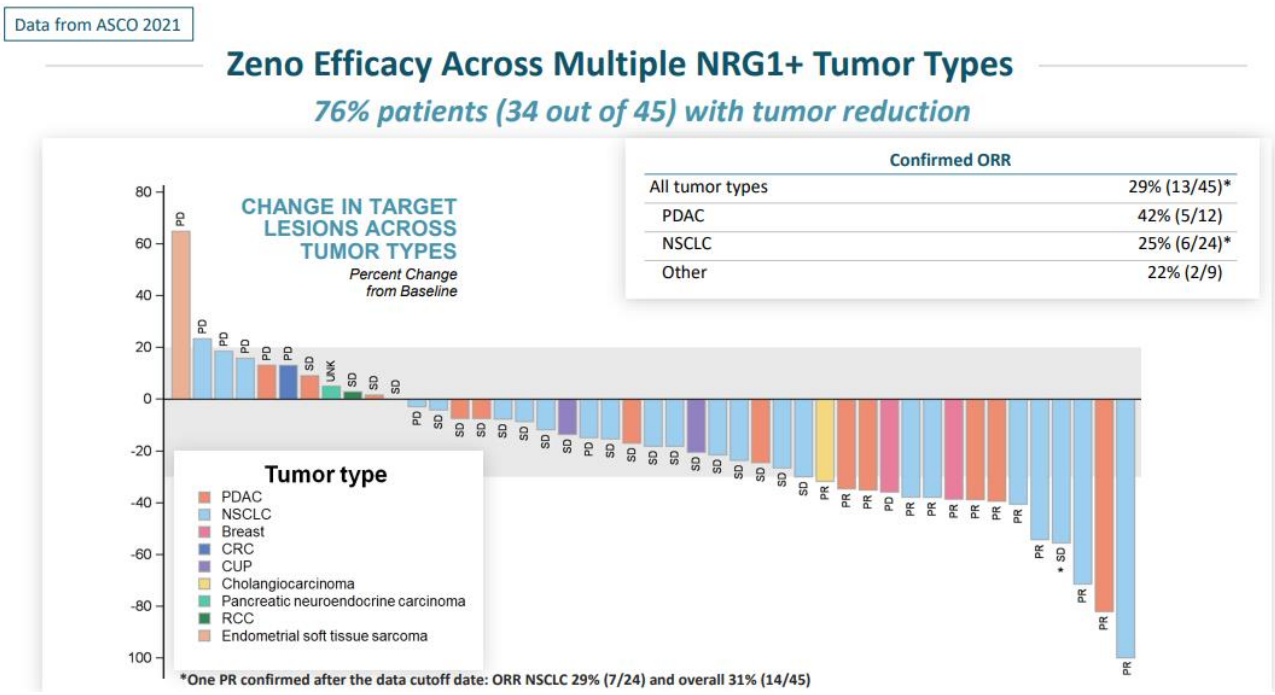
- **NRG1 Fusions**

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+ solid tumors. Enrolled patients will receive 750mg of zenocutuzumab every two weeks.

In June 2019, we opened a zenocutuzumab Expanded Access Program (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.

In January 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.

In June 2021, we provided an update on the eNRGy trial and EAP at the American Society for Clinical Oncology Annual Meeting (ASCO). The interim data, as of an April 13, 2021 efficacy data cutoff date, included enrollment of 61 patients with NRG1+ pancreatic, NSCLC, and other cancers, 47 of whom were evaluable for primary analysis with a median age of 56 (range 22-84), previously treated with a median of 2 lines of prior therapy. Of these patients, 45 patients were evaluable for response by local review with measurable disease and the opportunity for ≥ 1 post-baseline tumor assessment (two patients with non-measurable disease are included in the primary analysis of 47 patients, but not included in the 45 evaluable for response). Partial responses (PRs) were achieved across four different NRG1+ tumor types and multiple different fusion partners. Across NRG1+ tumor types, a 29% overall response rate (ORR) was observed, with 13 of 45 patients achieving PRs. One additional unconfirmed PR was confirmed after the April 13, 2021 data cutoff date leading to 14 of 45 patients achieving PR and a 31% ORR observed. The median duration of exposure was 5.5 months, with 40% of evaluable patients continuing on treatment. The duration of response ranges from 1+ to approximately 12 months. Tumor reduction was observed in 34 of 45 (76%) patients.



Zenocutuzumab was observed to have a favorable and tolerable safety profile (across 157 patients treated with zenocutuzumab monotherapy as of the January 12, 2021 safety data cutoff date). The majority of adverse events were mild or moderate (Grade 1 or 2) in severity, and an absence of severe gastrointestinal and skin toxicities and clinical cardiotoxicity, and a low incidence (7%) of infusion reactions was observed.

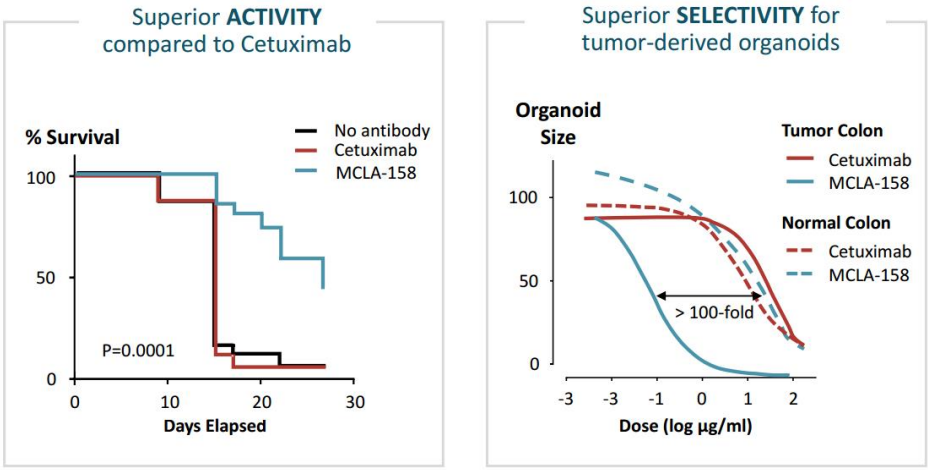
In November 2021, we provided a regulatory update for the zenocutuzumab program in NRG1 positive (NRG1+) solid tumors based on discussions with the FDA in an end-of-phase Type B meeting. Based on feedback received from the FDA, we believe that the trial design and planned enrollment will be appropriate to potentially support a BLA submission seeking a tumor agnostic indication for zenocutuzumab in patients with previously treated NRG1+ cancers and that, if the rate of enrollment and efficacy results remain consistent, a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, that could provide a potential registrational data set. We plan to provide a further clinical program update in the first half of 2022.

Petosemtamab (MCLA-158,Lgr5 x EGFR Biclonics®)

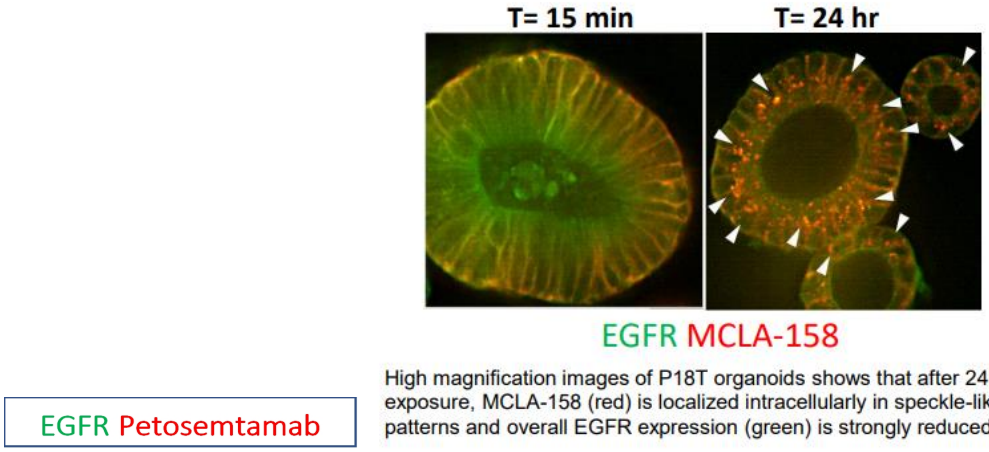
Petosemtamab, is an investigational antibody-dependent cell-mediated cytotoxicity (ADCC)-enhanced Biclonics® for the potential treatment of solid tumors that is designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor 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. Petosemtamab 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, petosemtamab demonstrated superior growth inhibition and selectivity versus the EGFR-targeting mAb, cetuximab. Petosemtamab was significantly more potent than cetuximab in inhibiting the growth of patient-derived colorectal cancer organoids. Additionally, petosemtamab was observed to be selectively more active in human tumor-derived organoids than in organoids derived from normal human colon. The activity of petosemtamab 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 petosemtamab on normal colon organoids and 20 to 100 times less than the activity of petosemtamab on tumor organoids. These ex-vivo observations of petosemtamab with organoid models were further observed *in vivo* in xenograft models generated from the same patient-derived organoids.

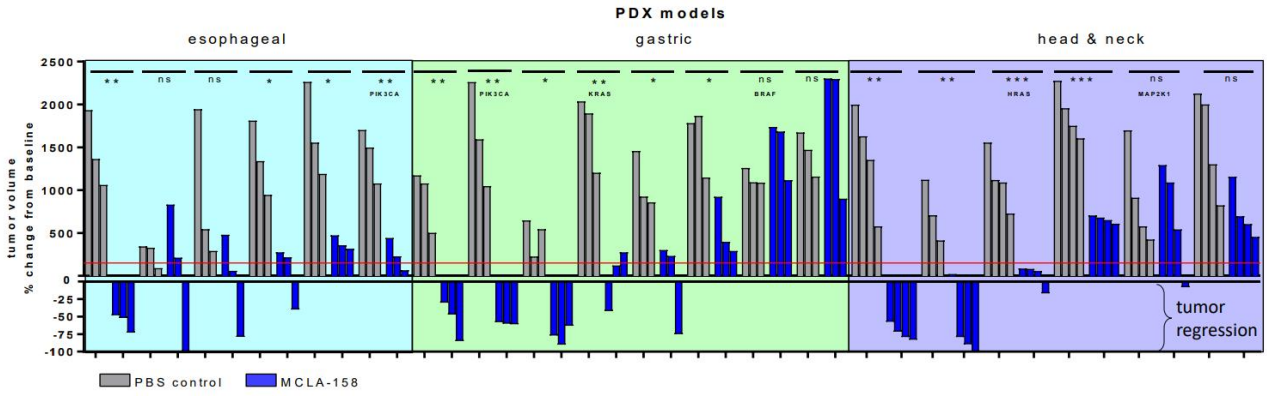


In our pre-clinical studies, petosemtamab further demonstrated significant induction of internalization of EGFR and LGR5, resulting in EGFR degradation, and elicited potential anti-tumor activity in patient-derived esophageal, gastric and HNSCC xenograft models.



High magnification images of P18T organoids shows that after 24h exposure, MCLA-158 (red) is localized intracellularly in speckle-like patterns and overall EGFR expression (green) is strongly reduced.

In vivo activity of MCLA-158 in gastric, esophageal and head & neck cancers



- **Solid Tumors**

Petosemtamab is currently being evaluated in a phase 1 open-label, multicenter study, and is 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.

The recommended phase 2 dose was established at 1500 mg administered intravenously once every two weeks. Enrollment continues at this dose in the expansion phase of the open-label, multicenter trial.

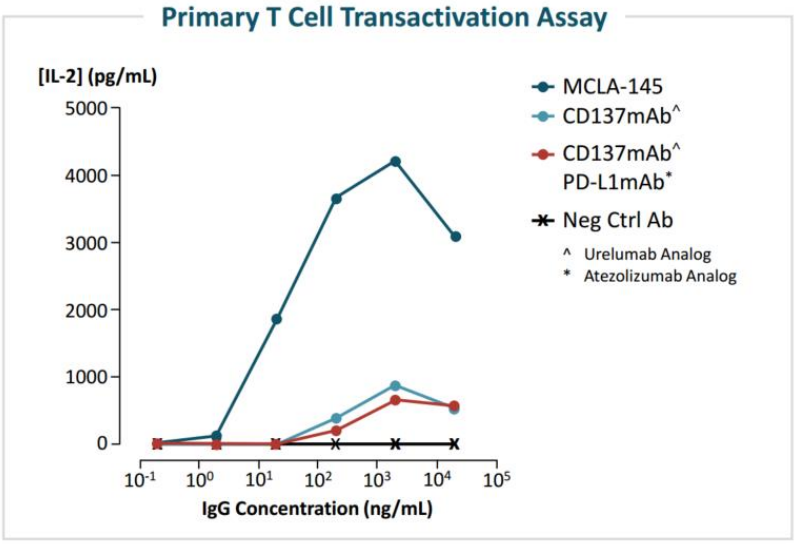
In October 2021, we presented interim clinical data from the ongoing phase 1 dose expansion cohort that is investigating the safety, tolerability, and anti-tumor activity of petosemtamab, including clinical responses observed in advanced head and neck squamous cell carcinoma (HNSCC), at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. As of the efficacy data cutoff date of August 9, 2021, 10 patients with advanced HNSCC were enrolled, with median age of 65 (range 50-77) years, and who were treated with a median of 2 lines of prior therapy. Seven patients were evaluable for an interim efficacy analysis by investigator assessment (three patients were enrolled <8 weeks from the cutoff date). Three of seven patients achieved partial responses, with one of these three achieving complete response after the data cutoff date. Tumor reduction was observed in all seven patients. The safety results for petosemtamab were based on 29 patients with advanced solid tumors who were treated at 1500 mg every two weeks across the phase 1 trial. The most frequent adverse events were infusion related reactions; 72% any grade, 7% grade ≥ 3 and mild to moderate skin toxicity; 3% grade ≥3. We plan to provide the next clinical program update in the second half of 2022.

MCLA-145 (CD137 x PD-L1 Biclonics®)

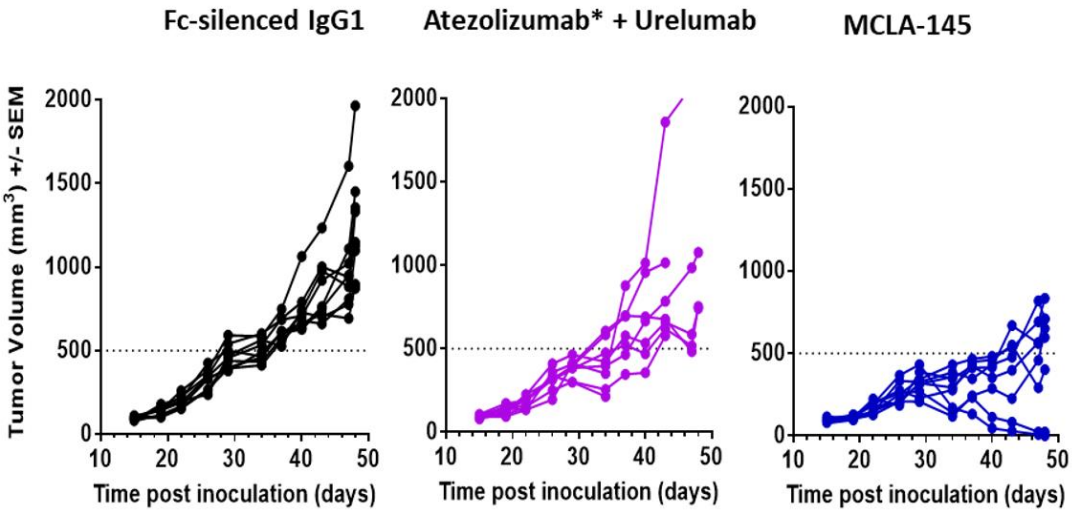
MCLA-145 is a Biclonics® T-cell engager that binds to human programmed death-ligand 1 (PD-L1) and CD137. MCLA-145 is designed to recruit, activate and prevent the exhaustion of tumor-infiltrating T cells, and to cause a potent and durable T-cell activation in the tumor microenvironment. MCLA-145's binding 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. Developed by Merus through an unbiased functional screening of multiple immunomodulatory target combinations, the unique immunostimulatory profile of MCLA-145 derives from the potential to potently activate immune effector cells in the context of the tumor microenvironment while blocking inhibitory signals among T-cells within the same immune cell population.

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**

MCLA-145 is currently enrolling a global, phase 1, open-label, single-agent clinical trial evaluating MCLA-145 in patients with solid tumors. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. Merus is also planning to evaluate the combination of MCLA-145 with a PD-1 blocking antibody.

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.

In December 2021, we presented interim clinical data on MCLA-145 from the phase 1 trial in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021. As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors with median age of 60.5 (range 27-81) years had been treated at 8 dose levels ranging from 0.4-75mg Q2W. The median (range)

duration of treatment with MCLA 145 was approximately 6 (1–74) weeks. Reported adverse events (AEs) were generally managed with drug interruption and/or administration of steroids in some patients. Treatment-emergent AEs (TEAEs) occurred in 33 patients (97.1%) and treatment-related TEAEs occurred in 23 patients (67.6%), most commonly fatigue (n=6, 17.6%) and decreased neutrophil count (n=6, 17.6%). Dose limiting toxicities (DLTs), defined as within 28 days from the first infusion, occurred in 4 patients (11.8%).
Laboratory alanine transaminase/aspartate transaminase (ALT/AST) elevations of any grade were observed in 15 patients (44.1%), with grade ≥3 ALT/AST elevations in 6 patients (17.6%). Preliminary evidence of antitumor activity has been observed at doses ≥25 mg biweekly. Analysis of peripheral blood showed robust T-cell activation, including activation of cytotoxic CD8+ cells and cytokines, across the 10 to 75 mg biweekly dosing range.

MCLA-129 (EGFR x c-MET Biclonics®)

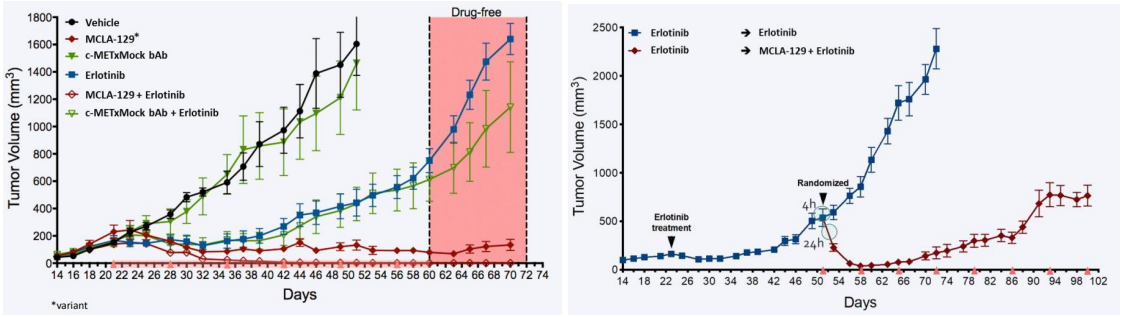
MCLA-129 is an investigational Biclonics®, designed to bind EGFR and c-MET, for the potential treatment of solid tumors. EGFR is an important oncogenic driver in many cancers. The upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. MCLA-129 has two distinct mechanisms 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.

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 and in October 2021, Betta announced that the first patient was dosed in Betta's sponsored phase 1/2 trial of MCLA-129 in China in patients with advanced solid tumors.

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.

MCLA-129 Inhibited TKI Resistant NSCLC | MCLA-129 Reversed Acquired TKI Resistance



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

• **Solid Tumors**

In May 2021, we commenced a phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer and other solid tumors. The phase 1/2, open-label clinical trial of MCLA-129 consists of dose

escalation followed by a planned dose expansion. Primary objectives of phase 1 are to determine the maximum tolerated dose and/or the recommended phase 2 dose, and the objectives of phase 2 are to evaluate safety, tolerability and potential clinical activity of the recommended phase 2 dose in patients with advanced solid tumors. We plan to provide an update in the second half of 2022.

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 patented platforms, 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. Following the election by Incyte to opt-out of its ex-U.S development of MCLA-145, discussed below, the collaboration encompasses up to 10 independent programs.

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 one of our current clinical programs, concerning MCLA-145, under the Collaboration Agreement, Incyte had received the exclusive right to develop and commercialize the product candidate outside the United States. In January 2022, we announced that Incyte elected to opt-out of its ex-U.S. development of MCLA-145, restoring full global rights to Merus. Under the terms of the Collaboration Agreement, Incyte will continue to support the program for a limited time while ex-U.S. activities are transitioned to Merus, and Incyte will also retain a right to a residual royalty of up to 4% on sales of future commercialization of MCLA-145, if approved.

For each program, where we have not elected to co-fund development or where we do not have such a co-funding option and which has not been dropped or terminated by Incyte, 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.

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").

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 €4.7 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 three of the specified pre-clinical milestones under this research and license agreement and have received an aggregate of €1.7 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.

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. 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 or petosemtamab, 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, petosemtamab, 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. We hired an Executive Vice President & Chief Commercial Officer in February 2022, to lead the commercial strategy for Merus' pipeline of multispecific product candidates in 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 side effects than any products that we may develop. Our competitors also may obtain FDA 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 Genmab A/S, Inhibrx, Inc., Janssen Pharmaceutical Companies, MacroGenics, Inc., Elevation Oncology, 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, 2022:

- 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 17 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 five PCT patent applications covering further methods of using zenocutuzumab, including in combination therapies to treat patients, concerning methods of treating patients with cancer harboring NRG1 gene fusions, three of which were filed on April 3, 2018, one filed on May 17, 2018 and one filed on October 23, 2020. Two of these five PCT patent applications entered national phases in the United States, Europe and 18 other foreign jurisdictions. One of these PCT patent applications entered national phases in the United States, Europe and 17 other foreign jurisdictions. One of these PCT patent applications entered national phases in the United States, Europe and four other foreign jurisdictions and for the fifth of these PCT filings, national phase entry is due in April of 2022.
- 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, with applications pending in the United States, Europe, and 19 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 petosemtamab consists of one PCT filed on October 21, 2016, with one issued patent in Europe, three issued patents in foreign jurisdictions and applications pending in the United States and 14 other foreign jurisdictions with an expiry no earlier than October, 2036. Claims are directed to the petosemtamab composition of matter and methods of using petosemtamab in the treatment or prevention of various solid tumors. In addition, our portfolio includes a PCT application filed on August 19th 2020, covering a combination treatment with a topoisomerase I inhibitor to treat patients.
- Our patent portfolio related our bispecific antibody candidate MCLA-145 consists of one PCT filed on September 22, 2017, with one issued patent in a foreign jurisdiction and with application pending in the United States, Europe and 18 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 one issued patent in a foreign jurisdiction and with applications pending in the United States, Europe and 18 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® and common light chain transgenic animal consists of five issued U.S. patents, seven pending U.S. applications, three issued European patents that have been validated in many countries, and three pending European applications, 21 issued foreign patents and 12 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 four issued foreign patents, with two foreign pending applications, all with an expected expiry not earlier than September 2032.

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® and Triclonics® technology platforms, improvements to those platforms, our 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, in combinations, dosages, methods of treatments among other features.

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, and common light chain generation platforms and techniques, 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;
- approval by an institutional review board (IRB) or ethics committee at each clinical site before the trial is commenced;
- 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. While the IND is active, progress reports summarizing the results of the clinical trials and nonclinical studies performed since the last progress report, among other information, must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or *in vitro* testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

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 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. There are also requirements governing the reporting of ongoing clinical trials and completed clinical trial results to public registries.

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.

In some cases, the FDA may require, or sponsors may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may also be made a condition to approval of the BLA.

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's goal is to review standard applications within ten months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification.

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.

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. 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 offers a number of expedited development and review programs for qualifying product candidates. For example, 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 Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. 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.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. The criteria for breakthrough therapy designation require preliminary clinical evidence that demonstrates the drug may have substantial improvement on at least one clinically significant endpoint over available therapy. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product candidate, including involvement of senior managers.

Any marketing application for a biologic product candidate submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for other types of FDA programs intended to expedite the FDA review and approval process. A BLA is eligible for priority review if a product candidate 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 candidate 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 advantages 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 or an intermediate clinical 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. At the time a product is granted accelerated approval, FDA has determined that an effect on the endpoint used to support approval—a surrogate endpoint or an intermediate clinical endpoint—is reasonably likely to predict clinical benefit. 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.

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.

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.
The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims that are in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product’s labeling and that differ from those tested and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict a manufacturer’s communications on the subject of off-label use of their products.

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.

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.

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.

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 are 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.

Non-Clinical Studies and Clinical Trials

Similarly to the U.S., the various phases of non-clinical and clinical research in the European Union (EU) are subject to significant regulatory controls.

Non-clinical studies are performed to demonstrate the health or environmental safety of new chemical or biological substances. Non-clinical studies must be conducted in compliance with the principles of good laboratory practice, or GLP, as set forth in EU Directive 2004/10/EC. In particular, non-clinical studies, both *in vitro* and *in vivo*, must be planned, performed, monitored, recorded, reported and archived in accordance with the GLP principles, which define a set of rules and criteria for a quality system for the organizational

process and the conditions for non-clinical studies. These GLP standards reflect the Organization for Economic Co-operation and Development requirements.

Clinical trials of medicinal products in the EU must be conducted in accordance with EU 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.

The regulatory landscape related to clinical trials in the EU has been subject to recent changes. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. Unlike directives, the CTR is directly applicable in all EU member states without the need for member states to further implement it into national law. The CTR notably harmonizes the assessment and supervision processes for clinical trials throughout the EU via a Clinical Trials Information System, which contains a centralized EU portal and database.

While the Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state, to both the competent national health authority and an independent ethics committee, much like the FDA and IRB respectively, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. 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. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed.

The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

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 EU, 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 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 EU. The centralized procedure is compulsory for certain 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 medicinal products, 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 and in particular for any other products containing new active substances not authorized in the EU or for product candidates which constitute a significant therapeutic, scientific, or technical innovation or for which the granting of authorization would be in the interests of public health in the EU.

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 competent authority of the EU member states decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal.

Under the centralized procedure and 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 EU also provides opportunities for market exclusivity. For example, in the EU, upon receiving MA, reference medicinal products generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents period prevents generic or biosimilar applicants from relying on the pre-clinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until 10 years have elapsed from the initial MA of the reference product in the EU. 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. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The criteria for designating an "orphan medicinal product" in the EU 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, protocol assistance, and access to the centralized procedure. Upon grant of a MA, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that during this period, the regulatory authorities 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 for a period of ten years. 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 or where the prevalence of the condition has increased above the threshold. 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 EU. 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.

The aforementioned EU rules are generally applicable in the European Economic Area (EEA) which consists of the 27 EU member states plus Norway, Liechtenstein and Iceland.

For other countries outside of the EU, 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.

Approval and Regulation of Companion Diagnostics

In the EU, 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).

The regulation of companion diagnostics will be subject to further requirements once the in-vitro diagnostic devices Regulation (No 2017/746) (IVDR) will become applicable on May 26, 2022. However on October 14, 2021, the European Commission proposed a “progressive” roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. The European Parliament and Council adopted the proposed regulation on December 15, 2021. The IVDR will fully apply on May 26, 2022 but there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation. The IDVR 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.

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. Similar laws exist in foreign jurisdictions as well.

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. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging.

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. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision. At present, the UK GDPR permits transfers of personal data from the United Kingdom to the EEA and to any countries which, as of December 31, 2020, were covered by an European Commission adequacy decision. This permission is to be kept under review by the UK Government.

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. On July 16, 2020, the Court of Justice of the European Union (CJEU) limited how organizations could lawfully transfer personal data from the EU to the United States by invalidating 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. Complementary, on September 8, 2020 the Federal Data Protection and Information Commissioner of Switzerland issued an opinion concluding that the Swiss-U.S. Privacy Shield Framework does not provide an adequate level of protection for data transfers from Switzerland to the United States pursuant to Switzerland's Federal Act on Data Protection. 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 preceded by a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under standard contractual clauses will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. 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. The European Commission issued revised standard contractual clauses on June 4, 2021, in order to replace the former sets that were adopted under the previous (repealed) Data Protection Directive 95/46/EC and align with the currently applicable GDPR provisions, as well as to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised standard contractual clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some remaining uncertainty around whether the revised clauses can and must be used for all types of cross-border data transfers to jurisdictions without an adequacy decision, particularly whether they can be relied on for data transfers to non-EEA entities, where processing is subject to the GDPR.

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, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order initiating a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare.

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, 2022, 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. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors.

Employees

As of January 31, 2022, we had 121 full-time employees and 54 part-time employees, including 62 employees with M.D. or Ph.D. degrees. Of these employees, 116 were primarily engaged in research and development activities and 59 were primarily engaged in general and administrative activities. We are proud of our diversity, with 80 employees identifying as male and 95 identifying as female and with over 15 different nationalities represented. None of our employees are part of a labor union, and we consider our employee relations to be good.

Code of Business Conduct and Ethics

All employees are expected to conduct business with the highest standard of business ethics. Each employee receives and agrees to follow the Merus Code of Business Conduct and Ethics. Employees are encouraged to discuss any related concerns with management or report concerns anonymously through an Ethics Hotline. Any report received on the Ethics Hotline is investigated by our General Counsel or the Audit Committee, as applicable. Further, we have three employee confidential advisors, as well as an external confidential advisor, with whom our employees may discuss ways of addressing, preventing and combating inappropriate behavior in the workplace. No one shall be subject to adverse action who in good faith reports an incident of violation of our policies, provides information, or otherwise assists in any investigation. Any employee who retaliates against another in violation of our policies will be subjected to disciplinary action, up to and including termination.

Employership, Leadership and Training

We perform biannual employee surveys, which give employees the opportunity to provide feedback on our employee engagement, commitment, leadership, work atmosphere, role clarity, psychological security, and employership, as well as annual surveys of a smaller scope. These surveys are managed by a third-party vendor to encourage openness and honesty in responding to questions regarding these important factors. In 2021, our employee response rate to our biannual survey was 87 percent, which we believe is an indication that our employees recognize that their feedback is important. Further, we were named a "World-Class Workplace" by the

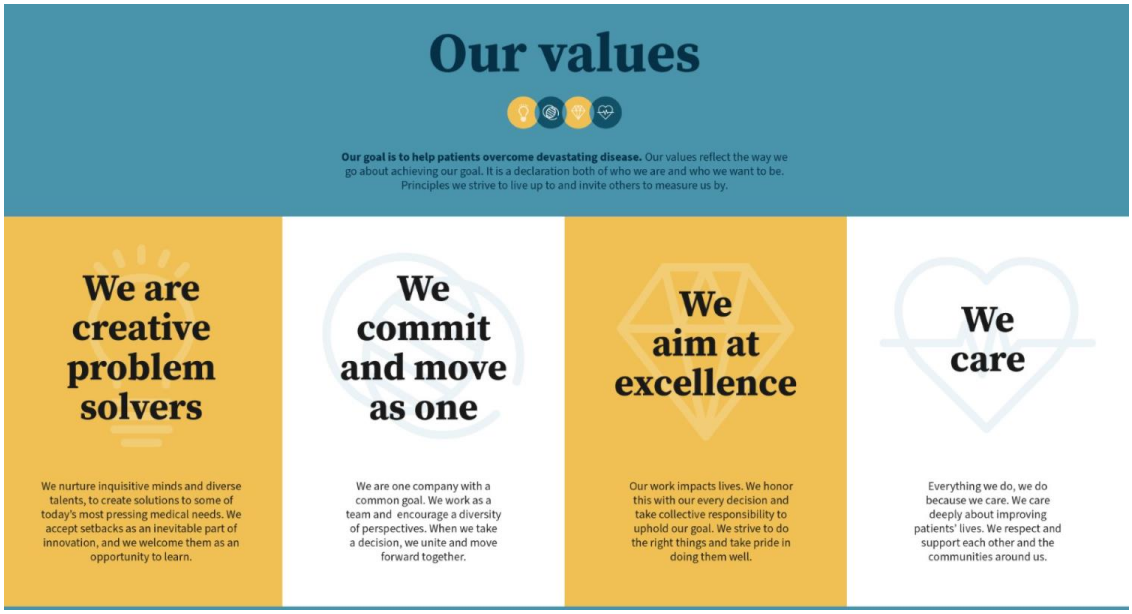
third-party vendor based on the outcome of the employee engagement survey, which demonstrated that Merus scored above other companies in the Netherlands on aspects of employership themes and how likely is it that an employee would recommend Merus as an employer to others. Further, we scored higher marks on pride of organization, inspiring vision of the future, leadership, work atmosphere and satisfaction about the organization than benchmarks for employership established by the vendor through its survey results based on average scores across surveys from over 500 other organizations.

Critical to our success is the hiring, training, retention and promotion of our employees, as we develop the competencies needed for the advancement of our company today and that will be needed in the coming years. Accordingly, we developed a variety of leadership and development opportunities under an umbrella program we refer to as the Merus Academy. A pillar of this program is a leadership development program, where we work with a third party provider to help train and enhance the leadership skills of employees at the director to vice president level. Another pillar is a leadership essentials training, which we offer to our scientists to help enhance their individual effectiveness, improve leadership ability, develop skills to address change and conflict management, and enhance their thought leadership within the organization. A third pillar is our implementation of an online learning platform, which offers our employees training courses across a variety of disciplines. Each of these pillars supports our talent management and advancement to drive our corporate goals.

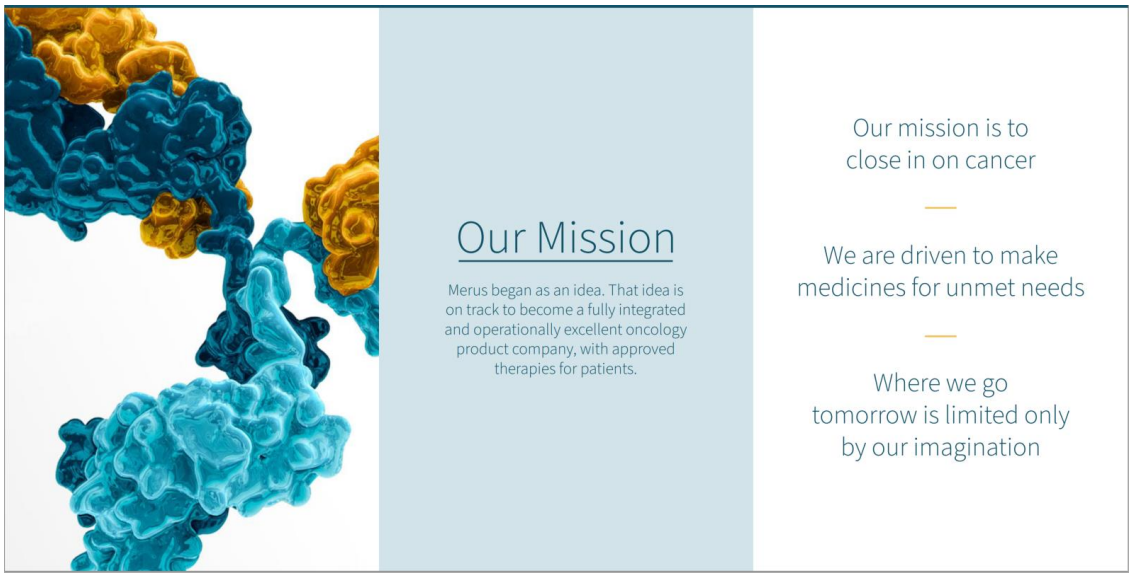
Our Values and Culture

Our goal is to help patients overcome the devastating disease of cancer. Our values reflect the way we go about achieving this goal. It is a declaration both of who we are and who we want to be. These are principles we strive to live up to and to be measured by:

- We are creative problem solvers – we nurture inquisitive minds and diverse talents, to create solutions to some of today's most pressing medical needs in oncology. We accept setbacks as an inevitable part of innovation, and we welcome them as an opportunity to learn.
- We commit and move as one – we are one company with a common goal of closing in on cancer. We work as a team and encourage a diversity of perspectives. When we take a decision, we unite and move forward together.
- We aim at excellence – our work impacts lives. We honor this with our every decision and take collective responsibility to uphold our goal. We strive to do the right things and take pride in doing them well.
- We care – everything we do, we do because we care. We care deeply about improving patients' lives. We respect and support each other and the communities around us.



We believe our values are an important facet of who we are and how we will deliver on our goals to close in on cancer, and meet our mission.



Compensation Philosophy, Incentives and Retention

Our human capital strategies, hiring and retention outcomes are reviewed on a regular basis with our board of directors, to align with our overall business strategies. Further, we review our compensation philosophy annually with the compensation committee of our board of directors, as well as on an ad hoc basis to receive input on new hires during the course of the year. Our compensation committee, relying on their extensive experience in the biopharmaceutical industry and receiving input from our external compensation advisors, review our short and long term incentive programs, and evaluate our group of peer companies to help achieve our hiring and retention goals during the course of the year. Our board of directors receives regular updates on these objectives, including headcount plans, achievement against goals and attrition rates during the year.

COVID-19 Health and Safety

The health and safety of our employees is a top priority. To date, the COVID-19 pandemic has created challenges associated with the normal function of businesses worldwide, as it has for Merus. We have adapted and met these challenges with the support and guidance of our COVID Task Force comprised of members of our management team, which meets regularly, and provides updates to the full management team, the board of directors, and company personnel on ways in which we are addressing the applicable 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). We have implemented workforce policies for our headquarters in the Netherlands, as well as our subsidiary in Cambridge, Massachusetts, for taking measures to comply with changing rules, regulations and recommendations by the CDC, RIVM, and local regulations. We have been able to support a distributed workforce, and recommend our employees in the Netherlands and employees of our subsidiary, Merus US, Inc., in the U.S. work remotely when possible. For those employees working at our offices and laboratory in Utrecht, they are required to follow requirements consistent with the guidance provided by the RIVM for the Netherlands, and employees of our subsidiary Merus US, Inc. are required to abide by the guidelines of the CDC, and Federal, state and local regulations for the U.S. While we use reasonable business practices to mitigate the risk of exposure to COVID-19 while on company-operated premises, including social distancing, ventilation and enhanced cleaning, 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.

Sustainability and Community Relations

We have a sustainability team, comprised of members from different business functions throughout the organization. In 2021, our sustainability team implemented Planet Tuesday at our company restaurant, introducing a weekly planet-friendly and healthy (vegetarian) menu. We implemented a sustainable mobility plan, which supports employees to purchase a new or second hand (e-)bike to commute to Merus, thereby reducing our carbon footprint, lowering city traffic, congestion, and improving the vitality of our employees. On Earth Day 2021, our sustainability team organized a Merus Cleanup in Utrecht, collecting more than 20 kg of garbage.

We donated our e-waste (outmoded information technology equipment) to the not-for-profit organization Close the Gap, which shipped these equipment to places in need to support educational, medical, entrepreneurial and social projects. We also donated 170 trees to Trees for All, contributing to reforestation projects in the Netherlands and abroad.

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 and amendments thereto 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 $66.8 million, $85.5 million and $55.2 million for the years ended December 31, 2021, 2020, and 2019, respectively. As of December 31, 2021, we had an accumulated loss of $466.9 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 expenses and operating losses for the foreseeable future as we continue to 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 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;
- conduct our ongoing Phase 1 clinical trial of MCLA-158 or petosemtamab for the treatment of solid tumors;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors;
- conduct our ongoing Phase 1/2 clinical trial for MCLA-129 for the treatment of solid tumors, which is subject to a collaboration with Betta, whereby Betta has exclusive rights to develop MCLA-129 in China, and Merus retains all rights ex-China;
- 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, potential commercialization 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, MCLA-145 and MCLA-129. 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 antibody candidates, discovering and developing additional 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 many 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, MCLA-145 and 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, 2021 will be sufficient to fund our operations beyond 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-158, MCLA-145 and the phase 1/2 clinical trial of MCLA-129;
- the success of our collaborations with Incyte to develop monospecific and bispecific antibodies candidates and with Lilly to develop bispecific antibody candidates;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of potential 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 year, 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 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 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 European Union (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 biologics 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, auditing and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper filling or 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, companion diagnostics may 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. The development of companion diagnostics in collaboration with or via license agreements with third parties, may make us potentially 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. Difficulties in developing and obtaining approval or certification for any companion diagnostics may be encountered, including as it concerns issues relating to selectivity/specificity, analytical validation, reproducibility or clinical validation. Any delay or failure to develop or obtain regulatory approval (or clearance, or certification) of companion diagnostics could delay or prevent approval of our antibody candidates. In addition, production difficulties may be encountered that could constrain the supply of the companion diagnostics, and difficulties may arise in gaining acceptance of the use of the companion diagnostics in the clinical community. If such companion diagnostics fail to gain market acceptance, it could 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-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® and Triclonics® technology platforms, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for zenocutuzumab, MCLA-158, MCLA-145 and 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 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, as well as the developing conflict between Russia and Ukraine, 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 was entered into force on May 1, 2021. 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, and it can be expected that there may be divergent local requirements in the UK from the EU in the future, which may impact our clinical and development activities that occur in the UK in the future. Similarly, clinical trial submissions and data for activity in the UK will not be able to be bundled with those of EU countries within the EMA Clinical Trial Information System (CTIS), adding further complexity, cost and potential risk to our future clinical and development activity in the UK. 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 remotely 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 have been and may in the future be restricted in the manner of travel 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 of our subsidiary located in the U.S. have been and may in the future be restricted in the manner of travel to the Netherlands. 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 imposing 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 remotely when possible. For those employees working at our offices and laboratory in Utrecht, they are required to follow requirements consistent with the guidance provided by the RIVM for the Netherlands, and employees of our subsidiary Merus US, Inc. are required to abide by the guidelines of the CDC, and Federal, state and local regulations for the U.S. 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., Europe 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 challenges for sourcing materials required for such manufacture that may be diverted for other purposes associated with COVID-19 or due to supply chain issues related to the COVID-19 pandemic, or difficulties or delays associated with testing of our pre-clinical antibody candidates associated with our collaborations with Incyte and Eli Lilly, 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, 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 and staff shortages, which may force us to reduce related workflows until such work and travel restrictions are lifted or staff issues resolved. 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, MCLA-145, and MCLA-129. Over the past year and 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 due to sites in countries that have been closed 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 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 potential IND-enabling studies or those of our collaborators and licensees, from which we may receive milestones or royalties;
- 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, treat and function with 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-to-mid-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, MCLA-129 or MCLA-145, 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, MCLA-145, and 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 or early 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;
- delays in, inability or failure to add new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or regulatory authorities, as applicable, to pause, suspend or terminate a trial if we or our collaborators or regulatory authorities, find that the participants are being exposed to unacceptable health risks or during evaluation of safety signals;
- 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 paused, 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 European Economic Area (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 may use different standards of diagnosis, screening and medical care.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation (CTR) which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application (CTA) to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR foresees a three-year transition period. The extent to which ongoing and new clinical trials will be governed by the CTR varies. For clinical trials whose CTA was made under the Clinical Trials Directive before January 31, 2022, the Clinical Trials Directive will continue to apply on a transitional basis for three years. Additionally, sponsors may still choose to submit a CTA under either the Clinical Trials Directive or the CTR until January 31, 2023 and, if authorized, those will be governed by the Clinical Trials Directive until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR.

It is currently unclear to what extent the United Kingdom will seek to align its regulations with the EU. The United Kingdom regulatory framework in relation to clinical trials is derived from existing EU legislation (as implemented into UK law, through secondary legislation).

On January 17, 2022, the United Kingdom MHRA, launched an eight-week consultation on reframing the UK legislation for clinical trials. The consultation closes on 14 March 2022 and aims to streamline clinical trials approvals, enable innovation, enhance clinical trials transparency, enable greater risk proportionality, and promote patient and public involvement in clinical trials. The outcome of the consultation will be closely watched and will determine whether the United Kingdom chooses to align with the regulation or diverge from it to maintain regulatory flexibility. A decision by the United Kingdom not to closely align its regulations with the new approach that will be adopted in the EU may have an effect on the cost of conducting clinical trials in the United Kingdom as opposed to other countries and/or make it harder to seek a marketing authorization in the EU for our product candidates on the basis of clinical trials conducted in the United Kingdom.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

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 and top-line 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 pandemic 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 decide to report interim or preliminary analyses of only certain endpoints (e.g., primary subject to investigator review) rather than all endpoints (e.g., including secondary subject to central review). As a result, interim, preliminary and 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 or final 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. Patients treated with zenocutuzumab have experienced adverse reactions that may be related to the treatment with a safety update provided for zenocutuzumab on June 4, 2021, at the American Society of Clinical Oncology, or ASCO, 2021 Annual Meeting, with a safety cut-off date of January 12, 2021. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors. Patients treated with MCLA-158 have experienced adverse reactions that may be treatment related, with a safety update provided for MCLA-158 on January 15, 2021, at ASCO GI, with a safety data cutoff date of September 7, 2020, where safety events were reported for patients treated with MCLA-158 as a single agent across 11 dose levels (5 to 1500mg), and at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics, on October 7-10, 2021, with a data cutoff date of August 9, 2021. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 in patients with solid tumors. Patients treated with MCLA-145 have experienced adverse events that may be related to the treatment, with a safety update provided for MCLA-145 on December 8-11, 2021 at the 2021 European Society for Medical Oncology-Immuno-Oncology (ESMO-IO) Congress, with a data cutoff date of July 14, 2021.

Results of our trials could reveal a high and unacceptable severity and prevalence of adverse events or side effects, including those that may be new or unexpected. In such an event, our trials or enrollment could be paused, suspended or terminated and the FDA, 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, investigator engagement and commitment and perception of the clinical candidate 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 250 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-158, we plan to enroll up to 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll up to 118 adult patients with solid tumors. In the Phase 1/2 clinical trial of MCLA-129, we plan to enroll up to 150 adult patients with solid tumors. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

Our clinical trials will 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 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 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 an 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 or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that 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 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 or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA or comparable foreign regulatory authorities and notified bodies 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 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 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 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 and have a material adverse effect on our business, financial condition and results of operations.

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 designation for an 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. Similar risk management measures may be required by foreign regulatory authorities. 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 or similar foreign 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, or fail to obtain or maintain relevant permits, we could be subject to fines or other sanctions or work stoppages, which could have a material adverse effect on our business, financial condition and results of operations.

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 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare. It is unclear how other healthcare reform measures of the Biden administration will impact 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, 2022, 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. 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. 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.

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 a 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 or as a post-marketing commitment. 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, difficulties may be encountered 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 and on October 14, 2021, the European Commission proposed a "progressive" roll-out of the IVDR to prevent disruption in the supply of in vitro diagnostic medical devices. The European Parliament and Council adopted the proposed regulation on December 15, 2021. The IVDR will fully apply on May 26, 2022 but there will be a tiered system extending the grace period for many devices (depending on their risk classification) before they have to be fully compliant with the regulation.

The regulation of companion diagnostics will be subject to further requirements as of the entry into force of the IVDR 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 and foreign regulatory authorities 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 or foreign regulatory

authorities' 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 FDA and foreign regulatory authorities 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, such as the EMA following its relocation to Amsterdam and resulting staff changes, 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, 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 COVID-19 pandemic, in March 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, in July 2020, the FDA resumed certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA utilized this risk-based assessment system to assist in determining when and where it was safest to conduct prioritized domestic inspections. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites, among other facilities. According to the guidance, the FDA may request such remote interactive evaluations where the FDA determines that remote evaluation would be appropriate based on mission needs and travel limitations. In May 2021, the FDA outlined a detailed plan to move toward a more consistent state of inspectional operations, and in July 2021, the FDA resumed standard inspectional operations of domestic facilities and was continuing to maintain this level of operation as of September 2021. More recently, the FDA has continued to monitor and implement changes to its inspectional activities to ensure the safety of its employees and those of the firms it regulates as it adapts to the evolving COVID-19 pandemic. Regulatory authorities outside the United States have adopted 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 FD&C Act 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. Certain states have also adopted comparable privacy and security laws and regulations governing the privacy, processing and protection of personal information. For example, California enacted legislation, the California Consumer Privacy Act (CCPA) which went into effect on January 1, 2020. The CCPA, among other things, creates new data privacy obligations

for covered companies and provides individual 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 voted into law by California residents. The CPRA significantly amends the CCPA and 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. Similar laws have passed in Virginia and Colorado, and have been proposed in other states and at the federal level, reflecting a trend toward more stringent privacy legislation in the United States. The enactment of such laws could have potentially conflicting requirements that would make compliance challenging. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

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 imposes 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, and the expiration of the transition period, from January 1, 2021, we have had 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, and it is unclear how United Kingdom data protection laws and regulations will develop in the medium to longer term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision.

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 Court of Justice of the EU (CJEU) limited how organizations could lawfully transfer personal data from the EU/EEA to the United States by invalidating the Privacy Shield for purposes of international transfers and imposing further restrictions on use 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). These restrictions include a requirement for companies to carry out a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under standard contractual clauses will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission issued revised standard contractual clauses on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised standard contractual clauses must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some remaining uncertainty around whether the revised clauses can and must be used for all types of cross-border data transfers to jurisdictions without an adequacy decision, particularly whether they can be relied on for data transfers to non-EEA entities, where processing is subject to the GDPR. 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.

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 for our antibody candidates, 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. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that during this period, the regulatory authorities cannot accept another application for a marketing authorization (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 MA application (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 potential 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 potential 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 or where the prevalence of the condition has increased above the threshold.

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 or additional orphan drug designations for zenocutuzumab, and we may seek such designation from the FDA and foreign regulatory authorities 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 for treatment of patients with pancreatic cancer and may obtain addition designations for zenucutuzumab, or orphan designations 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 foreign regulatory authorities can subsequently approve the same drug with the same active moiety for the same condition if the FDA or foreign regulatory authorities 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, if approved.

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 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, delay or inadequacy 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. Outside consultants may be relied upon 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, who 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 or similar foreign 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, 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;
- on a product-by-product basis (but not in its entirety), by Merus if Lilly challenges the Merus's patents for such product 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 agreement with Betta Pharma, and the research and license agreements 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 and license agreement with 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 the Ono license 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 and license agreement with Betta Pharma that permit us to supervise its development efforts for MCLA-129, , for which it has development and product rights in China, we cannot guarantee that this clinical antibody candidate will be developed in China in accordance with our standards as applied to our wholly owned programs or in a manner suitable for ex-China development. Ono is currently pursuing at least one antibody program generated by us under a license agreement with Merus through use of our proprietary Biclonics® platform. To the extent this asset does not successfully advance through clinical development, this may impair our ability to leverage our platform in future license agreements to further expand the use of our platform and generate future revenue. Should any of the Betta Pharma collaborations or Ono 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, depending on the stage of development and investment, 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 biotechnology 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 and Betta, under which we have licensed the certain development and commercialization rights 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 timing, 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 foreign regulatory authorities pursuant to inspections that will be conducted after we submit our BLA to the FDA, or similar applications to foreign regulatory authorities. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP or similar foreign requirements 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 or scarcity that may arise as a result of the COVID-19 pandemic 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 technology, our dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody pre-clinical and clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical 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 technology, our dimerization technology our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody pre-clinical and clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical 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 in the relevant jurisdiction.

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 technology, or our 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 patentability, 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 or at all.

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 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, 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 technology. We could also be required to pay substantial damages.

It is also possible that in our evaluation of third party intellectual property, 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 potentially 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 therapeutic candidates or products 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, if approved, 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.

Where we are asserting our intellectual property against third parties, or defending against an allegation of infringement, 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 Biclonics® technology and Triclonics® technology platforms, our common light chain transgenic technology, our dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and pre-clinical antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those pre-clinical antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology. 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. 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.

We currently have trademark and service mark rights relating to and covering our Biclonics® technology and Triclonics® technology platforms and other aspects of our company, its services and activities used in commerce. Our registered or unregistered trademarks, trade names or service marks may be challenged including during prosecution or through opposition proceedings, 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, or prevail in any opposition proceedings, 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, not including potential patent term extensions or adjustments that may be available in the U.S., and under comparable laws applicable outside the U.S., where certain conditions are met. 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 existing or future licensors, collaborators or partners 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 existing or future licensors, collaborators or partners 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, our practice is to provide regular trainings on the importance of maintaining confidentiality, to promulgate a business code of conduct requiring confidentiality, and prohibit the use of non-sanctioned devices with company confidential information. However, current or former employees, consultants, contractors, collaborators and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements and other precautions taken 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 and other remedies. 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 and theft of trade secret claims 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 pharmaceutical or biotechnology 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 improperly 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, as do our contractors, consultants, CROs, and third parties, including clinical trial participants. 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 or third parties 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, and conduct regular testing of our systems, 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, result in substantial costs and distract management. 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, result in substantial costs and distract management.

Risks Related to Employee Matters and Managing Growth

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel .

Our success depends upon the 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 antibody candidates 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 increasingly 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.

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 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.

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 members.

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 an independent special purpose foundation;
- 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.

The board of directors can invoke a statutory cooling-off period of up to 250 days in situations described below. When such cooling-off period is invoked, our general meeting of shareholders cannot dismiss, suspend or appoint members of the board of directors (or amend the provisions in our 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.

Under the Dutch Corporate Governance Code (DCGC), the board of directors may also invoke a response period of up to 180 days 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 which may result in a change in our strategy (including through the dismissal of

one or more of our board members). If this response period is invoked, the shareholders concerned must give the board of directors the opportunity to respond to their intentions before their request is dealt with at a general meeting of shareholders

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 we believe 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 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.

Our articles of association include a U.S. federal forum selection clause designating federal courts as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our shareholders, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Our articles of association provide that, unless we consent in writing to an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the Securities Act, to the fullest extent permitted by applicable law, shall be the federal district courts of the United States of America (the "Federal Forum Provision"). The Federal Forum Provision in our articles of association may impose additional litigation costs on shareholders in pursuing any such claims. Additionally, the forum selection clause may limit our shareholders' ability to bring a claim in a forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our shareholders. In addition, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on shareholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts may also reach different judgments or results than would other courts, including courts where a shareholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our shareholders.

We are no longer an "emerging growth company" or a "smaller reporting company" , and as a result we are subject to certain enhanced disclosure requirements which will require us to incur significant expenses and expend time and resources.

We are no longer an "emerging growth company" or a "smaller reporting company," and as a result, we are required to comply with various disclosure and compliance requirements that did not previously apply, such as the auditor attestation requirements of The Sarbanes-Oxley Act of 2002 (SOX) Section 404, the requirement that we hold a nonbinding advisory vote on executive compensation and obtain shareholder approval of any golden parachute payments not previously approved, and the requirement to provide full and more detailed executive compensation disclosure. Compliance with these additional requirements will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to these additional public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to delisting proceedings by the stock exchange on which our common shares are listed, or sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources.

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 2021, 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 2021. 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 now that 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. Additionally, we are no longer an emerging growth company or smaller reporting company and are 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 or significant deficiencies 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 will expire on March 31, 2023. 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. We further 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 this lease is ten years from the date that the premises are completed in accordance with certain specifications, which is planned for completion in April 2022.

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 our 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 21, 2022, 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, 2021.

Recent Sales of Unregistered Securities

None.

Item 6. [Reserved]

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 multispecific 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 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 for the potential treatment of solid tumors, and MCLA-129, for the potential treatment of lung and other solid tumors, which is subject to a 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 multispecific antibody candidates and advance them into clinical development.

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—Risks Related to Our Business and Industry—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 $430.7 million as of December 31, 2021 will fund our operations beyond 2024.

Clinical Programs

Zenocutuzumab, or "Zeno" (MCLA-128: HER3 x HER2 Biclonics®)
NRG1 gene fusion (NRG1+) Cancers: Phase 1/2 eNRGy trial clinical update planned for the first half of 2022

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. In November 2021, we announced that we met with the U.S. Food and Drug Administration (FDA) in an end-of-phase Type B meeting to discuss interim results from the ongoing phase 1/2 eNRGy trial and early access program (EAP) in NRG1+ cancers, and to discuss the development plan for zenocutuzumab. Based on feedback received from the FDA, we believe that the trial design and planned enrollment will be appropriate to potentially support a Biologics License Application (BLA) submission seeking a tumor agnostic indication for Zeno in patients with previously treated NRG1+ cancers. We believe that, if the rate of enrollment and efficacy results remain consistent, a sufficient number of patients will be enrolled in the eNRGy trial and EAP, with sufficient follow up, by mid-2022, which could provide a potential registrational data set.

In August 2020, Zeno was granted Orphan Drug Designation by the U.S. FDA for the treatment of pancreatic cancer and in January 2021, we announced that Zeno received 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
Dose expansion continues in phase 1 trial: update planned for second half of 2022

We are developing MCLA-158 for the potential treatment of solid tumors. Our phase 1 clinical trial of petosemtamab is ongoing in the dose expansion phase. In October 2021, we presented interim clinical data in patients with advanced head and neck squamous cell carcinoma (HNSCC) at the AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. As of the safety and efficacy data cutoff date of August 9, 2021, 10 patients with advanced HNSCC were enrolled and seven were evaluable for an interim efficacy analysis by investigator assessment. Three of seven patients achieved partial responses, with one of these three achieving complete response after the data cutoff date. Tumor reduction was observed in all seven patients. Enrollment of patients continues in the expansion phase of the open-label, multicenter trial. We plan to provide a clinical update in the second half of 2022.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial advancing

We are developing MCLA-145 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. The trial consists of a dose escalation phase, followed by a planned dose expansion phase. In December 2021, we presented interim clinical data on MCLA-145 from the phase 1 trial dose escalation study in patients with solid tumors at the ESMO Immuno-Oncology Congress 2021. As of the data cutoff date of July 14, 2021, 34 patients with advanced or metastatic solid tumors had been treated at eight dose levels ranging from 0.4-75mg every two weeks. Preliminary evidence of antitumor activity was observed at doses ≥25 mg biweekly. Further clinical evaluation of MCLA-145 is planned, both as monotherapy and in combination with a PD-1 blocking antibody.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Phase 1 trial advancing: update planned for second half of 2022

We are developing MCLA-129 as a potential treatment for solid tumors, including non-small cell lung cancer (NSCLC). In May 2021, we announced that the first patient was treated in the phase 1/2 dose escalation and expansion trial evaluating MCLA-129 for the treatment of patients with advanced NSCLC and other solid tumors. MCLA-129 is the subject to a collaboration and license agreement between us and Betta Pharmaceuticals Co. Ltd. (Betta), whereby we exclusively licensed Betta to develop MCLA-129 in China, while we retain full ex-China rights. In January 2021, Betta announced that the Chinese National Medical Products Administration had accepted its Investigational New Drug Application (IND) for MCLA-129 injection and in October 2021, Betta announced that the first patient was dosed in Betta's sponsored phase 1/2 trial of MCLA-129 in China in patients with advanced solid tumors.

We plan to provide an update in the second half of 2022.

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, petosemtamab, MCLA-145 and MCLA-129. We have observed a moderate impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic during the fourth quarter ended December 31, 2021, 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 and Eli Lilly, 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 require that our employees in the U.S. and Netherlands follow requirements consistent with the guidance provided by the Center for Disease Control and Prevention (CDC), federal, state and local regulations for the U.S. and Dutch National Institute for Health and Environment or Het Rijksinstituut voor Volksgezondheid en Milieu (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 offices 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, availability and effectiveness of vaccines, arising variants, and their impact on vaccination efforts, 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—Risks Related to Our Business and Industry—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—Collaborations Agreements,” Note 12, “Collaborations,” and Note 16, “Subsequent Events,” 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, 2021, 2020 and 2019

Revenue

The following is a comparison of collaboration revenue for the years ended December 31, 2021, 2020 and 2019:

	2021	Change	%	2020	Change	%	2019
Incyte	$ 29,604	$ 3,024	11.4%	$ 26,580	$ 749	2.9%	$ 25,831
Lilly	17,344	17,344	100.0%	—	—	—	—
Other	2,159	(1,204)	-35.8%	3,363	(2,154)	-39.0%	5,517
Total collaboration revenue	$ 49,107	19,164	64.0%	$ 29,943	(1,405)	-4.5%	$ 31,348
Grant revenue	—	—	0.0%	—	215	-100.0%	(215)
Total revenue	$ 49,107	$ 19,164	64.0%	$ 29,943	$ (1,190)	-3.8%	$ 31,133

Our revenue from each collaborator 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, 2021 increased $19.2 million as compared to the year ended December 31, 2020, primarily as a result of an increase of $17.3 million of amortization of upfront payment and reimbursement revenue related to Lilly collaboration agreement. Additionally, the achievement and recognition of Incyte milestone revenue during the year ended December 31, 2021 contributed to an increase of $2.0 million as compared to the year ended December 31, 2020. The change in exchange rates did not materially impact collaboration revenue.

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, 2021, we have total deferred revenue of $100.9 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and Lilly collaboration agreement. The payment of $73.3 million from the Incyte collaboration agreement is expected to be recognized over the next four years. The payment of $27.4 million from the Lilly collaboration agreement is expected to be recognized over time using a cost-to-cost measure of progress toward the development of a lead compound for each respective target.

In January 2022, we and Simcere Pharmaceuticals Group (Simcere) jointly agreed to terminate, effective March 30, 2022, an exclusive license to develop and commercialize up to three bispecific antibodies to be produced by us utilizing the our Biclonics® technology platform in China.

In January 2022, we announced that Incyte Corporation (Incyte) elected to opt-out of its ex-U.S. development of MCLA-145, from the parties joint collaboration agreement executed in 2017. At inception of the collaboration, for the designated product candidate (MCLA-145), we retained the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte obtained the exclusive right to develop and commercialize products and product candidates arising from such program outside the United States. For MCLA-145, the parties conducted and shared equally the costs of mutually agreed global development activities. Incyte's opt-out of ex-U.S. rights to MCLA-145 provides us the exclusive right to develop and commercialize potential MCLA-145 products globally. Under the collaboration, Incyte will continue to support the program for a limited time while ex-U.S. activities are transitioned to us, and Incyte will also retain a right to a residual royalty of up to 4% on sales of future commercialization of MCLA-145, if approved.

Operating Expenses

The following is a comparison of operating expenses for the years ended December 31, 2021, 2020 and 2019:

	2021	Change	%	2020	Change	%	2019
Research and development	$ 98,187	$ 28,147	40.2%	$ 70,040	$ 14,360	25.8%	$ 55,680
General and administrative	40,896	5,115	14.3%	35,781	1,671	4.9%	34,110
Total operating expenses	$ 139,083	$ 33,262	31.4%	$ 105,821	$ 16,031	17.9%	$ 89,790

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 enhance our platform technologies, 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, 2021 increased $28.1 million as compared to the year ended December 31, 2020, 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 MCLA-129, offset by decreases in costs for MCLA-117.

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 we continue to enhance our platform technologies, 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, legal and 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, 2021 increased $5.1 million as compared to the year ended December 31, 2020, primarily as a result increases in stock-based compensation of $3.5 million, insurance of $1.3 million, personnel related costs of $1.1 million, and facilities of $0.9 million, partially offset by a decrease in legal fees of $0.8 million, intellectual property related costs of $0.6 million and depreciation and amortization expense of $0.3 million.

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, regulatory and potential commercialization costs.

Other Income, Net

The following is a comparison of other income, net, for the years ended December 31, 2021, 2020 and 2019:

	2021	Change	%	2020	Change	%	2019
Interest (expense) income, net	$ (129)	$ (429)	-143.0%	$ 300	$ (1,589)	-84.1%	$ 1,889
Foreign exchange (losses) gains, net	24,663	34,095	-361.5%	(9,432)	(11,047)	-684.0%	1,615
Other (losses) gains, net	(1,135)	(1,135)	100.0%	—	(196)	-100.0%	196
Total other income (loss), net	$ 23,399	$ 32,531	-356.2%	$ (9,132)	$ (12,832)	-346.8%	$ 3,700

Other income, net consists of interest earned or paid 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. Other losses increase of $1.1 million for the year ended December 31, 2021 as compared to the year ended December 31, 2020 was attributed to loss associated with the derivative instrument recognized due to post-employment modification of our settlement agreement with a former executive.

Income Tax Expense

The following is a comparison of income tax expense for the years ended December 31, 2021, 2020 and 2019:

	2021	Change	%	2020	Change	%	2019
Current	$ 246	$ (379)	-60.6%	$ 625	$ 342	120.8%	$ 283
Deferred	(7)	115	-94.3%	(122)	(33)	37.1%	(89)
Income tax expense	$ 239	$ (264)	-52.5%	$ 503	$ 309	159.3%	$ 194

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, 2021 was $66.8 million, compared to $85.5 million for the year ended December 31, 2020. The decrease in net loss of $18.7 million was primarily due to the increase in collaboration revenue offset by increases in research and development and general and administrative expenses and changes in foreign exchange gains discussed above.

The increase in net loss of $30.3 million for the year ended December 31, 2020 compared to the net loss for the year ended December 31, 2019 of $55.2 million 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, 2021, we have raised an aggregate of $875.0 million, of which $165.4 million was non-equity funding through our collaboration agreements, $598.9 million was from the sale of common shares and $110.7 million was from private funding sources prior to our initial public offering. These amounts include 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, the aggregate net proceeds from the January 2021 follow-on offering of $129.7 million and the aggregate net proceeds from the November 2021 follow-on offering of $118.7 million. As of December 31, 2021, we had $430.7 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, licensing, other business development opportunities 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, licensing or other business development opportunities in the future, we may have to relinquish valuable rights to our technologies or intellectual property, 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, intellectual property 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, and the additional capital raised through the sale of equity in November 2021 described above, we expect that our existing cash, cash equivalents and marketable securities as of December 31, 2021, will be sufficient to fund our planned operating expenses and capital expenditure requirements beyond 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.

Cash Flows

The following is a summary of cash flows for the years ended December 31, 2021, 2020 and 2019:

	2021	Change	%	2020	Change	%	2019
Net cash used in operating activities	$ (59,627)	$ 20,274	-25%	$ (79,901)	$ (16,853)	27%	$ (63,048)
Net cash provided by (used in) investing activities	(146,623)	(145,137)	9767%	(1,486)	(25,658)	-106%	24,172
Net cash provided by financing activities	281,955	242,435	613%	39,520	(34,712)	-47%	74,232

Operating Activities

Net cash used in operating activities for the year ended December 31, 2021 decreased $20.3 million as compared to the year ended December 31, 2020 primarily as a result of operating cash receipts related to collaboration arrangements (upfront payments, milestones, and research and development reimbursements) increased $41.4 million, operating cash out flows related to operating expenses and taxes increased $17.4 million, and cash out flows related to other income decreased $3.7 million.

Net cash used in operating 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, 2021 increased $145.1 million as compared to the year ended December 31, 2020, primarily as a result of the increase in purchases of marketable securities using the receipt of proceeds from our equity issuances of $149.0 million offset by the increase net cash inflows from the maturity of debt securities used to fund current operations of $3.4 million.

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, 2021 increased $242.4 million as compared to the year ended December 31, 2020, primarily as a result of the increase in receipt of proceeds from our equity issuances of $226.5 million and increases in proceeds received from option exercises of $16.0 million.

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 judgment 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. Furthermore, estimates of progress towards satisfaction of performance obligations 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, 2021 would have decreased revenue recognized for the year ended December 31, 2021 by approximately $3.2 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, 2021 was $17.01. 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 decreased the weighted-average grant-date fair value of options granted for the year ended

December 31, 2021 to $17.88. Similarly, an increase of 1% in the estimated volatility of our shares would decrease the weighted-average grant-date fair value of options granted for the year ended December 31, 2021 to $17.14. We granted 1,522,210 options for the year ended December 31, 2021, 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.

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

We are not required to provide the information required by this Item until our Quarterly Report on Form 10-Q for the first quarter after the fiscal year in which it is determined that we are no longer 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, 2021.

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, 2021, our internal control over financial reporting was effective.

KPMG Accountants N.V., our independent registered public accounting firm, has audited our Consolidated Financial Statements included in this Annual Report on Form 10-K and has issued an attestation report on our internal control over financial reporting, which is included in Part IV, Item 15 of this Form 10-K.

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, 2021 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

[Not applicable.]

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Director Biographical Information

Anand Mehra, M.D., age 46, has served as a non-executive director of our board since August 2015 and as Chairperson 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.

Maxine Gowen, Ph.D., age 63, has served as a nonexecutive director to our board of directors since May 2021. Dr. Gowen was the founding President and Chief Executive Officer of Trevena, Inc. (Trevena), from 2007 to October 2018. Prior to this position, Dr. Gowen held a variety of leadership roles at GlaxoSmithKline (GSK) over a period of 15 years. As Senior Vice President for the company's Center of Excellence for Drug Discovery, she developed an innovative new approach to externalizing drug discovery. Dr. Gowen was previously President and Managing Partner at SR One, the venture capital subsidiary of GSK, where she led its investments in and served on the Board of Directors of numerous companies. Dr. Gowen also previously served as Vice President, Drug Discovery, Musculoskeletal Diseases at GSK, where she was responsible for drug discovery and early development for osteoporosis, arthritis and metastatic bone disease. Dr. Gowen holds a B.Sc. in biochemistry from the University of Bristol, U.K., received a Ph.D. in cell biology from the University of Sheffield, U.K., and received an MBA from the Wharton School of the University of Pennsylvania. Dr. Gowen currently serves on the board of directors of Aclaris Therapeutics, Idera Therapeutics, and Passage Bio, and served on the boards of Akebia Therapeutics (Akebia) and Trevena until May 2021. We believe that Dr. Gowen is qualified to serve on our board of directors due to her leadership, experience in the biotechnology industry and in the field of clinical drug development, her scientific experience and her tenure as CEO and independent director at several publicly traded biotechnology companies.

Mark Iwicki, age 55, 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 Chairperson of our board of directors. Mr. Iwicki currently serves as the Chairperson 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 60, 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 58, 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 61, has served as a non-executive director of our board of directors since May 2016 and Vice Chairperson 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 chairperson of its audit committee. From December 2011 to February 2016, Mr. Perry served on the board of directors of Ocata Therapeutics, including as chairperson 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 60, 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, ArQule Inc., until its acquisition by Merck Inc., and Trillium Therapeutics Inc., until its acquisition by Pfizer Inc. He currently serves on the boards of directors of publicly held life sciences companies West Pharmaceuticals Services, Inc., and Replimmune Group 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 55, 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 56, 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 55, 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.

Cecilia (“Cecile”) Anna Wilhelmina Geuijen, Ph.D, age 54, has served as our Chief Scientific Officer since May 2021. Her responsibilities include strategic scientific leadership, management of pre-clinical research, external collaborations, partnerships management and operational activities. Before joining Merus in 2009, Ms Geuijen worked as a senior scientist on the evaluation of new therapeutic targets in oncology at Genmab and the identification of new therapeutic targets in oncology at Crucell. She holds a Ph.D. in Biology from the University of Utrecht and was a Marie Curie Fellow at the Duve Institute in Brussels.

Cornelis Adriaan ("John") de Kruif, Ph.D., age 58, 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 49, 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 44, 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 management of the Company’s legal and intellectual property, information technology, facilities and human resource matters, and 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 2022 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 2022 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 2022 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 2022 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 2022 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 May 28, 2021	8-K	001-37773	3.1	5/28/21	
	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	
10.3.4	English language translation of the Lease dated June 3, 2021, by and between the Registrant and Stichting Incubator Utrecht	10-Q	001-37773	10.3.4	8/5/21	
	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	10-Q	001-37773	10.3.5	11/2/21	
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	10-K	001-37773	10.4.5	3/16/21	
	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.

††† 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) the type that the Registrant treats as private or confidential.

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: February 28, 2022

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	February 28, 2022
/s/ Harry Shuman **Harry Shuman**	Chief Accounting Officer	February 28, 2022
/s/ Anand Mehra **Anand Mehra**	Chairman of the Board of Directors	February 28, 2022
/s/ Mark T. Iwicki **Mark T. Iwicki**	Director	February 28, 2022
/s/ Len Kanavy **Len Kanavy**	Director	February 28, 2022
/s/ Greg D. Perry **Greg D. Perry**	Director	February 28, 2022
/s/ Paolo Pucci **Paolo Pucci**	Director	February 28, 2022
/s/ Victor Sandor **Victor Sandor**	Director	February 28, 2022
/s/ Maxine Gowen **Maxine Gowen**	Director	February 28, 2022

MERUS N.V.
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Report of Independent Registered Public Accounting Firm

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

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Merus N.V. and subsidiary (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2021, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission".

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing separate opinions on the critical audit matter or on the accounts or disclosures to which it relates.

Identification of distinct performance obligations and determining the over-time revenue recognition method for a collaboration and license agreement

As discussed in Note 12 to the consolidated financial statements, the Company entered into a collaboration and license agreement with Eli Lilly and Company (‘Lilly’). The Company allocated the fixed consideration of $43.5 million to the performance obligations identified and recognizes revenue over time using a cost-to-cost method measure of progress towards completion of the performance obligation.

We identified the evaluation of the distinct performance obligations identified by the Company and the determination of the appropriate method for measuring progress as a critical audit matter. Challenging auditor judgment was required in evaluating the terms and conditions in the agreement to assess the identification of distinct performance obligations and to assess the most appropriate method to measure progress towards complete satisfaction of the identified performance obligations.

The following are the primary procedures we performed to address this critical audit matter:

- We evaluated the design and tested the operating effectiveness of an internal control related to the Company’s revenue recognition process, including the identification of distinct performance obligations and the determination of the appropriate method to measure progress.

- We obtained and read the Lilly agreement and evaluated the terms and conditions of the agreement to assess that the performance obligations within the agreement were completely and accurately identified in accordance with the relevant accounting guidance, and an appropriate measure of progress has been selected that best depicts the transfer of control to the customer.

/s/ KPMG Accountants N.V.

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

Rotterdam, the Netherlands
February 28, 2022

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

	2021	2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 241,435	$ 163,082
Marketable securities	168,990	44,673
Accounts receivable	1,697	46
Accounts receivable (related party)	4,609	1,623
Prepaid expenses and other current assets	7,448	8,569
Total current assets	424,179	217,993
Marketable securities	20,297	—
Property and equipment, net	3,549	4,115
Operating lease right-of-use assets	3,733	3,907
Intangible assets, net	2,347	2,843
Deferred tax assets	417	410
Other assets	2,078	1,949
Total assets	$ 456,600	$ 231,217
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 13,237	$ 3,126
Accrued expenses and other liabilities	22,506	21,803
Income taxes payable	—	206
Current portion of lease obligation	1,494	1,432
Current portion of deferred revenue	16,613	625
Current portion of deferred revenue (related party)	18,048	19,554
Total current liabilities	71,898	46,746
Lease obligation	2,257	2,521
Deferred revenue, net of current portion	10,962	237
Deferred revenue, net of current portion (related party)	55,282	79,450
Total liabilities	140,399	128,954
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 and 45,000,000 shares authorized as at December 31, 2021 and 2020, respectively; 43,467,052 and 31,602,953 shares issued and outstanding as at December 31, 2021 and 2020, respectively	$ 4,481	$ 3,211
Additional paid-in capital	787,869	490,093
Accumulated deficit	(466,928)	(400,112)
Accumulated other comprehensive (loss) income	(9,221)	9,071
Total stockholders' equity	316,201	102,263
Total liabilities and stockholders' equity	$ 456,600	$ 231,217

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,		
	2021	2020	2019
Collaboration revenue	$ 19,503	$ 3,363	$ 5,517
Collaboration revenue (related party)	29,604	26,580	25,831
Grant revenue	—	—	(215)
Total revenue	49,107	29,943	31,133
Operating expenses:			
Research and development	98,187	70,040	55,680
General and administrative	40,896	35,781	34,110
Total operating expenses	139,083	105,821	89,790
Operating loss	(89,976)	(75,878)	(58,657)
Other income (loss), net:			
Interest (expense) income, net	(129)	300	1,889
Foreign exchange (losses) gains, net	24,663	(9,432)	1,615
Other (losses) gains, net	(1,135)	—	196
Total other income (loss), net	23,399	(9,132)	3,700
Loss before income tax expense	(66,577)	(85,010)	(54,957)
Income tax expense	239	503	194
Net loss	$ (66,816)	$ (85,513)	$ (55,151)
Other comprehensive income (loss):			
Currency translation adjustment	(18,292)	7,485	(1,308)
Comprehensive loss	$ (85,108)	$ (78,028)	$ (56,459)
Net loss per share allocable to common stockholders:			
Basic and diluted	$ (1.73)	$ (2.92)	$ (2.28)
Weighted-average common shares outstanding:			
Basic and diluted	38,638,434	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,		
	2021	**2020**	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$ (66,816)	$ (85,513)	$ (55,151)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of property and equipment	1,245	1,165	902
Amortization of intangible assets	240	279	236
Foreign exchange losses (gains)	(27,703)	8,957	(1,068)
Stock-based compensation expense	17,091	9,372	7,834
Amortization of discount on investments	450	40	(531)
Deferred tax benefit	(7)	(122)	(89)
Changes in operating assets and liabilities:			
Accounts receivable	(4,991)	1,149	633
Operating lease right-of-use assets and lease obligations	(24)	—	(112)
Prepaid expenses and other current assets	(1,092)	(2,895)	(1,029)
Accounts payable	10,715	(110)	22
Accrued expenses and other liabilities	2,127	7,023	3,317
Deferred revenue	9,138	(19,246)	(18,012)
Net cash used in operating activities	**(59,627)**	**(79,901)**	**(63,048)**
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchases of marketable securities	(215,839)	(66,845)	(60,413)
Proceeds from maturities of marketable securities	70,086	66,646	87,183
Purchases of intangible assets	—	—	(375)
Purchases of property and equipment	(870)	(1,287)	(2,223)
Net cash provided by (used in) investing activities	**(146,623)**	**(1,486)**	**24,172**
CASH FLOWS FROM FINANCING ACTIVITIES:			
Payment of offering costs	(572)	—	—
Proceeds from issuance of common stock, net	248,630	38,072	74,184
Proceeds from issuance of common stock - Lilly	16,477	—	—
Proceeds from stock options exercised	17,423	1,448	48
Repurchase of restricted stock units	(285)	—	—
Short-swing profit disgorgement	282	—	—
Net cash provided by financing activities	**281,955**	**39,520**	**74,232**
Foreign exchange impact on cash, cash equivalents and restricted cash	2,761	7,337	(2,273)
Net increase (decrease) in cash, cash equivalents and restricted cash	78,466	(34,530)	33,083
Cash, cash equivalents, and restricted cash, beginning of period	163,283	197,813	164,730
Cash, cash equivalents, and restricted cash, end of period	**$ 241,749**	**$ 163,283**	**$ 197,813**
SUPPLEMENTAL DISCLOSURES:			
Non-cash right-of-use assets acquired from operating lease obligations	$ 2,626	$ —	$ 3,875
Income taxes paid	$ (635)	$ (322)	$ (320)
Non-cash purchases of property, equipment and intangibles	$ —	$ 36	$ 187
Non-cash issuance of stock options	$ 573	$ —	$ —
Non-cash financing costs	$ —	$ 71	$ 164
Income tax refunds received	$ —	$ 24	$ —
CASH, CASH EQUIVALENTS AND RESTRICTED CASH			
Cash and cash equivalents	$ 241,435	$ 163,082	$ 197,612
Restricted cash included in other assets	314	201	201
	$ 241,749	$ 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 Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
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
Issuance of common stock, net	10,014,354	1,072	246,986	—	—	248,058
Issuance of common stock - Lilly	706,834	77	16,400	—	—	16,477
Exercise of stock options and vesting of restricted stock units	1,142,911	121	17,302	—	—	17,423
Repurchase of restricted stock units	—	—	(285)	—	—	(285)
Short-swing profit disgorgement	—	—	282	—	—	282
Stock-based compensation	—	—	17,091	—	—	17,091
Currency translation adjustment	—	—	—	—	(18,292)	(18,292)
Net loss	—	—	—	(66,816)	—	(66,816)
Balance at December 31, 2021	43,467,052	$ 4,481	$ 787,869	$ (466,928)	$ (9,221)	$ 316,201

See notes to consolidated financial statements.

1. The Company

Merus N.V. is a clinical-stage oncology company developing innovative 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 deficit of $466.9 million as of December 31, 2021. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its antibody candidates advance through discovery, pre-clinical development and clinical trials and as it seeks regulatory approval and pursues commercialization of any approved 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, business development and licensing opportunities with third parties. Adequate additional financing may not be available to the Company on acceptable terms, or at all. The Company’s inability to raise capital as and when needed would have a negative impact on its financial condition and ability to pursue its business strategy. The Company will need to generate significant revenues to achieve profitability and may never do so.

Based on the Company’s current operating plan, the Company expects that its existing cash, cash equivalents and marketable securities of $430.7 million as of December 31, 2021, will fund the Company’s operations beyond 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 clinical-stage programs and its plans to pursue commercialization of any antibody candidate, if approved, and after considering its existing cash, cash equivalents and marketable securities as of December 31, 2021, 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. Additional details of the Company's cash runway is described in Note 1 *The Company*.

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.

Restricted Cash

The Company maintains certain cash balances restricted to withdrawal or use. Restricted cash includes cash held as collateral for certain contractual agreements and is recorded in other assets in the consolidated balance sheets.

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, lack of 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 2021, 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;

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

d) whether the combined performance obligation is satisfied over time or at a point in time in step (v) above; and

e) the appropriate method for measuring progress toward complete satisfaction of a performance obligation in step (v) 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 years ended December 31, 2021, 2020, and 2019, the Company recognized $9.3 million, $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 therapeutics.

Recently Adopted 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 became effective for the Company at the beginning of 2021, but had no impact on amounts or disclosures previously reported or during the year ended December 31, 2021.

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 became effective for the Company at the beginning of 2021. None of the Company's arrangements fall within the scope of ASC 808, and the adoption of this standard had no impact on amounts or disclosures previously reported or during the year ended December 31, 2021.

3. Investments in Debt Securities

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

	December 31,	
	2021	2020
	Balance	Balance
	(in thousands)	
Cash equivalents	$ 5,684	$ 17,654
Current marketable securities	168,990	44,673
Non-current marketable securities	20,297	—
Total	$ 194,971	$ 62,327

The following table summarizes debt securities by maturity at December 31, 2021 (in thousands):

Maturity	Amortized Cost
Within one year	$ 174,674
After one year through five years	20,297
Total	$ 194,971

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

	Credit Quality Indicator as of December 31, 2021			
	AAA	AA- to AA+	A- to A+	Total
	(In thousands)			
Money market funds	$ 5,684	$ —	$ —	$ 5,684
Corporate paper and notes	—	28,898	126,141	155,039
U.S. government agency securities	—	2,093	—	2,093
U.S. treasuries	—	32,155	—	32,155
Total	$ 5,684	$ 63,146	$ 126,141	$ 194,971

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, 2021.

The following table summarizes the fair value of debt securities by major security type held at December 31, 2021 (in thousands):

Description	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Money market funds	$ 5,684	$ —	$ —	$ 5,684
Corporate paper and notes	155,039	—	(160)	154,879
U.S. government agency securities	2,093	—	(7)	2,086
U.S. treasuries	32,155	—	(31)	32,124
Total	$ 194,971	$ —	$ (198)	$ 194,773

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
Corporate paper and notes	27,978	2	—	27,980
U.S. government agency securities	9,150	—	—	9,150
U.S. treasuries	15,043	1	(2)	15,042
Total	$ 62,327	$ 3	$ (2)	$ 62,328

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,	
	2021	2020
	(In thousands)	
Prepaid clinical and manufacturing costs	$ 2,146	$ 4,971
Prepaid general and administrative costs	2,760	2,460
Interest receivable	367	80
Other	2,175	1,058
Total	$ 7,448	$ 8,569

Restricted cash included in other assets totaled $0.3 million and $0.2 million as of December 31, 2021 and 2020, 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,	
	2021	2020
	(In thousands)	
Laboratory equipment	$ 5,583	$ 5,695
Office equipment and furniture	1,222	1,300
Leasehold improvements	111	117
Construction in progress	1,056	496
Property and equipment	7,972	7,608
Less: accumulated depreciation and amortization	(4,423)	(3,493)
Property and equipment, net	$ 3,549	$ 4,115

Construction in progress relates to certain development and construction costs related to the office lease the Company entered into with Kadans Science Partner XII B.V. that is expected to complete during 2022. Additional details for the lease agreement is described in Note 9 *Operating Leases*. Depreciation and amortization expense was $1.2 million, $1.2 million and $0.9 million for the years ended December 31, 2021, 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,	
	2021	2020
	(In thousands)	
Licenses of intellectual property	$ 3,597	$ 3,898
Software licenses	266	288
Intangible assets	3,863	4,186
Less: accumulated amortization	(1,516)	(1,343)
Intangible assets, net	$ 2,347	$ 2,843

Amortization expense was $0.2 million, $0.3 million and $0.2 million for the years ended December 31, 2021, 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
2022	$ 276
2023	213
2024	181
2025	154
2026	154
Thereafter	1,369
Total remaining value	$ 2,347

7. Accrued Expenses and Other Liabilities

Accrued expenses consisted of the following:

	December 31,	
	2021	2020
	(In thousands)	
Accrued research and development expenses	$ 15,174	$ 15,372
Accrued personnel costs	4,861	4,854
Accrued general and administrative expenses	1,362	1,566
Other	1,109	11
Accrued expenses	$ 22,506	$ 21,803

8. Income Taxes

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

	Year ended December 31,		
	2021	2020	2019
		(In thousands)	
United States	$ (8,502)	$ (3,832)	$ (1,363)
Netherlands	(58,075)	(81,178)	(53,594)
Total loss before income taxes	$ (66,577)	$ (85,010)	$ (54,957)

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

	December 31,		
	2021	2020	2019
	(In thousands)		
U.S. federal	$ 173	$ 391	$ 243
U.S. state	73	234	40
Total current tax expense	$ 246	$ 625	$ 283
U.S. federal	$ (5)	$ (86)	$ (63)
U.S. state	(2)	(36)	(26)
Total deferred tax benefit	$ (7)	$ (122)	$ (89)
Total income tax expense	$ 239	$ 503	$ 194

The Company recognizes income tax expense (benefit) based on its continuing operations in the U.S. The parent company in the Netherland has net operating losses.

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,		
	2021	2020	2019
Netherlands statutory income tax rate	25.0%	25.0%	25.0%
Changes in tax rates	5.2	10.6	1.5
Non-deductible expenses	0.7	(2.4)	(3.7)
Change in valuation allowance	(31.4)	(33.5)	(23.3)
Other	0.1	(0.3)	0.1
Effective income tax rate	(0.4)%	(0.6)%	(0.4)%

In 2020 and 2021, 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,	
	2021	2020
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 78,709	$ 66,572
Deferred revenue	26,033	24,966
Excess interest carryforward	1,689	2,080
Lease obligation	1,006	1,058
Accrued expenses and other	478	494
Total deferred tax assets	107,915	95,170
Deferred tax asset valuation allowance	(106,440)	(93,645)
Total deferred tax assets, net of valuation allowance	1,475	1,525
Deferred tax liabilities:		
Operating lease right-of-use assets	$ 1,002	$ 1,048
Other	56	67
Total deferred tax liabilities	1,058	1,115
Net deferred tax asset	$ 417	$ 410

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 $106.4 million and $93.6 million as of December 31, 2021 and 2020, respectively. The increase in the

valuation allowance of $12.8 million and $35.8 million for the years ended December 31, 2021 and 2020, 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, 2021, the portion of the valuation allowance for deferred tax assets for which subsequently recognized tax benefits would be credited directly to contributed capital totaled $2.2 million.

As of December 31, 2021, 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 of $305.1 million as of December 31, 2021. Under Dutch tax law, net operating loss carryforwards may be used to offset future taxable income in full up to €1.0 million and 50% of taxable income that exceeds €1.0 million. Effective as of January 1, 2022, these losses can be carried forward indefinitely.

As of December 31, 2021, the Company had no unrecognized tax benefits. As of December 31, 2021, 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 2018. The statute of limitations for assessment by the Netherlands tax authorities is closed for tax years prior to 2016. The Company is not currently under examination by the IRS or any other jurisdictions for any tax years.

9. Operating Leases

Merus N.V. has non-cancellable operating leases for its corporate headquarters in Utrecht, the Netherlands. During the year ended December 31, 2021, the Company signed a lease amendment (the “Amendment”), which extended the lease term by approximately 1.5 years ending at the end of March 2023. The Amendment did not include additional right-of-use other than the extended lease term. There is no additional renewal term included in the Amendment to consider in the estimate of the lease term.

In March 2019, Merus US, Inc. entered into a non-cancellable operating 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.

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,	
	2021	2020
	(In thousands)	
Operating lease cost	$ 1,693	$ 1,611
Variable lease cost	408	375
Total lease cost included in operating expenses	$ 2,101	$ 1,986
Cash paid to lessors included in operating cash outflows	$ 1,704	$ 2,478

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, 2021 were as follows (in thousands):

Year	Operating Leases
2022	$ 1,616
2023	880
2024	645
2025	662
2026	222
Total lease payments	4,025
Less: amount representing interest	(274)
Total lease obligations	$ 3,751

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

	As of December 31,	
	2021	2020
Weighted-average remaining operating lease term (in years)	3.3	4.2
Weighted-average discount rate for operating leases	4.0%	4.9%

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, 2021.

Litigation

On April 5, 2018, an unnamed third party filed a notice 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 notice asserted, as applicable, added subject matter, lack of novelty, lack of inventive step, and insufficiency. On August 20, 2018, the Company timely responded to these submissions. 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 scheduled in May 2022. 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. The Company is not currently a party to any material legal proceedings.

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.

On January 18, 2021, the Company sold 706,834 common shares, at a price of $28.295 for aggregate proceeds of $16.5 million.

On January 21, 2021, the Company sold 5,575,757 common shares, at a price of $24.75 for aggregate proceeds of $129.4 million.

On November 9, 2021, the Company sold 4,438,597 common shares, at a price of $28.50 for aggregate proceeds of $118.7 million.

12. Collaborations

Lilly

On January 18, 2021, Eli Lilly and Company ("Lilly") agreed to pay the Company a $40.0 million, non-refundable upfront payment, and purchased 706,834 common shares at a stated price per share of $28.295, for an aggregate purchase price of $20.0 million. The Company and Lilly agreed to collaborate with respect to the discovery and research of bispecific antibodies utilizing the Company's 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 Lilly to be the subject of each program.

The objective of each program is to develop a lead compound that Lilly would be able to continue to develop through clinical trials. Lilly agreed to fund the research activities the Company conducts for each program under an agreed research plan and budget. Lilly receives 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 targeting CD3, or directed to such designated target(s) alone as a monospecific antibody or monospecific antibody drug conjugate, subject to rights granted by Merus to third parties under one or more existing third party agreements. Merus retains all rights not granted to Lilly. Lilly has certain rights to replace selected targets, including the right to substitute a target selection after initial selection for a period of time. The Company may be entitled to further milestones and royalties in the future dependent on development and commercialization of any resulting product.

The initial term of the arrangement includes a three-year research term for the Company to perform research and development activities, subject to two extension terms of six months at Lilly's discretion. While the arrangement may be terminated in its entirety or on a program-by-program basis at will by Lilly, there are no direct costs or penalties to Lilly to terminate the arrangement prior to the end of the initial term.

At inception of the arrangement, the Company identified a single performance obligation comprised of a combined delivery of a license and related activities, including research activities associated with a product candidate against the first target and the activities of the joint steering committee. The Company also identified two other combined performance obligations relating to options exercisable by Lilly to select a second and third target to advance a second and third product candidate against the selected targets through discovery and research.

The transaction price at inception was comprised of fixed consideration of $43.5 million that was derived from the $40.0 million upfront payment and $20.0 million share purchase proceeds, net of the fair value of shares of the shares delivered to Lilly of $16.5 million, and variable consideration associated with the funding of research services for the product candidate against the first target at inception. All other consideration under the arrangement was determined to be variable consideration and fully constrained at inception.

The fixed consideration was allocated equally amongst the three performance obligations and the variable consideration associated with each target was allocated to the performance obligation of each respective target. The equal allocation of the fixed consideration was based on the estimated standalone selling price of each performance obligation as each was materially the same.

On February 12, 2021, the Company and Lilly completed the initial exchange of fixed consideration and transfer of common shares. The Company initially deferred $43.5 million allocated to the performance obligations to be recognized as revenue over time using a cost-to-cost measure of progress toward the development of a lead compound for each respective target, anticipated to be recognized as revenue within the initial research term, along with research funding. Development milestones, commercialization milestones and royalties are variable consideration, fully constrained, to be included in the transaction price for each performance obligation and recognized in future periods in accordance with the Company's revenue recognition policy. The revenue recognized relating to each combined performance obligation is presented in the notes according to the source of consideration received (upfront, reimbursement revenue, milestone), reflective of their differing timing of receipt.

Incyte

In December 2016, pending regulatory clearance, Incyte Corporation (“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 10 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 retained the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte obtained 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.

As of December 31, 2021, the Company is currently engaged in clinical development activities for MCLA-145 and developing pre-clinical candidates for the other programs. Refer to Note 16, “Subsequent Events.” During the year ended December 31, 2021, the Company recognized a total of $2.0 million for achieving development milestones and received a $1.0 million payment. There were no development milestones achieved for the years ended December 31, 2020 and 2019.

ONO

In April 2014, the Company granted ONO Pharmaceuticals Co. Ltd. (“ONO”) an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market a limited number of bispecific antibody candidates based on the Company’s Biclonics® technology platform against two undisclosed targets directed to a particular undisclosed target combination.

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 a limited number of 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.

The Company received €3.7 million (approximately $4.1 million) for the year ended December 31, 2019 for development milestones. There were no development milestones achieved in the years ended December 31, 2021 and 2020.

Simcere

In January 2018, the Company granted Simcere Pharmaceuticals Group ("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 "Simcere Agreement"). 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. Refer to Note 16, "Subsequent Events."

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.

During the years ended December 31, 2021 and 2020, the Company has recognized $0.5 million for milestones achieved under the Simcere Agreement, respectively. There was no milestone achieved during the year ended December 31, 2019.

Betta

On December 10, 2018, the Company granted Betta an exclusive license to develop and commercialize in China MCLA-129, 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.

During the year 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. No milestones were achieved during the years ended December 31, 2021 and 2019, respectively.

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	Lilly	Other	Total
Contract assets				
Accounts receivable				
Balance at January 1, 2021	$ —	$ —	$ 46	$ 46
Billings	8,053	62,061	939	63,000
Cash receipts	(6,419)	(62,061)	(924)	(62,985)
Adjustments	—	—		—
Foreign exchange	—	—	(20)	(20)
Balance at December 31, 2021	1,634	—	41	41
Unbilled receivables				
Balance at January 1, 2021	$ 1,623	$ —	$ —	$ —
Accrued receivables	9,361	3,264	1,408	4,672
Billings	(8,030)	(2,061)	(939)	(3,000)
Adjustments	21	—	—	—
Foreign exchange	—	—	(16)	(16)
Balance at December 31, 2021	2,975	1,203	453	1,656
Contract liabilities				
Deferred revenue				
Balance at January 1, 2021	$ 99,004	$ —	$ 862	$ 862
Allocation of contract consideration	—	43,523	—	43,523
Revenue recognized in the period	(18,864)	(14,012)	(602)	(14,614)
Foreign exchange	(6,810)	(2,158)	(38)	(2,196)
Balance at December 31, 2021	73,330	27,353	222	27,575
Less: current portion	(18,048)	(16,391)	(222)	(16,613)
Non-current balance at December 31, 2021	55,282	10,962	—	10,962

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, 2021			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 18,864	$ 14,012	$ 602	$ 14,614
Reimbursement revenue	8,740	3,332	1,057	4,389
Milestones	2,000	—	500	500
Total collaboration revenue	$ 29,604	$ 17,344	$ 2,159	$ 19,503
Operating expenses:				
Research and development expense	$ 1,223	$ —	$ 151	$ 151
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	$ 1,223	$ —	$ 151	$ 151
Revenue recognized that was included in deferred revenue at the beginning of the period	$ 18,864	$ —	$ 602	$ 602

	For the Year Ended December 31, 2020			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 18,193	$ —	$ 895	$ 895
Reimbursement revenue	8,387	—	(12)	(12)
Milestones	—	—	2,480	2,480
Total collaboration revenue	$ 26,580	$ —	$ 3,363	$ 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	$ —	$ 938	$ 938

	For the Year Ended December 31, 2019			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 17,839	$ —	$ 839	$ 839
Reimbursement revenue	7,992	—	252	252
Milestones	—	—	4,426	4,426
Total collaboration revenue	$ 25,831	$ —	$ 5,517	$ 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	$ —	$ 1,141	$ 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, 2022 totaled 2,836,603.

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,		
	2021	2020	2019
	(In thousands)		
Research and development	$ 7,167	$ 2,969	$ 3,186
General and administrative	9,924	6,403	4,648
Total	$ 17,091	$ 9,372	$ 7,834

As of December 31, 2021, stock-based compensation expense related to unvested shares was $11.9 million. These shares are expected to vest and related 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. During the year ended December 31, 2020, the Company switched to using the Black-Scholes option-pricing model as part of its option plan administration system change. For the year ended December 31, 2019, 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,		
	2021	2020	2019
Risk-free interest rate	0.6%	1.3%	2.5%
Contractual life of options (years)	10.0	10.0	10.0
Expected term of options (years)	6.1	6.3	N/A
Expected volatility of underlying stock	85.7%	86.1%	87.0%
Expected dividend yield	0.0%	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, 2021:

	Number of Options	Weighted Average Exercise Price per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (In thousands)
Outstanding at January 1, 2021	3,748,911	$ 15.59		
Granted	1,522,210	23.78		
Exercised	(1,104,029)	15.90		
Forfeited or expired	(182,625)	20.43		
Outstanding at December 31, 2021	3,984,467	$ 18.40	7.4	$ 53,445
Exercisable at December 31, 2021	1,841,578	$ 15.64	5.8	$ 29,825

	Year Ended December 31,	
	2021	2020
Weighted-average fair value of options granted	$ 17.01	$ 11.75

RSU Activity

The following is a summary of RSU activity for the year ended December 31, 2021:

	Number of RSUs	Weighted Average Grant-date Fair Value
Non-vested at January 1, 2021	59,775	$ 16.48
Granted	24,976	23.40
Vested	(38,882)	17.17
Forfeited	(35,869)	17.15
Non-vested at December 31, 2021	10,000	$ 25.56

Intrinsic Value of Stock Options Exercised and Vested RSUs

	Year Ended December 31, (In thousands)	
	2021	2020
Total fair value of RSUs vested	$ 903	$ 961
Aggregate intrinsic value of options exercised	10,774	1,750

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 $2.9 million, $2.0 million, and $1.3 million in the years ended December 31, 2021, 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 for each of the years ended December 31, 2021, 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 was paid by the Company in January 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.

In April 2020, Mark Throsby, Ph.D. resigned as the Executive Vice President and Chief Scientific Officer of the Company effective July 31, 2020. In connection with his departure, Mr. Throsby entered into a Settlement Agreement with the Company, pursuant to which Mr. Throsby received a severance payment equal to 8 months of his annual salary and amortized bonus aggregating approximately $0.3 million. Further, subject to Mr. Throsby’s continued compliance with the terms and conditions of the Settlement Agreement, Mr. Throsby’s unvested equity awards continued to vest until October 31, 2020 as if Mr. Throsby had continued in full time service with the Company through such date. The post-termination exercise period of Mr. Throsby's options was extended to March 31, 2021. The Company incrementally recognized $0.1 million in respect of the severance payment and a net reversal of $0.4 million of stock-based compensation expense in respect of share-based payments in research and development expense in the consolidated statement of operations in the prior year.

In March 2021, the Company and Mr. Throsby amended the Settlement Agreement, extending the post-termination expiration period of his outstanding options to extend to October 31, 2021, three months following his performance of certain consulting services through July 31, 2021. As a result, additional compensation cost of $0.2 million was recognized for the quarter ended March 31, 2021. During the three months ended September 30, 2021, the Company and Mr. Throsby entered into the 2nd Amendment to the Settlement Agreement, extending Mr. Throsby’s consulting services period to November 30, 2021. The 2nd Amendment extends the post-termination expiration period of his outstanding options to February 28, 2022. As the modification occurred in Mr. Throsby’s post-employment period, the options cease to be within the scope of ASC 718 and are recharacterized as an issuance of a standalone derivative instrument. The Company recognized a $1.0 million net loss associated with the derivative instrument included as other losses, net in the statement of operations for the year ended December 31, 2021.

14. Loss per Share

The two-class method was not applied for the years ended December 31, 2021, 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,		
	2021	2020	2019
	(In thousands except per share data)		
Net loss	$ (66,816)	$ (85,513)	$ (55,151)
Weighted average shares outstanding	38,638,434	29,256,203	24,218,083
Basic and diluted loss per share allocable to common stockholders	$ (1.73)	$ (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 8.2%, 10.1% and 11.1% of the outstanding shares of the Company as of December 31, 2021, 2020 and 2019, respectively. During the year ended December 31, 2021, Incyte's holdings of the Company's outstanding shares fell below 10.0% of the Company's total outstanding shares due to the Company issuing additional shares of common stocks through various financing events of 2021. These consolidated financial statements present Incyte as a related party in order to simplify the presentation and clearly display transactional amounts incurred between Incyte and the Company, given the related party relationship in effect for a portion of the year.

16. Subsequent Events

In January 2022, the Company and Simcere agreed to terminate the Simcere Agreement, effective March 30, 2022 .

In January 2022, the Company announced that Incyte elected to opt-out of its ex-U.S. development of MCLA-145, from the parties joint collaboration agreement executed in 2017. At inception of the collaboration, for the designated product candidate (MCLA-145), the Company retained the exclusive right to develop and commercialize products and product candidates in the United States, while Incyte obtained the exclusive right to develop and commercialize products and product candidates arising from such program outside the United States. For MCLA-145, the parties conducted and shared equally the costs of mutually agreed global development activities. Incyte's opt-out of ex-U.S. rights to MCLA-145 provides the Company the exclusive right to develop and commercialize potential MCLA-145 products globally. Under the collaboration, Incyte will continue to support the program for a limited time while ex-U.S. activities are transitioned to the Company, and Incyte will also retain a right to a residual royalty of up to 4% on sales of future commercialization of MCLA-145, if approved.

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

As of December 31, 2021, 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 €12,150,000, comprised of 67,500,000 common shares and 67,500,000 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.

Federal Forum Provision

Our Articles of Association provide that, unless we consent in writing to the selection of an alternative forum, the sole and exclusive forum for any complaint asserting a cause of action arising under the U.S. Securities Act of 1933, as amended, to the fullest extent permitted by applicable law, shall be the U.S. federal district courts.

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.

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

Our board of directors can invoke a cooling-off period of up to 250 days when shareholders, using their right to have items added to the agenda for a general meeting or their right to request a general meeting, propose an agenda item for our general meeting to dismiss, suspend or appoint one or more directors (or to amend any provision in our Articles of Association dealing with those matters) or when a public offer for our company is made or announced without our support, provided, in each case, that our board of directors believes that such proposal or offer materially conflicts with the interests of our company and its business. During a cooling-off period, our general meeting cannot dismiss, suspend or appoint directors (or amend the provisions in our Articles of Association dealing with those matters) except at the proposal of our board of directors. During a cooling-off period, our board of directors must gather all relevant information necessary for a careful decision-making process and at least consult with shareholders representing 3% or more of our issued share capital at the time the cooling-off period was invoked, as well as with our Dutch works council (if we or, under certain circumstances, any of our subsidiaries would have one). 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, our 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. Shareholders representing at least 3% of our issued share capital may request the Enterprise Chamber for early termination of the cooling-off period. The Enterprise Chamber must rule in favor of the request if the shareholders can demonstrate that:

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

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 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (No. 333-211497, No. 333-230708 and No. 333-254345) on Form S-8 and registration statements (No. 333-233383 and No. 333-255903) on Form S-3 of Merus N.V. of our report dated February 28, 2022, with respect to the consolidated financial statements of Merus N.V. and the effectiveness of internal control over financial reporting.

/s/ KPMG Accountants N.V.

Rotterdam, The Netherlands
February 28, 2022

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: February 28, 2022

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, 2021 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: February 28, 2022

By: /s/ Sven A. Lundberg

Sven (Bill) Ante Lundberg
President, Chief Executive Officer and
Principal Financial Officer
(Principal Executive Officer and
Principal Financial Officer)