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, 2020

OR

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

For the transition period from _____ to _____

Commission File Number: 001-37773

MERUS N.V.

(Exact name of registrant as specified in its charter)

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

+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 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 30, 2020, the registrant had 29,088,670 common shares, nominal value €0.09 per share, outstanding.

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 and assumptions, including those described under the sections in this Quarterly Report on Form 10-Q entitled “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.

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, 2020	December 31, 2019
ASSETS		
Current assets:		
Cash and cash equivalents	$ 139,179	$ 197,612
Marketable securities	51,021	42,153
Accounts receivable	538	941
Accounts receivable (related party)	1,568	1,711
Prepaid expenses and other current assets	9,010	4,951
Total current assets	201,316	247,368
Marketable securities	—	2,009
Property and equipment, net	3,792	3,715
Operating lease right-of-use assets	4,229	5,215
Intangible assets, net	2,784	2,876
Deferred tax assets	291	288
Other assets	1,081	1,905
Total assets	$ 213,493	$ 263,376
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 4,720	$ 3,029
Accrued expenses	19,819	13,536
Current portion of lease obligation	1,536	1,380
Current portion of deferred revenue	699	941
Current portion of deferred revenue (related party)	18,657	17,901
Total current liabilities	45,431	36,787
Lease obligation	2,736	3,872
Deferred revenue, net of current portion	331	780
Deferred revenue, net of current portion (related party)	80,494	90,637
Total liabilities	128,992	132,076
Stockholders' equity:		
Common shares, €0.09 par value; 45,000,000 shares authorized; 29,074,536 and 28,882,217 shares issued and outstanding as at September 30, 2020 and December 31, 2019, respectively	$ 2,938	$ 2,918
Additional paid-in capital	448,617	441,395
Accumulated other comprehensive income	5,094	1,586
Accumulated deficit	(372,148)	(314,599)
Total stockholders' equity	84,501	131,300
Total liabilities and stockholders' equity	$ 213,493	$ 263,376

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,	
	2020	2019	2020	2019
Collaboration revenue	$ 695	$ 2,558	$ 1,207	$ 4,496
Collaboration revenue (related party)	7,875	5,690	19,720	19,061
Grant revenue	—	(93)	—	(216)
Total revenue	8,570	8,155	20,927	23,341
Operating expenses:				
Research and development	17,538	13,511	48,234	36,078
General and administrative	9,136	8,024	26,061	22,979
Total operating expenses	26,674	21,535	74,295	59,057
Operating loss	(18,104)	(13,380)	(53,368)	(35,716)
Other income (loss), net:				
Interest (expense) income, net	(12)	591	367	1,756
Foreign exchange (losses) gains	(4,782)	3,468	(4,243)	4,474
Other income (loss), net	(4,794)	4,059	(3,876)	6,230
Net loss before income taxes	(22,898)	(9,321)	(57,244)	(29,486)
Tax expense (benefit)	177	(54)	305	239
Net loss	$ (23,075)	$ (9,267)	$ (57,549)	$ (29,725)
Other comprehensive income (loss):				
Currency translation adjustment	4,414	(3,561)	3,508	(4,363)
Comprehensive loss	$ (18,661)	$ (12,828)	$ (54,041)	$ (34,088)
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (0.64)	$ (0.55)	$ (1.86)	$ (1.46)
Weighted-average common shares outstanding:				
Basic and diluted	29,061	23,403	29,014	23,388

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,	
	2020	**2019**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (57,549)	$ (29,725)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization of property and equipment	830	635
Amortization of intangible assets	206	173
Foreign exchange gain	3,828	(2,932)
Loss on disposal of property and equipment	17	—
Stock-based compensation expense	6,327	5,188
Amortization of discount on investments	(30)	(452)
Deferred tax (benefit) expense	(2)	105
Changes in operating assets and liabilities:		
Accounts receivable	634	1,473
Operating lease right-of-use assets and lease obligations	2	(124)
Prepaid expenses and other current assets	(2,935)	(3,778)
Accounts payable	1,587	(301)
Accrued expenses	5,707	(218)
Deferred revenue	(14,187)	(13,348)
Net cash used in operating activities	**$ (55,565)**	**$ (43,304)**
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchases of marketable securities	$ (49,359)	$ (49,385)
Proceeds from maturities of marketable securities	42,831	71,701
Purchases of intangible assets	—	(213)
Purchases of property and equipment	(858)	(2,079)
Net cash (used in) provided by investing activities	**$ (7,386)**	**$ 20,024**
CASH FLOWS FROM FINANCING ACTIVITIES:		
Payment of offering costs	$ (164)	$ —
Proceeds from stock options exercised	915	48
Net cash provided by financing activities	**$ 751**	**$ 48**
Foreign exchange impact on cash, cash equivalents and restricted cash	3,767	(6,900)
Net decrease in cash, cash equivalents and restricted cash	(58,433)	(30,132)
Cash, cash equivalents, and restricted cash, beginning of period	197,813	164,730
Cash, cash equivalents, and restricted cash, end of period	**$ 139,380**	**$ 134,598**
SUPPLEMENTAL DISCLOSURES:		
Income taxes paid	$ 235	$ 245
Non-cash purchases of property, equipment and intangibles	$ 5	$ 230
CASH, CASH EQUIVALENTS AND RESTRICTED CASH		
Cash and cash equivalents	139,179	134,457
Restricted cash included in non-current other assets	201	141
	$ 139,380	$ 134,598

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 Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2019	23,358,977	$ 2,366	$ 360,045	$ (259,448)	$ 2,894	$ 105,857
Exercise of stock options and vesting of restricted stock units	20,678	2	26	—	—	28
Stock-based compensation	—	—	1,260	—	—	1,260
Currency translation adjustment	—	—	—	—	(1,900)	(1,900)
Net loss	—	—	—	(7,083)	—	(7,083)
Balance at March 31, 2019	23,379,655	$ 2,368	$ 361,331	$ (266,531)	$ 994	$ 98,162
Exercise of stock options and vesting of restricted stock units	13,632	2	2	—	—	4
Stock-based compensation	—	—	1,860	—	—	1,860
Currency translation adjustment	—	—	—	—	1,098	1,098
Net loss	—	—	—	(13,375)	—	(13,375)
Balance at June 30, 2019	23,393,287	$ 2,370	$ 363,193	$ (279,906)	$ 2,092	$ 87,749
Exercise of stock options and vesting of restricted stock units	14,265	1	15	—	—	16
Stock-based compensation	—	—	2,068	—	—	2,068
Currency translation adjustment	—	—	—	—	(3,561)	(3,561)
Net loss	—	—	—	(9,267)	—	(9,267)
Balance at September 30, 2019	23,407,552	$ 2,371	$ 365,276	$ (289,173)	$ (1,469)	$ 77,005
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

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 $372.1 million as of September 30, 2020. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as its antibody candidates advance through discovery, pre-clinical development and clinical trials and as it seeks regulatory approval and pursues commercialization of any approved antibody candidate.

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

Based on the Company's current operating plan, the Company expects that its existing cash and cash equivalents and marketable securities of $190.2 million as of September 30, 2020 will be sufficient to fund its operations into the second half of 2022.

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, 2019, and the notes thereto, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, filed with the SEC on March 16, 2020 (as amended, 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, 2020.

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, 2020 and 2019 are referred to as the third quarter of 2020 and 2019, 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, 2019, 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 approved antibody candidate, and after considering its existing cash, cash equivalents and marketable securities as of September 30, 2020, the Company did not identify conditions or events that raise substantial doubt about the Company's ability to continue as a going concern within one year from the date these financial statements were issued.

Pending Accounting Pronouncements

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

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808),* which clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue when the collaborative arrangement participant is a customer in the context of a unit of account and precludes recognizing as revenue consideration received from a collaborative arrangement participant if the participant is not a customer. The ASU will be effective for the Company in the first quarter of 2021, with early adoption permitted. As of September 30, 2020, none of the Company's arrangements fall within the scope of ASC 808. However, as the Company may engage in future collaborative arrangements in the future, this ASU may apply to those new arrangements.

3. Investments in Debt Securities

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

	September 30, 2020	December 31, 2019
	(in thousands)	
Money market funds	$ 11,684	$ 34,053
Corporate paper and notes	20,751	38,679
U.S. government agency securities	9,187	3,987
U.S. treasuries	22,083	1,496
Total	$ 63,705	$ 78,215
Fair value of debt securities	$ 63,749	$ 78,254

	September 30, 2020	December 31, 2019
	(in thousands)	
Cash equivalents	$ 12,684	$ 34,053
Current marketable securities	51,021	42,153
Non-current marketable securities	—	2,009
Total	$ 63,705	$ 78,215

The Company does not intend to sell and 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, 2020	December 31, 2019
	(In thousands)	
Prepaid clinical and manufacturing costs	$ 5,085	$ 2,779
Prepaid general and administrative expenses	1,862	789
Interest receivable	187	259
Other	1,876	1,124
Total	$ 9,010	$ 4,951

Accrued expenses consisted of the following:

	September 30, 2020	December 31, 2019
	(In thousands)	
Accrued research and development expenses	$ 14,021	$ 6,618
Accrued general and administrative expenses	2,877	2,402
Accrued personnel costs	2,905	4,495
Other	16	21
Total	$ 19,819	$ 13,536

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,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
U.S. federal	$ 126	$ 47	$ 164	$ 145
U.S. state	131	(48)	143	(11)
Total current tax expense (benefit)	$ 257	$ (1)	$ 307	$ 134
U.S. federal	$ (56)	$ (41)	$ 6	$ 81
U.S. state	(24)	(12)	(8)	24
Total deferred tax (benefit) expense	$ (80)	$ (53)	$ (2)	$ 105
Total tax expense (benefit)	$ 177	$ (54)	$ 305	$ 239

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

There have been no changes in the Company's lease arrangements since December 31, 2019.

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Lease cost				
Operating lease cost	$ 411	$ 398	$ 1,203	$ 988
Variable lease cost	93	83	282	178
Total lease cost included in operating expenses	$ 504	$ 481	$ 1,485	$ 1,166
Other information				
Cash paid for amounts included in the measurement of lease liabilities included in operating cash flows	$ 412	$ 379	$ 1,201	$ 1,112

8. Collaborations

Incyte

On January 23, 2017, the Company completed the sale of shares and exchange of a license. 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, 2020, the Company is currently engaged in clinical development activities for MCLA-145 and developing pre-clinical candidates for the other programs. No development or commercialization milestones have been achieved to date.

ONO

On March 14, 2018, the Company granted ONO an exclusive, worldwide, royalty-bearing license, with the right to sublicense, research, test, make, use and market 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. The Company received €3.0 million (approximately $3.4 million) for the nine-month period ended September 30, 2019 for development milestones received from Ono based on their progress.

Simcere

In January 2018, the Company granted Simcere an exclusive license to develop and commercialize 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 two milestones under this agreement and has received an aggregate of $1.3 million in milestone payments, including a milestone payment of $0.5 million for the quarter ended September 30, 2020, concerning the generation of functional data associated with the second bispecific antibody research program. At September 30, 2020, research and development for three of the programs is on-going.

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	Ono	Other	Total
CONTRACT ASSETS				
Accounts receivable				
Balance at January 1, 2020	$ —	$ 786	$ —	**$ 786**
Billings	**4,862**	—	644	**644**
Cash receipts	**(4,903)**	(772)	(104)	**(876)**
Adjustments	**—**	—	(11)	**(11)**
Foreign exchange	**41**	(14)	9	**(5)**
Balance at September 30, 2020	**—**	—	538	**538**
Unbilled receivables				
Balance at January 1, 2020	**$ 1,711**	$ —	$ 155	**$ 155**
Accrued receivables	**4,690**	—	581	**581**
Billings	**(4,862)**	—	(644)	**(644)**
Adjustments	**—**	—	(94)	**(94)**
Foreign exchange	**29**	—	2	**2**
Balance at September 30, 2020	**1,568**	—	—	**—**
CONTRACT LIABILITIES				
Deferred revenue				
Balance at January 1, 2020	**$ 108,538**	$ 336	$ 1,385	**$ 1,721**
Revenue recognized in the period	**(13,415)**	(148)	(583)	**(731)**
Foreign exchange	**4,028**	8	32	**40**
Balance at September 30, 2020	**99,151**	196	834	**1,030**
Less: current portion	**(18,657)**	(196)	(503)	**(699)**
Non-current balance at September 30, 2020	**80,494**	—	331	**331**

The balance of unbilled receivables predominantly represents reimbursement revenue under the Company's collaboration arrangements earned in the period to be billed and collected in the next period, generally quarterly. Incyte is a related party as a shareholder, as more fully described in Note 10.

Contract Revenues and Expenses

	Three Months Ended September 30, 2020 (In thousands)			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 4,683**	$ 51	$ 153	**$ 204**
Reimbursement revenue	**3,192**	—	—	**—**
Milestones	**—**	—	491	**491**
Total collaboration revenue	**$ 7,875**	$ 51	$ 644	**$ 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**	$ 51	$ 156	**$ 207**

	Three Months Ended September 30, 2019 (In thousands)			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 4,466**	$ 49	$ 167	**$ 216**
Reimbursement revenue	**1,224**	—	36	**36**
Milestones	**—**	2,224	82	**2,306**
Total collaboration revenue	**$ 5,690**	$ 2,273	$ 285	**$ 2,558**
Operating expenses:				
Research and development expense	**$ 172**	$ —	$ —	$ —
General and administrative expense	**—**	—	—	—
Total operating expenses from collaborations	**$ 172**	$ —	$ —	$ —
Revenue recognized that was included in deferred revenue at the beginning of the period	**$ 4,466**	$ 49	$ 249	**$ 298**

	Nine Months Ended September 30, 2020 (In thousands)			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 13,414**	$ 148	$ 539	**$ 687**
Reimbursement revenue	**6,306**	—	(12)	**(12)**
Milestones	**—**	—	532	**532**
Total collaboration revenue	**$ 19,720**	$ 148	$ 1,059	**$ 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**	$ 148	$ 582	**$ 730**

	Nine Months Ended September 30, 2019 (In thousands)			
	Related Party	Third Party		
	Incyte	Ono	Other	Total
Upfront payments	**$ 13,393**	$ 147	$ 522	**$ 669**
Reimbursement revenue	**5,668**	99	119	**218**
Milestones	**—**	3,360	249	**3,609**
Total collaboration revenue	**$ 19,061**	$ 3,606	$ 890	**$ 4,496**
Operating expenses:				
Research and development expense	**$ 489**	$ —	$ —	**$ —**
General and administrative expense	**—**	—	—	**—**
Total operating expenses from collaborations	**$ 489**	$ —	$ —	**$ —**
Revenue recognized that was included in deferred revenue at the beginning of the period	**$ 13,393**	$ 147	$ 771	**$ 918**

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,	
	2020	2019	2020	2019
	(In thousands)		(In thousands)	
Research and development	$ 915	$ 766	$ 1,677	$ 2,351
General and administrative	1,929	1,302	4,650	2,837
Total	$ 2,844	$ 2,068	$ 6,327	$ 5,188

The weighted-average grant date fair value of options, estimated as of the grant date using the Black Scholes option pricing model (2019: Hull White), was $11.72 per option (2019: $7.45 per option) for the 1,236,484 options (2019: 1,113,371 options) granted during the nine months ended September 30, 2020. The significant weighted average valuation inputs included the risk-free interest rate 1.3% (2019: 2.5%), and volatility 86.0% (2019: 87.1%). A weighted average expected term of 6.1 years was used in the Black-Scholes option pricing model during the nine months ended September 30, 2020 and the weighted-average contractual term of 10.0 years was used in the Hull White model during the nine months ended September 30, 2019. The Company updates its valuation estimates and methodology to estimate the grant-date fair value of stock-based compensation periodically to reflect observable market data and exercise behavior.

In addition, the Company granted 46,474 RSUs during the nine months ended September 30, 2020 (2019: none) having a weighted average grant date fair value of $16.00 per unit.

Executive Settlements

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

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 will continue 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 for the nine months ended September 30, 2020.

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, 2019. Incyte is a shareholder with holdings representing approximately 11.0% of the outstanding shares of the Company as of September 30, 2020, and 11.1% as of December 31, 2019.

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. 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. 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™ allows 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 for the potential treatment of solid tumors; and MCLA-145, developed in collaboration with Incyte Corporation, for the potential treatment of solid tumors and a hematological malignancy, B-cell lymphoma. MCLA-117 is a first-in-class Biclonics® T-cell engager antibody that is designed to engage CD3 on T-cells and to bind to and kill AML blasts via the CLEC12A antigen. While we do not plan to continue enrollment into dose expansion cohorts in the MCLA-117 trial, insights from this trial are being used to inform and maximize development of our CD3 T-cell engager platform. We are also developing a late-stage pre-clinical candidate, MCLA-129 in collaboration with Betta Pharmaceuticals, 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—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 $190.2 million as of September 30, 2020 will be sufficient to fund our operations into the second half of 2022.

Clinical Programs

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

We continue to enroll patients in the Phase 1/2 eNRGy trial to assess the safety and anti-tumor activity of Zeno monotherapy in NRG1+ cancers. We believe that Zeno continues to demonstrate encouraging single agent activity in NRG1+ cancers and continues to be well tolerated, consistent with previously reported safety data in the overall patient population treated with Zeno monotherapy. The initial clinical responses reported in late 2019 support the potential for Zeno to be particularly effective in patients with NRG1+ cancers, a patient population with significant unmet need.

Earlier this year, Zeno was granted Orphan Drug Designation by the U.S. FDA for pancreatic cancer. Pancreatic cancer is estimated to occur in approximately 57,000 patients annually in the U.S., according to the National Cancer Institute SEER database. Pancreatic ductal adenocarcinoma (PDAC), the most common subtype of pancreatic cancer, is one of the most aggressive solid tumor cancers and the fourth leading cause of cancer-related deaths.

We plan to present efficacy data from the eNRGy trial and Early Access Program at a major medical conference in the second quarter of 2021 including results on more than 30 patients with NRG1+ pancreatic, non-small cell lung and other cancers with the opportunity for four or more months of follow up. At that time, we plan to also discuss details of the program and overall strategy.

Clinical trial site activation, patient identification and enrollment, and clinical operations activities for the eNRGy trial have increased since the second quarter of 2020. We previously noted that enrollment and clinical operations activities in this trial have continued, albeit at a slower pace throughout the COVID-19 pandemic. Over 30 clinical trial sites are now open globally, with additional sites planned for the coming months. We expect patient identification and enrollment to continue to accelerate through the our ongoing patient screening and patient identification initiatives, including several programs with clinical support and testing collaborators.

Our comprehensive patient recruitment strategy includes agreements with Caris Life Sciences (Caris), Foundation Medicine Inc., and Tempus Labs Inc., to identify NRG1+ patients and determine suitability of enrollment of these patients in the eNRGy trial and EAP. Separately, we have a collaboration with Caris, through which Caris has agreed to provide tumor DNA and RNA molecular testing, focused on pancreatic cancer, which is a patient population that may otherwise not undergo molecular diagnostic testing due to the current lack of personalized, molecularly-driven treatment options for this cancer type.

Details of the eNRGy trial, including current trial sites, can be found at www.ClinicalTrials.gov and our trial website at www.nrg1.com, or by calling 1-833-NRG-1234.

MCLA-158 (Lgr5 x EGFR Biclonics®): Solid Tumors
Phase 1 trial continues: Update expected by year end

MCLA-158 is currently being evaluated in a Phase 1 open-label, multicenter dose escalation study, including a safety dose expansion phase, in patients with solid tumors. The trial is ongoing and MCLA-158 has demonstrated a favorable safety profile with no observed dose limiting toxicities to date. We plan to provide a clinical update on the Phase 1 trial by year end.

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

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

MCLA-129 (EGFR x c-MET Biclonics®): Solid Tumors
IND-enabling studies ongoing, first patient planned to be dosed in 2021

We are currently conducting IND-enabling studies of MCLA-129 for the treatment of various solid tumors in collaboration with Betta Pharmaceuticals (Betta) and the first patient is planned to be dosed in 2021. We presented preclinical data in late 2019 demonstrating that MCLA-129 inhibited the growth of tyrosine kinase resistant Non-Small Cell Lung Cancer (NSCLC) cell lines and NSCLC tumors in xenograft models. Betta holds exclusive rights to develop MCLA-129 in China, while we retain full ex-China rights.

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-117, MCLA-158 and MCLA-145. We have observed a moderate to high impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic during the third quarter ended September 30, 2020, particularly at sites in countries not yet open to recruitment, and to a lesser extent in countries where COVID-19 related restrictions have been eased, with adjustments made to allow remote visits for some patient follow-up, and reduced onsite monitoring by the sponsor or contract research organization (CRO). As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials. The extent of the impact to our overall clinical development timeline is uncertain at this time and we continue to monitor and assess the COVID-19 pandemic on a regular basis.

As a result of the COVID-19 pandemic, certain of our CROs and third-party suppliers, as well as collaborators in the U.S. and China that are developing or collaborating with us to develop certain of our pre-clinical 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 pre-clinical antibody candidates, including MCLA-129, among other undisclosed pre-clinical candidates associated with our collaborations with Incyte and Simcere, which may delay or prevent their potential clinical development. While we currently do not anticipate any interruptions in our clinical trial supply of drug candidates, it is possible that the COVID-19 pandemic and response efforts may have an impact in the future on our third-party suppliers and contract manufacturing partners' ability to manufacture our clinical trial supply or source materials necessary for their manufacture.

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

At this time, there is significant uncertainty caused by the COVID-19 pandemic and impact of related responses. The future impact of COVID-19 on our business and clinical trials will largely depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the Netherlands, the United States and other countries, business closures or business disruptions, the ultimate impact of COVID-19 on financial markets and the global economy, and the effectiveness of actions taken in the Netherlands, the United States and other countries to contain and treat the disease. See “Risk Factors—The COVID-19 pandemic caused by the novel coronavirus has and may continue to adversely impact our business, including our pre-clinical studies and clinical trials, financial condition and results of operations.” in Part 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 for the year ended December 31, 2019, filed with the SEC on March 16, 2020 (as amended, the “Annual Report on Form 10-K”) for a description of the key terms of our arrangements.

Discussion and Analysis of our Results of Operations

In prior periods, we prepared our financial information in accordance with IFRS. As a consequence of becoming a U.S. domestic issuer as of January 1, 2020, we are required to present our financial information in accordance with U.S. GAAP and expressed in U.S. dollars from that date. The below financial information has been prepared in accordance with U.S. GAAP. The financial information should not be expected to correspond to figures we have previously presented under IFRS.

Comparison of the three and nine months ended September 30, 2020 and 2019

Revenue

The following is a comparison of revenue:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(In millions)			(In millions)		
Incyte	$ 7.9	$ 5.7	$ 2.2	$ 19.7	$ 19.1	$ 0.6
Ono	0.1	2.3	(2.2)	0.1	3.6	(3.5)
Other	0.6	0.3	0.3	1.1	0.9	0.2
Total collaboration revenue	8.6	8.3	0.3	20.9	23.6	(2.7)
Grant revenue	—	(0.1)	0.1	—	(0.2)	0.2
Total revenue	8.6	8.2	0.4	20.9	23.4	(2.5)

Collaboration revenue for the three months ended September 30, 2020 increased by $0.3 million as compared to the three months ended September 30, 2019, primarily as a result of an increase in Incyte reimbursement revenue of $2.0 million due to increased activities, and $0.5 million in other net increases, including the achievement of a Simcere milestone, partially offset by a decrease of $2.2 million in Ono milestone revenue due to the achievement of milestones in the prior year period that did not recur in the current year period. The change in exchange rates did not significantly impact collaboration revenue.

Collaboration revenue for the nine months ended September 30, 2020 decreased by $2.7 million as compared to nine months ended September 30, 2019 primarily as a result of a decrease of $3.4 million in Ono milestone revenue due to the achievement of milestones in the prior year period that did not recur in the current year period, partially offset by an increase in Incyte reimbursement revenue of $0.6 million due to increased activities.

As of September 30, 2020, we had total deferred revenue of $100.2 million, which primarily relates to the upfront payment received under our Incyte collaboration agreement and is expected to be recognized over the next six years.

Operating Expenses

The following is a comparison of operating expenses:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(In millions)			(In millions)		
Research and development	$ 17.5	$ 13.5	$ 4.0	$ 48.2	$ 36.1	$ 12.1
General and administrative	9.1	8.0	1.1	26.1	23.0	3.1
Total operating expenses	$ 26.6	$ 21.5	$ 5.1	$ 74.3	$ 59.1	$ 15.2

Research and development expense for the three months ended September 30, 2020 increased by $4.0 million as compared to the three months ended September 30, 2019, primarily as a result of an increase in headcount, higher manufacturing related costs, and higher pre-clinical research and development-related costs related to our programs, particularly increases in costs for zenocutuzumab.

Research and development expense for the nine months ended September 30, 2020 increased by $12.1 million as compared to the nine months ended September 30, 2019, primarily as a result of an increase in manufacturing related costs, and higher pre-clinical research and development-related costs related to our programs, particularly increases in costs for zenocutuzumab, offset by decreases in costs for MCLA-145. On a comparative basis, stock-based compensation included in research and development costs for the nine months ended September 30, 2020 decreased by $0.7 million compared to the nine months ended September 30, 2019, primarily due to the modification and forfeiture of awards held by departing executives.

General and administrative expense for the three months ended September 30, 2020 increased by $1.1 million as compared to the three months ended September 30, 2019, primarily as a result increases in stock-based compensation, insurance, intellectual property related costs and other items, partially offset by a decrease in consulting costs.

General and administrative expense for the nine months ended September 30, 2020 increased by $3.1 million as compared to the nine months ended September 30, 2019, primarily as a result increases in stock-based compensation, insurance, facilities, intellectual property related costs and other items, partially offset by a decrease in consulting costs.

Other Income (Loss), Net

The following is a comparison of other income, net:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(In millions)			(In millions)		
Interest income, net	$ —	$ 0.6	$ (0.6)	$ 0.4	$ 1.8	$ (1.4)
Foreign exchange gains (losses)	(4.8)	3.5	(8.3)	(4.2)	4.5	(8.7)
Total other income (loss), net	$ (4.8)	$ 4.1	$ (8.9)	$ (3.8)	$ 6.3	$ (10.1)

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

Income Tax Expense

The following is a comparison of income tax expense:

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2020	2019	Change	2020	2019	Change
	(In millions)			(In millions)		
Current	$ 0.3	$ —	$ 0.3	$ 0.3	$ 0.1	$ 0.2
Deferred	(0.1)	(0.1)	—	—	0.1	(0.1)
Total tax expense (benefit), net	$ 0.2	$ (0.1)	$ 0.3	$ 0.3	$ 0.2	$ 0.1

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

Net Loss

Net loss for the three and nine months ended September 30, 2020 was $23.1 million and $57.5 million, respectively, compared to net loss for the three and nine months ended September 30, 2019 of $9.3 million and $29.7 million, respectively. The change in net loss was primarily due to the change in collaboration revenue, changes in operating expenses and changes in other income (loss), net, as discussed above.

Material Changes in Financial Condition

Sources of Cash

As of September 30, 2020, we had $190.2 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.

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— 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, and government grants.

Except for any obligations of our collaborators or licensees to make license, milestone or royalty payments under our agreements with them, and government grants, we do not have any committed external sources of liquidity 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, 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 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, 2020, will be sufficient to fund our planned operating expenses and capital expenditure requirements into the second half of 2022, 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,		
	2020	2019	Change
	(In millions)		
Net cash used in operating activities	$ (55.6)	$ (43.3)	$ (12.3)
Net cash (used in) provided by investing activities	(7.4)	20.0	(27.4)
Net cash provided by financing activities	0.8	—	0.8

Net cash used in operating activities during the nine months ended September 30, 2020 decreased by $12.3 million as compared to the nine months ended September 30, 2019, primarily due to operating cash receipts related to revenue arrangements decreasing by $4.1 million, operating cash out flows related to operating expenses increasing by $5.1 million and a decrease in cash realized from interest income and foreign exchange of $2.9 million.

Net cash used in investing activities during the nine months ended September 30, 2020 principally reflects $49.4 million of purchases of marketable securities partially offset by maturities of marketable securities of $42.8 million. Net cash provided by investing activities during the nine months ended September 30, 2019 principally reflects $49.4 million of purchases of marketable securities, offset by maturities of marketable securities of $71.7 million.

Net cash provided by financing activities during the nine months ended September 30, 2020 primarily reflects proceeds received from stock option exercises of $0.9 million partially offset by payments of public offering costs of $0.2 million. Net cash provided by financing activities during the nine months ended September 30, 2019 primarily reflects cash received from stock option exercises of less than $0.1 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, 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, 2020.

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, 2020 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

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

From time to time, we may be involved in various other claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings, which could be 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 $57.5 million, and $29.7 million for the nine months ended September 30, 2020 and 2019, respectively. As of September 30, 2020, we had an accumulated deficit of $372.1 million. Our losses have resulted principally from expenses incurred in research and development of our antibody candidates and from management and administrative costs and other expenses that we have incurred while building our business infrastructure. We expect to continue to incur significant operating losses for the foreseeable future as we continue our research and development efforts and seek to obtain regulatory approval and commercialization of our antibody candidates. We anticipate that our expenses will increase substantially as we:

- conduct our ongoing, single agent, Phase 1/2 eNRGy clinical trial of zenocutuzumab, our most advanced bispecific antibody candidate, for the treatment of solid tumors harboring neuregulin 1 (NRG1) gene fusions and conclude our ongoing Phase 2 clinical trial for the treatment of metastatic breast cancer in combination with other therapies;
- complete our ongoing dose-escalation portion of our Phase 1 clinical trial of MCLA-117, our bispecific antibody candidate, for the treatment of acute myeloid leukemia (AML);
- conduct our ongoing Phase 1 clinical trial of MCLA-158 for the treatment of solid tumors;
- conduct our ongoing Phase 1 clinical trial for MCLA-145 for the treatment of advanced solid tumors and B-cell lymphomas, which is being co-developed with Incyte Corporation (Incyte);
- continue the research and development of our other pre-clinical antibody candidates, including the development of MCLA-129 in collaboration with Betta Pharmaceuticals Co. Ltd. (Betta);
- 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. 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-117, MCLA-158, and MCLA-145. We are in the early stages of development of our antibody candidates, and we have not completed development of any Biclonics® or any other drugs or biologics.

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

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

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

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

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct our ongoing clinical trials of zenocutuzumab, MCLA-158, and MCLA-145, complete the dose expansion phase of our trial of MCLA-117, complete IND-enabling studies for MCLA-129 and potentially enter clinical trials, 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, 2020 will be sufficient to fund our operations into the second half of 2022. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- the cost, progress and results of our ongoing clinical trials of zenocutuzumab and the Phase 1 clinical trials of MCLA-117, MCLA-158, and MCLA-145;

- the success of our collaboration with Incyte to develop monospecific and bispecific antibodies candidates, including our ongoing Phase 1 clinical trial for MCLA-145;
- the cost, progress and results of our IND-enabling studies and potential clinical trial for MCLA-129;
- the cost of manufacturing clinical supplies of our bispecific antibody candidates;
- the scope, progress, results and costs of pre-clinical development, laboratory testing and clinical trials for our other bispecific and multi-specific antibody candidates;
- the costs, timing and outcome of regulatory review of any of our antibody candidates;
- the costs and timing of future commercialization activities, including manufacturing, marketing, sales and distribution, for any of our antibody candidates to the extent any receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any potential future claims by third parties that we are alleged to be infringing upon their intellectual property rights;
- the costs and timing of securing, maintaining and/or obtaining freedom to operate for our technologies and products;
- the revenue, if any, received from commercial sales of our antibody candidates to the extent any receive marketing approval;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, including our existing collaborations and any other future licensing or collaboration arrangements for any of our antibody candidates.

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

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

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

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

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

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

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

We have not received regulatory approval for a therapeutic based on a full-length human bispecific or trispecific IgG approach. We cannot be certain that our approach will lead to the development of approvable or marketable products. In addition, our Biclonics® and Triclonics™ may have different effectiveness rates in various indications and in different geographical areas. Finally, the FDA, the EMA or other regulatory agencies may lack experience in evaluating the safety and efficacy of products based on Biclonics® and Triclonics™ therapeutics, which could result in a longer than expected regulatory review process, increase our expected development costs and delay or prevent commercialization of our antibody candidates.

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

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

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

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

Since our inception in 2003, we have devoted a significant portion of our resources to developing zenocutuzumab, MCLA-117, MCLA-158, MCLA-145 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-117, MCLA-158, and MCLA-145, and ongoing IND-enabling studies for MCLA-129, we have not 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 Brexit, and its potential impact on supply-chain and our personnel;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- 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 during which it will continue its ongoing and complex negotiations with the EU relating to the future relationship between the parties. Significant political and economic uncertainty remains about whether the terms of the relationship will differ materially from the terms before withdrawal, as well as about the possibility that a so-called "no deal" separation will occur if negotiations are not completed by the end of the transition period.

These developments have created significant uncertainty about the future relationship between the United Kingdom and the EU. Lack of clarity about future U.K. laws and regulations as the United Kingdom determines which EU-derived laws and regulations to replace or replicate as part of a withdrawal, including financial laws and regulations, tax and free trade agreements, intellectual property rights, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws, could further decrease foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict our access to capital. These developments, or the perception that any of them could occur, have 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 to 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 are not able to 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. are not able to travel to the Netherlands under current restrictions. Additionally, on March 18, 2020, we temporarily suspended our laboratory research activities at our facilities in Utrecht, the Netherlands to help secure the safety of our employees and to adhere to government recommendations of social distancing and limited public exposure in connection with the COVID-19 pandemic. We have since re-opened our offices and laboratory in Utrecht, maintaining social distancing and imposing other requirements consistent with government guidance. Further, we have recommended our employees in the U.S. and Netherlands work from home when possible and for those employees working at our offices and laboratory in Utrecht, and offices in Cambridge Ma. they are required to maintain social distancing and follow requirements consistent with the guidance provided by the CDC, Federal, state and local regulations for the U.S. and RIVM for the Netherlands. While we use reasonable business practices to mitigate the risk of exposure to COVID-19 while on Company-operated premises, we cannot guarantee that traveling to and from and visiting the office will not expose employees to infectious agent or eliminate inherent risks to our workforce and our business operations resulting from COVID-19. Given the uncertainty caused by the COVID-19 pandemic we cannot be certain that we will not suspend our laboratory research activities at our facilities or suspend use of our offices in the future.

As a result of the COVID-19 pandemic, certain of our contract research organizations (CROs) and third-party suppliers, as well as collaborators in the U.S. and China that are developing or collaborating with us to develop certain of our pre-clinical 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, including MCLA-129, among other undisclosed pre-clinical candidates associated with our collaborations with Incyte 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 pre-clinical antibody candidates, including 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 globally, which may force us to reduce related workflows until such 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-117, MCLA-158 and MCLA-145. To date, we have observed a moderate to high impact on clinical trial enrollment and operations as a consequence of the COVID-19 pandemic, particularly at sites in countries not yet open to recruitment, and to a lesser extent in countries where COVID-19 related restrictions have been eased, with adjustments made to allow remote visits for some patient follow-up, and reduced onsite monitoring by the sponsor or CRO and insufficient source verification of clinical data required for presentation of clinical data. The extent of the impact to our overall clinical development timeline is uncertain at this time and we continue to monitor this impact on a regular basis. As a result of the COVID-19 pandemic, we may experience further disruptions that could severely impact our business, preclinical studies and clinical trials, including:

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- risk that participants enrolled in our clinical trials will acquire 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, 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 to accept data from clinical trials in affected geographies;
- interruption or delays in our collaborations, including with Incyte, Betta Pharma, Simcere, and our license agreements with Ono and our academic collaborators, which may experience laboratory closures causing delays in preclinical, translational and development studies that support our clinical programs and IND-enabling studies;
- impacts from prolonged remote work arrangements, such as increased cybersecurity risks and strains on our business continuity plans; and
- delays or difficulties with equity offerings due to disruptions and uncertainties in the securities market.

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

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

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

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

To date, we have not completed any clinical trials required for the approval of any of our antibody candidates. Although we are conducting ongoing clinical trials for zenocutuzumab, MCLA-158, and MCLA-145, and continuing dose escalation for MCLA-117, and are conducting IND-enabling studies for 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 establishing the appropriate dose and schedule for antibody candidates in clinical trials;
- the difficulty in identifying the sub-populations that we are trying to treat in a particular trial, which may delay enrollment and reduce the power of a clinical trial to detect statistically significant results;
- lower than anticipated retention rates of patients in clinical trials;
- failure to have patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- investigator-sponsored studies of our product candidates, including expanded access protocols, may identify safety or efficacy concerns associated with our antibody candidates, or otherwise negatively affect patient enrollment in our ongoing and planned clinical trials;
- adding new clinical trial sites;
- safety or tolerability concerns could cause us or our collaborators or regulatory authorities, as applicable, to suspend or terminate a trial if we or our collaborators or regulatory authorities, find that the participants are being exposed to unacceptable health risks;
- failure to observe a meaningful clinical benefit;
- delays in or failure to obtain regulatory approval or authorizations to commence a trial;
- delays in or failure to obtain institutional review board (IRB) approval at each site;
- our third-party research contractors failing to comply with regulatory requirements or applicable law, or to meet their contractual obligations to us in a timely manner, or at all;
- changes in regulatory requirements, policies and guidelines;
- manufacturing sufficient quantities of antibody candidate for use in clinical trials;
- the quality or stability of an antibody candidate falling below acceptable standards;
- changes in the treatment landscape for our target indications that may make our antibody candidates no longer relevant;
- third party actions claiming infringement by our antibody candidates in clinical trials outside of the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires, epidemics or public health emergencies and U.S. or non-U.S. governmental actions or restrictions related thereto.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting, reporting on or completing our planned and ongoing clinical trials. We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs or Ethics Committees of the institutions in which such trials are being conducted, by the Data Review Committee or Data Safety Monitoring Board for such trial or by the FDA, the Competent Authorities

of the EEA Member States (the 27 EU Member States plus Iceland, Liechtenstein and Norway, and the United Kingdom (until the end of the transition period on December 31, 2020 provided for in the Withdrawal Agreement between the EU 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, the EU and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and Ethics Committees or IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our 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 EU and the United States may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of non-EU and non-U.S. CROs, as well as expose us to risks associated with clinical investigators who are unknown to the FDA or the EMA, and different standards of diagnosis, screening and medical care.

Interim and preliminary "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 or preliminary "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. In addition, we may report interim or preliminary analyses of only certain endpoints rather than all endpoints. 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 and preliminary data and analyses should be viewed with caution. Adverse differences between preliminary 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.

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

Undesirable side effects that may be caused by our antibody candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA, the EMA or other comparable foreign authorities. In February 2015, we commenced a Phase 1/2 clinical trial in Europe of our most advanced antibody candidate, zenocutuzumab, for the treatment of various solid tumors, which was amended to treat patients having solid tumors harboring a NRG1 gene fusion. Additionally, in January 2018 we commenced a Phase 2 clinical trial in Europe and the United States exploring zenocutuzumab, in combination with other agents, in patients with metastatic breast cancer. To date, patients treated

with zenocutuzumab have experienced adverse reactions that may be related to the treatment, including infusion-related reactions, diarrhea, vomiting, fatigue, skin rash, sore mouth and shortness of breath. In May 2016, we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-117. To date, patients treated with MCLA-117 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions including fever, cytokine release syndrome and chills. In May 2018 we commenced a Phase 1 clinical trial in Europe of our bispecific antibody MCLA-158 in patients with solid tumors. To date, patients treated with MCLA-158 have experienced adverse reactions that may be related to the treatment, most commonly infusion-related reactions and skin rash associated with mAb EGFR inhibitors. In May 2019, we commenced a Phase 1 clinical trial in the United States of our bispecific antibody MCLA-145 developed in collaboration with Incyte. To date, patients treated with MCLA-145 have experienced adverse events irrespective of causality including blood alkaline phosphatase increase, anemia, and hypoalbuminemia, lymphocyte count decrease, and white blood cell count decrease. Febrile neutropenia and elevated liver enzymes have been reported as serious adverse events.

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

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

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

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

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

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

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

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patient candidates. For our Phase 1/2 clinical trial of zenocutuzumab in solid tumors, we are enrolling up to 90 patients with tumors harboring NRG1 gene fusions. Solid tumors with NRG1 gene fusions occur infrequently, which could result in slow enrollment of clinical trial participants. In the

Phase 1 clinical trial of MCLA-117, we announced in May 2020 we will not continue enrollment into the planned dose expansion cohorts in the trial, but plan to continue enrollment in the dose escalation phase. In the Phase 1 clinical trial of MCLA-158, we plan to enroll approximately 120 adult patients with solid tumors. In the Phase 1 clinical trial of MCLA-145, we plan to enroll approximately 118 adult patients with solid tumors or B-cell lymphoma. These trials and other trials we conduct may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal.

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

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

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

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

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

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

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

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

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

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

- the FDA, the EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

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

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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Risks Related to Regulatory Approval of Our Antibody Candidates

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

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

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

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

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

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the Budget Control Act of 2011 resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute will remain in effect through 2029 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on our future customers and accordingly, our financial operations.

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

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

In the EU, similar political, economic and regulatory developments may affect our ability to profitably commercialize any future products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is

almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our antibody candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval. In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

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

Finally, policies of the individual government agencies, including the FDA or similar regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we or our collaborators are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or our collaborators are not able to maintain regulatory compliance, our antibody candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or paying any remuneration (including any kickback, bribe, or certain rebate),

directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid; a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the U.S. federal false claims and civil monetary penalties laws, including the civil False Claims Act, which, among other things, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 (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.

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

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer "adequate" protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. In addition, in July 2020, the Court of Justice of the European Union, or CJEU, invalidated the E.U.-U.S. Privacy Shield framework, which was put in place by the U.S. Department of Commerce and European Commission. Further, the United Kingdom's decision to leave the EU has created uncertainty with regard to the status of the UK as an "adequate country" for the purposes of data transfers outside the European Economic Area. In particular, it is unclear how data transfers to and from the UK will be regulated. While we employ model clauses which remain valid according to the recent CJEU decision, these changes and uncertainty in this area of law could require us to make operational changes and could increase costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

Although we work to comply with applicable laws, regulations and standards, our contractual obligations and other legal obligations, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner among jurisdictions in which we operate. We are likely to be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws both inside and outside the United States. Claims that we have violated individuals' privacy rights or breached our contractual obligations regardless of merit and even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

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

Risks Related to Commercialization of Our Antibody Candidates

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

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and

biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the United States and other jurisdictions. These organizations may have significantly greater resources than we do and conduct similar research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and marketing of products that compete with our antibody candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

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

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

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

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

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

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

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

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

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

We have never commercialized an antibody candidate, and we currently have no sales force, marketing or distribution capabilities. To achieve commercial success for our antibody candidates, if approved, which we may license to others, we will rely on the assistance and guidance of those collaborators. For antibody candidates for which we retain commercialization rights, we will have to develop our own sales, marketing and supply organization or outsource these activities to a third party. We may rely on outside consultants to provide advice on commercialization strategies, which may fail to deliver or provide effective guidance to maximize any commercial opportunity, if any, that may arise from our antibody candidates.

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

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

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

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

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

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

Risks Related to Our Dependence on Third Parties

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

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our pre-clinical studies and clinical trials and to monitor and manage data for our ongoing pre-clinical and clinical programs. We rely on these parties for execution of our pre-clinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EEA, and comparable foreign

regulatory authorities for all of our antibody candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, the EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with the antibody candidate produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

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

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

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

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

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

The Collaboration Agreement may be terminated:

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

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

Termination of the Collaboration Agreement could cause significant delays in our antibody candidate development and commercialization efforts, which could prevent us from commercializing our antibody candidates without first expanding our internal capabilities or entering into another agreement with a third party. Any suitable alternative collaboration or license agreement would take considerable time to negotiate and could also be on less favorable terms to us. In addition, under the Collaboration Agreement, Incyte agreed to conduct certain clinical development activities. If the Collaboration Agreement were to be terminated, and whether or

not we identify another suitable collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

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

The collaboration and license 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 out-licensed to these entities, which have product rights in China, we cannot guarantee that these assets will be developed in China in accordance with our standards as applied to our wholly owned programs. Ono is currently pursuing at least one antibody program generated by us through use of our proprietary Biclonics® platform in an area outside oncology. To the extent this asset does not successfully advance through clinical development, this may impair our ability to leverage our platform in areas outside oncology or to engage in future license agreements to further expand the use of our platform and generate future revenue. Should any of these collaborations or license agreements fail or be terminated, any suitable alternative collaboration or license agreement would take considerable time to negotiate, if at all, and could also be on less favorable terms to us. If these agreements were to be terminated, and whether or not we identify a suitable alternative collaborator, we may need to seek additional financing to support the research and development of any terminated antibody candidates so that we may continue development activities, or we may be forced to discontinue development of terminated antibody candidates, each of which could have a material adverse effect on our business.

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

Our product development programs and the potential commercialization of our antibody candidates will require substantial additional cash to fund expenses. Therefore, for some of our antibody candidates and with respect to our recently developed Triclonics™ technology platform, we may decide to enter into new collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of those bispecific and trispecific antibody candidates. For instance, we have license and collaboration agreements with Ono, Incyte, Simcere and Betta, under which we have licensed the development and commercialization of certain of our monospecific or bispecific antibody candidates.

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

- we may not be able to control the amount and timing of resources that the collaborator devotes to the product development program;

- the collaborator may experience financial difficulties;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator may experience technical, clinical, intellectual property, manufacturing or other setbacks in the research or development of a product program arising from our collaboration adversely affecting the financial return of our collaboration or the reputation of our technology platform;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our willingness to complete our obligations under any arrangement.

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

We rely on and expect to continue to rely on third-party contract manufacturing organizations (CMOs) for the supply of cGMP-grade clinical trial materials and commercial quantities of our antibody candidates and products, if approved. Reliance on third-party providers may expose us to more risk than if we were to manufacture antibody candidates ourselves. The facilities used by our CMOs to manufacture our antibody candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our BLA to the FDA. We have limited control over the manufacturing process of, and beyond contractual terms, we are completely dependent on our CMOs for compliance with cGMP for the manufacture of our antibody candidates. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, or are unable to do so in a timely manner, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities or may result in delay of our ability to obtain marketing authorization, if any, of our antibody candidates. In addition, we have limited control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our antibody candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our antibody candidates, if approved. In addition, any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our antibody candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. Furthermore, third-party providers may breach existing agreements they have with us because of factors beyond our control. They may also terminate or refuse to renew their agreement because of their own financial difficulties or business priorities, at a time that is costly or otherwise inconvenient for us. If we were unable to find an adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed. In addition, the fact that we are dependent on our collaborators, our CMOs and other third parties for the manufacture, filling, storage and distribution of our antibody candidates means that we are subject to the risk that the products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could adversely affect our business, financial condition and results of operations.

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

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

ability to generate revenues from the sale of our antibody candidates. Moreover, as a result of the COVID-19 pandemic, third-party manufacturers have been affected, which could disrupt or delay their activities or ability to source materials and as a result we could face difficulty sourcing key components necessary to produce supply of our product candidates, which may negatively affect our pre-clinical and clinical development activities.

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

Risks Related to Intellectual Property and Information Technology

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

Our commercial success depends in part on obtaining and maintaining patents and other forms of intellectual property rights for our Biclonics® technology platform, Triclonics™ technology platform, our common light chain transgenic murine technology, our CH3 domain dimerization technology, our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, bispecific antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, among other aspects of our technology or on licensing-in such rights. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our platform technologies, and antibody candidates.

The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our licensors, licensees or collaborators will fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Further, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or collaborators' patent rights are highly uncertain. Our and our licensors' pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or collaborators to narrow the scope of the claims of our or our licensors', licensees' or collaborators' pending and future patent applications, which may limit the scope of patent protection that may be obtained. We cannot assure you that all of the potentially relevant prior art relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, or have issued and even if such patents cover our Biclonics® technology platform, Triclonics™ technology platform, our common light chain transgenic murine technology, our CH3 domain dimerization technology our heavy chain variable regions and binding domains that bind particular antigens, our monospecific antibodies, antibody, trispecific antibody and antibody clinical candidates, products, their format and methods and host cells used to produce, screen, manufacture and purify those antibody and antibody clinical candidates, the methods for treating patients using those candidates, and other technologies, third parties may initiate opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated. Our and our licensors', licensees' or collaborators' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

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

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

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

that one or more of our patents will be held invalid (in whole or in part, on a claim-by-claim basis) or held unenforceable. Such an adverse court ruling could allow third parties to commercialize technology covered by our patents we seek to enforce, such as those covering our antibody candidates or methods, our Biclonics® technology and Triclonics™ technology platforms, our common light chain transgenic murine technology, or our CH3 domain dimerization technology, among other technologies, and then compete directly with us, without payment to us.

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

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

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

It is also possible that we failed to identify relevant patents or applications. For example, U.S. applications filed before November 29, 2000 and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our products or platform technologies could have been filed by others without our knowledge. Furthermore, we operate in a highly competitive field, and given our limited resources, it is unreasonable to monitor all patent applications purporting to claim broad coverage in the areas in which we are active. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our platform technologies, our methods, antibody candidates or the use of our bispecific and trispecific antibody candidates.

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

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

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

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

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

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

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

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

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

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

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

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

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

methods of use, processes, or other third-party intellectual property rights from third parties that we may identify as necessary for our antibody candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources, and greater clinical development and commercialization capabilities.

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

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

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

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

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

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

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

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

Competitors may use our and our existing or future licensors', collaborators' or partners' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories

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

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

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

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

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

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

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

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

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

of the time from invention to filing of a patent application, circumstances could prevent us from promptly filing patent applications for our inventions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Despite the implementation of security measures, our computer systems and data and those of our current or future CROs or other contractors and consultants are vulnerable to compromise or damage from computer hacking, malicious software, fraudulent activity, employee misconduct, human error, telecommunication and electrical failures, natural disasters, or other cybersecurity attacks or accidents. Future acquisitions could expose us to additional cybersecurity risks and vulnerabilities from any newly acquired information technology infrastructure. Cybersecurity attacks are constantly increasing in sophistication and are made by groups and individuals with a wide range of motives (including industrial espionage) and expertise, including by organized criminal groups, “hacktivists,” nation states, and others. As a company with an increasingly global presence, our systems are subject to frequent attacks, which are becoming more commonplace in the industry, including attempted hacking, phishing attempts, such as cyber-related threats involving spoofed or manipulated electronic communications, which increasingly represent considerable risk. Due to the nature of some of these attacks, there is a risk that an attack may remain undetected for a period of time. While we continue to make investments to improve the protection of data and information technology, including in the hiring of 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 recent transition of our former President and Chief Executive Officer, and recent resignations of our former Chief Medical Officer, hiring of our new Chief Medical Officer and resignation of our former Chief Scientific Officer.

Our success depends upon the contributions of our senior leaders, including our board of directors, our senior management, and other key scientific and technical personnel, many of whom have been instrumental for us and have substantial experience with our therapies and related technologies. The loss of key senior management, managers and senior scientists could delay our research and development and clinical trial activities or impair our ability operate the company effectively. In addition, the competition for qualified personnel in the biopharmaceutical and pharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly-skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business. Our success also depends on our ability to manage transitions among our senior management and other key personnel. In December 2019, Ton Logtenberg, Ph.D., stepped down as an executive director, a position he held since co-founding our company in 2003, and as President, Chief Executive Officer and Principal Financial Officer, and Sven “Bill” Lundberg, M.D. was appointed as an executive director and as President, Chief Executive Officer and Principal Financial Officer as of January 1, 2020. In April 2020, L. Andres Sirulnik, M.D., Ph.D. resigned as Executive Vice President, Chief Medical Officer effective April 24, 2020, and Andrew Joe, M.D., was appointed as senior vice president and Chief Medical Officer, effective July 27, 2020. Further, in April 2020, and Mark Throsby, Ph.D., resigned as the Executive Vice President and Chief Scientific Officer of the Company with an effective date of July 31, 2020. These recent changes in our senior management may be disruptive to our business, and if we are unable to manage orderly transitions in these cases or for other key personnel in the future, or if we are unable to recruit suitable replacements for the Chief Scientific Officer positions, or retain our existing senior leaders, 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

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.

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

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

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

Pursuant to Section 404 of SOX (Section 404) we are required to furnish a report by our management on our internal control over financial reporting with our Annual Report on Form 10-K. While we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To maintain compliance with Section 404, we engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we continue to dedicate internal resources and have engaged outside consultants and adopted a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to maintain effective internal control over financial reporting as required by Section 404. Material weaknesses in our internal control over financial reporting could also reduce our ability to obtain financing or could increase the cost of any financing we obtain. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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 a settlement agreement with Regeneron Pharmaceuticals, we entered into a Share Subscription Agreement with Regeneron, pursuant to which we issued and sold to Regeneron 600,000 of our common shares. Regeneron's ability to sell these common shares is subject to certain limitations, including limitations on the volume of shares that may be sold during a given time period.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As of January 1, 2020, we were no longer a foreign private issuer, and we are required to comply with all of the provisions applicable to a U.S. domestic issuer under the Exchange Act, including filing an annual report on Form 10-K, quarterly periodic reports and current reports for certain events, complying with the sections of the Exchange Act regulating the solicitation of proxies, requiring insiders to file public reports of their share ownership and trading activities and insiders being liable for profit from trades made in a short period of time. We are also no longer exempt from the requirements of Regulation FD promulgated under the Exchange Act related to selective disclosures. We are also no longer permitted to follow our home country’s rules in lieu of the corporate governance obligations imposed by Nasdaq, and are required to comply with the governance practices required by U.S. domestic issuers listed on Nasdaq. We are also required to comply with all other rules of Nasdaq applicable to U.S. domestic issuers, including that our articles of association specify a quorum of no less than one-third of our outstanding voting common shares for meetings of our common shareholders, the solicitation of proxies and the approval by our shareholders in connection with certain events such as the acquisition

of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control and certain private placements. In addition, we are required to report our financial results under U.S. Generally Accepted Accounting Principles, including our historical financial results, which have previously been prepared in accordance with International Financial Reporting Standards. We expect to continue to incur significant legal, accounting, insurance and other expenses and to expend greater time and resources to comply with these requirements. In addition, we may need to develop our reporting and compliance infrastructure and may face challenges in complying with the new requirements applicable to us.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act and a smaller reporting company under the rules promulgated under the Exchange Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved, and reduced executive compensation disclosure. We may take advantage of these exemptions until we are no longer an emerging growth company. We could be an emerging growth company for up to five years following the initial public offering of our common shares, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our common shares held by non-affiliates exceeds $700 million as of the end of our second fiscal quarter, in which case we would no longer be an emerging growth company as of the fiscal year-end.

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

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

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

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

We may be classified as a passive foreign investment company (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 2019, 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 2019. 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, and a U.S. Holder does not make an election to treat us as a qualified electing fund (QEF) or a mark-to-market election, excess distributions to a U.S. Holder, and any gain recognized by a U.S. Holder on a disposition of our ordinary shares, would be taxed in an unfavorable way. 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. In addition, gains on the sale of our shares would be treated in the same way as excess distributions. 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. U.S. Holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares. 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 United States Internal Revenue Code of 1986, as amended (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.

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

On December 22, 2017, the U.S. government enacted the TCJA, a comprehensive tax legislation that includes significant changes to the taxation of business entities. The TCJA remains unclear in many respects and has been, and may continue to be, the subject of amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, which have lessened or increased certain adverse impacts of the TCJA and may do so in the future. We continue to examine the impact the TCJA may have on our business. The effect of the TCJA on our business, whether adverse or favorable, is uncertain, and may not become evident for some period of time. Holders of our common shares should consult their legal and tax advisors regarding the TCJA and the potential tax consequences of investing in our common shares.

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	
3.1	Articles of Association of Merus N.V., as amended on December 5, 2019	6-K	001-37773	3	12/6/19	
10.1	Employment Agreement, dated July 2, 2020 between Andrew Joe and Merus US, Inc.	10-Q	001-37773	10.4	8/6/20	
10.2	Open Market Sale Agreement, dated as of August 6, 2020, by and between Merus N.V. and Jefferies LLC	8-K	001-37773	10.1	8/7/20	
10.3	Employment Agreement, dated August 20, 2020 between Peter Silverman and Merus N.V.					*
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.

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 5, 2020

MERUS N.V.

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

EMPLOYMENT AGREEMENT
THE EXECUTIVE

between

Peter B. Silverman
as the Executive

and

Merus N.V.
as the Company

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EMPLOYMENT AGREEMENT

THIS AGREEMENT IS MADE ON MAY 25, 2020 BETWEEN

1. **Mr. Peter B. Silverman**, born in **New York, U.S.A.** on **August 26, 1977** (the "**Executive**"); and

2. **Merus N.V.**, a limited liability company, having its corporate seat in Amsterdam (address: Yalelaan 62, 3584 CM Utrecht trade register number: 30189136) (the "**Company**").

WHEREAS

A. The Company and the Executive previously entered into an employment agreement, dated as of **December 24th, 2016** (as the same may have been amended from time to time), pursuant to which the Executive currently serves as the Company's **Executive Vice President, General Counsel and Head of Utrecht office**.

B. It is the desire of the Company to continue to assure itself of the services of the Executive on the terms set forth in this Agreement.

C. The Company and the Executive intend that as of the Effective Date, this Agreement will supersede any prior employment agreements between the Parties and/or between the Executive and an affiliate of the Company in all respects.

NOW HEREBY AGREE AS FOLLOWS

1 DEFINITIONS AND INTERPRETATION

1.1 Definitions

1.1.1 In this Agreement the definitions shall apply as referred to in Annex A to this Agreement.

1.2 Interpretation

1.2.1 References to statutory provisions are to those provisions as they are in force from time to time.

1.2.2 Terms that are defined in the singular have a corresponding meaning in the plural.

1.2.3 No provision of this Agreement shall be interpreted adversely against a Party solely because that Party was responsible for drafting that particular provision.

1.2.4 Although this Agreement has been drafted in the English language, this Agreement pertains to Dutch legal concepts. Any consequence of the use of English words and expressions in this Agreement under any law other than Dutch law shall be disregarded.

1.2.5 The word "including" is used to indicate that the matters listed are not a complete enumeration of all matters covered.

1.2.6 The titles and headings in this Agreement are for construction purposes as well as for reference. No Party may derive any rights from such titles and headings.

2 EFFECTIVE DATE AND NOTICE PERIOD

2.1 Effective date

2.1.1 The provisions of this Agreement shall be effective as of **August 20, 2020** (the "**Effective Date**").

2.2 Notice period

2.2.1 Each Party shall be entitled to terminate the Employment Agreement by giving notice in writing equal to a period of 4 (four) months if given by the Company and 2 (two) months if given by the Executive.

3 EMPLOYEE PROPRIETARY INFORMATION AND INVENTIONS ASSIGNMENT AGREEMENT

As a condition to the effectiveness of this Agreement, Executive will execute and deliver to the Company contemporaneously herewith an Amended and Restated Employee Proprietary Information and Inventions Assignment Agreement (the “Proprietary Information Agreement”), which Proprietary Information Agreement contains certain non-competition, non-solicitation, non-disclosure and assignment of inventions provisions in favour of the Company. Executive agrees to abide by the terms of the Proprietary Information Agreement, which are hereby incorporated by reference into this Agreement. Executive acknowledges that the provisions of the Proprietary Information Agreement will survive the termination of Executive’s employment and the termination of the term for the periods set forth in the Proprietary Information Agreement.

4 TASKS, DUTIES AND NON-COMPETE

4.1 Performance of tasks and duties

4.1.1 The Executive shall serve as **Executive Vice President, General Counsel and Head of Utrecht Office**, with such responsibilities, duties and authority normally associated with such positions and as may from time to time be assigned to the Executive by the Management Board or authorized committee thereof (in, either case, the "**Board**").

4.1.2 The Executive's normal place of work shall be at the Company's office in Utrecht, the Netherlands.

4.1.3 The Executive will work full-time for the Company based on an average working week of 40 hours. The exact working hours will be determined by the Company in consultation with the Executive. There will be no separate remuneration for overtime work.

4.1.4 The Executive shall devote substantially all of the Executive's working time and efforts to the business and affairs of the Company (which shall include service to its affiliates, if applicable) and shall not engage in outside business activities (including serving on outside boards or committees) without the consent of the Board, provided that the Executive shall be permitted to (i) manage the Executive's personal, financial and legal affairs, (ii) participate in trade associations, and (iii) serve on the board of directors of not-for-profit or tax-exempt charitable organizations, in each case, subject to compliance with this Agreement and provided that such activities do not materially interfere with the Executive's performance of the Executive's duties and responsibilities hereunder.

4.2 Organisational Documents

4.2.1 The Executive has received copies of the Organizational Documents and is familiar with the contents thereof. The Executive agrees to be bound by, and comply with, the Organizational documents.

5 COMPENSATION AND BENEFITS

5.1 Base Salary

5.1.1 As compensation for the Executive's services pursuant to this Agreement, the Company shall pay the Executive a gross fixed annual salary of EUR 374.900,--, which includes holiday allowance (the "**Base Salary**"). The Base Salary shall be paid in accordance with the customary payroll practices of the Company and shall be pro-rated for partial years of employment. The Base Salary shall be reviewed (and may be adjusted upwardly) from time to time by the Board.

5.2 Annual bonus

5.2.1 The Executive will be eligible to participate in an annual incentive program established by the Board, being the Short Term Incentive Policy (STIP). The Executive's annual incentive compensation under such incentive program (the "**Annual Bonus**") shall be targeted at **40%** of the Executive's Base Salary (the "**Target Bonus**"). The Annual Bonus payable under the incentive program shall be based on the achievement of performance goals to be determined by the Board. The payment of any Annual Bonus pursuant to the incentive program shall be subject to the Executive's continued employment with the Company through the date of payment, except as otherwise agreed by the Board or pursuant to severance payment(s) made under Section 6.

5.2.2 The granting of a bonus and/or profit sharing arrangement in respect of one or more financial years shall not, in and of itself, entitle the Executive to similar compensation in any subsequent financial year.

5.2.3 During the Term, the Company shall reimburse Executive for all reasonable travel and other business expenses incurred by Executive in the performance of Executive’s duties to the Company in accordance with the Company’s expense reimbursement policy.

5.3 LTIP / equity awards

5.3.1 At the discretion of the Board, the Executive shall be eligible to participate in the Company's long term incentive plan or equity compensation plan, as may be applicable and amended from time to time, and subject to the rules and provisions of any such plan.

5.4 Benefits

5.4.1 The Executive shall be eligible to participate in employee benefit plans, programs and arrangements of the Company pursuant to the Company's employee handbook, made available to other similarly-situated employees of the Company, consistent with the terms thereof and as such plans, programs and arrangements may be amended from time to time. The Company shall reimburse Executive up to a maximum amount of €30,000 for reasonable, documented permanent relocation expenses incurred prior to October 30, 2020 as a result of Executive’s relocation to the Utrecht area, which relocation expense reimbursement will be paid (subject to all tax withholdings which the Company reasonably determines are required) in calendar year 2020, and following Executive’s timely submission of documentation reasonably requested by the Company.

6 SEVERANCE PAYMENT

6.1 Termination for Cause and other

6.1.1 If The Executive's employment shall terminate as a result of (i) the Executive's death, or (ii) for Cause or as a result of Executive's Disability, or (iii) for the Executive's resignation from the Company without Good Reason, then the Executive shall not be entitled to any severance payments or benefits, except and insofar as such entitlements exists on the basis of mandatory rules of Dutch law.

6.2 Termination without Cause and other

6.2.1 If The Executive's employment is terminated by the Company without Cause (other than due to Disability) or due to the Executive's resignation for Good Reason, in either case, which termination does not occur within 12 (twelve) months following the date of a Change in Control, then, subject to Executive signing on or before the 21st day following Executive's termination of employment, and not revoking, a release of claims in a form reasonably acceptable to the Company (the "Release"), and Executive's continued compliance with the Proprietary Information Agreement, the Executive shall receive:

i. a severance amount in cash equal to 1 (one) times the Base ; and

ii. any unpaid Annual Bonus earned by the Executive for the year prior to the year in which the termination occurs, as determined by the Board based upon actual performance achieved, which Annual Bonus, if any, shall be paid to the Executive when bonuses for such year are paid to actively employed senior the Executives of the Company;

6.3 Change in Control

6.3.1 In lieu of the payments and benefits set forth in Article 6.2.1, in the event the Executive's employment is terminated by the Company without Cause or due to the Executive's resignation for Good Reason, in either case, on or within 12 (twelve) months following the date of a Change in Control, then, subject to Executive signing on or before the 21st day following Executive's termination of employment, and not revoking the Release, and Executive's continued compliance with the Proprietary Information Agreement, the Executive shall receive the following:

i. a severance amount in cash equal to (A) 1 (one) times the Base Salary and (B) the Target Bonus, which shall be paid in a lump sum on the First Payment Date (as defined below);

ii. any unpaid Annual Bonus earned by the Executive for the year prior to the year in which the termination occurs, as determined by the Board based upon actual performance

achieved, which Annual Bonus, if any, shall be paid to the Executive when bonuses for such year are paid to actively employed senior the Executives of the Company; and

iii. immediate vesting of all unvested equity or equity-based awards held by the Executive under any equity compensation plans of the Company that vest solely based on the passage of time (with any such awards that vest in whole or in part based on the attainment of performance-vesting conditions being governed by the terms of the applicable award agreement).

7 PROPERTY OF THE COMPANY

7.1 Ownership of property

7.1.1 All items, including documents, computer files and data carriers, obtained by the Executive from the Company and/or any Subsidiary during the term of this Agreement are, and shall remain, the property of the entity providing such items unless explicitly agreed otherwise.

7.2 Return of property

7.2.1 The Executive shall, at the Company's first request and in any event upon the termination of this Agreement, promptly return all items referred to in Article 7.1.1 to the Company, except to the extent that the Executive is required by applicable law to retain such items.

8 MISCELLANEOUS PROVISIONS

8.1 Employee handbook

8.1.1 The employee handbook of the Company applies to this Agreement.

8.2 Data protection

8.2.1 The Company may process personal data relating to the Executive within the framework of this Agreement and the performance of services thereunder, provided that all such personal data shall be processed in a proper and careful manner in accordance with applicable law. For that purpose, the Company may transfer the Executive's personal data to third parties, both inside and outside the European Union, provided that there is a legitimate interest in doing so.

8.3 Notices

8.3.1 All notices given under this Agreement shall be given or made by electronic means of communication or in writing and, in the latter case, shall be sent by courier service or by

registered mail (with a copy of such notice or request being sent in advance by electronic means of communication).

8.3.2 All notices given under this Agreement to a Party which are sent by courier or by registered mail shall be sent:

a. if to the Executive, to the address as on file with the Company at that time; and

b. if to the Company, to address as registered with the Dutch trade registry at that time, for the attention of the Management Board.

8.3.3 All notices given under this Agreement to a Party by electronic means of communication shall be sent:

a. if to the Executive, to: p.silverman@merus.nl

b. if to the Company, to: b.lundberg@merus.nl

8.4 Entire agreement

8.4.1 This Agreement replaces and supersedes any existing employment or service agreement between the Parties.

8.5 No implied waiver

8.5.1 Nothing shall be construed as a waiver under this Agreement unless a document to that effect has been signed by the Parties or a notice to that effect has been given.

8.5.2 The failure of a Party to exercise or enforce any right under this Agreement shall not constitute a waiver of the right to exercise or enforce such right in the future.

8.6 Amendment

8.6.1 No amendment to this Agreement shall have any force or effect unless it is in writing and signed by both Parties, provided that the Company may unilaterally amend this Agreement if it has a substantial interest in doing so (including in case of a change of control in respect of the Company or its business).

8.7 Invalidity

8.7.1 In the event that a provision of this Agreement is null and void or unenforceable (either in

whole or in part):

a. the remainder of this Agreement shall continue to be effective to the extent that, given the substance and purpose of this Agreement, such remainder is not inextricably related to the null and void or unenforceable provision; and

b. the Parties shall make every effort to reach agreement on a new provision which differs as little as possible from the null and void or unenforceable provision, taking into account the substance and purpose of this Agreement.

8.8 No rescission or nullification

8.8.1 To the extent permitted by law, the Parties hereby waive their rights to rescind or nullify or to demand the rescission, nullification or amendment of this Agreement, in whole or in part, on any grounds whatsoever.

8.9 No transfer, assignment or encumbrance

8.9.1 No Party may transfer, assign or encumber its contractual relationship, any of its rights or any of its obligations under this Agreement.

9 GOVERNING LAW AND JURISDICTION

9.1 Governing law

9.1.1 This Agreement shall be governed by and construed in accordance with the laws of the Netherlands.

9.2 Jurisdiction

9.2.1 The Parties agree that any dispute in connection with this Agreement or any agreement resulting therefrom shall be submitted to the exclusive jurisdiction of the competent court in Amsterdam.

10 **SECTION 409A**.

10.1 *General*. The intent of the Parties is that, to the extent applicable, the payments and benefits under this agreement comply with or be exempt from Section 409A of the United States Internal Revenue Code ("Section 409A") and, accordingly, to the maximum extent permitted, this agreement shall be interpreted to be in compliance therewith.

10.2 *Separation from Service*. Notwithstanding anything in this Agreement to the contrary, any compensation or benefits payable under this Agreement that are designated under this Agreement as payable upon Executive's termination of employment shall be payable only upon Executive's "separation from service" with the Company within the meaning of Section 409A (a "Separation from Service") and, except as provided below, any such compensation or benefits described in Section 6 shall not be paid, or, in the case of installments, shall not commence payment, until the 30th day following Executive's Separation from Service (the "First Payment Date"). Any installment payments that would have been made to Executive during the 30-day period immediately following Executive's Separation from Service but for the preceding sentence shall be paid to Executive on the First Payment Date and the remaining payments shall be made as provided in this Agreement.

10.3 *Specified Employee*. Notwithstanding anything in this Agreement to the contrary, if Executive is deemed by the Company at the time of Executive's Separation from Service to be a "specified employee" for purposes of Section 409A, to the extent delayed commencement of any portion of the benefits to which Executive is entitled under this Agreement is required in order to avoid a prohibited distribution under Section 409A, such portion of Executive's benefits shall not be provided to Executive prior to the earlier of (i) the expiration of the 6-month period measured from the date of Executive's Separation from Service with the Company or (ii) the date of Executive's death. Upon the first business day following the expiration of the applicable Section 409A period, all payments deferred pursuant to the preceding sentence shall be paid in a lump sum to Executive (or Executive's estate or beneficiaries), and any remaining payments due to Executive under this Agreement shall be paid as otherwise provided herein.

10.4 *Expense Reimbursements*. To the extent that any reimbursements under this Agreement are subject to Section 409A, any such reimbursements payable to Executive shall be paid to Executive no later than December 31 of the year following the year in which the expense was incurred, provided that Executive submits Executive's reimbursement request promptly following the date the expense is incurred. The amount of expenses reimbursed in one year shall not affect the amount eligible for reimbursement in any subsequent year, other than medical expenses referred to in Section 105(b) of the Code, and Executive's right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

10.5 *Installments*. Executive's right to receive any installment payments under this Agreement, including without limitation any continuation of salary payments that are payable on Company payroll dates, shall be treated as a right to receive a series of separate payments and, accordingly, each such installment payment shall at all times be considered a separate and distinct payment as permitted under Section 409A. Except as otherwise permitted under Section 409A, no payment hereunder shall be accelerated or deferred unless such acceleration or deferral would not result in additional tax or interest pursuant to Section 409A.

10.6 Legal Fees. The Company agrees to pay Executive's reasonable legal fees incurred in connection with the negotiation related to this Agreement, up to a maximum of seven thousand dollars (€5,000). The Company will pay such legal fees within sixty (60) days following receipt of an invoice establishing such fees which invoice shall be provided by Executive to the Company in September 2020.

(signature page follows)

Signature page to the employment agreement

/s/ S A Lundberg

A.S. Lundberg
Title: CEO & President

/s/ Peter B Silverman

P.B. Silverman
Title : Executive Vice President, General Counsel and Head of Utrecht Office

ANNEX A - DEFINITIONS

Agreement	This employment agreement.
Annual Bonus	Has the meaning as described in Article 5.2.1
Article	An article of this Agreement.
Base Salary	The Executive's fixed annual salary referred to in Article 5.1.
Board	Has the meaning as described in Article 4.1.1

Cause Means:

(i) an urgent cause (in Dutch: *dringende reden*) within the meaning of section 7:677 jo. 7:678 DCC;

The Company deems the following to in any case qualify as Cause:

- the Executive's wilful failure to (A) substantially perform his duties as contemplated under this Agreement (other than any such failure resulting from the Executive's Disability) or (B) comply with, in any material respect, any of the Company's Organisational Documents;
- the Executive's wilful failure in any material respect to carry out or comply with any lawful and reasonable directive of the Board;
- the Executive's breach of a material provision of this Agreement;
- the Executive's conviction or confession for any felony or crime;
- the Executive's unlawful use (including being under the influence) or possession of illegal drugs on the Company's (or any of its affiliate's) premises or while performing the Executive's duties and responsibilities under this Agreement; or
- the Executive's commission of an act of fraud, embezzlement, misappropriation, wilful misconduct, or breach of fiduciary duty against the Company or any of its affiliates;

provided that such "Cause" shall be deemed to occur only after the Company has given notice thereof to the Executive specifying in reasonable detail the conduct constituting "Cause," and, to the extent curable and correctable and the failure is not another breach after a prior cure period, the Executive fails to cure and correct his conduct within thirty (30) days after such notice;

Change in control	(I) A transaction or series of related transactions (other than an offering of common shares of the Company to the general public through a registration statement filed with the Securities and Exchange Commission or a transaction or series of related transactions that meets the requirements of clauses (A) and (B) of subsection (II) below) whereby any "person" or related "group" of "persons" (as such terms are used in sections 13(d) and 14(d)(2) of the U.S. Securities Exchange Act of 1934 (the "Exchange Act")) (other than the Company, any of its subsidiaries, an employee benefit plan maintained by the Company or any of its subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, the Company) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of securities of the Company possessing more than 50% of the total combined voting power of the Company's securities outstanding immediately after such acquisition; or (II) The consummation by the Company (whether directly involving the Company or indirectly involving the Company through one or more intermediaries) of (x) a merger, consolidation, reorganization, or business combination or (y) a sale or other disposition of all or substantially all of the Company's assets in any single transaction or series of related transactions or (z) the acquisition of assets or stock of another entity, in each case other than a transaction: (A)which results in the Company's voting securities outstanding immediately before the transaction continuing to represent (either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of the Company's assets or otherwise succeeds to the business of the Company (the Company or such person, the "Successor Entity")) directly or indirectly, at least a majority of the combined voting power of the Successor Entity's outstanding voting securities immediately after the transaction, and (B)after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the Successor Entity; provided, however, that no person or group shall be treated for purposes of this clause (B) as beneficially owning 50% or more of the combined voting power of the Successor Entity solely as a result of the voting power held in the Company prior to the consummation of the transaction.
DCC	The Dutch Civil Code.

Disability	Means Executive's inability to perform, with or without reasonable accommodation, the essential functions of Executive's position hereunder for a total of three months during any six-month period as a result of incapacity due to mental or physical illness as determined by a physician selected by the Company or its insurers and acceptable to Executive or Executive's legal representative, with such agreement as to acceptability not to be unreasonably withheld or delayed. Any refusal by Executive to submit to a medical examination for the purpose of determining Disability shall be deemed to constitute conclusive evidence of Executive's Disability.
Effective Date	Has the meaning as described in Article 2.1.1
Good reason	For the sole purpose of determining the Executive's right to severance pay, the Executive's resignation will be for "Good Reason" if the Executive resigns within 90 (ninety) days or where such events are continuing in nature, within ninety days of the last such occurrence of any of the following events, after any of the following events, unless the Executive consents in writing to the applicable event: (i) a decrease in the Executive's Annual Base Salary, other than a reduction in Annual Base Salary of less than 10% that is implemented in connection with a contemporaneous reduction in annual base salaries affecting other senior executives of the Company, (ii) a material decrease in the Executive's authority or areas of responsibility as are commensurate with the Executive's title or position (other than in connection with a corporate transaction where the Executive continues to hold the position referenced in Article 4.1.1 with respect to the Company's business, substantially as such business exists prior to the date of consummation of such corporate transaction, but does not hold such position with respect to the successor corporation), or (iii) the relocation of the Executive's primary office to a location more than 50 miles from Utrecht. Notwithstanding the foregoing, no Good Reason will have occurred unless and until the Executive has: (i) provided the Company, within 60 (sixty) days of the Executive's knowledge of the occurrence of the facts and circumstances underlying the Good Reason event, written-notice stating with specificity the applicable facts and circumstances underlying such finding of Good Reason; and (ii) provided the Company, as applicable, with an opportunity to cure the same within 30 (thirty) days after the receipt of such notice.
Management Board	The Company's management board (in Dutch: *bestuur*).

Organisational Documents	The Company's internal rules, codes and policies of the Company applicable to the Executive, as these documents may read from time to time.
Party	A party to this Agreement.
Stock Exchange	Any of the following (including, for the avoidance of doubt, NASDAQ): a.a regulated market or multilateral trading facility as defined in section 1:1 of the Dutch Financial Supervision Act; or b.a system comparable with a regulated market or multilateral trading facility as referred to under a. above, operating in a state which is not a member state of the European Union or the European Economic Area.
Subsidiary	A subsidiary of the Company within the meaning of section 2:24a DCC.
Target Bonus	Has the meaning as described in Article 5.2.1
Urgent Cause	Urgent cause (in Dutch: dringende reden) for the employer as defined in section 7:678 DCC.

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 5, 2020

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, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 5, 2020

By: /s/ Sven A. Lundberg

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