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

FORM 10-Q

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

For the quarterly period ended September 30, 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)	**(Zip code)**

+31 85 016 2500
(Registrant's telephone number, including area code)

N/A
(Former name, former address and former fiscal year, if changed since last report)

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)**

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of October 29, 2021, the registrant had 38,807,463 common shares, nominal value €0.09 per share, outstanding.

PART I — FINANCIAL INFORMATION

PART II — OTHER INFORMATION

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the safe harbor provisions of 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. All statements other than statements of historical facts contained in this Quarterly Report on Form 10-Q 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," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including 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 anticipated impact of the COVID-19 pandemic on our business and operations, 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 are forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q 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 Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties, assumptions and other important factors, including those described under the sections in this Quarterly Report on Form 10-Q entitled "Summary Risk Factors," "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this Quarterly Report on Form 10-Q.

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.

SUMMARY RISK FACTORS

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

- We have incurred significant net losses since inception and we expect to continue to incur significant net losses for the foreseeable future.
- We have a limited operating history, have not successfully 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 phases of clinical trials may not be predictive of the success of later phases of clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.
- The clinical trial and regulatory approval processes are lengthy, time consuming and inherently unpredictable, and we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Our antibody candidates may have serious adverse, undesirable or unacceptable side effects which may delay or prevent marketing approval. If such side effects are identified during the development of our antibody candidates or following approval, if any, we may need to abandon our development of such antibody candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

- We depend on enrollment of patients in our clinical trials for our antibody candidates, including patients having NRG1 fusion tumors, which are rare, tumorigenic genomic events. If we are unable to enroll patients in our clinical trials or do so in a timely manner, including those patients having these rare tumorigenic events, our research and development efforts and business, financial condition and results of operations could be materially adversely affected.
- We rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations or CROs, to conduct our pre-clinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our antibody candidates and our business could be substantially harmed.

- Due to our limited resources and access to capital, we must, and have in the past decided to prioritize development of certain antibody candidates over other potential candidates. These decisions may prove to have been wrong and may adversely affect our revenues.
- The competition for qualified personnel is particularly intense in our industry. If we are unable to retain or hire key personnel, we may not be able to sustain or grow our business.

- We operate in highly competitive and rapidly changing industries, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- Our success depends on our ability to protect our intellectual property and our proprietary technologies. If we are unable to adequately protect our intellectual property and our proprietary technologies, or obtain and maintain issued patents which are sufficient to protect our product candidates and 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.
- Risks related to our ceasing to qualify as an emerging growth company and a smaller reporting company after December 31, 2021.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 159,121	$ 163,082
Marketable securities	150,617	44,673
Accounts receivable	1,642	46
Accounts receivable (related party)	1,595	1,623
Prepaid expenses and other current assets	6,747	8,569
Total current assets	319,722	217,993
Marketable securities	23,489	—
Property and equipment, net	3,450	4,115
Operating lease right-of-use assets	4,143	3,907
Intangible assets, net	2,471	2,843
Deferred tax assets	219	410
Other assets	2,433	1,949
Total assets	$ 355,927	$ 231,217
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 5,401	$ 3,126
Accrued expenses and other liabilities	27,526	21,803
Income taxes payable	—	206
Current portion of lease obligation	1,506	1,432
Current portion of deferred revenue	18,649	625
Current portion of deferred revenue (related party)	18,451	19,554
Total current liabilities	71,533	46,746
Lease obligation	2,647	2,521
Deferred revenue, net of current portion	14,810	237
Deferred revenue, net of current portion (related party)	61,168	79,450
Total liabilities	150,158	128,954
Commitments and contingencies - Note 6		
Stockholders' equity:		
Common shares, €0.09 par value; 67,500,000 and 45,000,000 shares authorized as at September 30, 2021 and December 31, 2020, respectively; 38,605,096 and 31,602,953 shares issued and outstanding as at September 30, 2021 and December 31, 2020, respectively	$ 3,976	$ 3,211
Additional paid-in capital	656,536	490,093
Accumulated other comprehensive income	(2,236)	9,071
Accumulated deficit	(452,507)	(400,112)
Total stockholders' equity	205,769	102,263
Total liabilities and stockholders' equity	$ 355,927	$ 231,217

See accompanying notes to the Unaudited Condensed Consolidated Financial Statements.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Collaboration revenue	$ 5,919	$ 695	$ 12,636	$ 1,207
Collaboration revenue (related party)	7,750	7,875	21,762	19,720
Total revenue	13,669	8,570	34,398	20,927
Operating expenses:				
Research and development	26,018	17,538	71,436	48,234
General and administrative	10,171	9,136	30,073	26,061
Total operating expenses	36,189	26,674	101,509	74,295
Operating loss	(22,520)	(18,104)	(67,111)	(53,368)
Other (loss) income, net:				
Interest (expense) income, net	(25)	(12)	(158)	367
Foreign exchange (losses) gains, net	7,756	(4,782)	15,434	(4,243)
Other losses, net	(75)	—	(460)	—
Total other (loss) income, net	7,656	(4,794)	14,816	(3,876)
Net loss before income taxes	(14,864)	(22,898)	(52,295)	(57,244)
Income tax (benefit) expense	(11)	177	100	305
Net loss	$ (14,853)	$ (23,075)	$ (52,395)	$ (57,549)
Other comprehensive income (loss):				
Currency translation adjustment	(5,391)	4,414	(11,307)	3,508
Comprehensive loss	$ (20,244)	$ (18,661)	$ (63,702)	$ (54,041)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.39)	$ (0.64)	$ (1.39)	$ (1.86)
Weighted-average common shares outstanding:				
Basic and diluted	38,513	29,061	37,708	29,014

See accompanying notes to the Unaudited Condensed Consolidated Financial Statements.

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

	Nine Months Ended September 30,	
	2021	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (52,395)	$ (57,549)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	946	830
Amortization of intangible assets	219	206
Foreign exchange (gain) loss	(14,181)	3,828
Loss on disposal of property and equipment	—	17
Stock-based compensation expense	12,290	6,327
Amortization of premium (discount) on investments	139	(30)
Deferred tax expense (benefit)	190	(2)
Changes in operating assets and liabilities:		
Accounts receivable	(1,718)	634
Operating lease right-of-use assets and lease obligations	(32)	2
Prepaid expenses and other current assets	(2,477)	(2,935)
Accounts payable	2,567	1,587
Accrued expenses and other liabilities	6,931	5,707
Deferred revenue	19,492	(14,187)
Net cash used in operating activities	**$ (28,029)**	**$ (55,565)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	$ (204,456)	$ (49,359)
Proceeds from maturities of marketable securities	74,129	42,831
Purchases of property and equipment	(537)	(858)
Net cash used in investing activities	**$ (130,864)**	**$ (7,386)**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of offering costs	$ —	$ (164)
Proceeds from issuance of common stock, net	129,398	—
Proceeds from issuance of common stock - Lilly	16,477	—
Proceeds from stock options exercised	9,041	915
Repurchase of restricted stock units	(285)	—
Short-swing profit disgorgement	282	—
Net cash provided by financing activities	**$ 154,913**	**$ 751**
Foreign exchange impact on cash, cash equivalents and restricted cash	19	3,767
Net decrease in cash, cash equivalents and restricted cash	(3,961)	(58,433)
Cash, cash equivalents, and restricted cash, beginning of period	163,283	197,813
Cash, cash equivalents, and restricted cash, end of period	**$ 159,322**	**$ 139,380**
SUPPLEMENTAL DISCLOSURES:		
Non-cash right-of-use assets acquired from operating lease obligations	$ 1,662	$ —
Income taxes paid	$ 621	$ 235
Non-cash purchases of property, equipment and intangibles	$ —	$ 5
Non-cash issuance of stock options	$ 573	$ —
CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	$ 159,121	$ 139,179
Restricted cash included in non-current other assets	201	201
	$ 159,322	$ 139,380

See accompanying notes to the Condensed Consolidated Financial Statements.

MERUS N.V.
CONDENSED CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(UNAUDITED)
(Amounts in thousands, except share amounts)

	Common Stock		Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Shares	Amount	Capital	Deficit	Income (Loss)	Equity
Balance at January 1, 2020	28,882,217	$ 2,918	$ 441,395	$ (314,599)	$ 1,586	$ 131,300
Exercise of stock options and vesting of restricted stock units	127,205	13	589	—	—	602
Stock-based compensation	—	—	2,291	—	—	2,291
Currency translation adjustment	—	—	—	—	(3,107)	(3,107)
Net loss	—	—	—	(16,500)	—	(16,500)
Balance at March 31, 2020	29,009,422	2,931	444,275	(331,099)	(1,521)	114,586
Exercise of stock options and vesting of restricted stock units	37,922	4	287	—	—	291
Stock-based compensation	—	—	1,192	—	—	1,192
Currency translation adjustment	—	—	—	—	2,201	2,201
Net loss	—	—	—	(17,974)	—	(17,974)
Balance at June 30, 2020	29,047,344	2,935	445,754	(349,073)	680	100,296
Exercise of stock options and vesting of restricted stock units	27,192	3	19	—	—	22
Stock-based compensation	—	—	2,844	—	—	2,844
Currency translation adjustment	—	—	—	—	4,414	4,414
Net loss	—	—	—	(23,075)	—	(23,075)
Balance at September 30, 2020	29,074,536	$ 2,938	$ 448,617	$ (372,148)	$ 5,094	$ 84,501
Balance at January 1, 2021	31,602,953	$ 3,211	$ 490,093	$ (400,112)	$ 9,071	$ 102,263
Issuance of common stock, net	5,575,757	610	128,793	—	—	129,403
Issuance of common stock - Lilly	706,834	77	16,400	—	—	16,477
Exercise of stock options and vesting of restricted stock units	386,097	42	4,782	—	—	4,824
Repurchase of restricted stock units	—	—	(285)	—	—	(285)
Stock-based compensation	—	—	3,400	—	—	3,400
Currency translation adjustment	—	—	—	—	(9,391)	(9,391)
Net loss	—	—	—	(10,154)	—	(10,154)
Balance at March 31, 2021	38,271,641	3,940	643,183	(410,266)	(320)	236,537
Exercise of stock options and vesting of restricted stock units	172,939	19	1,885	—	—	1,904
Stock-based compensation	—	—	4,559	—	—	4,559
Currency translation adjustment	—	—	—	—	3,475	3,475
Net loss	—	—	—	(27,388)	—	(27,388)
Balance at June 30, 2021	38,444,580	$ 3,959	$ 649,627	$ (437,654)	$ 3,155	$ 219,087
Exercise of stock options and vesting of restricted stock units	160,516	17	2,296	—	—	2,313
Short-swing profit disgorgement			282			282
Stock-based compensation	—	—	4,331	—	—	4,331
Currency translation adjustment	—	—	—	—	(5,391)	(5,391)
Net loss	—	—	—	(14,853)	—	(14,853)
Balance at September 30, 2021	38,605,096	$ 3,976	$ 656,536	$ (452,507)	$ (2,236)	$ 205,769

See accompanying notes to the Unaudited Condensed Consolidated Financial Statements.

1. Overview

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 $452.5 million as of September 30, 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.

On January 21, 2021, the Company completed an offering of common shares in which the Company sold 5,575,757 common shares, including 727,272 common shares pursuant to the underwriters' option to purchase additional shares, at a price to the public of $24.75 for aggregate net proceeds of $129.4 million.

Based on the Company's current operating plan, the Company expects that its existing cash and cash equivalents and marketable securities of $333.2 million as of September 30, 2021, will fund the Company's operations into the second half of 2024.

2. Summary of Significant Accounting Policies

The principal accounting policies applied in the preparation of these unaudited condensed consolidated financial statements are described in the Company's audited financial statements as of and for the year ended December 31, 2020, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021 (the "Annual Report on Form 10-K"). There have been no material changes in the Company's significant accounting policies during the nine months ended September 30, 2021.

Basis of Presentation

The Company prepared its unaudited consolidated condensed 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").

The unaudited condensed consolidated financial statements include the accounts of Merus N.V. and its wholly owned, controlled subsidiary, Merus US, Inc. All intercompany transactions and balances of subsidiaries have been eliminated in consolidation. In the opinion of management, these financial statements reflect all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the unaudited condensed consolidated financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The three months ended September 30, 2021 and 2020 are referred to as the third quarter of 2021 and 2020, respectively. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

The unaudited condensed consolidated financial statements presented herein do not contain the required disclosures under U.S. GAAP for annual financial statements. Therefore, these unaudited condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended December 31, 2020, included in the Annual Report on Form 10-K.

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 securities balances. After considering the Company's current research and development plans, 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 September 30, 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.

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 period.

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, the adoption of this standard had no impact on amounts or disclosures previously reported or during the period.

3. Investments in Debt Securities

The following tables summarize the Company's investments in debt securities and their presentation in the condensed consolidated balance sheet:

	September 30, 2021	December 31, 2020
	(in thousands)	
Money market funds	$ 29,890	$ 10,156
Corporate paper and notes	154,792	27,978
U.S. government agency securities	1,092	9,150
U.S. treasuries	25,222	15,043
Total	$ 210,996	$ 62,327
Fair value of debt securities	$ 210,944	$ 62,328

	September 30, 2021	December 31, 2020
	(in thousands)	
Cash equivalents	$ 36,890	$ 17,654
Current marketable securities	150,617	44,673
Non-current marketable securities	23,489	—
Total	$ 210,996	$ 62,327

The Company does not intend to sell and believes it is unlikely that the Company will be required to sell the above investments before recovery of their amortized cost bases, which may be at maturity. The Company determined that there was no material change in the credit risk of any of its investments.

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. Supplemental Balance Sheet Information

Prepaid expenses and other current assets consisted of the following:

	September 30, 2021	December 31, 2020
	(In thousands)	
Prepaid clinical and manufacturing costs	$ 2,762	$ 4,971
Prepaid general and administrative expenses	2,484	2,460
Interest receivable	362	80
Other	1,139	1,058
Total	$ 6,747	$ 8,569

Accrued expenses and other liabilities consisted of the following:

	September 30, 2021	December 31, 2020
	(In thousands)	
Accrued research and development expenses	$ 22,383	$ 15,372
Accrued general and administrative expenses	1,570	1,566
Accrued personnel costs	3,128	4,854
Other	445	11
Total	$ 27,526	$ 21,803

5. Income Taxes

The Company files income tax returns in the U.S. federal and Massachusetts jurisdictions as well as in the Netherlands. The components of the income tax expense (benefit) from continuing operations are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands)		(In thousands)	
U.S. federal	$ 50	$ 126	$ (62)	$ 164
U.S. state	19	131	(28)	143
Total current income tax (benefit) expense	$ 69	$ 257	$ (90)	$ 307
U.S. federal	$ (61)	$ (56)	$ 146	$ 6
U.S. state	(19)	(24)	44	(8)
Total deferred income tax (benefit) expense	$ (80)	$ (80)	$ 190	$ (2)
Total income tax (benefit) expense	$ (11)	$ 177	$ 100	$ 305

After consideration of all positive and negative evidence, we believe that it is more-likely-than-not that the Netherlands deferred tax assets, that are not supported by reversing temporary differences, will not be realized. As a result, we established a full valuation allowance against deferred tax assets of the Netherlands.

6. Commitments and Contingencies

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 to be scheduled 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.

7. Leases

The Company has noncancelable operating leases for offices and lab spaces expiring at various dates through 2026.

The components of lease expense for the three and nine months ended September 30, 2021 and 2020 are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands)		(In thousands)	
Lease cost				
Operating lease cost	$ 440	$ 411	$ 1,292	$ 1,203
Variable lease cost	100	93	323	282
Total lease cost included in operating expenses	$ 540	$ 504	$ 1,615	$ 1,485
Other information				
Cash paid for amounts included in the measurement of lease liabilities included in operating cash flows	$ 433	$ 412	$ 1,296	$ 1,201

During the nine months ended September 30, 2021, the Company signed a lease amendment (the "Amendment") for offices and lab spaces in Utrecht, Netherlands. The Amendment extended the lease term by approximately 1.5 years ending at the end of March 2023 and did not include additional right-of-use other than the extended lease term.

8. 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. At inception of the arrangement, Lilly had selected its first target.

The objective of each program would be 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 Eli 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.

As of September 30, 2021 no milestones have been achieved.

Incyte

On January 23, 2017, the Company completed the sale of shares and exchange of a license with Incyte Corporation ("Incyte"). The Company initially deferred $152.6 million of the transaction price allocated to the license and related 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 Company's intellectual property covering its Biclonics® technology platform for the generation of potential product candidates. Development milestones, commercialization milestones and royalties are variable consideration, fully constrained, to be recognized in future periods in accordance with the Company's revenue recognition policy. Cost reimbursements for research services are recognized as they are performed over time as these are considered a separate performance obligation.

At September 30, 2021, the Company is currently engaged in clinical development activities for MCLA-145 and developing pre-clinical candidates for the other programs. During the three months ended September 30, 2021, the Company received a $1.0 million payment for achieving a development milestone.

ONO

On March 14, 2018, 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. 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. Certain of 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.

Amounts related to the provision of a license are amortized over the intended period of use.

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 Company received an upfront, non-refundable payment of $2.75 million, relating to three separate research programs. The Company may be entitled to future development milestone payments. The Company will be eligible to receive tiered royalty payments on sales of any products resulting from the collaboration in China from Simcere. Simcere will be eligible to receive tiered royalty payments on sales outside of China from the Company.

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

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

To date, the Company has achieved three milestones under this agreement and has received an aggregate of $1.8 million in milestone payments. Research and development activities are on-going as of September 30, 2021.

Contract Assets and Liabilities

The following tables provide amounts by year indicated and by line item included in the Company's accompanying condensed 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	6,419	61,112	809	61,921
Cash receipts	(6,419)	(61,107)	(308)	(61,415)
Adjustments	—	—	—	—
Foreign exchange	—	(5)	(6)	(11)
Balance at September 30, 2021	—	—	541	541
Unbilled receivables				
Balance at January 1, 2021	$ 1,623	$ —	$ —	$ —
Accrued receivables	6,501	2,112	960	3,072
Billings	(6,418)	(1,112)	(809)	(1,921)
Adjustments	—	—	—	—
Foreign exchange	(111)	(40)	(10)	(50)
Balance at September 30, 2021	1,595	960	141	1,101
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	(14,260)	(8,911)	(501)	(9,412)
Foreign exchange	(5,125)	(1,483)	(31)	(1,514)
Balance at September 30, 2021	79,619	33,129	330	33,459
Less: current portion	(18,451)	(18,319)	(330)	(18,649)
Non-current balance at September 30, 2021	61,168	14,810	—	14,810

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 more fully described in Note 10.

Contract Revenues and Expenses

	Three Months Ended September 30, 2021 (In thousands)			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 4,745	$ 4,000	$ 150	$ 4,150
Reimbursement revenue	2,005	983	286	1,269
Milestones	1,000	—	500	500
Total collaboration revenue	$ 7,750	$ 4,983	$ 936	$ 5,919
Operating expenses:				
Research and development expense	$ 362	$ —	$ 151	$ 151
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	$ 362	$ —	$ 151	$ 151
Revenue recognized that was included in deferred revenue at the beginning of the period	$ 4,745	$ 4,000	$ 149	$ 4,149

	Three Months Ended September 30, 2020 (In thousands)			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 4,683	$ —	$ 204	$ 204
Reimbursement revenue	3,192	—	—	—
Milestones	—	—	491	491
Total collaboration revenue	$ 7,875	$ —	$ 695	$ 695
Operating expenses:				
Research and development expense	$ 666	$ —	$ —	$ —
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	$ 666	$ —	$ —	$ —
Revenue recognized that was included in deferred revenue at the beginning of the period	$ 4,683	$ —	$ 207	$ 207

	Nine Months Ended September 30, 2021 (In thousands)			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 14,270	$ 8,912	$ 500	$ 9,412
Reimbursement revenue	6,492	2,115	609	2,724
Milestones	1,000	—	500	500
Total collaboration revenue	$ 21,762	$ 11,027	$ 1,609	$ 12,636
Operating expenses:				
Research and development expense	$ 1,010	$ —	$ 151	$ 151
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	$ 1,010	$ —	$ 151	$ 151
Revenue recognized that was included in deferred revenue at the beginning of the period	$ 14,270	$ —	$ 499	$ 499

	Nine Months Ended September 30, 2020 (In thousands)			
	Related Party	Third Party		
	Incyte	Lilly	Other	Total
Upfront payments	$ 13,414	$ —	$ 687	$ 687
Reimbursement revenue	6,306	—	(12)	(12)
Milestones	—	—	532	532
Total collaboration revenue	$ 19,720	$ —	$ 1,207	$ 1,207
Operating expenses:				
Research and development expense	$ 1,618	$ —	$ —	$ —
General and administrative expense	—	—	—	—
Total operating expenses from collaborations	$ 1,618	$ —	$ —	$ —
Revenue recognized that was included in deferred revenue at the beginning of the period	$ 13,414	$ —	$ 730	$ 730

9. Employee Benefits

Stock-Based Compensation

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
	(In thousands)		(In thousands)	
Research and development	$ 1,619	$ 915	$ 5,106	$ 1,677
General and administrative	2,712	1,929	7,184	4,650
Total	$ 4,331	$ 2,844	$ 12,290	$ 6,327

The weighted-average grant date fair value of options, estimated as of the grant date using the Black Scholes option pricing model was $17.27 per option for the 1,389,310 options granted during the nine months ended September 30, 2021. The following assumptions were used to estimate the fair value of the options granted during the nine months ended September 30, 2021.

Volatility	86.6%
Risk-free interest rate	0.6%
Expected holding period (in years)	6.1
Dividend yield	-

In addition, the Company granted 24,976 RSUs during the nine months ended September 30, 2021 with a weighted average grant date fair value of $23.40 per unit.

Executive Settlement

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 Second Amendment to the Settlement Agreement, extending Mr. Throsby's consulting services period to November 30, 2021. The Second 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 $0.5 million net loss associated with the derivative instrument included as other losses, net in the statement of operations for the nine months ended September 30, 2021

10. Related Party Transactions

The Company has entered into the Incyte collaboration and license agreement and the Incyte share subscription agreement with amounts related to transactions under the arrangement disclosed in Note 8 and the arrangement described in the Company's annual consolidated financial statements for the year ended December 31, 2020. Incyte is a shareholder with holdings representing approximately 9.2% of the outstanding shares of the Company as of September 30, 2021, and 10.1% as of December 31, 2020.

Item 2. 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 unaudited condensed consolidated financial statements included in this Quarterly Report on Form 10-Q, which have been prepared by us in accordance with accounting principles generally accepted in the United States, or U.S. GAAP, and with Regulation S-X promulgated under the Securities Exchange Act of 1934, as amended, or Exchange Act. This discussion and analysis is intended to assist in providing an understanding of our financial condition, changes in financial condition and results of operations and should be read in conjunction with these unaudited condensed consolidated financial statements and the notes thereto included elsewhere in this Quarterly Report on Form 10-Q and the discussion and analysis included in our Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 16, 2021 (the "Annual Report on Form 10-K"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, 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 factors, including those factors set forth in Part II, Item 1A. Risk Factors of this Quarterly Report on Form 10-Q, 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 multi-specific antibody candidates are generated from our proprietary technology platforms, which are able to generate a diverse array of antibody binding domains, or Fabs, against virtually any target. Each antibody binding domain consists of a target-specific heavy chain paired with a common light chain. Multiple binding domains can be combined to produce novel bispecific and trispecific antibodies that bind to a wide range of targets and display novel and innovative biology. These platforms referred to as Biclonics® and Triclonics® allow us to generate large numbers of diverse panels of bispecific and trispecific antibodies, respectively, which can then be functionally screened in large-scale cell-based assays to identify those unique molecules that possess novel biology, which we believe are best suited for a given therapeutic application. Further, by binding to multiple targets, Biclonics® and Triclonics® may be designed to provide a variety of mechanisms of action, including simultaneously blocking receptors that drive tumor cell growth and survival and mobilizing the patient's immune response by engaging T cells, and/or activating various killer cells to eradicate tumors.

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

Using our Biclonics® platform we have produced, and are currently developing, the following candidates: MCLA-128, or zenocutuzumab, for the potential treatment of solid tumors that harbor Neuregulin 1 (NRG1) gene fusions; MCLA-158 or petosemtamab, for the potential treatment of solid tumors; MCLA-145, developed in collaboration with Incyte Corporation, for the potential treatment of solid tumors, and MCLA-129 for the potential treatment of solid tumors. Furthermore, we have a pipeline of proprietary antibody candidates in pre-clinical development and intend to further leverage our Biclonics® technology platform and Triclonics® technology platform to identify additional multi-specific antibody candidates and advance them to 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 II, Item 1A of this Quarterly Report on Form 10-Q. 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 $333.2 million as of September 30, 2021 will be sufficient to fund our operations into the second half of 2024.

Clinical Programs

Zenocutuzumab, or "Zeno" (MCLA-128: HER3 x HER2 Biclonics®)

Phase 2 part of the phase 1/2 trial continues: update planned for 1H 2022

In the third quarter of 2021, we met with the 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 fusion (NRG1+) cancers, and to discuss the development plan for Zeno. Merus and the FDA officials discussed the available Zeno monotherapy data and a potential data package to support a biologics license application (BLA) submission.

- Merus designed the phase 1/2 eNRGY trial to support potential registration in either a tumor-specific or a tumor agnostic NRG1+ indication(s). Based on the 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 Zeno in patients with previously treated NRG1+ cancers. We also believe that, if the rate of enrollment and efficacy remains consistent, a sufficient number of patients will be enrolled in the eNRGy trial and EAP, and will have accrued sufficient follow up by mid-2022, that could provide a potential registrational data set.

As of September 1, 2021, more than 80 patients with NRG1+ cancers have been treated with Zeno monotherapy in the eNRGy trial and EAP.

We plan to provide a further clinical program update in the first half of 2022.

In August 2020, Zeno was granted Orphan Drug Designation by the U.S. Food and Drug Administration 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.

Also in the third quarter of 2021, we presented preclinical data on Zeno at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. The bispecific HER2/HER3 antibody Zeno blocked cell growth 100 fold more potently than the bivalent HER3 antibody derived from Zeno, in an NRG1 driven growth assay, and potently blocked NRG1-fusion mediated downstream signaling and growth in vitro and in vivo models. Zeno induced both antibody-dependent cellular cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP) mediated killing of cancer cells in a dose-dependent manner.

MCLA-158 (petosemtamab: Lgr5 x EGFR Biclonics®): Solid Tumors
Phase 1 trial continues: dose expansion cohorts ongoing: update planned for 2022

The phase 1 open label, multicenter clinical trial of MCLA-158 is ongoing in the dose expansion phase. Enrollment of patients continues.

We shared early interim clinical data of our MCLA-158 program in patients with advanced HNSCC at the 2021 AACR-NCI-EORTC Virtual International Conference on Molecular Targets and Cancer Therapeutics. Among 10 patients with previously treated advanced head and neck squamous cell carcinoma (HNSCC), as of the August 9, 2021 safety and efficacy data cutoff, the median age was 65 and the median number of prior lines of therapy was two. 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 a best response of partial response, with one achieving complete response after the data cutoff date. Tumor reduction was observed in the target lesions for all seven patients. The safety results presented for MCLA-158 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 (AEs) were infusion related reactions with 72% any grade and 7% grade 3 or greater. Mild to moderate skin toxicity (3% grade ≥3) was also observed.

We plan to provide an update at a medical conference in the in 2022.

MCLA-145 (CD137 x PD-L1 Biclonics®): Solid Tumors
Phase 1 trial continues: update planned for ESMO Immuno-Oncology Congress 2021

The phase 1, open-label, single-agent clinical trial of MCLA-145 is ongoing and consists of a dose escalation phase, to be followed by a planned dose expansion phase. MCLA-145 is the first drug candidate co-developed under our global collaboration and license agreement with Incyte Corporation, which permits the development and commercialization of up to 11 bispecific and monospecific antibodies from the Merus Biclonics® platform. We retain full rights to develop and commercialize MCLA-145, if approved, in the United States; and Incyte holds full rights to develop and commercialize MCLA-145 outside the United States. We plan to provide an update in the fourth quarter of 2021 at the ESMO Immuno-Oncology Congress.

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
Phase 1 trial ongoing in patients with solid tumors.

The phase 1/2, open-label, single-agent clinical trial of MCLA-129 is ongoing and consists of a dose escalation phase, to be followed by planned expansion cohorts evaluating MCLA-129 for the treatment of patients with advanced non-small cell lung cancer (NSCLC) and other solid tumors. MCLA-129 is a Biclonics®, which binds to EGFR and c-MET and is being investigated for the treatment of solid tumors. EGFR is an important oncogenic driver in many cancers, and upregulation of c-MET signaling has been associated with resistance to EGFR inhibition. We plan to provide an update after the recommended phase 2 dose has been reached.

MCLA-129 is subject to a collaboration and license agreement with Betta Pharmaceuticals Co. Ltd. (Betta), which permits Betta to exclusively develop MCLA-129 in China, while we retain full ex-China rights.

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.

Impact of COVID-19 Pandemic

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

While we are currently continuing our ongoing clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials and source verification of clinical data required for presentation of clinical data for zenocutuzumab, MCLA-158, MCLA-145 and MCLA-129. We continued to observe a moderate to high impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic during the quarter ended September 30, 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 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 of our antibody candidates, including those associated with our collaborations with Incyte, Lilly, Betta and Simcere, which may delay or prevent their potential clinical development. While we currently do not anticipate any interruptions in our clinical trial supply of drug candidates, it is possible that the COVID-19 pandemic and response efforts may cause delays or otherwise 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 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 II, Item 1A of this Quarterly Report on Form 10-Q.

Collaborations

Refer to Item 1, "Business—Our Collaborations" and Note 12, "Collaborations," of the notes to our consolidated financial statements included in our Annual Report on Form 10-K and Note 8, "Collaborations," to our unaudited condensed consolidated interim financial statements elsewhere in this Quarterly Report on Form 10-Q for a description of the key terms of our arrangements.

Discussion and Analysis of our Results of Operations

Comparison of the three and nine months ended September 30, 2021 and 2020

Revenue

The following is a comparison of revenue:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In millions)			(In millions)		
Incyte	$ 7.8	$ 7.9	$ (0.1)	$ 21.8	$ 19.7	$ 2.1
Lilly	5.0	—	5.0	11.0	—	11.0
Other	0.9	0.7	0.2	1.6	1.2	0.4
Total revenue	13.7	8.6	5.1	34.4	20.9	13.5

Collaboration revenue for the three months ended September 30, 2021 increased by $5.1 million as compared to the three months ended September 30, 2020, substantially as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues that commenced in the first quarter of 2021. The change in exchange rates did not significantly impact collaboration revenue.

Collaboration revenue for the nine months ended September 30, 2021 increased by $13.5 million as compared to the nine months ended September 30, 2020, primarily as a result of an increase from a Lilly upfront payment amortization and reimbursement revenues of $11.0 million that commenced in the first quarter of 2021, and $1.0 million of milestone revenue related to Incyte reflecting activities in the period. The change in exchange rates did not significantly impact collaboration revenue.

As of September 30, 2021, we had total deferred revenue of $113.1 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and Lilly collaboration agreement and is expected to be recognized over the next five and three years, respectively.

Operating Expenses

The following is a comparison of operating expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In millions)			(In millions)		
Research and development	$ 26.0	$ 17.5	$ 8.5	$ 71.4	$ 48.2	$ 23.2
General and administrative	10.2	9.1	1.1	30.1	26.1	4.0
Total operating expenses	$ 36.2	$ 26.6	$ 9.6	$ 101.5	$ 74.3	$ 27.2

Research and development expense for the three months ended September 30, 2021 increased by $8.5 million as compared to the three months ended September 30, 2020, primarily as a result of an increase in clinical and manufacturing costs related to our programs and stock-based compensation.

Research and development expense for the nine months ended September 30, 2021 increased by $23.2 million as compared to the nine months ended September 30, 2020, primarily as a result of an increase in clinical and manufacturing costs related to our programs and stock-based compensation.

General and administrative expense for the three months ended September 30, 2021 increased by $1.1 million as compared to the three months ended September 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses, partially offset by decreases in legal and depreciation expenses.

General and administrative expense for the nine months ended September 30, 2021 increased by $4.0 million as compared to the nine months ended September 30, 2020, primarily as a result of an increase in stock-based compensation and other personnel related expenses as well as facilities and professional fees, partially offset by decreases in legal and IP related costs and depreciation expenses.

Other (Loss) Income, Net

The following is a comparison of other (loss) income, net:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In millions)			(In millions)		
Interest (expense) income, net	$ —	$ —	$ —	$ (0.1)	$ 0.4	$ (0.5)
Foreign exchange (losses) gains, net	7.8	(4.8)	12.6	15.4	(4.2)	19.6
Other losses, net	(0.1)	—	(0.1)	(0.5)	—	(0.5)
Total other (loss) income, net	$ 7.7	$ (4.8)	$ 12.5	$ 14.8	$ (3.8)	$ 18.6

Other (loss) income, net consists of interest earned and fees paid on our cash and cash equivalents held on account, accretion of investment earnings and net foreign exchange (losses) gains on our foreign denominated cash, cash equivalents and marketable securities. Other gains or losses relate to the issuance and settlement of financial instruments.

Income Tax Expense

The following is a comparison of income tax expense:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	Change	2021	2020	Change
	(In millions)			(In millions)		
Current	$ 0.1	$ 0.3	$ (0.2)	$ (0.1)	$ 0.3	$ (0.4)
Deferred	(0.1)	(0.1)	—	0.2	—	0.2
Total tax expense (benefit), net	$ —	$ 0.2	$ (0.2)	$ 0.1	$ 0.3	$ (0.2)

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 we believe it is not more likely than not that they will be recovered.

Net Loss

Net loss for the three and nine months ended September 30, 2021 was $14.9 million and $52.4 million, respectively, compared to net loss for the three and nine months ended September 30, 2020 of $23.1 million and $57.5 million, respectively. The change in net loss was primarily due to the change in collaboration revenue, changes in operating expenses and changes in other (loss) income, net, as discussed above.

Material Changes in Financial Condition

Sources of Cash

As of September 30, 2021, we had $333.2 million in cash, cash equivalents and marketable securities that are available to fund our current 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 and

research license 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.

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

On January 21, 2021, the Company entered into an underwriting agreement with Jefferies LLC and SVB Leerink LLC, as representatives of the several underwriters named therein (collectively, the "Underwriters"), in connection with the issuance and sale by the Company in a public offering of 4,848,485 common shares of the Company, nominal value €0.09 per share, at a public offering price of $24.75 per share, less underwriting discounts and commissions. The Company also granted the Underwriters an option exercisable for 30 days to purchase up to an additional 727,272 common shares at the public offering price, less underwriting discounts and commissions. On January 21, 2021, the Underwriters exercised this option in full. The closing of the offering occurred on January 25, 2021, resulting in aggregate net proceeds to the Company of $129.4 million.

Funding Requirements

Our primary uses of capital are, clinical trial costs, chemistry manufacturing and control costs to manufacture and supply drug product for our clinical trials, third-party research and development services, laboratory and related supplies, financial services, legal and other regulatory expenses and general overhead costs.

Because our product candidates are in various stages of clinical and pre-clinical development and the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or whether, or when, we may achieve profitability. In addition, the magnitude and duration of the COVID-19 pandemic and its impact on our liquidity and future funding requirements is uncertain as of the filing date of this Quarterly Report on Form 10-Q, as the pandemic continues to evolve globally. See "Impact of COVID-19 Pandemic" above 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 II, Item 1A of this Quarterly Report on Form 10-Q for a further discussion of the possible impact of the COVID-19 pandemic on our business.

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, license agreements, other business development opportunities with third parties.

Except for any obligations of our collaborators or licensees to make license, milestone or royalty payments under our agreements with them, we do not have any committed external sources of liquidity and currently have no credit facility. To the extent that we raise additional capital through the future sale of equity or debt, the ownership interest of our stockholders may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. 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, license agreements 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 development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Outlook

Based on our current operating plan, research and development plans and our timing expectations related to the progress of our programs, we expect that our existing cash, cash equivalents and marketable securities as of September 30, 2021 will fund the Company's operations into the second half of 2024, without giving effect to any potential milestone payments we may receive under our collaboration and license agreements. 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 and in light of the

uncertainties associated with the magnitude and duration of the COVID-19 pandemic. As a result, we could use our capital resources sooner than we expect.

Cash Flows

The following is a summary of cash flows:

	Nine Months Ended September 30,		
	2021	2020	Change
	(In millions)		
Net cash used in operating activities	$ (28.0)	$ (55.6)	$ 27.6
Net cash used in investing activities	(130.9)	(7.4)	(123.5)
Net cash provided by financing activities	154.9	0.8	154.1

Net cash used in operating activities during the nine months ended September 30, 2021 decreased by $27.6 million as compared to the nine months ended September 30, 2020, primarily due to operating cash receipts related to revenue arrangements principally from the receipt of payments received from Eli Lilly of which $43.5 million relates to deferred revenue, partially offset by operating expenses during the period.

Net cash used in investing activities during the nine months ended September 30, 2021 principally reflects $204.5 million of purchases of marketable securities partially offset by maturities of marketable securities of $74.1 million.

Net cash provided by financing activities during the nine months ended September 30, 2021 increased primarily due to proceeds received from the issuance of common stock of $129.6 million, proceeds from the stock issuance to Eli Lilly of $16.5 million, and an increase in stock option exercise proceeds of $8.1 million.

Critical Accounting Policies and Use of Estimates

Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies” in our Annual Report on Form 10-K and in Note 2 to our consolidated financial statements included in the Annual Report on Form 10-K. As disclosed in Note 2 to our consolidated financial statements included in the Annual Report on Form 10-K, the preparation of financial statements in conformity with U.S. GAAP 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. During the period covered by this Quarterly Report on Form 10-Q, there were no material changes to our critical accounting policies from those discussed in our Annual Report on Form 10-K, other than updating our use of the option pricing model and associated estimates as described in Note 9 to our unaudited condensed consolidated interim financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recently Adopted Accounting Pronouncements

For detailed information regarding recently issued accounting pronouncements and the expected impact on our condensed consolidated financial statements, see Note 2, *Summary of Significant Accounting Policies—Pending Accounting Pronouncements*, in the accompanying notes to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable as a Smaller Reporting Company.

Item 4. 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, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, 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 financial officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

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) during the quarter ended September 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

See Note 6, *Commitments and Contingencies*, in the accompanying notes to the unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q.

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

Item 1A. Risk Factors

Careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC, in evaluating our company and our business. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition and results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing our company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition and results of operations.

Risks Related to Our Business and Industry

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

We are a clinical-stage oncology company with a limited operating history. We have incurred net losses of $52.4 million, and $57.5 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021, we had an accumulated deficit of $452.5 million. Our losses have resulted principally from expenses incurred in research and development of our antibody candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing, single agent, Phase 1/2 eNRGy clinical trial of zenocutuzumab, our most advanced bispecific antibody candidate, for the treatment of solid tumors harboring neuregulin 1 (NRG1) gene fusions and conclude our ongoing Phase 2 clinical trial for the treatment of metastatic breast cancer in combination with other therapies;
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors, which is being co-developed with Incyte;
- 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 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 are in the early stages of development of our antibody candidates, and we have not completed development of any Biclonics® or any other drugs or biologics.

To become and remain profitable, we must succeed in developing and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing pre-clinical testing and clinical trials of our 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 most of these activities. We may never succeed in these activities and, even if we do, may never generate revenue that is significant enough to achieve profitability.

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

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of zenocutuzumab, MCLA-158, 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 September 30, 2021 will be sufficient to fund our operations into the second half of 2024. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost, progress and results of our ongoing clinical trials of zenocutuzumab and the phase 1 clinical trials of MCLA-158, MCLA-145 and the phase 1/2 clinical trial of MCLA-129;
- the success of our collaboration with Incyte to develop monospecific and bispecific antibodies candidates, including our ongoing Phase 1 clinical trial for MCLA-145;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our antibody candidates to the extent any receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any potential future claims by third parties that we are alleged to be infringing upon their intellectual property rights;

- the costs and timing of securing, maintaining and/or obtaining freedom to operate for our technologies and products;
- the revenue, if any, received from commercial sales of our antibody candidates to the extent any receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including our existing collaborations and any other future licensing or collaboration arrangements for any of our antibody candidates.

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

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

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

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

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

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

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

We have not received regulatory approval for a therapeutic based on a full-length human bispecific or trispecific IgG approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Biclonics® and Triclonics® may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA, the

EMA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on Biclonics® and Triclonics® therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our antibody candidates.

Our Biclonics® and Triclonics® technology platforms rely on third parties for biological materials. Some biological materials have not always met our expectations or requirements, and any disruption in the supply of these biological materials could materially adversely affect our business. Although we have control processes and screening procedures, biological materials are susceptible to damage and contamination and may contain active pathogens. Improper storage of these materials, by us or any third-party suppliers, may require us to destroy some of our biological raw materials or antibody candidates.

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

We may seek to identify patient subsets within a disease category that may derive selective and meaningful benefit from the antibody candidates we are developing. Through collaborations or license agreements, 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 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 would have an adverse effect on our ability to derive revenues from sales of our products. In addition, the diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic that we anticipate using in connection with development and commercialization of our antibody candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative companion diagnostic test for use in connection with the development and commercialization of our antibody candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our antibody candidates.

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

Since our inception in 2003, we have devoted a significant portion of our resources to developing zenocutuzumab, MCLA-158, MCLA-145, MCLA-129 and our other antibody candidates, building our intellectual property portfolio, developing our clinical manufacturing supply chain, generating and enhancing our Biclonics® technology platform, generating our Triclonics® technology platform, planning our business, raising capital and providing general and administrative support for these operations. While we have ongoing clinical trials for zenocutuzumab, MCLA-158, 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 2 clinical trial or any Phase 3 or other pivotal clinical trials, obtain regulatory approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf or conduct sales and marketing activities necessary for successful product commercialization. Additionally, we expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

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

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

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

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our antibody candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. For example, the trading prices for our and other biopharmaceutical companies' stock have been highly volatile as a result of the COVID-19 pandemic. As a result, we may face difficulties raising capital through sales of our common stock and any such sales may be on unfavorable terms. If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any of our antibody candidates, if approved, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

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

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

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

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

Due to the international scope of our operations, fluctuations in exchange rates, particularly between the euro and the U.S. dollar, may adversely affect us. Although we are based in the Netherlands, we source research and development, manufacturing, consulting and other services from several countries. Further, potential future revenue may be derived from abroad, particularly from the United States. Additionally, our funding has mainly come from investors and collaborators mainly in the United States. As a result, our business and share price may be affected by fluctuations in foreign exchange rates between the euro and these other currencies, which

may also have a significant impact on our reported results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

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

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

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

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

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

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

Following a national referendum and enactment of legislation by the government of the United Kingdom, the United Kingdom formally withdrew from the EU on January 31, 2020 and entered into a transition period. On December 24, 2020, the United Kingdom and the EU announced that they had agreed to the terms of their future trading relationship in the EU—UK Trade and Cooperation Agreement ("TCA"), which became binding on both the EU and the United Kingdom on January 1, 2021, and 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 from home pursuant to guidance provided by national, state and local officials including the U.S. Center for Disease Control and Prevention (CDC) and European local health agencies, including the Dutch National Institute for Health and Environment or *Het Rijksinstituut voor Volksgezondheid en Milieu* (RIVM). For example, most of our employees located in the Netherlands 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 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 home 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 sourcing materials required for such manufacture that may be diverted for other purposes associated with COVID-19, or difficulties or delays associated with testing of our pre-clinical antibody candidates associated with our collaborations with Incyte, Eli Lilly and Simcere, which may delay or prevent their potential clinical development. Additionally, our collaborators, CROs and third-party suppliers may in the future experience closures and labor shortages, which may delay or prevent our development of our antibody candidates, including zenocutuzumab, MCLA-158, MCLA-145 and MCLA-129. Moreover, although our collaborators based in China and elsewhere have resumed operations, we may experience labor shortages associated with these chemistry manufacturing and controls, or pre-clinical development activities due to the current restrictions on travel and work globally, which may force us to reduce related workflows until such work and travel restrictions are lifted. Also, there can be no assurances that the applicable governments will not renew or extend these closures.

With respect to our clinical trials, the COVID-19 pandemic and related precautions have directly or indirectly impacted enrollment, new, planned clinical trial site openings, patient visits, and on-site monitoring of our clinical trials and source verification of clinical data required for presentation of clinical data for zenocutuzumab, MCLA-158, 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, Simcere, and our license agreements with Ono and our academic collaborators, which may experience laboratory closures causing delays in preclinical, translational and development studies that support our clinical programs and 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 and treat the disease.

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

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

To obtain the requisite regulatory approvals to market and sell any of our antibody candidates, we or any collaborator for such candidates must demonstrate through extensive pre-clinical studies and clinical trials that such candidates are safe, pure and potent in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of pre-clinical studies and early-stage clinical trials of our antibody candidates

may not be predictive of the results of later-stage clinical trials. Antibody candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through pre-clinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Our future clinical trial results may not be successful.

To date, we have not completed any clinical trials required for the approval of any of our antibody candidates. Although we are conducting ongoing clinical trials for zenocutuzumab, MCLA-158, 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;
- adding 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 different standards of diagnosis, screening and medical care.

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

From time to time, we may publish interim, preliminary or "top-line" data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. Further, as a result of the COVID-19 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, 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, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. A further safety update was 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 related to the treatment, most commonly infusion-related reactions and skin rash associated with mAb EGFR inhibitors. A safety update was provided for MCLA-158 on January 15, 2021, at ASCO GI, with a safety data cutoff 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 cutoff date of August 9, 2021 based on 29 patients with solid tumors treated at 1500mg every two weeks, with most common adverse events being infusion-related reactions. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 developed in collaboration with Incyte. Patients treated with MCLA-145 have experienced adverse events irrespective of causality including diarrhea, blood alkaline phosphatase increase, anemia, and hypoalbuminemia, lymphocyte count decrease, and white blood cell count decrease. Febrile neutropenia and elevated liver enzymes have been reported as serious adverse events.

Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials or enrollment could be paused, suspended or terminated and the FDA, the EMA, EEA Competent Authorities, or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our antibody candidates for any or all targeted indications. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Additionally, if any of our antibody candidates receives marketing approval and we or others later identify undesirable or unacceptable side effects caused by such products, a number of potentially significant negative consequences could result, including:

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

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

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For our Phase 1/2 clinical trial of zenocutuzumab in solid tumors, we are enrolling up to 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 approximately 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors. In the Phase 1/2 clinical trial of MCLA-129, we plan to enroll approximately 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, the EMA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our antibody candidates, our business will be substantially harmed.

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

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

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA, the EMA or comparable foreign regulatory authorities that an antibody candidate is safe and effective for its proposed indication;
- we may be unable to demonstrate that an antibody candidate's clinical and other benefits outweigh its safety risks;
- the FDA, the EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;
- the data collected from clinical trials of our antibody candidates may not be sufficient to support the submission of a BLA or other submission or to obtain regulatory approval in the United States, the EU or elsewhere;

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

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

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

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

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

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

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

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

If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory authority may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of

manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

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

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

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

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

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

A key element of our strategy is to use and expand our Biclonics® technology platform to build a pipeline of antibody candidates and progress these antibody candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in a pipeline of antibody candidates directed at various cancers, we may not be able to develop antibody candidates that are safe and effective.

Another important element of our strategy is to develop, use and exploit our Triclonics® technology platform to build a pipeline of trispecific antibody candidates and collaborate with third parties in potentially researching and developing these trispecific antibody candidates through pre-clinical and clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have resulted in proof of concept pre-clinical candidates, we may not be able to develop or monetize these trispecific antibody candidates or demonstrate in the clinic that they are safe and effective. Even if we are successful in continuing to build our bispecific and trispecific pipelines, the potential antibody candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop and begin to commercialize our bispecific antibody candidates or if we do not successfully develop, collaborate, license or begin to commercialize our trispecific antibody candidates, we will face difficulty in obtaining product revenues in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and efficacy. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional pre-clinical studies or clinical trials which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. Satisfying these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the

process for regulatory approval in other countries. We currently do not have any antibody candidates approved for sale in any jurisdiction, whether in the Netherlands, the United States or any other international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our products, if any, will be harmed.

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Approval of Our Antibody Candidates

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

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

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

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. 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, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA 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 December 31, 2021, unless additional Congressional

action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

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

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

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

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. 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 adopted a proposal recommending the postponement of the application of some of the provisions of the IVDR.

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 to review and or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global pandemic of COVID-19, on March 10, 2020 the FDA announced its intention to postpone most foreign inspections of manufacturing facilities and products through April 2020, and subsequently, on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. 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. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact

the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal Food, Drug and Cosmetic Act (FDCA) which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the U.S. federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report annually to the CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other health care professionals beginning in 2022, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members;
- analogous state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; and state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, and that require the tracking and reporting of gifts and other remuneration and items of value provided to healthcare professionals and entities; and
- European and other foreign law equivalents of each of the laws, including reporting requirements detailing interactions with and payments to healthcare providers.

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other

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

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

Most health care providers, including research institutions from which we or our collaborators obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by HITECH. Any person may be prosecuted under HIPAA's criminal provisions either directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered health care provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information.

In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. Even when HIPAA does not apply, according to the Federal Trade Commission (FTC), failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act. The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule. As such, we, our collaborators, research institutions, health care providers and other entities that provide personally identifiable information to us may be subject to state information security laws, and state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

The United States and global data protection landscape is rapidly evolving, and we may be affected by or subject to new or amended laws and regulations in the future. For example, California recently enacted legislation, the California Consumer Privacy Act (CCPA) which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for "protected health information" maintained by a covered entity or business associate, it may regulate or impact our processing of personal information depending on the context. Further, the CPRA was also recently voted into law by California residents. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required.

Our and our collaborators' clinical trial programs and research collaborations outside the U.S. may implicate international data protection laws, including, in Europe, the GDPR and local laws further implementing or supplementing the GDPR. The GDPR 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. During this period, the EMA 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.

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 EMA for other clinical assets, where supported by data in the appropriate indications that meet the criteria for orphan status. Even though we obtained orphan designation in the United States for zenocutuzumab 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 the EMA can subsequently approve the same drug with the same active moiety for the same condition if the FDA or the EMA concludes that the later drug is safer, more effective, or makes a major contribution to patient care. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we intend to seek orphan drug designation, when appropriate, we may not receive such designation.

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

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford products such as our antibody candidates, assuming approval. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize and attract additional collaborators to invest in the development of our antibody candidates. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future. Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our antibody candidate and other therapies as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our antibody candidate, pricing of existing drugs may limit the amount we will be able to charge for our antibody candidate. These payors may deny or revoke the reimbursement status of a given drug product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our antibody candidates and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse health care providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our antibody candidates, 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, the EMA or any other regulatory authority approves the marketing of any antibody candidates that we develop on our own or with a collaborator, physicians, healthcare providers, patients or the medical community may not accept or use them. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenues or any profits from

operations. The degree of market acceptance of any of our antibody candidates that are approved will depend on a variety of factors, including:

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

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

We currently have no marketing, sales or distribution infrastructure. If we are unable to develop sales, marketing and distribution capabilities on our own or through collaborations, we will not be successful in commercializing our antibody candidates.

We currently have no marketing, sales and distribution capabilities because all of our antibody candidates are still in clinical or pre-clinical development. If any of our antibody candidates are approved, we intend either to establish a sales and marketing organization with technical expertise and supporting distribution capabilities to commercialize our antibody candidates, or to outsource this function to a third party. Either of these options would be expensive and time consuming. These costs may be incurred in advance of any approval of our antibody candidates. In addition, we may not be able to hire a sales force that is sufficient in size or has adequate expertise in the medical markets that we intend to target. Any failure, 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. We may rely on outside consultants to provide advice on commercialization strategies, which may fail to deliver or provide effective guidance to maximize any commercial opportunity, if any, that may arise from our antibody candidates.

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

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

The ACA includes a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCIA) which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference

biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first approved by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first approved. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own pre-clinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

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

Jurisdictions in addition to the United States have established abbreviated pathways for regulatory approval of biological products that are biosimilar to earlier approved reference products. For example, the EU has had an established regulatory pathway for biosimilars since 2006.

The increased likelihood of biosimilar competition has increased the risk of loss of innovators' market exclusivity. Due to this risk, and uncertainties regarding patent protection, if our antibody candidates are approved for marketing, it is not possible to predict the length of market exclusivity for any particular product with certainty based solely on the expiration of the relevant patent(s) or the current forms of regulatory exclusivity. It is also not possible to predict changes in United States regulatory law that might reduce biological product regulatory exclusivity. The loss of market exclusivity for a product would likely materially and negatively affect revenues and we may not generate adequate or sufficient revenues from them or be able to reach or sustain profitability.

Risks Related to Our Dependence on Third Parties

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

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

Further, these investigators and CROs are not our employees and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our antibody candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our antibody candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of any antibody candidates that we develop. Moreover, as a result of the COVID-19 pandemic, certain of our third-party CROs have been affected and in some instances have experienced cessation or mitigation of activity and may experience closures and labor shortages, which may negatively affect our pre-clinical and clinical development activities. In addition, the use of third-party service providers may require us to disclose our proprietary information to these parties, which could increase the risk that this information will be misappropriated.

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

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or

meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our antibody candidates. As a result, our results of operations and the commercial prospects for our antibody candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

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

The Collaboration Agreement may be terminated:

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

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

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

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

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

The Lilly Collaboration Agreement may be terminated:

- in its entirety or on a program-by-program basis by Eli Lilly for convenience;
- 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 agreements with Simcere, and Betta Pharma, and the research and license agreement with Ono are important to our business. If our Biclonics® antibodies licensed in these collaboration and license agreements fail to advance or experience unacceptable safety or efficacy results if clinically developed, this could adversely impact the reputation of our platform and our ability to engage in future collaborations.

If our collaboration agreements with Simcere or Betta Pharma or our research and license agreements with Ono are terminated with respect to one or more programs, or the pre-clinical assets associated with these agreements fail to advance into the clinic, or experience negative results with respect to safety, efficacy, manufacturability, or other features of research and development, this could adversely affect the reputation of our Biclonics® technology platform and our ability to engage in future collaborations or licensing agreements. While we have certain contractual provisions in place in our collaboration agreements with Simcere and Betta Pharma that permit us to supervise development efforts associated with our pre-clinical assets with respect to Simcere, or MCLA-129, with Betta Pharma, which have development and product rights in China, we cannot guarantee that these assets will be developed in China in accordance with our standards as applied to our wholly owned programs or in a manner suitable for ex-China development. Ono is currently pursuing at least one antibody program generated by us 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 these collaborations or license agreements fail or be terminated, any suitable alternative collaboration or license agreement would take considerable time to negotiate, if at all, and could also be on less favorable terms to us. If these agreements were to be terminated, and whether or not we identify a suitable alternative collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could, 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, Simcere 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 pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP for the manufacture of our antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities or may result in delay of our ability to obtain marketing authorization, if any, of our antibody candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our antibody candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our antibody candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our antibody candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our antibody candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials 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 clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our platform technologies, and antibody candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, or have issued and even if such patents cover our Biclonics® technology platform, Triclonics® technology platform, our common light chain transgenic 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 clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, and other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology 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 example, lack of utility, novelty, obviousness, non-enablement or lack of written description or as constituting unpatentable subject matter. Grounds for an unenforceability assertion could be an allegation that someone substantively involved in prosecution of the patent withheld but-for material information from the U.S. Patent and Trademark Office (USPTO) or engaged in affirmatively egregious misconduct, during prosecution, with a specific intent to deceive the USPTO. The outcome following legal assertions of invalidity and unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we could lose at least part, and perhaps all, of the patent protection on one or more of our technologies, products, methods or certain aspects of our Biclonics® technology and Triclonics® technology platforms. Such a loss of patent protection could have a material adverse impact on our business. Patents and other intellectual property rights also will not protect our technology if competitors design around our protected technology without infringing our patents or other intellectual property rights.

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

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

It is also possible that we failed to identify relevant patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technologies could have been filed by others without our knowledge. Furthermore, we operate in a

highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, antibody candidates or the use of our bispecific and trispecific antibody candidates.

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

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

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

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

The various markets in which we plan to operate are subject to frequent and extensive litigation regarding patents and other intellectual property rights. In addition, many companies in intellectual property-dependent industries, including those producing 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.

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 antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology. Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, maintain or use these proprietary rights. In addition, our antibody candidates may require specific formulations to work effectively and efficiently or companion diagnostics for safely and effective administration of our therapeutic candidates and the rights to these formulations and companion diagnostics may be held by others. We may be unable to acquire or in-license any compositions, methods of use, processes, or other third-party intellectual property rights from third parties that we may identify as necessary for our antibody candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Changes in patent laws or patent jurisprudence could diminish the value of patents in general, thereby impairing our ability to protect our antibody candidates and technology platforms.

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

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

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

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

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

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

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

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

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

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

Many of our employees, including our senior management, were previously employed at universities or at other 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 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, there can be no assurance that our efforts will prevent service interruptions or security breaches.

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

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

Risks Related to Employee Matters and Managing Growth

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

Our success depends upon the contributions of our senior leaders, including our board of directors, our senior management, and other key scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our 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. Our success also depends on our ability to manage transitions among our senior management and retain our senior management and other key personnel. In April 2020, L. Andres Sirulnik, M.D., Ph.D. resigned as Executive Vice President, Chief Medical Officer effective April 24, 2020, and Andrew Joe, M.D., was appointed as Senior Vice President and Chief Medical Officer, effective July 27, 2020. Further, in April 2020, Mark Throsby, Ph.D., resigned as the Executive Vice President and Chief Scientific Officer of the Company with an effective date of July 31, 2020. In May 2021, we appointed Dr. Cecile Geuijen as Senior Vice President and Chief Scientific Officer with an effective date of May 3, 2021. These changes in our senior management were disruptive to our business, and if we are unable to continue to manage orderly transitions in these cases or for other key personnel in the future, or if we are unable to adequately integrate the new Chief Scientific Officer, or retain our other existing senior management, managers and senior scientists, our business may be adversely affected.

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

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

Risks Related to Our Common Shares

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. We have registered and intend to continue to register all common shares that we may issue under our equity compensation plans. Once registered, these common shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates who hold such shares. In addition, in connection with entering into the Collaboration Agreement, we entered into a Share Subscription Agreement with Incyte, pursuant to which we issued and sold to Incyte 3,200,000 of our common shares. Incyte's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period. On August 21, 2019, we filed a Registration Statement on Form F-3, as amended by Post-Effective Amendment No. 1 to Form F-3 on Form S-3, to register the shares of common stock sold to Incyte. As a result, these shares can be freely sold in the public market. In addition, in connection with entering into the Lilly Collaboration Agreement, we entered into a Lilly Share Subscription Agreement with Eli Lilly, pursuant to which we issued and sold to Eli Lilly 706,834 of our common shares. Eli Lilly's ability to sell these common shares is

subject to certain limitations, including that Eli Lilly has agreed not to transfer, sell, or otherwise dispose of the shares for a certain period of time following the closing date, subject to certain customary exceptions.

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

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

- the authorization of a class of preferred shares that may be issued to 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.

As of May 1, 2021 a statutory cooling-off period of up to 250 days has been introduced in the Netherlands. 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.

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

a) the expiration of 250 days from:

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

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

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

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

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

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

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

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

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

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

Ultimately one week following the last day of the cooling-off period, the board of directors must publish a report in respect of its policy and conduct of affairs during the cooling-off period on our website. This report must remain available for inspection by

shareholders and others with meeting rights under Dutch law at our office and must be tabled for discussion at the next general meeting of shareholders. This legislation may make it more difficult for a third party or group of third parties to acquire control of us or effect a change in our board of directors.

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

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

The preferred shares will be issued to the foundation for their nominal value, of which only 25% will be due upon issuance. The voting rights of our shares are based on nominal value and as we expect our shares to continue to trade substantially in excess of nominal value, preferred shares issued at nominal value can obtain significant voting power for a substantially reduced price and thus be used as a defensive measure. These preferred shares will have both a liquidation and dividend preference over our common shares and will accrue cash dividends at a fixed rate. Subject to the foundation exercising its call option under the call option agreement, the board may issue these preferred shares to protect us from influences that 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 Dutch Corporate Governance Code (DCGC). The DCGC contains both principles and best practice provisions for board of directors, shareholders and general meetings of shareholders, financial reporting, auditors, disclosure, compliance and enforcement standards. The DCGC applies to all Dutch companies listed on a government-recognized stock exchange, whether in the Netherlands or elsewhere, including Nasdaq. The principles and best practice provisions apply to our board (in relation to role and composition, conflicts of interest and independence requirements, board committees and remuneration), shareholders and the general meeting of shareholders (for example, regarding anti-takeover protection and our obligations to provide information to our shareholders) and financial reporting (such as external auditor and internal audit requirements). We do not comply with all the best practice provisions of the DCGC. As a result, the rights of our shareholders may be affected and our shareholders may not have the same level of protection as a shareholder in another Dutch public company with limited liability (*naamloze vennootschap*) listed in the Netherlands that fully complies with the DCGC.

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

We are incorporated under the laws of the Netherlands. Most of our assets are located outside the United States. The United States and the Netherlands currently do not have a treaty providing for the reciprocal recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. With respect to choice of court agreements in civil or commercial matters, we note that the Hague Convention on Choice of Court Agreements entered into force for the Netherlands, but has not entered into force for the United States. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in the Netherlands. In order to obtain a judgment which is enforceable in the Netherlands, the party in whose favor a final and conclusive judgment of the U.S. court has been rendered will be required to file its claim with a court of competent jurisdiction in the Netherlands. Such party may submit to the

Dutch court the final judgment rendered by the U.S. court. If and to the extent that the Dutch court finds that the jurisdiction of the U.S. court has been based on grounds which are internationally acceptable and that proper legal procedures have been observed, the court of the Netherlands will, in principle, give binding effect to the judgment of the U.S. court, unless such judgment contravenes principles of public policy of the Netherlands or is irreconcilable with a judgement of a Dutch court or foreign court that is acknowledged in the Netherlands. Dutch courts may deny the recognition and enforcement of punitive damages or other awards. Moreover, a Dutch court may reduce the amount of damages granted by a U.S. court and recognize damages only to the extent that they are necessary to compensate actual losses or damages. Enforcement and recognition of judgments of U.S. courts in the Netherlands are solely governed by the provisions of the Dutch Code of Civil Procedure (*Wetboek van Burgerlijke Rechtsvordering*). As a result of the above, it may not be possible for investors to effect service of process within the United States upon us or members of our board or certain experts named herein who are residents of the Netherlands or countries other than the United States or to enforce any judgments against the same obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

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

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We are also no longer exempt from the requirements of Regulation FD promulgated under the Exchange Act related to selective disclosures. We are also no longer permitted to follow our home country's rules in lieu of the corporate governance obligations imposed by Nasdaq, and are required to comply with the governance practices required by U.S. domestic issuers listed on Nasdaq. We are also required to comply with other rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. In addition, we are required to report our financial results under U.S. Generally Accepted Accounting Principles, including our historical financial results, which have previously been prepared in accordance with International Financial Reporting Standards. We expect to continue to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources to comply with these requirements and may face challenges in complying with these additional requirements applicable to us.

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 will remain an "emerging growth company" and a "smaller reporting company" until December 31, 2021 and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our common shares less attractive to investors. Once are no longer an emerging growth company or a smaller reporting company, we will be subject to certain enhanced disclosure requirements.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act and a smaller reporting company under the rules promulgated under the Exchange Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute

payments not previously approved, and reduced executive compensation disclosure. We may take advantage of these exemptions until we are no longer an emerging growth company.

We are also a smaller reporting company, and we will remain a smaller reporting company until December 31, 2021. Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosure, and have certain other reduced disclosure obligations, including, among other things, being required to provide only two years of audited financial statements and not being required to provide selected financial data or supplemental financial information.

We cannot predict if investors will find our common shares less attractive because we may rely on these exemptions. If some investors find our common shares less attractive as a result, there may be a less active trading market for our common shares and the price of our common shares may be more volatile.

Moreover, we expect that the loss of emerging growth company status and smaller reporting company status as of December 31, 2021 and 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 2020, we do not believe we were a PFIC for U.S. federal income tax purposes for that taxable year. A non-U.S. company generally will be considered a PFIC for any taxable year if (i) at least 75% of its gross income is passive income (including interest income), or (ii) at least 50% of the value of its assets (based on an average of the quarterly values of the assets during a taxable year) is attributable to assets that produce or are held for the production of passive income. The value of our assets generally is determined by reference to the market price of our common shares, which may fluctuate considerably. In addition, the composition of our income and assets is affected by how, and how quickly, we spend the cash we raise. It is possible the Internal Revenue Service could determine that we were a PFIC for the taxable year 2020. If we were to be treated as a PFIC for any taxable year during which a U.S. Holder holds a common share, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. Once treated as a PFIC, for any taxable year in which a U.S. Holder owns equity in such foreign corporation, a foreign corporation will generally continue to be treated as a PFIC for all subsequent taxable years with respect to such U.S. Holder. If we were to be a PFIC, “excess distributions” (as such term is defined in the United States Internal Revenue Code of 1986, as amended (U.S. Tax Code)) to a U.S. Holder, and any gain recognized by a U.S. Holder on a disposition of our common shares would be taxed in potentially unfavorable ways. Among other consequences, our dividends would be taxed at the regular rates applicable to ordinary income, rather than the 20% maximum rate applicable to certain dividends received by an individual from a qualified foreign corporation, and, to the extent that they constituted excess distributions, certain interest charges may apply, and gains on the sale of our shares would be treated in the same way as excess distributions. In addition, the U.S. Holder would be subject to detailed reporting obligations. The tests for determining PFIC status are applied annually and it is difficult to make accurate predictions of future income and assets, which are relevant to the determination of any future PFIC status. As such, we cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. Further, we cannot provide any assurances that we will furnish to any U.S. Holder information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares, including the potential availability and advisability of an election to treat us as a qualified electing fund or a mark-to-market election. A “U.S. Holder” is a holder who, for U.S. federal income tax purposes, is a beneficial owner of our common shares and is:

(1) a citizen or individual resident of the United States;

(2) a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

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

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

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

If a U.S. Holder is treated as owning (directly, indirectly or constructively) at least 10% of the value or voting power of our common shares, such U.S. Holder may be treated as a “United States shareholder” with respect to each “controlled foreign corporation” in our group (if any) as such term is defined in the Tax Code. A United States shareholder of a controlled foreign corporation may be required to report annually and include in its U.S. taxable income, as ordinary income, its pro rata share of “Subpart F income,”

"global intangible low-taxed income" and investments in U.S. property by controlled foreign corporations, regardless of whether we make any distributions. An individual that is a United States shareholder with respect to a controlled foreign corporation generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder that is a corporation. Failure to comply with these reporting obligations may subject a United States shareholder to significant monetary penalties and may extend the statute of limitations with respect to such United States shareholder's U.S. federal income tax return for the year for which reporting was due. We cannot provide any assurances that we will assist investors in determining whether we or any of our future non-U.S. subsidiaries is treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholders information that may be necessary to comply with the aforementioned reporting and tax payment obligations. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares. The risk of being subject to increased taxation may deter our current shareholders from increasing their investment in us and others from investing in us, which could impact the demand for, and value of, our common shares.

Dividends distributed by us, if any, to related entities in low-taxing states or non-cooperative jurisdictions for tax purposes may become subject to an additional withholding tax on dividends in the Netherlands as of January 1, 2024.

We have never paid or declared any cash dividends on our common shares, and we do not anticipate paying any cash dividends on our common shares in the foreseeable future. However, if we do pay dividends, such dividends are in principle subject to a regular Dutch dividend withholding tax and may, in certain circumstances, become subject to a conditional Dutch withholding tax.

Under current Dutch tax law, dividends paid on our common shares are in principle subject to Dutch dividend withholding tax at a rate of 15% under the Dutch Dividend Withholding Tax Act (Wet op de dividendbelasting 1965), unless a domestic or treaty exemption or reduction applies. On March 25, 2021, the Dutch State Secretary for Finance submitted a proposal of law to the Dutch parliament pursuant to which a conditional withholding tax will be imposed on dividends paid to related entities in low-tax jurisdictions or non-cooperative jurisdictions for tax purposes, effective January 1, 2024. The legislation proposal has been approved by the House of Representative (Tweede Kamer) of the Dutch parliament on September 30, 2021 and is expected to be approved by the Senate (Eerste Kamer) of the Dutch parliament in or about November 2021, as a result of which it will enter into force as of January 1, 2024. The conditional withholding tax on dividends may also apply in situations where artificial structures are put in place with the main purpose or one of the main purposes to avoid the conditional withholding tax or in the event of a hybrid mismatch. The conditional withholding tax will be imposed at the highest Dutch corporate income tax rate in effect at the time of the distribution (currently 25%). The conditional withholding tax on dividends will be reduced, but not below zero, by any regular Dutch dividend withholding tax withheld in respect of the same dividend payment. As such, based on the currently applicable rates, the overall effective tax rate of withholding the regular dividend withholding tax and conditional withholding tax will not exceed the highest corporate income tax rate in effect at the time of the distribution (currently 25%). As of January 1, 2024, the withholding tax rate on dividends paid to shareholders that are entities related to the Company and established in a low-taxing state or non-cooperative jurisdiction for tax purposes may rise from 15% to the highest corporate tax rate (currently 25%).

General Risk Factors

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

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

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

- other events and factors, many of which are beyond our control.

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

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

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

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

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

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

As a public company, and particularly after we no longer qualify as an emerging growth company or a smaller reporting company, we will continue to incur significant legal, accounting and other expenses related to our operation as a public company. The Sarbanes-Oxley Act of 2002 (SOX), the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market, or Nasdaq, and other applicable securities rules and regulations impose various requirements on reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our board of directors and other personnel will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations have and will continue to increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

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

Pursuant to Section 404 of SOX (Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K. Additionally, once we are no longer an emerging growth company or smaller reporting company after December 31, 2021, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources and have engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to maintain effective internal control over financial reporting as required by Section 404. Material weaknesses 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 5. Other Information

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are as follows:

Exhibit Number	Exhibit Description	Incorporated by Reference to Filings Indicated				Filed/ Furnished
		Form	File No.	Exhibit No.	Filing Date	
3.2	Articles of Association of Merus N.V., as amended on May 28, 2021	8-K	001-37773	3.1	5/28/21	
10.3.4	English language translation of the Lease date June 3, 2021, by and between the Registrant and Stichting Incubator Utrecht	10-Q	001-37773	10.3.4	8/5/21	
10.3.5	Contract Research and License Agreement and Addendum dated April 8, 2014, by and between the Registrant and ONO Pharmaceutical Co., Ltd.					*
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 (embedded within the Inline XBRL document)					*

* Filed herewith.

** Furnished herewith.

† 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Dated: November 2, 2021

MERUS N.V.

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

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

Exhibit 10.3.5

CONTRACT RESEARCH AND LICENSE AGREEMENT

THIS CONTRACT RESEARCH AND LICENSE AGREEMENT (this **"Agreement"**) is entered into as of April 8, 2014 (the **"Effective Date"**) by and between **MERUS B.V.**, a Dutch company having an office at Padualaan 8, 3584 CH Utrecht, the Netherlands (**"Merus"**), and Ono Pharmaceutical Co., Ltd., a Japanese company with its head offices located at 8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8564, Japan (**"Ono"**). Merus and Ono may each be referred to individually as a "Party", and collectively as the "Parties".

RECITALS

WHEREAS, Merus is the owner of proprietary MeMo® mouse, Spleen to Screen™, CH3 dimerization and CH2 silencing technologies for the efficient generation of next generation Biclonics™ bispecific antibodies for therapy; and

WHEREAS, Merus has expertise and intellectual property related to the above mentioned technologies, including related know how and materials; and

WHEREAS, Ono is engaged in the research, development and commercialization of pharmaceutical products; and

WHEREAS, Ono and Merus desire to enter into a collaborative relationship whereby Merus will use its MeMo® mouse, Spleen to Screen™, CH3 dimerization and CH2 silencing technologies for the efficient generation of next generation Biclonics™ [***] bispecific antibodies with immunosuppressive properties to be further characterized and developed by Ono under a license from Merus for preclinical development, clinical development and commercialization by Ono, subject to the terms and conditions set forth herein.

AGREEMENT

NOW, THEREFORE, in consideration of the foregoing premises and the mutual covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties agree as follows:

1. DEFINITIONS

1.1 Capitalized Terms. For purposes of this Agreement (including its appended schedules and exhibits), the capitalized terms used in this Agreement shall have the defined meanings set forth below or elsewhere in this Agreement. Capitalized singular, plural, and other variant forms of the defined terms shall have the corresponding meanings.

"Affiliate"means, with respect to a Party, any company or other entity controlled by, controlling, or under common control with such Party, where the term "controlled by" (with correlative meanings for the terms "controlling" and "under common control with") means for purposes of this definition the possession, through ownership or control, directly or indirectly, of at least 50% of the voting power, which voting power in the case of a corporation is entitled to vote for the election of directors, or otherwise has the actual right and ability to control and direct the management and business affairs.

"**Antibody**" or "**Antibodies**" shall mean a molecule, or a set of genes encoding such a molecule, comprising or containing one or more immunoglobulin variable domains or any existing or future fragments, variants, modifications or derivatives thereof.

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"Biclonics Antibody" or **"Biclonics"** means any bispecific Antibody generated using Merus Technology, specifically the [***], from [***] contains a [***] and a [***], which bispecific antibody binds to 2 different targets as described in Exhibit A of this Agreement.

"Business Day(s)" means any day other than (i) Saturday, Sunday or other national holidays in Japan and/or the Netherlands, and (ii) a day within Ono's or Merus' corporate holidays. Each Party shall provide the other Party with the relevant corporate calendar of the following year promptly after it is available.

"[***]**"** means [***] encoded by the [***] gene.

"Commercial Sale" means, with respect to a Product, the sale in a commercial arms'-length transaction of such Product intended for end use or consumption for any application in the Field of Use in a country after the governing Regulatory Authority of such country has granted Regulatory Approval of the Product for such end use or consumption in the Field of Use (which will include sales of a Product occurring prior to Regulatory Approval in a country if such sold Products are intended to be used and are sold for use by an end user in such country after Regulatory Approval is obtained in such country). Sale to an Affiliate or Sublicensee for distribution will not constitute a Commercial Sale.

"Confidential Information" has the meaning provided in Section 10.1.

"Controlled"means, in reference to any information, materials, Patent Rights or other intellectual property, that the applicable Party owns, possesses, or has a license to such intellectual property or intellectual property right (including through control of an Affiliate or through a license from an Affiliate or Third Party) of the right or ability to grant the other Party a license or a sublicense or other right (as applicable) under same as provided in this Agreement without violating the terms of any agreement or other arrangement with any Third Party.

"Cover" means, with respect to a claim of any Patent Rights in reference to specified subject matter (such as a composition of matter or method of use), reading on or literally, or by the doctrine of equivalents, encompassing such subject matter, whether generically or specifically.

"EMA" means the European Medicines Agency, a decentralized body of the European Union, located in London, whose main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices in the European Union.

"FDA" means the United States Food and Drug Administration, or any successor agency thereto having the administrative authority to regulate the marketing of human pharmaceutical products or biological therapeutic products, delivery systems and devices in the United States of America.

"[***]**"** means the [***].

"**FTE**" or "**Full Time Equivalent**" means the equivalent of the work of one scientist full time during one full year of work during the Research Term, meaning a total of at least 1600 working hours. Each Party understands that scientists who are working on the Research Program subject to the terms and conditions of this Agreement also may be working (during periods that do not count towards the FTE allocation devoted to the Research Program) on other independent projects.

"Human Antibodies" shall mean any [***]; specifically (a) the [***] or (b) from [***].

"IND" means an investigational drug application, including any amendments, to perform clinical investigation(s) of a Product as an investigational new drug or investigational medicinal product or the like that is filed with a Regulatory Authority in any jurisdiction for approval to conduct clinical studies of such Product in humans prior to

the delivery of a Regulatory Approval or any request for authorization to use in an emergency situation filed with a Regulatory Authority in any jurisdiction prior to delivery of a Regulatory Approval.

"**Joint Steering Committee**" or "**JSC**" means the committee comprised of three representatives of each of Ono and Merus, unless otherwise agreed by the Parties, to oversee the Research Program pursuant to Section 3.1.

"**Know-How**" means all know-how, whether or not reduced to writing, technical information, data, ideas, concepts, materials (including but not limited to chemical and biological materials), techniques, specifications, processes, software, algorithms, practices, methods, material compositions, formulas, discoveries, inventions, trade practices, and trade secrets, whether or not patentable.

"Lead Biclonics" means one or more Target Specific Biclonics that is/are functional and identified by Ono in accordance with the Specifications as further described in Exhibit B of this Agreement. For clarity, Lead Biclonics includes Successful Biclonics and Licensed Biclonics.

"Licensed Biclonics" means any and all Successful Biclonics that is/are identified and selected by Ono for further research, development and commercialization as a Product.

"Merus IP" means (i) Merus Patent Rights, (ii) Merus Know-How and (iii) any related Research Tool Controlled by Merus as of the Effective Date.

"**Merus Know-How**" means the Know-How Controlled by Merus as of the Effective Date or developed by Merus during the Term that are necessary for research, development, use manufacturing and/or commercialization activities of Ono, its Affiliates or Sublicensees with respect to Lead Biclonics and/or Products. For clarity, Merus Know-How will not include Merus Patent Rights and/or Ono Patent Rights.

"**Merus Patent Rights**" means the Patent Rights (a) Controlled by Merus as of the Effective Date relating to the Merus Technology or (b) Covering any invention and discovery conceived, developed or reduced to practice solely by either Party, or jointly by both Parties during the Term relating to (i) any improvement of Merus Technology, (ii) any process or material for making, delivering, or formulating bispecific Antibodies generated using Merus Technology, (iii) any method of using bispecific Antibodies generated using Merus Technology, or (iv) any Research Tool or any process or material for making or using a Research Tool, or (v) a Human Antibody against either [***] or the [***], but excluding Human Antibody of Lead Biclonics, in each case of subsection (i) through (v) in this paragraph excluding Ono Patent Rights. The Merus Patent Rights include the Patent Rights listed in Exhibit C.

"Merus Technology" means [***] for the efficient generation of Biclonics™ bispecific antibodies.

"Net Sales" means the gross amount invoiced on sales of a Product by Ono or its Affiliates or Sublicensees to Third Party distributor(s), wholesaler, medical institution or otherwise, less the following deductions related to the Products: (i) direct credits and allowances or adjustments granted to such Third Parties on account of price adjustments, government or other rebates, rejections or returns in respect of the Products; (ii) any trade or cash discounts, rebates, charge-backs or administrative fees or other price reductions granted to such Third Parties who are involved in the acquisition, dispensing, utilization or management of prescriptions; (iii) any sales or other like taxes (but specifically excluding any taxes based on net income imposed upon the sale of the Products) to the extent included in the gross sales price, (iv) the costs of freight, transport, insurance, postage, handling and any other similar charges relating to the sale, transportation, delivery or return of the Development Product, (v) commissions related to import of the Product paid to Third Parties, (vi) [***], and (vii) [***]. In the event any combination product, sold in a finished dosage form containing a Licensed Biclonics and other therapeutic component(s) which is not the Licensed Biclonics, all as active pharmaceutical ingredients (as opposed to excipients or additives) is sold in any country, the Parties shall discuss in good faith to agree on the calculation method of Net Sales of such combination product reflecting relative value of the Licensed Biclonics and other therapeutic component(s) contained in such combination product by means of prices listed in publicly available drug tariff of Development

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Product containing the Licensed Biclonics and a pharmaceutical product containing such other therapeutic component each as a sole active pharmaceutical ingredient and sold as a single agent, or by any other means.

"**Ono IP**" means (i) Ono Patent Rights, (ii) Ono Know-How and (iii) any related Research Tool Controlled by Ono as of the Effective Date.

"**Ono Know-How**" means the Know-How Controlled by Ono as of the Effective Date or developed by Ono during the Term under this Agreement and that are reasonably required for the practice of Ono Patent Rights. For clarity, Ono Know-How will not include Merus Patent Rights and/or Ono Patent Rights.

"**Ono Patent Rights**" means the Patent Rights (a) Controlled by Ono as of the Effective Date specifically relating to the Research Program or (b) Covering any invention or discovery conceived, developed or reduced to practice solely by either Party, or jointly by both Parties, during the Term relating to (i) any composition of matter claims relating to Lead Biclonics and/or Human Antibody of Lead Biclonics, (ii) any process or material for making, delivering, or formulating Lead Biclonics, (iii) any method of using Lead Biclonics, or (iv) any Research Tool or any process or material for making or using a Research Tool specifically relating to Lead Biclonics.

"Ono Proceeds" means the gross amounts [***] by Ono to any of its Affiliates or Sublicensees, including but not limited to [***], [***] in partial consideration [***] and the later of [***]. For clarity Ono Proceeds shall not include [***] and [***].

"Patent Rights" means, with respect to a particular invention, any and all original (priority-establishing) patent applications filed anywhere in the world including any claim Covering the invention, including provisional and non-provisional applications, and all related applications thereafter filed including any claim Covering such invention or including a common priority right, including any continuations, continuations-in-part, divisional and substitute applications, any patents issued or granted from any such patent applications, and any reissues, renewals, reexaminations, extensions (including by virtue of any supplementary protection certificates) of any such patents, and any confirmation patents, inventor's certificates or registration patents or patents of addition based on any such patents, and all foreign counterparts or equivalents in any country or jurisdiction of any of the foregoing.

"[***]**"** means [***] encoded by the gene [***].

"Phase I Clinical Trial" means that portion of a clinical drug development program which provides a clinical trial involving the first introduction into humans of a Product with the purpose of determining human toxicity, metabolism, absorption, elimination and/or other pharmacological action, as more fully defined in 21 C.F.R. § 312.21(a), or its successor regulation, or the equivalent in any foreign country.

"Phase IIb Clinical Trial" means that portion of a clinical drug development program which provides a definitive, well controlled clinical trial of a Product in the relevant patient population for the purpose of determining its safety and efficacy in the proposed therapeutic indication, as more fully described in 21 C.F.R. § 312.21(b), or its successor regulation, or the equivalent in any foreign country.

"Phase III Clinical Trial" means that portion of a clinical drug development program which provides an expanded trial of a Product on sufficient numbers of patients to establish the safety and efficacy of a Product and generate pharmaco-economic/benefit-risk data to support Regulatory Approval in the proposed therapeutic indication or provide an adequate basis for physician labeling, as more fully defined in 21 C.F.R. § 312.21(c), or its successor regulation, or the equivalent in any foreign country.

"PMDA" means the Pharmaceuticals and Medical Devices Agency, a Japanese regulatory agency, working together with Ministry of Health, Labour and Welfare with the obligation to protect the public health by assuring safety, efficacy and quality of pharmaceuticals and medical devices.

"Preclinical Proof of Mechanism" means immune suppressive effects mediated through [***] in one relevant animal model as more specifically set forth in Exhibit B.

"Product" means a pharmaceutical product containing a Licensed Biclonics in final form suitable for human use.

"**Prosecute**", "**Prosecuting**" or "**Prosecution**" means, with regard to specified Patent Rights, preparing, filing, prosecuting, maintaining, and defending such Patent Rights, including with respect to any reexamination, review, reissue, interference, or opposition proceedings. For the avoidance of doubt, "Prosecuting" excludes any infringement suits or other legal proceedings to enforce the specified Patent Rights, regardless of whether or not such proceedings involve the defense of the Patent Rights in suit.

"Regulatory Approval" means receipt of any and all approvals, licenses, registrations, or authorizations of any country, federal, supranational, state or local regulatory agency, ministry, department, bureau or other government entity that are necessary for the use or sale of a particular Product in the jurisdiction for a particular indication, including any approvals for importation, manufacture, pricing, and/or reimbursement where necessary.

"**Regulatory Authority**" means any country, federal, supranational, state or local regulatory agency, ministry, department, bureau or other governmental entity having authority in any country, region, or supra-national jurisdiction to grant a Regulatory Approval, such as the FDA, EMA, PMDA or any equivalent governmental entity in any other country.

"Research" means any research work performed by any of the Parties or on their behalf under the Research Program pursuant to the Research Plan.

"Research Budget" means the itemized budget described in Exhibit A specifying those Merus FTEs to be funded by Ono pursuant to Section 6.2 and any personnel, equipment, reagents and all other expenses including support staff and overhead for or associated with an FTE, which budget and any amendment thereto shall be in writing and signed by duly authorized representatives of both Parties.

"Research Plan" means the written plan outlining the Parties' respective responsibilities for conducting the Research Program, setting forth the Research Budget, and allocating the Merus FTEs funded by Ono, as such plan may be amended from time to time by the Parties. The initial Research Plan has been agreed upon by the Parties as of the Effective Date and is described in Exhibit A.

"Research Program" means a collaborative research program carried out by Merus and Ono during the Research Term pursuant to Articles 3 and 4 to conduct pre-clinical research and process development related to Target Specific Biclonics in the Field of Use.

"Research Term" means the period beginning on the Effective Date and ending on the date of Ono's payment of RME4 in accordance with Section 6.3(a), or earlier terminated on early termination of this Agreement in accordance with Article 11.

"**Research Tool**" means any assay method, protocol, reagent, or material Controlled by Merus or Ono and necessary or useful for carrying out Research activities pursuant to the Research Plan.

"**Royalty Term**" means with respect to a particular Product in a particular country, the period commencing on the first Commercial Sale of the Product in such country and ending upon the expiration of the last to expire Valid Claim of the licensed Merus Patent Rights in such country Covering the Product.

"Senyoh Jisshiken Tohroku" has the meaning set forth in Section 5.3.

"Sublicensee" means a Third Party or Affiliate to whom Ono has granted a license or sublicense of the right to use, have used, make, have made, market, have marketed, offer for sale, have offered to sell, sell, have sold, export and/or import one or more Licensed Biclonics and/or Products.

"Successful Biclonics" means one or more Target Specific Biclonics within the Lead Biclonics for which Preclinical Proof of Mechanism is demonstrated as further described in Exhibit B of this Agreement.

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"Target Combination" means [***] and [***].

"Target Specific Biclonics" means one or more Biclonics that bind to the Target Combination and that is/are transferred by Merus to Ono for identification of the Lead Biclonics.

"[***]**"** means [***] made up of [***].

"Territory" means the entire world.

"Term" means the term of this Agreement as further provided in Section 11.1.

"Third Party" means any entity other than Merus or Ono or an Affiliate of Merus or Ono.

"Valid Claim" means (a) an unexpired claim of an issued patent that has not been found or held to be invalid or unenforceable by a court or other authority in the subject country of competent jurisdiction, from which decision no appeal is taken or can be taken; or (b) a pending allowed or finally unrejected claim of a pending application that has its earliest priority date (by filing or claiming the benefit of the earlier filing date of one or more related applications) no more than [***] ([***]) years prior to the date upon which pendency of the claim is determined.

1.2 Miscellaneous Interpretation Aids.

(a) Each use in this Agreement of the term "including", "comprising", or "containing" (or a variant form thereof) shall be understood to have an open, non-limiting meaning. Thus, e.g., "including" shall be interpreted as meaning "including without limitation" or "including but not limited to", regardless of whether the words "without limitation" or "but not limited to" actually follow the term "including". Similarly, the terms "such as", "for example", and "e.g." shall be understood as referring to non-limiting illustrations or examples.

(b) "Herein," "hereby," "hereunder," "hereof," and other equivalent words shall be understood as referring to this Agreement in its entirety, and not solely to the particular provision or portion of this Agreement in which any such word is used.

(c) Wherever used herein, any pronoun or pronouns shall be understood to cover all genders.

(d) All references to days, months, quarters, or years shall be understood to refer, respectively, to calendar days, calendar months, calendar quarters, or calendar years, unless otherwise indicated.

(e) Any reference to a supranational, national, federal, state, local, or foreign statute or law shall be understood to refer to the applicable version of the law or statute then in force (as it may have been amended or superseded) as well as all rules and regulations promulgated thereunder, unless the context requires otherwise.

(f) All references to "€" shall mean EUROS.

2. RESEARCH COLLABORATION

2.1 Diligence. Subject to the terms and conditions set forth herein, and commencing on the Effective Date, the Parties will each use commercially reasonable efforts during the Research Term to conduct their respective activities in the Research Program on a collaborative basis and in accordance with this Agreement, with the goal of performing pre-clinical research related to Target Specific Biclonics and Successful Biclonics. The Parties will conduct the Research Program in accordance with the Research Plan (Exhibit A), as may be amended or revised by the JSC from time to time. The Research Plan will specify the scientific direction and Research activities, and allocate Research Program responsibilities and resources between the Parties in a manner consistent with this Agreement.

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2.2 Exclusive Collaboration.

(a) Merus' conduct of research activities related to Target Specific Biclonics shall be exclusively carried out for the sole benefit of Ono in the Research Program or in support thereof as provided for hereunder. Neither Merus nor its Affiliates shall conduct, alone or in collaboration with any Third Parties, (i) any independent research, development or commercialization of [***] or (ii) any independent development or commercialization of any [***] and shall [***] during (a) [***], or (b) [***].

(b) Notwithstanding the provisions set forth in Section 2.2(a), if Ono does not perform any relevant research activities for a period of more than [***] ([***]) months following [***] without any reasonable justification, the exclusivity under this Section 2.2 will terminate and Merus may then [***], provided that [***].

(c) Notwithstanding the provisions set forth in Section 2.2(a), in case of an assignment of this Agreement by Merus as indicated in Section 14.6(a) to a Third Party that, prior to the transfer or sale of all or substantially all of the business of Merus, already had a license from Merus under Merus Technology that included the Target Combination, the exclusivity conditions under Section 2.2(a) will not apply to such Third Party.

3. GOVERNANCE

3.1 Joint Steering Committee. The Parties shall establish the Joint Steering Committee within [***] ([***]) days of the Effective Date of this Agreement. The Parties' initial members of the JSC are identified in Exhibit E. Promptly after the Effective Date, one member of the JSC will be selected by each Party to act as the chairperson of the JSC. The JSC will meet at least [***] per year during the Research Term. Such meetings may be conducted by videoconference, teleconference or in person, as agreed by the Parties, and each Party shall bear its own costs, including travel, lodging, food and telephone or video conference costs, for its personnel serving on the JSC or attending any meeting of the JSC. Upon completion of the Research Term, the JSC will be disbanded. Promptly after the Effective Date, the Parties will establish a project team (the "Project Team") consisting of key employees of both Parties performing or involved in the Research Program. One of the Project Team members of each Party shall be appointed as a project manager (a "Project Manager") to coordinate its part of the activities under the Research Program. The Project Managers will be the primary contacts between the Parties with respect to all Research activities performed under the Research Program. Meetings of the Project Team may be conducted by videoconference, teleconference or in person, to discuss the results of the Research and progress or delay thereof, at least once a month, or will be held *ad hoc* upon reasonable request of Project Manager of a Party and acceptable by the same of the other Party, acceptance of which will not be unreasonably withheld or delayed. Either Party may change its Project Manager upon written notice to the other Party. A Project Manager may be a member of the JSC.

3.2 Decision making. The purpose of the JSC is to coordinate the Research efforts of the Parties and oversee the progress of the work being done under the Research Plan during the Research Term. The JSC will set specific Research goals, evaluate the results of the Research, discuss information relating to the Research, assign priorities and ensure that there is appropriate scientific direction for the collaboration of the Parties under the Research Plan. Subject to the terms and conditions of this Agreement, the JSC may modify the Research Plan with respect to the Parties' respective Research responsibilities as deemed appropriate and submit recommended Research Budget modifications to the Parties for review and approval. The specific number of Merus FTEs that Ono will fund is specified in the Research Plan. Regardless of the number of representatives, each Party will present one consolidated view via one vote. All decisions of the JSC will be made by unanimous vote, and if the JSC is unable to reach a decision by unanimous vote, Section 13.1 shall apply. If following the application of Section 13.1(a) there is still no consensus, then [***] on such matter.

3.3 Minutes. The JSC chairperson, or his or her designee, will prepare and distribute draft of complete and accurate minutes of all discussions occurring at the JSC meetings regarding matters within its purview and all matters decided upon at the meetings within [***] ([***]) Business Days after such meeting, except that matters reflecting legal advice of counsel will not be included in such minutes, and the minutes shall be finalized by agreement of both Parties. Communications reflecting legal or regulatory advice may, to the extent desired, shall be kept in a separate file with the legend "Attorney-Client Communications Privileged and Confidential".

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3.4 Responsibilities. The JSC shall have no authority to modify any provision set forth in the body of this Agreement, including any payment conditions or terms, periods for performance, or obligations of the Parties, and such modification is only effective and in force in a writing expressly stated for such purpose and signed by the Parties hereto pursuant to Section 14.2. The JSC shall have authority to:

(a) allocate (and reallocate from time to time) activities in the Research Program to the Ono funded FTEs committed by Merus to the ongoing Research Program;

(b) modify the Research Plan, excluding the Research Budget, or propose modifications to the Research Budget, subject to the applicable provisions of this Agreement;

(c) provide general oversight for the Parties' activities in the Research Program; and

(d) periodically review the goals, strategies, and results of the Research Program.

3.5 Research Plan. The initial Research Plan as agreed to by the Parties as of the Effective Date is described in Exhibit A. The JSC will be responsible for reviewing and approving any updates or amendments to the Research Plan except as related to the Research Budget and for making any recommendations for additional resources or otherwise proposing any changes to the Research Budget.

4. RESEARCH AND DEVELOPMENT OF SUCCESSFUL BICLONICS

4.1 Merus Research Commitment and Performance. During the Research Term, Merus will devote to the Research Program the FTEs as designated in the Research Plan, which shall be funded by Ono, subject to Ono's compliance with its funding obligations under Section 6.2. Merus shall use commercially reasonable efforts in performing the Research to carry out its Research obligations as specified in the Research Plan. Merus will conduct its activities under the Research Program in accordance with good scientific standards and practices and in compliance in all material respects with the requirements of applicable laws and regulations and with applicable good research practices. In conformity with standard pharmaceutical and biotechnology industry practices and the terms and conditions of this Agreement, Merus will prepare and maintain, or will cause to be prepared and maintained, complete and accurate laboratory notebooks and other written records, accounts, notes, reports and data with respect to activities conducted pursuant to the Research Plan for [***] ([***]) years after expiration or termination of the Research Term and, upon Ono's written request and at its expense, will send legible copies of the aforesaid to Ono. Notwithstanding anything to the contrary herein, Merus shall, at its sole cost, supply any research reagents, similar materials and any standard laboratory equipment (and any replacements thereto) that it needs to carry out its duties under the Research Plan.

4.2 Ono Research Commitment and Performance. During the Research Term, Ono will devote to the Research Program such number of FTEs of Ono or its Affiliates or contract out a part of its work to any Third Party research organization as are necessary for Ono to fulfill its obligations under the Research Plan. Ono will be responsible for the payment of all costs and expenses for such FTEs and other activities it undertakes in conducting its responsibilities under the Research Plan. Ono will conduct its activities under the Research Program in accordance with good scientific standards and practices and in compliance in all material respects with the requirements of applicable laws and regulations and with applicable good laboratory practices. Ono will, directly or through its Affiliates, maintain laboratories, offices and all other facilities reasonably necessary to carry out the activities to be performed by it pursuant to the Research Plan. In conformity with standard pharmaceutical and biotechnology industry practices and the terms and conditions of this Agreement, Ono will prepare and maintain, or will cause to be prepared and maintained, complete and accurate laboratory notebooks and other written records, accounts, notes, reports and data with respect to activities conducted pursuant to the Research Plan for [***] ([***]) years after expiration or termination of the Research Term.

4.3 Research Reports. Each Party will keep the other reasonably informed as to the progress achieved and results, discoveries and technical developments made in the course of performing activities under the Research Program pertaining to any Target Specific Biclonics. Each Party will prepare, and distribute to all members of the JSC, no

later than [***] ([***]) Business Days prior to the next scheduled JSC meeting, a reasonably detailed written summary regarding the Party's results and progress of performance in the Research Program during the period following the last such report (if any). In the event of early termination hereof, Merus shall submit a final report covering all the work performed by Merus under the Research Program up to such termination within [***] ([***]) days after the effective date of such termination.

4.4 Subcontracts. Either Party may perform appropriate Research under the Research Plan pursuant to this Agreement through one or more Third Party subcontractors approved by the JSC, provided that such Party engages each Third Party subcontractor through a written agreement consistent with the terms and conditions of this Agreement, and further provides that (a) no rights or obligations of either Party under this Agreement are diminished or otherwise adversely affected as a result of such subcontracting, (b) the subcontractor undertakes the obligations of confidentiality and non-use regarding Confidential Information which are substantially the same as those undertaken by the Parties pursuant to Article 9 hereof, and (c) the subcontractor agrees that any intellectual property developed in the course of the work hereunder shall be assigned to the Party engaging the subcontractor or such Party's designee, so as to permit re-assignment as required by the terms and conditions of this Agreement. The Party engaging any such Third Party subcontractor shall be responsible for all compensation due to the Third Party subcontractor (or its employees or agents) arising from such subcontracting.

4.5 Technology Transfer. Commencing promptly after the Effective Date and from time to time thereafter during the Research Term and as indicated in the Research Plan, Merus shall transfer to Ono the identified Target Specific Biclonics, necessary Research Tools and related Know-How Controlled by Merus as the JSC reasonably determines to be necessary or useful for Ono to perform its Research under the Research Program and to exercise the licenses granted to Ono under Article 5 hereof. Commencing promptly after the Effective Date and from time to time thereafter during the Research Term, Ono will use its commercially reasonable efforts to disclose to Merus such materials and related Know-How Controlled by Ono as the JSC reasonably determines to be necessary or useful for Merus to perform its Research under the Research Program and to otherwise exercise the licenses granted to Merus under Article 5 hereof. During the Term, Merus will provide Ono with reasonable technical assistance (in an amount to be set forth in the Research Plan) relating to (i) the use of such Target Specific Biclonics and Research Tools, (ii) manufacturing of Licensed Biclonics, and (iii) related Know-How with respect to subsections (i) and (ii) in this Section 4.5, in each case of subsection (i), (ii) and (iii), transferred and/or disclosed by Merus to Ono solely to the extent permitted under the license rights granted to Ono under Article 5. During the Term, Ono will provide Merus with reasonable technical assistance (in an amount to be set forth in the Research Plan) relating to the use of the materials and related Know-How disclosed by Ono to Merus solely to the extent permitted to perform the Research Program.

4.6 Conditions for Technology Transfer. All supplied Target Specific Biclonics, Research Tools and related Know-How will be used in confidence by the other Party only for purposes of the Research or otherwise as permitted under the applicable license rights granted under Article 5, and subject to all the other restrictions and obligations under this Agreement. Except as otherwise provided under this Agreement, all such materials and related Know-How delivered to the other Party will remain the sole property of the supplying Party, will be used only for purposes of the Research Program or as otherwise permitted by this Agreement, will not be used or delivered to or for the benefit of any Third Party except as otherwise permitted under this Agreement without the prior written consent of the supplying Party, and will be used in compliance with all applicable laws, rules and regulations. The materials and related Know How supplied under this Agreement shall be used by the receiving Party at its own risk and with prudence and appropriate caution in any experimental work because not all of their characteristics may be known. Except as expressly set forth herein, THE MATERIALS AND RELATED KNOW HOW ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR EXCEPT AS OTHERWISE PROVIDED IN THIS AGREEMENT ANY WARRANTY THAT THE USE OF THE MATERIALS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER PROPRIETARY RIGHTS OF ANY THIRD PARTY.

4.7 Regulatory Affairs Responsibility. Ono (directly or through its Affiliates or Third Party subcontractors) shall be solely responsible for conducting all its activities contemplated by the Research Plan to be performed for

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Successful Biclonics, including Preclinical Proof of Mechanism Product. Thereafter, Ono shall have the sole responsibility, for each Product, to file all clinical research exemptions for any clinical trials and all INDs related thereto.

4.8 Ongoing Disclosure Regarding Development. Ono (directly or through its Affiliates or Third Party subcontractors) shall solely control and be responsible for selection of Licensed Biclonics from Successful Biclonics and conducting all further non-clinical and clinical development activities for Licensed Biclonics and Products, including manufacture of sufficient amounts of all research, non-clinical and clinical supplies of Licensed Biclonics and Product for non-clinical studies and clinical trials to be performed by Ono, as well as relating to process development (including scale-up) for (pre-)clinical and/or commercial manufacture of Licensed Biclonics and Product.

Ono will keep Merus informed about Ono's development of the Licensed Biclonics and Product, including the results from such development progress towards meeting goals and milestones during the development of the Licensed Biclonics and Product, significant findings and developments, any delays and any proposed changes in its plans. Such disclosures will be made in a written report provided to Merus at least annually, or more often at Ono's election, the contents of which shall be treated as Ono's Confidential Information.

4.9 Exclusive Commercialization Rights. Subject to the terms and conditions of this Agreement, Ono will control and have exclusive rights over the worldwide commercialization of all approved Products, including the worldwide supply of Products for use in all such commercialization activities. Ono will be solely responsible for all costs and expenses in the commercialization of Products.

5. LICENSES AND OBLIGATIONS

5.1 License Grants. The grants of rights provided in this Section 5.1 are subject to the terms and conditions of this Agreement.

(a) License to Ono. Merus hereby grants to Ono an exclusive (even as to Merus but subject to subsection (b) below of this Section 5.1) royalty-bearing license, with the right to sublicense, under the Merus IP to (i) research, test, and/or study Target Specific Biclonics and Lead Biclonics, and (ii) use, have used, make, have made, market, have marketed offer to sell, have offered to sell, sell, have sold, export and/or import Licensed Biclonics and/or Products in the Field of Use in the Territory.

(b) Merus Retained Rights. Merus retains all rights to use and commercialize any Human Antibodies that are generated under the Research Program but which are not Human Antibodies of Lead Biclonics, and provided that such retained use or commercialization is not with respect to the Target Combination.

(c) For the avoidance of doubt, Third Parties to whom Merus has or will grant a license under Merus IP, have been or will be granted rights to research, develop and commercialize bispecific Antibodies generated using Merus Technology against either [***] or [***] or the Target Combination, provided that, for as long as the exclusivity of the collaboration between the Parties exists as specified in Section 2.2, neither Merus nor its Affiliates shall conduct, alone or in collaboration with any such Third Party licensees, directly or indirectly, any research or development of such bispecific Antibodies generated using Merus Technology against the Target Combination, and shall neither sell, supply, provide nor transfer directly or indirectly, any Target Specific Biclonics to any Third Party.

(d) Sublicenses. Ono shall have the right to grant sublicenses under the licenses granted under Section 5.1(a), and Ono shall notify Merus of each grant of a sublicense right to any Third Party within the rights granted in Section 5.1(a), and each such Sublicensee shall be identified in a notice to Merus, which Merus shall treat as Ono's Confidential Information. Notwithstanding any such sublicensing, Ono shall remain liable to Merus for the performance of its Sublicensees hereunder, and Ono shall use reasonable measures to ensure that its Sublicensees comply with the applicable terms and conditions of this Agreement.

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(e) License to Merus. Ono hereby grants to Merus a perpetual, royalty-free, non-exclusive worldwide license, with the right to sublicense,

(i) under the Ono IP to conduct the Research under the Research Program as contemplated in this Agreement, and

(ii) under Ono IP other than those Controlled by Ono on the Effective Date, to research, develop, use, make, have made, offer to sell, have offered to sell, sell, have sold, export and/or import any products containing monospecific or bispecific Antibodies, but not any products containing bispecific Antibodies against the Target Combination, alone or in collaboration with any Third Parties, subject to the provisions of Section 2.2.

Merus shall be permitted to sublicense the license granted under this Section 5.1(e)(ii) only to such other licensees of Merus Patent Rights for bispecific Antibodies generated using Merus Technology ("Merus Licensees") that are contractually obligated to license to Merus (with the right to sublicense to other Merus Licensees) rights under such other Merus Licensees' Patent Rights and Know How rights in improvements to the Merus IP developed by or on behalf of such other Merus Licensees.

5.2 No Implied Licenses. Except as for expressly provided for herein, no other right or license under any Patent Rights or Know How Controlled by a Party is granted to the other Party.

5.3 Senyoh Jisshiken Tohroku. Upon Ono's request, Merus agrees that Ono shall be entitled to register, at Ono's sole expense, Ono's exclusive license to the extent granted pursuant to Section 5.1(a) with respect to Merus IP in Japan ("Senyoh Jisshiken Tohroku") in accordance with the patent law of Japan, and, at Ono's request, Merus shall render reasonable assistance for such registration by Ono, including providing Ono with any documents duly signed by an authorized personnel of Merus in the English language reasonably necessary for such registration; provided, however, that Ono shall promptly cancel such registration of Senyoh Jisshiken Tohroku in the event of termination of this Agreement pursuant to Section 11 hereof.

5.4 Exclusive option. For a term starting on the Effective Date until the earlier of [***] ([***]) months after the Effective Date or [***] ([***]) months after the [***], Merus hereby grants to Ono an exclusive option to enter into an exclusive license agreement to develop and commercialize bispecific Antibodies that bind to the [***] and [***] target combination. For clarity the grant of the exclusive option set forth in this Section 5.4 shall not prevent Merus from performing any research on the [***] and [***] target combination alone. Promptly after Ono's written exercise notice, the Parties shall engage in good-faith negotiations so as to, within [***] ([***]) months, conclude an exclusive license agreement, which shall grant Ono an exclusive license, with the right to sublicense, under the applicable Merus IP Controlled by Merus, to make, have made, use, have used, make, have made, market, have marketed, offer to sell, have offered to sell, sell, have sold, export and/or import pharmaceutical products containing a Bioclonics Antibodies that bind to the [***] and [***] target combination in final form suitable for human use. Such agreement will include financial terms and conditions as set forth herein *mutatis mutandis*, except that the upfront fee will be €[***].

6. FEES AND PAYMENTS

6.1 Upfront Fee. Ono will pay to Merus a non-refundable, non-creditable upfront fee of €1,000,000 (one million euros), exclusive of VAT, which shall be due upon execution of this Agreement and payable within [***] ([***]) days after Ono's receipt of the relevant invoice. Notwithstanding the non-refundable condition of the upfront fee set forth in this Section 6.1, if [***], and [***], Merus shall [***] within [***] ([***]) days after its receipt of such [***].

6.2 Research Funding.

6.2.1 Funded Merus FTEs. Except as expressly provided herein, each Party shall be responsible for its costs and expenses incurred in performing its Research in the Research Program. Ono will agree to fund [***] of the Research Term. Any further Merus FTEs above the specified number of FTEs to be funded by Ono during the Research Term shall be specified in a written amendment executed by duly authorized representatives of the Parties setting forth in

the Research Plan the specific number of Merus FTEs to be so funded. Merus shall be reimbursed for the funded FTEs actually contributed pursuant to the Research Plan (up to the maximum specified therein) at the rate of €[***] per FTE per year. Such rate shall include all personnel, equipment, consumables, materials reagents and all other expenses including support staff and overhead for or associated with an FTE, and in no event shall Ono be obligated to make any other funding to support the Research to be performed by Merus except as expressly set forth in this Agreement Exhibit A unless otherwise agreed in writing and signed by duly authorized representatives of both Parties. In the event that Merus contributes any additional FTEs to Research other than those agreed upon to be funded by Ono as specified in the Research Plan, Merus shall be solely responsible for the costs of such additional FTEs. On a quarterly basis during the Research Term, Ono shall reimburse Merus in arrears for the funded Merus FTEs actually expended in Research pursuant to the Research Plan.

6.2.2 FTE Payment Terms. The payments for the funded FTEs under Section 6.2.1 shall be paid by Ono in arrears upon receipt of a proper invoice from Merus on a quarterly basis based on Merus' actual work performed by qualified FTEs. Ono shall pay Merus such amount within [***] ([***]) days of Ono's receipt of the invoice.

6.2.3 General Payment Terms. Any payment for an amount due under this Section 6.2 or Section 6.3 below shall be payable within [***] ([***]) days after Ono's receipt of an invoice from Merus for such amount, which invoice shall specifically refer to this Agreement and contain the information describing such payment as specified in sample invoice set forth at Exhibit F. All payments shall be made by wire to such bank account as Merus may designate in writing to Ono. Any payments due and payable under this Agreement on a date that is not a Business Day may be made on the next Business Day.

6.3 Milestone Payments.

(a) Subject to the terms and conditions provided in subsections (b) and (c) below and in consideration for the license granted and the ownership rights that are assigned hereunder (provided that any Ono IP is generated by Merus), the following amounts shall be due, each one time only upon the first attainment of the specified event by the first Product regardless of subsequent or repeated achievement of such milestone except as specified in Section 6.3(d), from Ono to Merus upon the first occurrence of the specified milestone event listed below with respect to the Licensed Biclonics or Product (whether such milestone event is achieved by Ono directly or through its Affiliates or any Third Party Sublicensees). Milestone payments shall be made by Ono within [***] ([***]) days of receipt of the corresponding invoice issued by Merus, which invoice may be issued upon the same date as achieving the milestone. In the event any Target Specific Biclonics delivered to Ono later than [***] ([***]) months from the Effective Date fulfills RME1 for the first time, the amount of RME1 payment set forth in the table below will be reduced by [***] percent ([***]%) and if any Target Specific Biclonics delivered to Ono later than [***] ([***]) months from the Effective Date fulfills RME1 for the first time, the amount of RME1 payment set forth in the table below will be reduced by [***] percent ([***]%).

Research Milestone Events	EURO
RME1: [***]	€ [***]
RME2: [***]	€ [***]
RME3: [***]	€ [***]
RME4: [***]	€ [***]
Clinical Development Milestone Events	
[***]	€ [***]
[***]	€ [***]
[***]	€ [***]
[***]	€ [***] [***]% of the Ono Proceeds]
[***]	€ [***] [***]% of the Ono Proceeds]

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[***]	€ [***] [***]% of the Ono Proceeds]
[***]	€ [***]

(b) The Clinical Development Milestones are minimum payments. If Ono grants a sublicense to a Sublicensee under the Merus IP to use, have used, make, have made, market, have marketed, offer to sell, have offered to sell, sell, have sold and import Products in the Field of Use in any country other than Japan, Ono shall pay Merus the larger of either [***] or [***]% of the Ono Proceeds. The [***]% Ono Proceeds shall be applied pro-rata to the Phase III Clinical Trial and Regulatory Approval milestones for the United States of America and Europe indicated above. Each of the development and approval milestone payments set forth above will be due one time only upon the first attainment of the specified event by the first Product regardless of subsequent or repeated achievement of such milestone except as specified in Section 6.3(d).

(c) If the development of a Product is being abandoned after any of the milestone payments under Section 6.3(a) has been made (such Product, the **"Discontinued Product"**), and Ono (or its Affiliate or Sublicensee) then commences and conducts development of a replacement Product for the Discontinued Product, then only those milestone payments under this Section 6.3 that were not previously made with respect to such Discontinued Product will be payable with respect to achievement by the replacement Product of any further milestone events as provided above.

(d) Notwithstanding anything to the contrary contained in Section 6.3(a), in the event [***], Ono shall pay [***]% amount of the Clinical Development Milestones of those specified in the table of Section 6.3(a) above for [***]. In the event [***], Ono shall pay [***]% amount of the Clinical Development Milestones of those specified in the table of Section 6.3(a) above for [***]. For clarity, Ono will not be obliged to pay any milestone payments for [***].

6.4 Royalties.

6.4.1 Royalty Rate. In consideration for the license granted and the ownership rights that are assigned hereunder (provided that any Ono IP is generated by Merus), on a Product-by-Product basis and country-by-country basis, Ono will pay Merus a royalty of [***] % based on the aggregate Net Sales of any Product sold in such country by Ono (directly or through its Affiliates, distributors, or Sublicensees) for each calendar quarter (or portion thereof) during the Royalty Term. For clarity, a royalty rate of [***]% set forth in this Section 6.4.1 shall apply to Net Sales of the second and further Products. These royalties will be paid in each country where at least one Valid Claim of the licensed Merus Patent Rights Covers the Product or its use. Royalties due shall be calculated by multiplying the applicable total(s) of Net Sales of each Product sold in such countries against the applicable royalty rate of [***]%, such amounts converted from local currency to Euros where necessary and as detailed below in article 7.3.

6.4.2 Royalty Term for Products. As to sales of a particular Product in a country, the royalty payments specified in Section 6.4 will be due on all Net Sales of the Product in such country occurring during the Royalty Term. After the Royalty Term expires with respect to a particular Product in a given country, Ono's license rights with respect to such Product will be fully paid-up and perpetual and continue on a royalty-free basis.

6.4.3 No Royalty Reductions. Parties hereby agree that there will be no royalty reductions under any circumstance, including but not limited to the event in which Ono would have to grant compulsory licenses or obtain additional licenses under third party intellectual property rights related to the sale of Products.

7. PAYMENT; RECORDS; AUDITS

7.1 Research Program Payments. In consideration for Merus' performance of its obligations under the Research Program, and subject to the terms contained in this Agreement, Ono shall provide the FTE funding as provided for in Section 6.2.

7.2 Royalty Payments; Reports. Within [***] ([***]) days after the end of each calendar quarter for which royalties are due by Ono to Merus, Ono shall pay Merus all such amounts payable by it under Section 6.4 by wire

transfer on a country by country basis. Each such payment shall be accompanied with a report, providing in reasonable detail an accounting of all Net Sales made during such calendar quarter and the calculation of any royalties due under Section 6.4.

7.3 Exchange Rate. If any currency conversion shall be required in connection with the calculation of royalties hereunder, such conversion shall be made using the following procedures. Sales recorded during each calendar quarter will be translated to Euro values at the rate on the last working day of that calendar quarter based on the exchange rates published on the European Central Bank website. Any changes to procedures for currency conversion shall only apply after such notice has been delivered and provided that such changes are consistently applied across Ono's operating units and continue to maintain a set methodology for currency conversion.

7.4 Tax Matters.

(a) Ono Payments to Merus Without Withholding. Ono will make all payments to Merus under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by law in effect at the time of payment.
(b) Ono Payment of Tax. Any tax required to be withheld on amounts payable to Merus under this Agreement will promptly be paid by Ono on behalf of Merus to the appropriate governmental authority, and Ono will furnish Merus with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Merus.

(c) Cooperation Between Ono and Merus. Ono and Merus will cooperate with respect to all documentation required by any government taxing authority or reasonably requested by Ono to secure a reduction in the rate of applicable withholding taxes to the maximum extent permitted by law. The documentation referred in this Section 7.4(c) as of the Effective Date includes Form 3 and Form 17 (application form for the relief from Japanese Income Tax on Royalties) and Certificate of Residence of Merus issued and signed by the tax authority in the Netherlands, or thereafter any other document that may be required for the similar purpose from time to time during the Term. Notwithstanding the provisions of Section 6.2.3 Merus agrees that Ono's payments of upfront fee, research and development milestones and royalties payments respectively set forth in Section 6.1, 6.3 and 6.4 will not be made until all the procedures required for such withholdings or its reduction is accepted by the authority, or Ono will pay to Merus the amount due in accordance with this Agreement deducting the applicable withholding tax if Merus so requests. In such case Ono will pay the applicable withholding tax to the Japanese tax authority, and provide Merus with the relevant tax proof.

7.5 Audits.

(a) Each Party shall keep, and cause its Affiliates and Third Party subcontractors or Sublicensees to keep, complete and accurate records for [***] ([***]) years which are relevant to the determination of any payment to be made by such Party under this Agreement, including without limitation, FTE records, records on Net Sales and royalty calculations, and records relating to the milestone events covered in Section 6.3. At the request and expense of a Party, the other Party and its applicable Affiliates and its Third Party subcontractors or Sublicensees shall permit an independent certified public accountant appointed by such requesting Party and reasonably acceptable to the other Party, at reasonable times and upon [***] ([***]) days prior notice, to examine in confidence such records as may be necessary to determine, with respect to any records pertaining to any financial report or payment due in any quarter ending not more than [***] months prior to such Party's request, to verify the correctness or completeness of any such report or payment made under this Agreement.

(b) The foregoing right of examination may be exercised only once per [***]-month period during the Term and only [***] with respect to any such financial report or payment due hereunder. Results of any such examination shall be limited to information relating to the applicable reporting and payment obligations, and made available to the audited Party. The accountant shall disclose to the auditing Party only whether the applicable reports and payments were correct or incorrect and the amount of any discrepancy between an amount due and an amount paid. The Party requesting the audit shall bear the expenses of such independent certified public accountant related to the performance of any such audit, unless such audit discloses such a discrepancy to the detriment of the auditing Party

of more than [***] percent ([***]%) from the amount of the original payment made; in such case, the Party being audited shall bear the such expenses for the performance of such audit.

(c) If such audit reveals that the audited Party, its Affiliate or Third Party subcontractor or Sublicensee has failed to accurately report information causing a discrepancy resulting in the underpayment of any amounts owed, the audited Party shall promptly pay any amounts due to the auditing Party together with interest on such amount, calculated from the date originally owed at the interest rate set forth in Section 7.6. In the event of a discrepancy resulting in an overpayment, any amount of such overpayment shall be fully credited against amounts payable by the audited Party in subsequent periods or reimbursed to the audited Party.

7.6 Late Payments. In the event that any payment due under this Agreement is not made when due, the payment will accrue interest from the date due until paid, calculated on a daily basis, based on the total number of days payment is delinquent at a rate per annum equal to the [***] ([***]) month USD LIBOR rate quoted [***] Business Days prior to the due date by the British Bankers' Association plus a premium of [***] percent ([***]%), *provided*, *however*, that in no event will such rate exceed the maximum legally permissible annual interest rate. The payment of such interest will not limit either Party from exercising any other rights it may have as a consequence of the lateness of any payment.

8. INTELLECTUAL PROPERTY

8.1 Ownership.

8.1.1. Ono's Ownership. Ono IP is and will remain the sole property of Ono and all rights to any Ono IP generated under this Agreement solely vests in Ono, subject to the license grants of Section 5.1. If the perfection and documentation of the assignment of ownership set forth in Section 8.1.4 as contemplated in Section 8.1.2 is not technically practical or feasible in Prosecution, then such Patent Rights nevertheless remain the sole property of Ono subject to the license granted set forth in Section 5.1(e).

8.1.2. Merus' Ownership. Merus IP is and will remain the sole property of Merus and all rights to any Merus IP generated under this Agreement solely vests in Merus. If assignment of ownership set forth in Section 8.1.4 as contemplated in Section 8.1.1 is not technically practical or feasible in Prosecution, then such Patent Rights nevertheless remain the sole property of Merus subject to the license granted set forth in Section 5.1(a), (c) and (d).

8.1.3. Negative Covenant. Except as expressly provided hereunder, Merus (a) shall not acquire, or attempt to acquire, pursuant to this Agreement any right, title or interest to any Lead Biclonics and any Patent Rights solely owned by Ono pursuant to Section 8.1.1 (b) shall not (and shall not attempt to purport to attempt to) transfer, assign, sell, have sold, lease, offer to sell or lease, distribute, license, sublicense or otherwise transfer title in, commercialize or exploit any Lead Biclonics and Patent Rights solely owned by Ono pursuant to Section 8.1.1, and (c) shall not, directly or indirectly, file, Prosecute, or maintain, in any country, any Patent Rights applicable to such Lead Biclonics and Patent Rights solely owned by Ono pursuant to Section 8.1.1.

8.1.4. Assignment of Ownership; Assistance. Either Party hereby assigns and transfers to the other Party all right, title and interest including ownership rights to and in all inventions falling into the scope of the other Party's ownership rights as set forth in Section 8.1.1 or 8.1.2 hereof. Each Party undertakes that it shall do or procure to be done all such acts and things, and execute, or procure the execution of, all such documents, as the other Party may from time to time reasonably require to give it the full benefit of any assignment contemplated in Article 8, and shall cause its employees to have any documents or instruments required by laws or regulations duly executed by signing in order to effect such assignment and transfer. In no event shall either Party be liable for compensation for inventions conceived, developed or reduced to practice by the other Party' employee(s) regardless of which Party has ownership rights to such invention.

8.2 Patent Prosecution.

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(a) General Principle. The Parties will discuss in good faith and mutually agree on the best strategy for the Prosecution of Patent Rights for Lead Biclonics and its use, provided, that, in any event, [***] shall have the final right to Prosecute and to decide the scope of claims on patent applications, in which countries and when patent claims shall be filed, and whether patent claims shall be filed within one or several patents or patent applications.

(b) Prosecution. Unless otherwise agreed between the Parties, [***] shall, at its sole expense, control the Prosecution of all Patent Rights relating to Lead Biclonics, but that for clarity excludes Merus Patent Rights. Upon reasonable request of [***] shall, at [***] expense, reasonably cooperate with [***] in relation to such Prosecution. In particular in case of any interference, opposition, reexamination request, nullity proceeding, appeal or other interparty action, [***] shall review it with [***] as reasonably requested, and make employees of [***] available in any course of such interference, opposition, reexamination request, nullity proceeding, appeal or other interparty action for testimony, deposition or hearing, and [***] shall [***] in connection with such cooperation including [***] of its own employees.

(c) Cooperation. [***] agrees to cooperate with [***], and perform such lawful acts, and execute such documents in order to reasonably assist [***] with respect to the Prosecution of Patent Rights pursuant to Section 8.2.

8.3 Infringement of Third Party Patent Rights.

(a) If either Party after the Effective Date is warned or sued by a Third Party alleging or charging infringement of any patents or published patent applications of a Third Party arising out of or resulting from the use of the Merus Technology, the Party, which is warned or sued, shall notify promptly the other Party.

(b) Merus shall be responsible, at its expense, for settling and/or defending such warning or litigation for patent infringement in which the alleged infringing process or product giving rise to liability for damages involves [***]. In so far as any such settlement or defense effects is likely to have an effect on Ono activities, Merus shall promptly inform Ono and Merus and Ono shall confer as to any modification of any right granted to Ono hereunder. Upon Merus' written request, Ono agrees to reasonably assist Merus in any such defense, if such infringement action might have an effect on Ono activities.

(c) Ono shall be responsible, [***], for settling and/or defending such warning or litigation for patent infringement in which the alleged infringing process or product giving rise to liability for damages involves [***]. If Merus should suffer any [***] and [***] as a result of such dispute, including [***], [***] any such [***].

9. REPRESENTATIONS, WARRANTIES, AND COVENANTS

9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other that: (a) it is duly organized and validly existing under the laws of its jurisdiction of incorporation or formation, and has full corporate or other power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it is duly authorized to execute and deliver this Agreement and to perform its obligations hereunder, and each person executing this Agreement on its behalf has been duly authorized to do so by all requisite corporate or partnership action; and (c) this Agreement is legally binding upon it, enforceable in accordance with its terms, and does not conflict with any agreement, instrument or understanding, oral or written, to which it is a Party or by which it may be bound, nor violate any applicable law or regulation of any court, governmental body or administrative or other agency having jurisdiction over it.

9.2 Merus IP Warranties. Merus represents and warrants to Ono as of the Effective Date that:

(a) to Merus' knowledge, Merus Patent Rights listed in Exhibit C are accurate and complete and identifies all Patent Rights Controlled by Merus or any of its Affiliates as of the Effective Date that include any claim Covering or otherwise directly relating to the Merus Technology; and

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

(b) Merus has not granted any Third Party any right, license or interest in or under, nor assigned, transferred, conveyed or encumbered any right, title and interest in and to, any of the Merus Patent Rights, or any of Merus Know-How disclosed therein, that is in conflict with the rights and licenses granted to Ono under this Agreement.

(c) to Merus' knowledge, Merus IP are free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental entity or subdivision thereof, has or shall have any claim of ownership whatsoever with respect to Merus IP.

(d) Except for the individual cases as more specifically described in Exhibit D, Merus has not received notice from, or been prosecuted through a legal action by, any Third Party claiming that the use or exploitation of Background IP infringes any Third Party's Patent Rights and Know-How.

(e) no consent by any Third Party or governmental entity is required with respect to the execution and delivery of this Agreement by Merus or the consummation by Merus of the transactions contemplated hereby.

(f) Except for the individual cases as more specifically described in Exhibit D, to Merus' knowledge, there is no unauthorized use, infringement or misappropriation of any of Background IP by any employee or former employee of Merus, or any other Third Party.

(g) Any and all fact based statement(s) contained in Exhibit D is/are true.

(g) Merus Patent Rights listed on Exhibit C hereto constitute all of Merus' Patent Rights that are, to Merus' knowledge, necessary for the performance of the Research Program by Merus and/or Ono as contemplated herein.

(h) to Merus' knowledge, all inventors identified in Merus Patent Rights, or all employees or sub-contractors of Merus have agreed to assign or license to Merus their entire rights, title and interest to and in any Intellectual Property that may be made, discovered or developed by them as a result of performance of their activities contemplated herein.

9.3 Disclaimer. Except as expressly set forth herein, THE KNOW-HOW, MATERIALS AND INTELLECTUAL PROPERTY RIGHTS PROVIDED BY EACH PARTY HEREUNDER ARE PROVIDED "AS IS". WITH RESPECT TO SUCH KNOW-HOW AND MATERIALS SUPPLIED HEREUNDER, EACH SUPPLYING PARTY EXPRESSLY DISCLAIMS ANY AND ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE WARRANTIES OF DESIGN, MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, OR NONINFRINGEMENT OF THE INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES. Without limiting the generality of the foregoing, each Party expressly does not warrant, and disclaims any warranties with regards to: (a) the success of any study or test commenced under the Research Program, (b) the safety or usefulness for any purpose of the materials it provides or discovers under this Agreement; and/or (c) the validity or enforceability of any intellectual property rights existing as of the Effective Date licensed to the other Party under this Agreement.

9.4 Limitation of Liability. EXCEPT FOR LIABILITY FOR BREACH OF ARTICLE 9, NEITHER PARTY WILL BE ENTITLED TO RECOVER FROM THE OTHER PARTY ANY SPECIAL, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES IN CONNECTION WITH THIS AGREEMENT OR ANY LICENSE GRANTED HEREUNDER; *provided, however,* that this Section 9.4 will not be construed to limit either Party's indemnification obligations under Article 12.

9.5 Covenants of the Parties

(a) Throughout the Term, Merus and Ono will comply (and will cause their respective Affiliates and Sublicensees to comply) in all material respects with all applicable laws and regulations concerning any of their activities hereunder, including with respect to performing Research and to the research, manufacture, use and sale of Products.

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(b) Each of the Parties will, at the reasonable request of the other Party, use reasonable efforts to execute and deliver any further or additional instruments or documents, and to perform any other acts, as are necessary in order to effectuate and carry out the terms of this Agreement, but *provided that* the foregoing shall not be interpreted to require such Party to incur any additional expenses or grant any other rights to the other Party, other than rights expressly granted elsewhere in the Agreement.

10. CONFIDENTIALITY

10.1 Confidential Information. Except to the extent expressly authorized by this Agreement or agreed in writing by the Parties, each Party agrees that, during the Term and for [***] ([***]) years thereafter, the receiving Party and its Affiliates and Sublicensees and Third Party subcontractors will keep confidential and will not publish or otherwise disclose, and will not use for any purpose other than as expressly permitted in this Agreement, any information furnished to it or its Affiliates, Sublicensees or Third Party subcontractors by the other Party pursuant to this Agreement or information acquired or developed on such other Party's behalf (collectively, **"Confidential Information"**). For the avoidance of doubt, as long as Ono retains license rights to any Lead Biclonics and/or Products hereunder, data and other information relating thereto shall be considered Ono's Confidential Information. Each Party may use such Confidential Information of the other Party only to the extent required to accomplish the purposes of this Agreement or exercise its rights under the licenses granted to it under this Agreement. Each Party will use at least the same standard of care as it uses to protect proprietary or confidential information of its own, but in no event less than stringent as set forth in this Article 10. Each Party shall use reasonable efforts to ensure that its and its Affiliates' and Sublicensees' and Third Party subcontractors' employees, agents, consultants, investors and other representatives comply with the Party's obligations hereunder and do not disclose or make any unauthorized use of the Confidential Information, and that the terms of any subcontracts will be in all essential aspects consistent with the obligations and restrictions hereunder, including by providing a confidentiality term that is of equivalent duration or no less than what is reasonable to protect the Confidential Information to be disclosed or developed in the subcontractual arrangement. Each Party will promptly notify the other upon discovery of any unauthorized use or disclosure of the other Party's Confidential Information. The Parties further acknowledge that each Party has disclosed to the other Party (or its Affiliates), prior to the Effective Date, certain Confidential Information pursuant to non-disclosure and/or material transfer agreements entered into between the Parties (or a Party's Affiliates), that limit the disclosure and use of such information by the receiving Party. The Parties hereby agree that any such Confidential Information earlier disclosed by one Party to the other (or its Affiliates) under such earlier agreements will be deemed to be the Confidential Information of the disclosing Party and subject to all the terms of this Article 10 and Section 4.6, as well as the additional terms covering such information and materials (if any) under the earlier agreements.

10.2 Exceptions. The obligations of non-disclosure and non-use under Section 10.1 will not apply as to particular Confidential Information of a disclosing Party to the extent that the receiving Party can prove by competent written evidence that such Confidential Information: (a) is at the time of receipt, or thereafter has become, through no act or failure to act on the part of the receiving Party (or its Affiliates or Sublicensees or Third Party subcontractors), published, generally known or otherwise available in the public domain; (b) is known by the receiving Party at the time of receiving such information, as evidenced by its records; (c) is hereafter furnished to the receiving Party by a Third Party, as a matter of right and without restriction on disclosure; (d) is independently discovered or developed by the receiving Party without reference to Confidential Information belonging to the disclosing Party; or (e) is the subject of a written permission to disclose provided by the disclosing Party.

10.3 Authorized Disclosure. Each Party may disclose Confidential Information belonging to the other Party solely to the extent such disclosure is reasonably necessary in connection with the following:

(a) Prosecuting Patent Rights as permitted by this Agreement;

(b) in connection with regulatory filings for Licensed Biclonics and/or Products that such Party has a license or right to develop hereunder;

(c) prosecuting or defending litigation as permitted by this Agreement;

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(d) complying with applicable court orders or governmental regulations;

(e) disclosure to Affiliates, Sublicensees, Third Party subcontractors, clinical or non-clinical institutions, and consultants (including their potential entities) on a need to know basis and only for purposes of performance of such Party's obligations under this Agreement, and provided, in each case, that any such Affiliate, Sublicensee, or Third Party subcontractor, clinical or non-clinical institutions, and consultants (including their potential entities) agrees to be bound by similar terms of written confidentiality and non-use at least equivalent in scope to those set forth in this Article 10; or

(f) disclosure to existing or potential Third Party investors, merger partners, acquirers, and professional advisors (including lawyers, accountants, and investment bankers) solely as reasonably necessary in the context of a potential transaction to which the Confidential Information is material, provided, that any such Third Party agrees to be bound by similar terms of confidentiality and non-use at least equivalent in scope to those set forth in this Article 10.

Notwithstanding the foregoing, in the event a Party is required to make a disclosure of the other Party's Confidential Information pursuant to Section 10.3(d) or (f), it will, except where impracticable, give reasonable advance notice to the other Party of such planned disclosure and use reasonable efforts to secure, or to assist the other Party in securing, confidential treatment of and/or a protective order regarding such information. In the case of authorized disclosure set forth in Section 10.3(a) through (f) above such Party shall disclose only such Confidential Information of such other Party as is required to be disclosed. The receiving Party of Confidential Information shall take all steps reasonably necessary, including obtaining an order of confidentiality or redacting financial terms of conditions of this Agreement, to ensure the continued confidential treatment of such Confidential Information. Each Party agrees that it shall cooperate fully with the other with respect to all disclosures regarding this Agreement as required under the regulations of Securities and Exchange Commission in the US or similar regulatory agency in any other country including requests for confidential information or proprietary information of either Party to be included in any such disclosure. Authorized disclosure of the Confidential Information pursuant to this Section 10.3 shall not be deemed exceptions pursuant to Section 10.2 unless and until publicly available.

10.4 Publications.

10.4.1 If either Party seeks to publish any information relating to any results of Research conducted under this Agreement or which includes any Confidential Information of the other Party, including any information relating in any way to any Target Specific Biclonics or Product, the Party seeking to publish will provide the other Party the material proposed for publication, such as by draft slide presentation, manuscript, poster, or abstract, at least [***] ([***]) days in advance of submitting the material to a publisher or an organizing committee or other equivalent organization of scientific meeting, and the other Party will have the right to review and comment on all such material. The Parties will reasonably agree on the content of any such publication, *except that* Ono shall be free to publish the results of and/or information concerning research and development of Lead Biclonics and/or Product subject to Section 10.4.2 below.

10.4.2 If Ono seeks to publish any of Merus' Confidential Information relating to the results of its Research conducted under this Agreement in connection with a proposed publication concerning development of Lead Biclonics and/or Product, Ono will deliver the draft material to Merus at least [***] ([***]) days prior to submitting the material to a publisher or an organizing committee or other equivalent organization of scientific meeting. Merus will review any such material and give its comments to Ono as soon as practicable and will give written notice whether it authorizes the disclosure of its Confidential Information or requests deletion of Merus Confidential Information, but shall not unreasonably withhold such authorization.

10.5 Publicity. No disclosure of the existence, or the terms, of this Agreement may be made by either Party, and neither Party shall use the name, trademark, trade name or logo of the other Party, its Affiliates or their respective employees in any publicity, promotion, news release or disclosure relating to this Agreement or its subject matter, without the prior express written consent of the other Party, except as may be required by law. Without prior written consent, the name of a Party or any other of its Affiliates may not be used by the other Party for any advertising or promotional purposes. Either Party may make subsequent public disclosure of the same contents as previously done

pursuant to this Section 10.5. Each Party agrees not to issue any other press release or other public statement, whether oral or written, disclosing the existence of this Agreement, the terms hereof or any information relating to this Agreement without the prior written consent of the other Party.

10.6 Public Announcement. No public announcement with respect to this Agreement or any activities under the Research Program shall be made, whether directly or indirectly, by either Party without prior agreement of the other Party. A Party desiring to make public announcement shall provide the other Party with the proposed text of such announcement with sufficient time prior to public release for the other Party's review and comments, and such desiring Party shall use its reasonable efforts to incorporate the other Party's comments. Both Parties shall discuss in good faith and agree on the timing, nature and text of such announcement. Subject to Section 10.7 below, either Party may make public announcement repeatedly to the extent that once it has been made pursuant to this Section 10.6, without first obtaining the written approval of the other Party. Either Party agrees that it may include the other Party's name and short description of its business and the collaboration on a list of strategic partners in its corporate documents to be made publicly available, including the corporate website, financial reports for its shareholders or such documents submitted to Securities and Exchange Commission in the US or similar regulatory agency in any other country.

10.7 Combination of Features or Disclosures. Any combination of features or disclosures shall not be deemed to fall within the foregoing exceptions contemplated in Section 10.3 merely because individual features are published or available to the general public or in the rightful possession of the receiving Party unless the combination itself and principle of operation are published or available to the public or in the rightful possession of the receiving Party.

10.8 Return of Confidential Information. Upon termination of this Agreement, the receiving Party shall promptly return to the disclosing Party or destroy the disclosing Party's Confidential Information, including all copies thereof, except to the extent that retention of such Confidential Information is reasonably necessary for the receiving Party to exploit any continuing rights it may have and/or to fulfil its obligations contemplated herein, including its obligations of non-disclosure and non-use hereunder. Any such destruction requested by the disclosing Party shall be certified in writing to the disclosing Party by an authorized officer of the receiving Party. The return and/or destruction of such Confidential Information as provided above shall not relieve the receiving Party of its obligations under this Agreement.

11. TERM AND TERMINATION

11.1 Term of Agreement. The term of this Agreement (the **"**Term**"**) will commence on the Effective Date and continue until expiration of the later of expiration or termination of all payment obligations of Ono accruing prior to the effective date of early termination under this Agreement or expiration of the Royalty Term for all Products licensed hereunder, unless earlier terminated as provided below.

11.2 Termination for Cause. Each Party will have the right to terminate this Agreement upon sixty (60) days' prior written notice to the other Party upon the material breach by such other Party of any obligation under this Agreement, including a breach of any diligence obligations, *provided that* such notice has given sufficient detail of the basis for the breach and the breaching Party has not cured such breach within the 60-day period following such written notice. The right of a Party to terminate this Agreement under this Section, and the notice period for such termination, will be tolled during the period of any dispute resolution process (including arbitration) that is invoked under Article 13 to resolve the issue of whether the alleged breaching Party has in fact committed a material breach of this Agreement, or whether such Party has cured such breach.

11.3 Termination by Ono Without Cause During The Research Term. At any time during the Research Term, Ono may terminate this Agreement by providing Merus at least forty-five (45) days prior written notice. Ono agrees to pay Merus within forty-five (45) days of such termination an amount equal to the research funding owed under Section 6.2 for a ninety (90) day period. The calculation of such amount will be made based on the annual FTE rate set forth in Section 6.2.1 above *pro-rata* to the Business Days of Merus up to the end of such ninety (90) day period.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

11.4 Termination by Ono Without Cause. At any time after expiration of the Research Term, by providing Merus at least ninety (90) days prior written notice to Merus, Ono may terminate this Agreement in its entirety.

11.5 Termination for Insolvency. Either Party may terminate this Agreement by written notice to the other with immediate effect if the other Party becomes insolvent, is compelled to file bankruptcy, is determined otherwise imminently subject to control by a bankruptcy trustee, liquidator or administrator or the equivalent, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party pursuant to the laws of the jurisdiction in which such Party is doing business; provided, however, that in the case of any involuntary bankruptcy proceeding such right to terminate shall only become effective if the Party consents to the involuntary bankruptcy or such proceeding is not dismissed within ninety (90) days after the filing thereof.

11.6 Effect of Termination; Surviving Obligations.

11.6.1 Except in the case of termination by Ono for cause pursuant to Section 11.2, upon early termination of this Agreement, all rights under the licenses granted by Merus to Ono under this Agreement, if then in effect, will automatically terminate and revert to Merus; in the case of termination by Ono for cause pursuant to Section 11.2, the provisions of this Section 11.6.1 shall not apply and Ono's license granted hereunder will be fully paid-up and perpetual and continue on a royalty-free basis; and

11.6.2 Except in the case of termination by Ono for cause pursuant to Section 11.2, upon early termination of this Agreement by either Party, at Merus' written request, Ono and its Affiliates shall destroy all Research Tools and all supplies of Target Specific Biclonics, Licensed Biclonics and Product, and shall promptly thereafter confirm such destruction in writing to Merus.

11.6.3 Expiration or termination of this Agreement will not relieve the Parties of any obligation accruing prior to such expiration or termination. The following provisions of this Agreement will survive expiration or termination of this Agreement: Articles 1, 4.1, 4.2, 4.3, 5.1 (e)ii, 6.4.2, 7.5, 8.1, 9, 10, 11.6, 11.8, 12, 13, and 14 until expiration of a period of performance of its obligations set forth in the relevant Section or, if such period is not expressly provided, completely performed of its obligations.

11.6.4 Within [***] ([***]) days following the expiration or termination of this Agreement, except to the extent and for so long as a Party retains license rights hereunder pertaining to any of the other Party's Confidential Information or materials, at a Party's request the other Party will deliver to the requesting Party any other Confidential Information and materials of the requesting Party in its possession or at the requesting Party's option, will destroy such Confidential Information and materials and will certify to the requesting Party in writing that it has so destroyed such Confidential Information and materials.

11.7 Exercise of Right to Terminate. The use by either Party hereto of a termination right provided for under this Agreement will not in and of itself give rise to the payment of damages or any other form of compensation or relief to the other Party with respect thereto.

11.8 Damages; Relief. Subject to Sections 9.4 and 11.6 above, termination of this Agreement will not preclude either Party from claiming or seeking or being entitled to any other damages, compensation or relief that it may be entitled to which accrued prior to such termination based on the Agreement.

12. INDEMNIFICATION

12.1 Indemnification by Merus. Merus hereby agrees to save, defend and hold harmless Ono and its Affiliates and their respective directors, officers, employees and agents (each, a **"Ono Indemnitee"**) from and against any and all claims, suits, actions, demands, liabilities, damages, expenses and/or loss, including reasonable legal expense and attorneys' fees (collectively, **"Losses"**), to which any Ono Indemnitee may become subject, to the extent such Losses result from any claim, demand, action or other proceeding against the Ono Indemnitee by any Third Party to the extent based upon: (i) the [***], but provided that Merus is not obliged to enter litigation and defend Ono for [***] against Ono (ii) the [***], or (iii) the breach by Merus of any warranty, covenant or agreement made by Merus

in this Agreement; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Ono Indemnitee or the breach by Ono of any warranty, covenant or agreement made by Ono in this Agreement. For avoidance of doubt, such indemnification shall not apply to any Loss caused by the sale of any Product by Ono to any Third Party.

12.2 Indemnification by Ono. Ono hereby agrees to save, defend and hold harmless Merus and its Affiliates and their respective directors, officers, employees and agents (each, a **"Merus Indemnitee"**) from and against any and all Losses to which any Merus Indemnitee may become subject, to the extent such Losses result from any claim, demand, action or other proceeding against the Merus Indemnitee by any Third Party to the extent based upon: (i) the [***], including the practice by Ono (or its Affiliate or any Third Party subcontractor or Sublicensee) of [***] under this Agreement, (ii) the manufacture, use, handling, storage, sale or other disposition of any Product and/or Licensed Biclonics by Ono, its Affiliates or Sublicensees, or (iii) the breach by Ono of any warranty, covenant or agreement made by Ono in this Agreement; except, in each case, to the extent such Losses result from the negligence or willful misconduct of any Merus Indemnitee or the breach by Merus of any warranty, covenant or agreement made by Merus in this Agreement.

12.3 Control of Defense. Any Party or any of its indemnitees entitled to indemnification under this Article 12 will give notice to the indemnifying Party of any Losses for which it is claiming indemnification promptly after learning of such Losses, and the indemnifying Party will assume the defense of such Losses with counsel reasonably satisfactory to the indemnified Party. If such defense is assumed by the indemnifying Party with counsel so selected, the indemnifying Party will not be liable for any settlement of such Losses made by the indemnified Party without consent of the indemnifying Party (provided that such consent is not unreasonably withheld or delayed), and will not be obligated to pay the fees and expenses of any separate counsel retained by the indemnified Party with respect to such Losses or indemnification claim.

12.4 Insurance. Each Party shall maintain at its expense insurance coverage consistent with normal business practices and adequate to cover the risks associated with its performance of any activities hereunder, and each Party acknowledges and agrees that the maintenance of such insurance coverage shall not relieve either Party of its obligations under this Agreement. Ono, at its own expense, will maintain product liability insurance (or self-insure) in an amount consistent with industry standards during the Term of this Agreement. Ono will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to Merus upon request. Merus, at its own expense, will maintain during the Research Term and for a period of at least [***] ([***]) years thereafter to maintain (a) workers' compensation insurance for all of its employees, the limits of which shall be as required under statute; and (b) commercial general liability insurance on a claims made basis having limits of not less than €[***] in the aggregate and €[***] per occurrence. Merus will provide a certificate of insurance (or evidence of self-insurance) evidencing such coverage to Ono upon request. For avoidance of doubt, such insurance obligation by Merus shall not apply to cover any Loss caused by the sale of any Product by Ono to any Third Party.

13. DISPUTE RESOLUTION

13.1 Discussion by Senior Executives.

(a) If there is a matter within the JSC's authority for which the JSC is unable to reach a decision, or if any dispute (including any claim or controversy arising from or related in any way to this Agreement or the interpretation, application, breach, termination or validity thereof, including any claim of inducement of breach of this Agreement by fraud or otherwise) arises between the Parties under this Agreement, such matter or dispute will be referred to the Chief Executive Officer of Merus and the Executive Director of Discovery and Research of Ono, for further discussion and resolution. These individuals will as soon as practicable meet and attempt in good faith to resolve the matter or dispute and reach agreement. These individuals may obtain the advice of other employees or consultants as they deem necessary or advisable to facilitate resolution.

(b) If an unresolved JSC matter or the dispute with respect to performance of Ono under its sole responsibility is not resolved by such senior executives, the decision by Ono's senior executive shall be final and bind on the Parties as set forth the last sentence of Section 3.2. For all other disputes, if the senior executives cannot reach agreement as to

the dispute within [***] ([***]) days of the dispute being referred to them by either Party in writing, then the dispute (an "**Unresolved Issue**") will be resolved as provided in Section 13.2 or 13.3, as applicable.

13.2 Arbitration.

(a) Any Unresolved Issue not resolved under Section 13.3 shall be resolved by arbitration pursuant to the rules then pertaining under the Rules of Arbitration of the International Chamber of Commerce ("ICC") by [***] ([***]) arbitrators, except where these Rules conflict with this provision, in which case this provision controls. The arbitration will be held in New York, in the U.S.A., and shall be conducted in the English language. The arbitrators shall decide the Dispute in accordance with the law governing this Agreement. In the case that no ICC rules exist, the Parties will in that case agree in good faith on alternate arbitration rules to govern any arbitration conducted under this Section 13.2.

(b) The panel will consist of [***] ([***]) arbitrators each of whom is a lawyer with a law firm or corporate law department or was a judge of a court of general jurisdiction who, in either case, has at least [***] ([***]) years of experience in the biopharmaceutical field. Notwithstanding the foregoing, if the aggregate damages sought by the claimant are stated to be less than €[***], and the aggregate damages sought by the counterclaimant are stated to be less than €[***], and neither side seeks equitable relief, then a single arbitrator will be chosen, having the same qualifications and experience specified above. Each arbitrator will be neutral, independent, disinterested, and impartial.

(c) Each Party shall nominate in the request for arbitration and the answer thereto one arbitrator and the two arbitrators so named shall then jointly appoint the third arbitrator as chairman of the arbitration tribunal, each of them reasonably acceptable to the other Party, acceptance of which shall not be unreasonably withheld. If one Party fails to nominate its arbitrator or, if the Parties' arbitrators cannot agree on the person to be named as chairman within [***] ([***]) days, the President of the ICC shall make the necessary appointments. After appointment, the Parties shall have no ex-parte communication with their proposed arbitrator.

(d) Within [***] ([***]) days of initiation of arbitration, the Parties shall reach agreement upon and thereafter follow procedures assuring that the arbitration shall be concluded and the award rendered within no more than [***] ([***]) months from selection of the arbitrators. Failing such agreement, the ICC Arbitration Rules shall control the scheduling and the Parties shall follow procedures that meet such a time schedule. Each Party has the right before or, if the arbitrators cannot hear the matter within an acceptable period, during the arbitration to seek and obtain from any court of competent jurisdiction provisional remedies such as attachment, preliminary injunction, replevin, etc., to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration. Any request for such provisional measures by a Party to a court shall not be deemed a waiver of this agreement to arbitrate. In addition, the arbitration tribunal may, at the request of a Party, order provisional or conservatory measures (including preliminary injunctions to prevent breaches hereof) and the Parties shall be able to enforce the terms and provisions of such orders in any court having jurisdiction. The decision of the arbitration tribunal must be in writing and must specify the basis on which the decision was made, and the award of the arbitration tribunal shall be final, non-appealable and binding upon the Parties and judgment upon such an award may be entered in any competent court or application may be made to any competent court for judicial acceptance of such an award and order of enforcement. THE ARBITRATION TRIBUNAL SHALL NOT AWARD ANY PARTY PUNITIVE, EXEMPLARY, MULTIPLIED OR CONSEQUENTIAL DAMAGES, AND EACH PARTY HEREBY IRREVOCABLY WAIVES ANY RIGHT TO SEEK SUCH DAMAGES. NO PARTY MAY SEEK OR OBTAIN PREJUDGMENT INTEREST OR ATTORNEY'S FEES OR COSTS.

13.3 Preliminary Injunctive Relief. Notwithstanding anything to the contrary, either Party may at any time seek to obtain provisional remedies such as attachment, preliminary injunctive relief, replevin, etc., solely to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration in equity from a court of competent jurisdiction with respect to an issue arising under this Agreement if the rights of such Party would be prejudiced absent such relief, including any dispute relating to (i) the determination as to the infringement, validity or claim interpretation of a Party's Patent Rights, or (ii) the misuse and/or misappropriation of a Party's Confidential Information, in each case, a Party may submit such dispute to the competent court.

13.4 Diligence Disputes. For any Unresolved Dispute that involves a claim by either Party that the other Party has breached its diligence obligations under the Agreement, the arbitrators of such Unresolved Dispute will, under the arbitration conducted under Section 13.2, determine if such other Party materially breached such diligence obligations.

14. GENERAL PROVISIONS

14.1 Governing Law. This Agreement will be governed by, and construed and enforced in accordance with, the laws and regulations of the State of New York, U.S.A., as well as United States federal law and regulations, without giving effect to any conflicts of laws principles.

14.2 Entire Agreement; Modification. This Agreement, including its appendices and exhibits, is both a final expression of the Parties' agreement and a complete and exclusive statement with respect to all of its terms. In the event of any inconsistency between the terms of the body of this Agreement and the terms of any appendices or exhibits, the body of this Agreement shall control. This Agreement supersedes all prior and contemporaneous agreements and communications between the Parties, whether oral, written or otherwise, concerning the subject matter contained herein. No rights or licenses with respect to any intellectual property of either Party are granted or deemed granted hereunder or in connection herewith, other than those rights expressly granted in this Agreement. This Agreement may only be modified or supplemented in a writing expressly stated for such purpose and signed by the Parties to this Agreement.

14.3 Relationship of the Parties. The Parties' relationship, as established by this Agreement, is solely that of independent contractors. This Agreement does not create any partnership, joint venture or similar business relationship between the Parties. Neither Party is a legal representative or agent of the other Party, and neither Party can assume or create any obligation, representation, warranty or guarantee, express or implied, on behalf of the other Party for any purpose whatsoever.

14.4 Performance by Affiliates and Sublicensees. The Parties recognize that each may perform some or all of its obligations under this Agreement through Affiliates or Third Party subcontractors or Sublicensees, *provided, however,* that each Party will remain responsible and be guarantor of the performance by its Affiliates and Third Party subcontractors and Sublicensees and will cause them to comply with the provisions of this Agreement in connection with such performance. In particular, if any Affiliate of a Party or its Third Party subcontractor participates in Research under this Agreement or its Sublicensee with respect to Target Specific Biclonics, (a) the restrictions and obligations of this Agreement which apply to the activities of a Party will apply equally to the activities of such Affiliate and Third Party subcontractors and Sublicensees, and (b) the Party performing through such Affiliate or Third Party subcontractor or Sublicensee will assure, and hereby guarantees, that such performance will be consistent with the provisions of this Agreement. Any action or omission by a Party's Affiliate, Third Party subcontractor, or a Sublicensee which would, if such action or omission were conducted by the Party, constitute a breach of the Party's obligations under this Agreement will constitute a breach by the Party.

14.5 Non-Waiver. The failure of a Party to insist upon strict performance of any provision of this Agreement or to exercise any right arising out of this Agreement will neither impair that provision or right nor constitute a waiver of that provision or right, in whole or in part, in that instance or in any other instance. Any waiver by a Party of a particular provision or right to be effective must be in writing signed by such Party, and will be limited to the specified matter and, if applicable, the specified period of time in such writing.

14.6 Assignment. Except as expressly provided hereunder, neither this Agreement nor any rights or obligations hereunder may be assigned or otherwise transferred by either Party without the prior written consent of the other Party (which consent will not be unreasonably withheld); *provided, however*, that either Party may assign this Agreement or any of its license rights granted hereunder without the other Party's consent:

(a) to its successor in interest in connection with the transfer or sale of all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, provided that in the event of a transaction (whether this Agreement is actually assigned or is assumed by the acquiring Party by

operation of law), intellectual property rights of the acquiring party to such transaction (if other than one of the Parties to this Agreement) will not be included in the technology licensed hereunder, and, provided further that the such acquiring party will remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations of the assigning Party; or

(b) to an Affiliate, provided that the assigning Party will remain liable and responsible to the non-assigning Party hereto for the performance and observance of all such duties and obligations by such Affiliate.

The rights and obligations of the Parties under this Agreement will be binding upon and inure to the benefit of the successors and permitted assigns of the Parties. Any assignment not in accordance with this Agreement will be void.

14.7 No Third Party Beneficiaries. This Agreement is neither expressly nor impliedly made for the benefit of any party other than those Parties executing it.

14.8 Severability. If, for any reason, any part of this Agreement is adjudicated invalid, unenforceable or illegal by a court of competent jurisdiction, all other portions will remain in full force and effect, and the Parties will use their reasonable efforts to substitute for the invalid, unenforceable or illegal provision a valid, enforceable and legal provision which conforms as nearly as possible with the original intent of the Parties.

14.9 Notices. Any notice to be given under this Agreement must be in writing and delivered either in person, by Express or certified mail (return receipt requested) (in each case postage prepaid), or by an internationally recognized express courier, or by facsimile with confirmed transmission, to the Party to be notified at its address(es) given below, or at any address such Party has previously designated by prior written notice to the other. Notice will be deemed sufficiently given for all purposes upon the earliest of: (a) the date of actual receipt; (b) if mailed, [***] ([***]) days after the date of postmark; or (c) if delivered by express courier, [***].

If to Ono, notices must be addressed to:

Ono Pharmaceutical Co., Ltd
Minase Research institute
1-1, Sakurai, 3-chome,
Shimamoto, Mishima, Osaka, 618-8585, Japan
Attn: Director, Discovery Research Alliance
Facsimile: [***]

If to Merus, notices must be addressed to:

Merus B.V.
Padualaan 8
3584 CH Utrecht
the Netherlands
Attention: Mark Throsby, CSO
Telephone: [***]
Email: [***]

with a copy to:

Shelley Margetson, CFO
Email: [***]

14.10 Force Majeure. Each Party will be excused from liability for the failure or delay in performance of any obligation under this Agreement by reason of any event beyond such Party's reasonable control, including but not limited to Acts of God, fire, flood, explosion, earthquake, or other natural forces, war, terrorism, civil unrest, accident, destruction or other casualty, any lack or failure of transportation facilities, any lack or failure of supply of raw materials, any strike or labor disturbance, or any other event similar to those enumerated above. Such excuse

from liability will be effective only to the extent and duration of the event(s) causing the failure or delay in performance and provided that the Party has not caused such event(s) to occur and continues to use diligent, good faith efforts to avoid the effects of such event and to perform the obligation. Notice of a Party's failure or delay in performance due to force majeure must be given to the other Party within [***] ([***]) days after its occurrence. All delivery dates under this Agreement that have been affected by force majeure will be tolled for the duration of such force majeure. The Party failing or delaying in performance of any obligation under this Agreement by reason of such force majeure event will use reasonable effort to recover from such force majeure event to perform its obligations, provided that in no event will any Party be required to prevent or settle any labor disturbance or dispute. Notwithstanding the foregoing, should the event(s) of force majeure suffered by a Party extend beyond a nine-month period, the other Party may then terminate this Agreement by written notice to the non-performing Party, with the consequences of such termination as set forth in Section 11.5.

14.11 Interpretation.

(a) Captions & Headings. The captions and headings of clauses contained in this Agreement preceding the text of the articles, sections, subsections and paragraphs hereof are inserted solely for convenience and ease of reference only and will not constitute any part of this Agreement, or have any effect on its interpretation or construction.

(b) Singular & Plural. All references in this Agreement to the singular will include the plural where applicable, and all references to gender will include both genders and the neuter.

(c) Articles, Sections & Subsections. Unless otherwise specified, references in this Agreement to any article will include all sections, subsections, and paragraphs in such article; references in this Agreement to any section will include all subsections and paragraphs in such sections; and references in this Agreement to any subsection will include all paragraphs in such subsection.

(d) Ambiguities. Ambiguities and uncertainties in this Agreement, if any, will not be interpreted against either Party, irrespective of which Party may be deemed to have caused the ambiguity or uncertainty to exist.

(e) English Language. All notices required or permitted to be given hereunder, and all written, electronic, oral or other communications between the Parties regarding this Agreement will be in the English language.

14.12 Counterparts. This Agreement may be executed in any number of counterparts, each of which will be deemed an original document, and all of which, together with this writing, will be deemed one instrument. Signing and delivery of this Agreement may be evidenced by an electronic transmission of the front and signed signature page to the other Party, provided however, that such electronic signing and delivery is confirmed in written paper copy signed by and delivered to each Party promptly following electronic signing and delivery.

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

IN WITNESS WHEREOF, the Parties have duly executed this Agreement as of the Effective Date.

MERUS B.V.

By: /s/ Ton Logtenberg
Name: Ton Logtenberg
Title: CEO

ONO PHARMACEUTICAL Co. Ltd.

By: /s/ Gyo Sagara
Name: Gyo Sagara
Title: President, Representative Director and Chief Executive Officer

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

EXHIBIT A

Initial Research Plan

1. Rationale

[***]

2. Background information

[***]

3. Objective

[***]

4. Endpoint / Outcome

[***]

5. Go /No go decision points (time + resources)

[***]

6. Proposed start and end date

[***]

7. Time line for Merus activities

[***]

8. Merus Research Budget

[***]

9. Allocation of Funded Merus FTE

[***]

10. Overview of Joint responsibilities & research activities leading up to early milestones

[***]

11. Detailed research plan

[***]

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EXHIBIT B

[***]

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EXHIBIT C

MERUS PATENT RIGHTS

[***]

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EXHIBIT D

Intellectual Property Summary

[***]

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EXHIBIT E

INITIAL MEMBERS OF JSC

Members representing Merus:

[***]

Members representing Ono:

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

EXHIBIT F

Form of Invoice

Invoice to be printed on official Merus letterhead with date, payee's tax ID, and Ono's (or its designated Affiliate payor's) P.O. number inserted:

DATE:

INVOICE NO.: Merus* Tax ID: [***]

Bill To:
Ono Pharmaceutical Co., Ltd.
3-1-1 Sakurai, Shimamoto-cho
Mishima-gun, Osaka 618-8585, Japan

Ono P.O. Number:

Terms: Net [***]

Amount of payment due: Euro

Payment due according to CONTRACT RESEARCH AND LICENSE AGREEMENT between Merus B.V. and ONO Pharmaceuticals Inc. dated , 2014,

for:
(If Research Funding) Relevant Research Period:
(If Milestone Payment) Milestone Event:

Ship To:
Director, Research Licensing, Discovery Research Alliance, Discovery and Research
Ono Pharmaceutical Co., Ltd.
3-1-1 Sakurai, Shimamoto-cho
Mishima-gun, Osaka 618-8585, Japan

Wire Instructions for Remittance to Merus:

** Merus to provide details and contact information*

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

ADDENDUM TO CONTRACT RESEARCH AND LICENSE AGREEMENT

This Addendum ("Addendum") is made on this 27th day of March, 2015 (the "Effective Addendum Date") by and between:

MERUS B.V., a private company with limited liability, having its registered office at Padualaan 8, 3584 CH Utrecht, the Netherlands ("**Merus**");

and

ONO PHARMACEUTICAL Co. Ltd., a Japanese company with its head offices located at 8-2, Kyutaromachi 1-chome, Chuo-ku, Osaka 541-8564, Japan ("**Ono**");

Hereinafter also referred to individually as "Party" or collectively as the "Parties".

WHEREAS:

(A) Merus and Ono have entered into a Contract Research and License Agreement dated April 8, 2014 (the "Agreement");

(B) Merus and Ono have agreed to amend the Agreement as set forth in this Addendum.

THERFORE, the Parties have agreed as follows:

1. Definitions and Interpretation

1.1. Capitalized terms used in this Addendum shall, where not defined herein, have the meaning attributed to such terms in the Agreement.

2. Upfront fee

2.1 The Parties agree that upfront fee of €1,000,000 (one million euros) shall be under no circumstances refundable to Ono. The Parties hereby understand and confirm that the second sentence of Section 6.1 of the Agreement will no longer be applicable.

3. Funded Merus FTEs

3.1 In accordance with Section 6.2.1 of the Agreement Merus hereby agrees to make available to Ono an additional **[***]** FTE over the following **[***]** months (**[***]** – **[***]**) at the rate of €**[***]** per FTE per year. This will allow Merus to support Ono with productions, a swift technology transfer and cover the project management costs. Merus aims to transfer the Research Program by the end of **[***]**.

4. Objective under Initial Work Plan

4.1 In the objective under Initial Work Plan (page 37, Section 3 of the Agreement), the Parties agreed about the option for Merus to make available to Ono a panel of **[***]** (**[***]**) existing Human Antibodies against **[***]** as further specified in the attached Exhibit A to this Addendum ("Merus **[***]**") in combination with newly obtained Human Antibodies against **[***]**. Merus hereby agrees to transfer Merus **[***]** for use in Lead Biclonics to Ono at no extra charge. For clarity, any Target Specific Biclonics containing any Merus **[***]** that is functional and identified by Ono in accordance with the Specifications shall be deemed and construed as Lead Biclonics under the Agreement.

4.2 In connection with such transfer pursuant to the preceding Section, the Parties further agree that the definitions of "Merus Know-How", "Merus Patent Rights", and "Ono Patent Rights" of the Agreement shall be deleted in their entirety and replaced with the following paragraphs, respectively;

" '**Merus Know-How**' means the Know-How Controlled by Merus as of the Effective Date or developed by Merus during the Term that are necessary for research, development, use manufacturing and/or commercialization activities of Ono, its Affiliates or Sublicensees with respect to Lead Biclonics and/or Products. Merus Know-How includes Merus **[***]**. For clarity, Merus Know-How will not include Merus Patent Rights and/or Ono Patent Rights.

" '**Merus Patent Rights**' means the Patent Rights (a) Controlled by Merus as of the Effective Date relating to the Merus Technology or (b) Covering any invention and discovery conceived, developed or reduced to practice solely by either Party, or jointly by both Parties during the Term relating to (i) any improvement of Merus Technology, (ii) any process or material for making, delivering, or formulating bispecific Antibodies generated using Merus

Technology, (iii) any method of using bispecific Antibodies generated using Merus Technology, (iv) any Research Tool or any process or material for making or using a Research Tool, (v) a Human Antibody against either **[***]** or **[***]**, but excluding Human Antibody of Lead Biclonics, and/or (vi) Merus **[***]**, in each case of subsection (i) through (vi) in this paragraph excluding Ono Patent Rights. The Merus Patent Rights include the Patent Rights listed in Exhibit C."

" '**Ono Patent Rights**' means the Patent Rights (a) Controlled by Ono as of the Effective Date specifically relating to the Research Program or (b) Covering any invention or discovery conceived, developed or reduced to practice solely by either Party, or jointly by both Parties, during the Term relating to (i) any composition of matter claims relating to Lead Biclonics, (ii) any composition of matter claims relating to Human Antibody of Lead Biclonics, but excluding Merus **[***]**, (iii) any process or material for making, delivering, or formulating Lead Biclonics, (iv) any method of using Lead Biclonics, and/or (v) any Research Tool or any process or material for making or using a Research Tool specifically relating to Lead Biclonics."

For clarity, Ono shall **[***]** that contain any Merus **[***]**.

4.3 The Parties agree that Sections 5.1(b) of the Agreement shall be deleted in its entirety and replaced with the following paragraph;

"(b) **Merus Retained Rights.** Subject to Section 4.1 of the Addendum dated on March 27th, 2015, Merus retains all rights to use and commercialize (i) any Human Antibodies that are generated under the Research Program but which are not Human Antibodies of Lead Biclonics and (ii) Merus **[***]** whether or not they are Human Antibodies of Lead Biclonics, and provided that such retained use or commercialization is not with respect to the Target Combination."

4.4 While it is understood that Merus is free to file any patent application or submit any publication with respect to Merus **[***]** based on its retained rights stipulated in the preceding Section 4.3, Merus will notify Ono of the date of such patent filing or submission of publication at least **[***]** (**[***]**) days prior to such date.

5. Specifications for Lead Biclonics

5.1 In light of Ono's use of Merus **[***]** pursuant to Section 4.1 of this Addendum, the Parties hereby agree that Exhibit B of the Agreement shall be deleted in its entirety and replaced by Exhibit B-1 as attached below.

6. Miscellaneous

6.1. Except as expressly modified by this Addendum, the Agreement shall remain in full force and effect in accordance with its terms.

6.2. Any terms of this Addendum may be amended or waived only with the written consent of the Parties and any such amendment or waiver will be binding on all Parties.

6.3. If one or more provisions of this Addendum is held by any court of competent jurisdiction to be wholly or partially illegal, void, invalid or unenforceable, the remaining provisions shall remain in force and the Parties undertake to replace the invalid or unenforceable provisions of this Addendum by provisions which are effective and which deviate as little as possible from the invalid or unenforceable provisions, taking into account the object and purpose of this Addendum.

6.4. This Addendum and the Agreement shall constitute the whole and only agreement between the Parties relating to the subject matter.

6.5. This Addendum will be governed by, and construed and enforced in accordance with, the laws and regulations of the State of New York, U.S.A., as well as United States federal law and regulations, without giving effect to any conflicts of laws principles.

6.6. This Addendum may be executed in counterparts with each Party having received its copy, each of which will be deemed an original, but both of which together shall constitute one and the same agreement.

[*Signatures to follow*]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

IN WITNESS WHEREOF, the parties hereto have caused this Addendum to be signed by their duly authorised officers the date above written.

MERUS B.V.

By: /s/ Ton Logtenberg
Name: Ton Logtenberg
Title: Chief Executive Officer

By: /s/ Shelley Margetson
Name: Shelley Margetson
Title: Chief Financial Officer

ONO PHARMACEUTICAL Co. Ltd.

By: /s/ Kazuhito Kawabata
Name: Kazuhito Kawabata, Ph.D.
Title: Member of the Board of Directors, Executive Officer, Executive Director Discovery and Research

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

EXHIBIT A

[***]

[***] Certain information in this document has been excluded pursuant to Regulation S-K, Item (601)(b)(10). Such excluded information is both (i) not material and (ii) the type that the Registrant treats as private or confidential.

EXHIBIT B-1

Specifications for Lead Biclonics and Preclinical Proof of Mechanism
[***]

US-DOCS\127260760.1

Exhibit 31.1

CERTIFICATION

I, Sven (Bill) Ante Lundberg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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: November 2, 2021

By: /s/ Sven A. Lundberg

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

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Quarterly Report on Form 10-Q of Merus N.V. (the "Company") for the period ended September 30, 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: November 2, 2021

By: /s/ Sven A. Lundberg

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