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

FORM 10-Q

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

For the quarterly period ended September 30, 2021
OR

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

For the transition period from to
Commission file number 001-38650

Y-mAbs Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**47-4619612**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

230 Park Avenue
Suite 3350
New York, NY 10169
(Address of principal executive offices)
(Zip Code)

(646)-885-8505
(Registrant's telephone number, including area code)

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

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Stock, $0.0001 par value	YMAB	NASDAQ Global Select 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, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

There were 43,643,916 shares of Common Stock ($0.0001 par value) outstanding as of November 2, 2021.

FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our business strategy, future operations and results thereof, future financial position, future revenue, projected costs, prospects, current and prospective products, product approvals, research and development costs, current and prospective collaborations, timing and likelihood of success, plans and objectives of management, expected market growth and future results of current and anticipated products, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We have based these forward-looking statements largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risk factors, uncertainties and assumptions, the future events and trends discussed in this Quarterly Report on Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements contained in this Quarterly Report on Form 10-Q are made as of the date of this Quarterly Report on Form 10-Q, and we undertake no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise.

Unless expressly indicated or the context requires otherwise, the terms ""Y-mAbs,” "company," "we," "us," and "our" in this document refer to Y-mAbs Therapeutics, Inc., a Delaware corporation, and, where appropriate, its subsidiaries.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, licensing agreements, collaborations, joint ventures or investments that we may make.

SUMMARY OF RISK FACTORS

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, financial condition, results of operations, cash flows, and prospects.

These risks are discussed more fully below and include, but are not limited to, risks related to:

- our ability to successfully commercialize DANYELZA® (naxitamab-gqgk), referred to as DANYELZA, for the treatment of relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow, in the United States and to successfully launch and commercialize in any other jurisdictions where we may receive marketing approval in the future;

- the implementation of our business model and our plans to obtain regulatory approval and develop and commercialize our lead product candidate omburtamab and other product candidates, including the potential clinical efficacy, safety and other benefits thereof;
- the rate and degree of market acceptance and clinical utility for DANYELZA or any current or future product candidate for which we may receive marketing approval;
- the timing of our resubmission and potential approval of our Biological License Application, or BLA, for omburtamab;
- our ability and plans for continuing to build out our commercial infrastructure and successfully launching, marketing, and selling DANYELZA, omburtamab, if approved, and any other current or future product candidate for which we may receive marketing approval, including our plans with respect to the focus and activities of our sales force, the nature of our marketing efforts, market access and patient support activities of DANYELZA and related assumptions;
- the pricing, coverage and reimbursement of, and the extent to which patient assistance programs are utilized for DANYELZA, omburtamab, if approved, or any other current or future product candidate for which we may receive marketing approval;
- our ongoing and future clinical trials for DANYELZA, our lead product candidate omburtamab and other product candidates, whether conducted by us or by any of our collaborators, including the timing of initiation of these trials, the pace of enrollment, the completion of enrollment, the availability of data from these trials, the expected dates of any BLA, submission and approval by the United States Food and Drug Administration, or FDA, and equivalent foreign regulatory authorities and of the anticipated results;
- our ability to manage our business, operations and pre-clinical and clinical development plans and timelines could be adversely affected by the effects of health epidemics, including the ongoing COVID-19 pandemic, on the manufacturing, pre-clinical studies, clinical trials and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturing organizations, or CMOs, contract research organizations, or CROs, shippers and others;
- our ability to attract, integrate, manage and retain qualified personnel or key employees;
- current and future pre-clinical studies and clinical trials for our product candidates and our research and development programs, whether conducted by us or by any of our third party collaborators, including the timing of initiation of these studies and trials, the pace of enrollment, the expected date of completion and of the anticipated results;
- the timing and our ability to obtain and maintain regulatory, marketing and reimbursement approvals for our product candidates;
- our ability to retain the continued service of our key employees and to identify, hire and retain additional qualified employees, including a direct sales force;
- our ability to continue to comply with Section 404(a) and 404(b) of the Sarbanes-Oxley Act;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and strategy and the scope of protection we are able to establish and maintain for the intellectual property rights covering our product candidates and technology;
- our ability to identify and develop additional product candidates and technologies with significant commercial potential;
- our plans and ability to enter into collaborations or strategic partnerships with third parties for the development and commercialization of our product candidates and future operations;
- our ability to continue to maintain and leverage our relationship with Memorial Sloan Kettering Cancer Center, or MSK, including our exclusive rights to current and any future technology granted to us under our license agreements with MSK;
- our relationship with MSK as a prescriber of DANYELZA and any future products;
- the potential benefits of any future collaboration or strategic partnerships we may enter into with third parties;
- our expectations related to the use of our cash and cash equivalents and the duration for which such cash is expected to last;
- the need for, timing, type, terms and amount of any future financing transaction;
- our financial performance, including our estimates regarding revenues, expenses, operating cash flow and capital expenditure requirements;

- developments relating to our competitors and our industry;
- any adverse effects on our business, financial condition and results of operations from the global COVID-19 pandemic, including the pace of global economic recovery from the pandemic and the ability of our employees to be able to come to work as a result of COVID-19 or any other health epidemic;
- the impact of government laws and regulations;
- our dependence on, and difficulty to find a suitable replacement for, a small number of third party CMOs that we currently use for the complex and difficult manufacturing of our product candidates;
- our ability to comply with healthcare laws and regulations in the United States and any foreign countries, including, without limitation, where we may apply for and receive approval for marketing and sale of pharmaceutical products;
- our expectations related to the use of our available cash balances and any further financing transaction we may undertake or the use of revenues that we may generate; and
- other risks and uncertainties described in the section herein entitled “Risk Factors.”

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You should read this Quarterly Report and the documents we have filed as exhibits to this Quarterly Report on Form 10-Q completely and with the understanding that our actual future results may be materially different from the plans, intentions, and expectations disclosed in the forward-looking statements we may make.

PART I – FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(in thousands, except share data)

	September 30, 2021	December 31, 2020
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 215,730	$ 114,634
Accounts receivable, net	7,264	—
Inventories	4,787	—
Other current assets	2,799	7,729
Total current assets	230,580	122,363
Property and equipment, net	1,846	1,825
Operating lease right-of-use assets	2,802	4,569
Other assets	4,751	3,290
TOTAL ASSETS	$ 239,979	$ 132,047
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 11,024	$ 9,372
Accrued liabilities	12,486	8,197
Operating lease liabilities, current portion	1,849	1,966
Total current liabilities	25,359	19,535
Accrued milestone and royalty payments	2,250	2,695
Operating lease liabilities, long-term portion	654	2,013
Other liabilities	871	1,968
TOTAL LIABILITIES	29,134	26,211
Commitments and contingencies (Note 8)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized at September 30, 2021 and December 31, 2020; none issued at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2021 and December 31, 2020; 43,643,916 and 40,688,447 shares issued at September 30, 2021 and December 31, 2020, respectively	4	4
Additional paid in capital	514,198	391,558
Accumulated other comprehensive income /(loss)	225	(526)
Accumulated deficit	(303,582)	(285,200)
TOTAL STOCKHOLDERS' EQUITY	210,845	105,836
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 239,979	$ 132,047

The accompanying notes are an integral part of the consolidated financial statements

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
REVENUE				
Product revenue, net	$ 8,965	$ —	$ 23,299	$ —
License revenue	—	—	2,000	—
Total revenue	8,965	—	25,299	—
OPERATING COSTS AND EXPENSES				
Cost of goods sold	550	—	843	—
Licensing royalties	—	—	210	—
Research and development	23,131	21,005	64,488	69,686
Selling, general, and administrative	13,988	11,636	39,433	30,155
Total operating costs and expenses	37,669	32,641	104,974	99,841
Loss from operations	(28,704)	(32,641)	(79,675)	(99,841)
OTHER INCOME, NET				
Gain from sale of priority review voucher, net	—	—	62,010	—
Interest and other income / (loss)	(154)	(191)	(717)	437
NET LOSS	$ (28,858)	$ (32,832)	$ (18,382)	$ (99,404)
Other comprehensive income / (loss)				
Foreign currency translation	238	(12)	751	(78)
COMPREHENSIVE LOSS	$ (28,620)	$ (32,844)	$ (17,631)	$ (99,482)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.66)	$ (0.82)	$ (0.43)	$ (2.49)
Weighted average common shares outstanding, basic and diluted	43,598,350	40,187,173	43,019,217	39,971,766

The accompanying notes are an integral part of the consolidated financial statements

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Changes in Stockholders' Equity

(unaudited)

(In thousands, except share data)

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2019	39,728,416	$ 4	$ 364,712	$ 50	$ (165,863)	$ 198,903
Exercise of stock options	25,778	—	370	—	—	370
Stock-based compensation expense	3,429	—	2,211	—	—	2,211
Foreign currency translation	—	—	—	25	—	25
Net loss	—	—	—	—	(26,179)	(26,179)
Balance March 31, 2020	39,757,623	4	367,293	75	(192,042)	175,330
Issuance of common stock	256,896	—	8,707	—	—	8,707
Stock-based compensation expense	—	—	2,455	—	—	2,455
Foreign currency translation	—	—	—	(91)	—	(91)
Net loss	—	—	—	—	(40,393)	(40,393)
Balance June 30, 2020	40,014,519	4	378,455	(16)	(232,435)	146,008
Exercise of stock options	57,916	—	215	—	—	215
Issuance of common stock to non-employees	400,000	—	—	—	—	—
Stock-based compensation expense	—	—	3,133	—	—	3,133
Foreign currency translation	—	—	—	(12)	—	(12)
Net loss	—	—	—	—	(32,832)	(32,832)
Balance September 30, 2020	40,472,435	$ 4	$ 381,803	$ (28)	$ (265,267)	$ 116,512

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2020	40,688,447	$ 4	$ 391,558	$ (526)	$ (285,200)	$ 105,836
Issuance of common stock to investors, net of issuance costs	2,804,878	—	107,725	—	—	107,725
Exercise of stock options	46,000	—	110	—	—	110
Stock-based compensation expense	9,094	—	4,698	—	—	4,698
Foreign currency translation	—	—	—	435	—	435
Net income	—	—	—	—	33,413	33,413
Balance March 31, 2021	43,548,419	4	504,091	(91)	(251,787)	252,217
Exercise of stock options	28,332	—	131	—	—	131
Stock-based compensation expense	199	—	4,827	—	—	4,827
Foreign currency translation	—	—	—	78	—	78
Net loss	—	—	—	—	(22,937)	(22,937)
Balance June 30, 2021	43,576,950	4	509,049	(13)	(274,724)	234,316
Exercise of stock options	66,160	—	248	—	—	248
Stock-based compensation expense	806	—	4,901	—	—	4,901
Foreign currency translation	—	—	—	238	—	238
Net loss	—	—	—	—	(28,858)	(28,858)
Balance September 30, 2021	43,643,916	$ 4	$ 514,198	$ 225	$ (303,582)	$ 210,845

The accompanying notes are an integral part of the consolidated financial statements

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Nine months ended September 30,	
	2021	2020
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (18,382)	$ (99,404)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from sale of priority review voucher, net	(62,010)	—
Depreciation and amortization	491	279
Stock-based compensation	14,426	7,799
Non-cash expense in connection with equity issuance to MSK/MIT	—	1,331
Non-cash expense in connection with equity issuance to inventors	—	7,376
Foreign currency transactions	751	(62)
Changes in assets and liabilities:		
Accounts receivable, net	(7,264)	—
Inventories	(4,787)	—
Other current assets	4,930	1,939
Other assets	(1,461)	2
Accounts payable	1,652	1,800
Accrued liabilities and other	2,961	5,404
NET CASH USED IN OPERATING ACTIVITIES	(68,693)	(73,536)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	(512)	(131)
Loans to inventors	—	(2,610)
Net proceeds from sale of priority review voucher	62,010	—
NET CASH PROVIDED BY/ (USED IN) INVESTING ACTIVITIES	61,498	(2,741)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of issuance costs	107,725	—
Proceeds from exercised stock options	489	585
NET CASH PROVIDED BY FINANCING ACTIVITIES	108,214	585
Effect of exchange rates on cash and cash equivalents	77	(177)
NET INCREASE / (DECREASE) IN CASH AND CASH EQUIVALENTS	101,096	(75,869)
Cash and cash equivalents at the beginning of period	114,634	207,136
Cash and cash equivalents at the end of period	$ 215,730	$ 131,267
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Right-of-use assets obtained in exchange for lease obligations	—	2,679

The accompanying notes are an integral part of the consolidated financial statements

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

NOTE 1—ORGANIZATION AND DESCRIPTION OF BUSINESS

Y-mAbs Therapeutics, Inc. (“we,” “us,” “our,” the “Company,” or “Y-mAbs”) is a commercial-stage clinical biopharmaceutical company focused on the development and commercialization of novel, antibody based therapeutic products for the treatment of cancer. We are leveraging our proprietary antibody platforms and deep expertise in the field of antibodies to develop a broad portfolio of innovative medicines.

The Company is headquartered in New York, New York and was incorporated on April 30, 2015 under the laws of the State of Delaware.

NOTE 2—BASIS OF PRESENTATION

Except for the quarter ended March 31, 2021, the Company has incurred quarterly losses since inception. Operations of the Company are subject to certain risks and uncertainties, including, among others, uncertainty of drug candidate development; technological uncertainty; uncertainty regarding patents and proprietary rights; uncertainty in obtaining FDA approval in the United States and regulatory approval in other jurisdictions; marketing or sales capability or experience; uncertainty in obtaining adequate payer coverage and reimbursement; dependence on key personnel; compliance with government regulations and the need to obtain additional financing. The Company’s drug candidates currently under development will require significant additional research and development efforts, including extensive pre-clinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel infrastructure and extensive compliance reporting capabilities.

The Company’s drug candidates are in various stages of development. DANYELZA (naxitamab-gqgk) was approved by the U.S. FDA in November 2020, but there can be no assurance that the Company’s other research and development will be successfully completed, that adequate protection for the Company’s intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company’s product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies.

The Company’s financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. The Company has experienced negative cash flows from operations since inception, and had an accumulated deficit of $303,582,000 as of September 30, 2021 and $285,200,000 as of December 31, 2020. Through September 30, 2021, the Company has funded its operations primarily through proceeds from sales of shares of its common stock, including its initial public offering in September 2018 and its subsequent public offerings in November 2019 and February 2021.

On February 22, 2021, the Company announced the closing of its public offering of 2,804,878 shares of its common stock, at a public offering price of $41.00 per share, which included the exercise in full of the underwriters' option to purchase 365,853 additional shares of common stock. The aggregate gross proceeds to the Company, before deducting underwriting discounts and commissions and offering expenses payable by the Company, were approximately $115,000,000.

As of September 30, 2021, the Company had cash and cash equivalents of $215,730,000, and as of December 31, 2020 the Company had cash and cash equivalents of $114,634,000. As of the issuance date of the financial statements for the third quarter ended September 30, 2021, the Company expects that its cash and cash equivalents at

September 30, 2021 will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next 12 months, irrespective of whether any additional product approvals are obtained.

The Company may raise additional capital to fund future operations through the sale of its equity securities, incurring debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. Sufficient funds may not be available to the Company on attractive terms or at all when needed from equity or debt financing. If FDA approval for omburtamab does not occur or is significantly delayed, and the Company is unable to obtain additional financing from these or other sources when needed, it will likely be necessary to take other actions to enhance its liquidity position which may include significantly reducing the current rate of spending through delaying, scaling back current operations, or suspending certain research and development programs and other operational programs.

The accompanying unaudited consolidated financial statements reflect the accounts of the Company and its wholly owned subsidiaries and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information, Accounting Standards Codification ("ASC") Topic 270-10 and with the instructions to Form 10-Q. Accordingly, these financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim financial statements include all adjustments (consisting only of normal recurring nature) necessary in the judgment of management for a fair statement of the results for the periods presented. All intercompany balances and transactions have been eliminated. The Company has evaluated subsequent events through the date of this filing. Operating results for the three and nine-month period ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending December 31, 2021, any other interim periods, or any future year or period. The December 31, 2020 consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by GAAP. You should read these unaudited interim condensed consolidated financial statements in conjunction with the consolidated financial statements and notes included in the Company's Annual Report on Form 10-K for the year ended December 31, 2020.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Our significant accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2020.

Operating Leases

The Company determines if an arrangement includes a lease at inception. Operating lease right-of-use assets represent the Company's right to use an underlying asset for the lease term and operating lease liabilities represent its obligation to make lease payments arising from the lease. Operating lease right-of-use assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the net present value of lease payments, the Company uses its estimated incremental borrowing rate based on information available at the lease commencement date. Because most of the Company's leases do not provide an implicit rate of return, an incremental borrowing rate is used based on the information available at the commencement date in determining the present value of lease payments on an individual lease basis. The Company's incremental borrowing rate for a lease is the estimated rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms.

The Company's leases may include options to extend or terminate the lease which are included in the lease term when it is reasonably certain that it will exercise any such options. None of the Company's leases contain any residual value guarantees. Lease expense is recognized on a straight-line basis over the expected lease term. Related variable lease costs incurred are not material to the Company.

The Company currently elects the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, we will not recognize right-of-use assets or liabilities, and this includes not recognizing right-of-use assets or liabilities for existing short-term leases of those assets in transition. We also elect the practical expedient to not separate lease and non-lease components for all of our leases. The Company has made an

accounting policy election to account for each separate lease component of a contract and its associated non-lease components as a single lease component. See the Lease Agreements section in Note 8 for the related disclosures.

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less from date of purchase to be cash equivalents. All cash and cash equivalents are held in highly rated securities including a treasury money market fund which is unrestricted as to withdrawal or use. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term and liquid nature. To date, the Company has not experienced any losses on its cash and cash equivalents, and we do not anticipate any losses with respect to such cash balances. While we maintain cash balances in excess of insured limits within a limited number of financial institutions, we mitigate our risk by maintaining the majority of our cash and equivalents with high quality financial institutions.

Trade Accounts Receivables

The Company's trade accounts receivable balance consists of amounts due from sales of our approved product, DANYELZA. Receivables from product sales are recorded net of allowances which generally include chargebacks, doubtful accounts, rebates, returns, and discounts. The Company accrues allowances based on the estimation of each individual sales transaction.

The Company has not experienced any write-offs related to our customers and has not recognized any allowance for doubtful accounts.

Concentration of Credit Risk

The Company product sales are made through arrangements primarily with three national specialty distributors in the United States of America. As of September 30, 2021, the receivables balances from such distributors totaled 99% of our outstanding accounts receivable. The Company has contractual payment terms with each of its customers and the Company monitors their financial performance, historical payment terms and credit worthiness to timely assess and respond to any changes in their credit profile.

Inventory

The Company values its inventories at the lower of cost or net realizable value on a first-in, first-out basis. The Company's inventory costs include amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, and indirect overhead costs. Raw and intermediate materials that may be utilized for both commercial and clinical programs are identical and given the alternative future use such amounts are initially classified as inventory. Amounts in inventory associated with clinical development programs are charged to research and development expense when the product enters the research and development process and can no longer be used for commercial purposes and, therefore, does not have an alternative future use.

The Company capitalizes inventory costs related to products to be sold in the ordinary course of business. The Company makes a determination of capitalizing inventory costs for a product based on, among other factors, status of regulatory approval, information regarding safety, efficacy and expectations relating to commercial sales and recoverability of costs. For DANYELZA, the Company commenced capitalization of inventory at the receipt of FDA approval.

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of goods sold. The determination of whether inventory costs will be realizable requires estimates by management. No material inventory write-downs occurred in the three and nine months ended September 30, 2021.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (i.e. an exit price). The accounting guidance includes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The three levels of the fair value hierarchy are as follows:

• Level 1 — Unadjusted quoted prices for identical assets or liabilities in active markets;

• Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability; and

• Level 3 — Unobservable inputs for the asset or liability, which include management's own assumption about the assumptions market participants would use in pricing the asset or liability, including assumptions about risk.

Cash equivalents held in money market funds are valued using other significant observable inputs, which represent a Level 2 measurement within the fair value hierarchy. The Company has no other cash equivalents.

The following tables present the Company’s fair value hierarchy for its cash equivalents, which are measured at fair value on a recurring basis (in thousands):

	Fair Value Measurements at September 30, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 187,717	$ —	$ 187,717
	$ —	$ 187,717	$ —	$ 187,717

	Fair Value Measurements at December 31, 2020 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 97,302	$ —	$ 97,302
	$ —	$ 97,302	$ —	$ 97,302

During the quarter ended September 30, 2021, there were no transfers between Level 1, Level 2, and Level 3.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, net product revenues, the accrual for research and development expenses, the accrual of milestone and royalty payments, and the valuation of stock options. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Revenue Recognition - Product revenue

We recognize revenue from sales of DANYELZA at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt at the end-user hospital.

The amount of revenue we recognize from sales of DANYELZA varies due to rebates, chargebacks and discounts provided under governmental and other programs, distribution related fees and other sales-related deductions. In order to determine those deductions, we estimate, utilizing the expected value method, the amount of revenue that we will ultimately be entitled to. This estimate is based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, estimated payor mix, and other relevant factors. Calculating these amounts involves estimates and judgments.

Revenue Recognition - License revenue

In December 2020, the Company entered into a development and commercialization arrangement with SciClone International Pharmaceuticals Ltd. ("SciClone") for certain indications of DANYELZA and omburtamab within China. As part of the agreement, we received a nonrefundable up-front fee of $20,000,000 for the transfer of the license and know-how related to the product indications. The Company may receive regulatory-based milestone payments up to $40,000,000 and sales-based milestone payments up to $60,000,000 and is entitled to royalties based upon the net sales generated by SciClone related to the product indications in the territory. We considered the license to be distinct from other promises within the arrangement based on the rights and know-how transferred, late-stage development of the underlying indications and anticipated lack of significant involvement required from the joint steering committee associated with the indications. Accordingly, the full transaction price of $20,000,000 was recognized upon transferring of the license and know-how to SciClone. The future potential regulatory milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606. As part of our evaluation of the regulatory milestones constraint, we determined that the achievement of such milestones are contingent upon regulatory approvals which are not within our control and therefore not deemed probable. We expect that the sales-based milestone payments and royalty arrangements will be recognized when the related sales occur or the milestone is achieved. We reevaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur, we assess whether this resolves the constraint and revenue will be recognized. We also considered that the manufacturing and supply terms, included within the arrangement, did not represent a material right to SciClone at inception as the terms reflected stand-alone selling price for similar goods or services. During the three and nine-month period ended September 30, 2021, revenue of $113,000 was recognized related to this arrangement and no milestones were achieved.

In May 2021, the Company entered into an exclusive distribution agreement with Adium Pharma S.A. ("Adium") to be the exclusive distributor in Latin America of the Company's antibodies, including DANYELZA and omburtamab. As part of this agreement, we received and recognized a nonrefundable up-front fee of $2,000,000 for the transfer of the license and know-how related to the product indications during nine-month period ended September 30, 2021. The Company may also receive regulatory-based milestone payments up to $3,500,000 and is entitled to royalties based upon the net sales generated by Adium related to the product indications in the territories. We considered the license to be distinct from other promises within the arrangement based on the rights and know-how transferred, late-stage development of the underlying indications and anticipated lack of significant involvement required from the joint steering committee associated with the indications. The future potential regulatory milestone amounts were not included in the transaction price, as they were all determined to be fully constrained following the concepts of ASC 606.

Segment Information

The Company is engaged solely in the discovery and development of novel antibody-based therapeutic products for the treatment of cancer. Accordingly, the Company has determined that it operates in one operating segment.

Recently Issued Accounting Pronouncements – Adopted

In March 2020, the FASB issued Accounting Standards Update No. 2020-04 ("ASU 2020-04"), Reference rate reform (Topic 848)—Facilitation of the effects of reference rate reform on financial reporting. The amendments in this Update provide optional guidance for a limited time to ease the potential burden in accounting for (or recognizing the effects) of reference rate reform on financial reporting. The amendments in this Update provide optional expedients and exceptions for applying generally accepted accounting principles (GAAP) to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. The amendments in this Update are effective for all entities as of March 12, 2020 through December 31, 2022. The adoption of this standard on January 1, 2021 did not have a material impact on our consolidated financial statements and related disclosures.

In December 2019, the FASB issued Accounting Standards Update No. 2019-12 ("ASU 2019-12"), Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes. The amendments in this Update affect entities within the scope of Topic 740, Income Taxes, and are effective for fiscal years beginning after December 15, 2020, and interim periods within those fiscal years. The adoption of this standard on January 1, 2021 did not have a material impact on our consolidated financial statements and related disclosures.

NOTE 4—PRODUCT REVENUE

The Company's product revenues were generated from sales of DANYELZA and totaled $8,852,000 and $23,186,000 for the three and nine months ended September 30, 2021. There were no product sales during the three and nine months ended September 30, 2020.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, discounts, distribution-related fees and other sales-related deductions. Accruals for chargebacks and discounts are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees and other sales-related deductions are recorded within accrued liabilities. As of September 30, 2021, the company had recorded accounts receivable allowances of approximately $277,000 and accrued liabilities of $2,285,000 related to product sales.

An analysis of the change in reserves for discounts and allowances is summarized as follows:

	Discounts (in thousands)	Contractual Allowances and Government Rebates (in thousands)	Returns (in thousands)	Total (in thousands)
Balance, December 31, 2020	$ —	$ —	$ —	$ —
Current provisions relating to sales in current year	51	3,308	(122)	3,237
Payments/credits relating to sales in current year	(37)	(760)	122	(675)
Balance, September 30, 2021	$ 14	$ 2,548	$ —	$ 2,562

Substantially all of the Company's product sales were in the United States. The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three and nine months ended September 30, 2021. Two wholesalers accounted for 66.3% and 23.9%, respectively, of our gross product revenue for the three months ended September 30, 2021 and two wholesalers accounted for 72.8% and 17.4%, respectively, of our gross product revenue for the nine months ended September 30, 2021.

NOTE 5—NET LOSS PER SHARE

Basic net loss per share ("EPS") is calculated by dividing net income or loss attributable to common stockholders by the weighted average common stock outstanding. Diluted EPS is calculated by adjusting weighted average common shares outstanding for the dilutive effect of common stock options and restricted stock units. In periods in which a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be antidilutive. Securities that could potentially dilute basic EPS in the future were not included in the computation of diluted EPS because to do so would have been antidilutive. The calculations of basic and diluted net loss per share are as follows (in thousands, except per share amounts):

	Three months ended September 30,		Nine months ended September 30,	
	2021	2020	2021	2020
	(in thousands, except per share amounts)			
Net income / (loss) (numerator)	$ (28,858)	$ (32,832)	$ (18,382)	$ (99,404)
Weighted-average shares (denominator), basic and diluted	43,598	40,187	43,019	39,972
Basic and diluted net income / (loss) per share	$ (0.66)	$ (0.82)	$ (0.43)	$ (2.49)

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options outstanding and unvested restricted stock units totaled 5,832,317 shares as of September 30, 2021 and 5,056,288 shares as of September 30, 2020.

NOTE 6—INVENTORY

Inventories consist of the following (in thousands):

	As of September 30, 2021			
	Raw Material	Work In Progress	Finished Goods	Total
Inventories	$ —	$ 4,711	$ 76	$ 4,787

There were no inventories as of December 31, 2020.

NOTE 7—ACCRUED LIABILITIES

Accrued short-term liabilities at September 30, 2021 and December 31, 2020 are as follows (in thousands):

	September 30, 2021	December 31, 2020
Accrued licensing, milestone and royalty payments	$ 2,302	$ 3,608
Accrued clinical costs	1,007	678
Accrued compensation and board fees	4,048	2,603
Accrued manufacturing costs	2,202	983
Accrued sales reserves	2,285	—
Other	642	325
Total	$ 12,486	$ 8,197

NOTE 8—LICENSE AGREEMENTS AND COMMITMENTS

As of September 30, 2021, the Company has entered into two license agreements and certain other agreements with Memorial Sloan Kettering Cancer Center ("MSK"). The license agreements, as previously disclosed in our annual report on Form 10-K, are the MSK License Agreement and the CD33 License Agreement. In addition, the Company entered into the SADA License Agreement with MSK and Massachusetts Institute of Technology ("MIT") in 2020. Through a 2019 Settlement and Assumption and Assignment of the MSK License Agreement and Y-mAbs Sublicense Agreement ("SAAA") with MabVax, Inc. ("MabVax") and MSK, the Company has established a direct license with MSK relating to the GD2-GD3 Vaccine, which was originally sublicensed by the Company in 2018 from MabVax. These license agreements with MSK and MIT grant the Company certain patent rights and intellectual property rights, and in consideration thereof, the Company agreed to make certain payments and issue shares of the Company's common stock to MSK and MIT. Certain of the payments are contingent milestone and royalty payments, as disclosed in the table below. Amounts disclosed in Note 7 for accrued milestone and royalty payments are inclusive of obligations under the MSK License Agreement, CD33 License Agreement and SADA License Agreement, collectively.

We have the following significant license agreements and related commitments which include all obligations that have been paid or accrued as of and for the period three and nine months ended September 30, 2021 (in thousands):

Agreements	**Cash paid** Nine months ended September 2021	**Cash paid** Nine months ended September 2020	**Expense** Three months ended September 2021	**Expense** Nine months ended September 2021	**Expense** Three months ended September 2020	**Expense** Nine months ended September 2020	**Accrued liabilities** Current as of September 2021	**Accrued liabilities** Non-current as of September 2021	**Accrued liabilities** Current as of December 2020	**Accrued liabilities** Non-current as of December 2020
MSK	$ 1,480	$ 80	$ 321	$ 531	$ -	$ -	$ 697	$ 1,800	$ 305	$ 1,640
CD33	100	—	—	—	—	—	—	450	100	450
MabVax	10	—	—	10	—	—	—	—	—	—
SADA	1,000	1,995	—	—	—	13,307	1,605	—	1,000	1,605

As of September 30, 2021, the Company has $1,800,000 of gross intangible assets related to the product rights for DANYELZA that were recorded under the MSK License Agreement and are included in "Other Assets" on the consolidated balance sheets. Amortization expense recorded during the period was not material.

The below table represents the maximum clinical, regulatory or sales-based milestones as reflected within the agreements, certain of which have been paid in prior periods or are accrued as presented in the table above (in thousands):

Agreements	**Maximum Clinical Milestones**	**Maximum Regulatory Milestones**	**Maximum Sales-based milestones**
MSK	$ 2,450	$ 9,000	$ 20,000
CD33	550	500	7,500
MabVax	200	1,200	—
SADA	4,730	18,125	23,750

Certain minimum royalties and clinical and regulatory milestones that become due based upon the passage of time under the CD33 License Agreement, the SADA Agreement and the MabVax Agreement are not recorded as a liability as the Company does not consider such obligations to be probable as of September 30, 2021.

Research and development is inherently uncertain and should such research and development fail the CD33 License Agreement, the SADA Agreement and the MabVax Agreement are cancelable at the Company's option. The Company will also consider the development risk and each party's termination rights under the agreement when considering whether any clinical or regulatory based milestone payments, certain of which also contain time-based payment requirements, are probable. The Company records milestones in the period in which the contingent liability is probable and the amount is reasonably estimable. With respect to the SADA Agreement, all time-based milestones coming due within 36 months of the effective date of the agreement have been accrued, as this continues to represent the

time period we expect will be required to gather necessary clinical data to determine which patent rights to further pursue, if any, under the SADA License Agreement.

Other agreements

We have also entered into various other support agreements with MSK including a sponsored research agreement to provide research services related to the intellectual property licensed under the MSK License Agreement; a master data services agreement, for services provided by approximately five full-time employees at MSK, who are engaged in transferring clinical data, databases, regulatory files and other know-how included in the MSK License Agreement to the Company; a master clinical trial agreement pursuant to which we committed to fund certain clinical trials at MSK; two separate core facility service agreements pursuant to which we committed to obtaining certain laboratory services from MSK; and in October 2020 we entered into a SADA sponsored research agreement pursuant to which we agreed to pay MSK to provide research services over a period of three years related to the intellectual property licensed under the SADA License Agreement. For three months ended September 30, 2021 and 2020, we incurred research and development expenses of $833,000 and $1,050,000, respectively, under these agreements. For nine months ended September 30, 2021 and 2020, we incurred research and development expenses of $2,728,000 and $3,028,000, respectively, under these agreements.

Lease Agreements

In July 2019, the Company entered a development, manufacturing and supply agreement with SpectronRx in South Bend, Indiana, to secure access to clinical and commercial scale radiolabeling capacity for omburtamab. Under the terms of the agreement, SpectronRx has agreed to establish a manufacturing unit designated for the Company within its existing facilities, at which both clinical and commercial supply of radiolabeled omburtamab can be produced. Since the Company possesses the right to substantially all the economic benefits and directs the use of the production area, the Company accounts for the payments related to the access to the manufacturing space under ASC 842 as an operating lease. The term of the lease is two years from the commencement date of August 31, 2020. Upon the lease commencement date, we recorded $3,617,000 as right of use asset and $2,679,000 as lease liability with the difference of $938,000 resulting from certain prepayments and other costs incurred. The company pays equal monthly installments of approximately $117,000 in additional access fees through September 2022 resulting in total payments of $1,282,000 remaining under the agreement. There are no renewal options in this agreement.

In February 2019, the Company entered into a lease agreement in connection with its 4,548 square feet laboratory in New Jersey. In December 2019, we expanded the space with an additional 235 square feet. The term of the lease is three years from the date the Company occupied the premises, with an option to extend for an additional two years which the Company expects to exercise and has included in the determination of the related lease liability. Fixed rent payable under the lease is approximately $144,000 per annum and is payable in equal monthly installments of approximately $12,000.

In January 2018, the Company entered into a lease agreement in connection with its corporate headquarters in New York. The term of the lease is five years from the date the Company began to occupy the premises. Fixed rent payable under the lease is approximately $384,000 per annum and is payable in equal monthly installments of approximately $32,000, which are recognized on a straight-line basis.

In February 2018, the Company entered a three-year lease agreement for the lease of certain office space in Denmark, as amended in November 2018 and February 2019. The lease is payable in monthly installments of approximately $19,000, which are recognized on a straight-line basis.

Additionally, on September 26, 2021, the Company entered into a lease agreement in Denmark to expand the size of its current office space to a total of 29,288 square feet. The new lease is expected to last for 48 months and commence in the fourth quarter of 2021 when the additional office space is made available to the Company by the landlord.

Total operating lease costs were $644,000 and $330,000 for the three months ended September 30, 2021 and 2020, respectively, and $1,936,000 and $680,000 for the nine months ended September 30, 2021 and 2020, respectively.

For the three months ended September 30, 2021, the operating lease expenses were recorded as $584,000 in research and development expense and $60,000 in general and administrative expense. For the three months ended September 30, 2020, the expenses were recorded as $280,000 in research and development expense and $50,000 in general and administrative expense. For the nine months ended September 30, 2021, the expenses were recorded as $1,758,000 in research and development expense and $178,000 in general and administrative expense. For the nine months ended September 30, 2020, the expenses were recorded as $529,000 in research and development expense and $151,000 in general and administrative expense.

Cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2021 was $548,000 and $1,641,000, respectively, and cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2020 was $201,000 and $594,000, respectively. These payments were included in net cash used in operating activities in the Company's Consolidated Statements of Cash Flows.

Maturities of operating lease liabilities at September 30, 2021 were as follows (in thousands):

	Operating Leases at September 30, 2021
Remainder of 2021	$ 542
Years ending December 31,	
2022	1,586
2023	539
2024	64
Total lease payments	2,731
Less: Imputed interest	(228)
Total operating lease liabilities at September 30, 2021	$ 2,503

Maturities of operating leases at December 31, 2020 were as follows (in thousands):

	Operating Leases at December 31, 2020
2021	$ 2,180
2022	1,593
2023	540
2024	64
Total lease payments	4,377
Less: Imputed interest	(398)
Total operating lease liabilities at December 31, 2020	$ 3,979

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its estimate of its incremental borrowing rate based on the information available at the lease commencement date. As of September 30, 2021, the weighted average remaining lease term is 1.56 years and the weighted average discount rate used to determine the operating lease liability was 7.6%. As of December 31, 2020, the weighted average remaining lease term is 2.18 years and the weighted average discount rate used to determine the operating lease liability was 7.6%.

Legal Matters

The Company has been named a nominal defendant in a lawsuit instigated by a stockholder against our Chairman of Board and President, Mr. Thomas Gad, seeking to compel Mr. Gad to disgorge alleged short swing profits stemming from a certain transaction involving the Company's common stock undertaken by Mr. Gad on March 10, 2021. The Company is of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company had been informed by Mr. Gad that he also believes the claim is without merit, that he has strong defenses against such claim and that he intends to vigorously defend the action. The Company has assessed the proceedings and does not believe that it is probable that a gain or a liability will be realized by the Company. As a result, the Company did not record any loss or gain contingencies for this matter.

NOTE 9—STOCKHOLDERS' EQUITY

Authorized Stock

As of September 30, 2021 and December 31, 2020, the Company has authorized a total of 105,500,000 shares, 100,000,000 of which are common stock, par value $0.0001 per share, and 5,500,000 of which are preferred stock, par value $0.0001 per share.

Common Stock

Each share of common stock is entitled to one vote. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to preferential dividend rights of the preferred stock, none of which have been issued. The Company had issued 43,643,916 shares of its common stock as of September 30, 2021 and 40,688,447 shares of its common stock as of December 31, 2020.

Preferred Stock

Preferred stock may be issued from time to time in one or more series with such designations, preferences and relative participating, optional or other special rights and qualifications, limitations or restrictions as approved by the Company's Board of Directors. No preferred stock has been issued as of September 30, 2021 or December 31, 2020.

Stock grant agreements with non-employees

In August 2015, we entered into stock grant agreements with certain non-employees of the Company. We agreed to issue a total of 2,800,000 shares to two non-employee researchers who were involved in the development of technology licensed from MSK in consideration for their prior service. The shares are released according to a vesting schedule. A total of 560,000; 448,000; 448,000; 544,000; and 400,000 shares, respectively, were issued in each year from 2015 through 2019. The remaining 400,000 shares were issued in August 2020. The total awards were expensed at its estimated fair value in 2015, as no future service was required to continue to vest in and receive the shares. No future shares will be issued under these awards.

In April 2020, in connection with the SADA License Agreement, we entered into certain stock grant agreements pursuant to which we agreed to issue a total of 213,996 shares to two non-employee researchers who were involved in the development of the SADA technology licensed from MSK and MIT in consideration for their prior service. All 213,996 shares were issued in April 2020 into escrow with 40% of the shares immediately vesting at the time of issuance and the remaining 60% of the shares subject to vesting ratably over the next three years on the anniversary date of the agreement. In accordance with the terms of the agreement, during the nine months ended September 30, 2021, the non-employee researchers vested in an additional 20% of the awards. Therefore, as of September 30, 2021, the two non-employee researchers have vested in 60% of the total grant with the remaining 40% vesting ratably over the next two years on the anniversary date of the agreement. The shares are subject to forfeiture to the extent the SADA License Agreement is terminated prior to the vesting of the shares. There is no cash settlement

feature, and no future service is required for the non-employee researchers to vest and receive the shares. While the shares vest over time, there is no performance condition for the shares. In April 2020, we recorded an expense within research and development totaling $7,376,000 related to the shares which represented the fair value of the shares on the grant date.

In July 2020, pursuant to the stock grant agreements, we also loaned the two researchers a total of $2,610,000 related to their individual tax payments due in conjunction with the stock grants. Each of the loans are evidenced by a three year Secured Promissory Note. The outstanding principal amounts of the loans, together with all accrued interest thereon at the rate of 1% per annum, is due and payable on the maturity date of the loans. The loans are secured by Pledge and Security Agreements, pursuant to which the researchers have pledged the shares as security for repayment of the loans with interest rates that are at market. The loans are recorded at amortized cost, which approximates fair value due to the maturity dates of the loan and minimal changes in market interest rates.

Issuance of common stock

On February 22, 2021, we completed a third public offering of our common stock pursuant to which we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our secondary public offering of $115,000,000, with aggregate net proceeds of approximately $107,725,000 after deducting underwriting discounts and commissions and offering expenses.

NOTE 10—SHARE-BASED COMPENSATION

2015 Equity Incentive Plan

Our board of directors and stockholders have approved and adopted the 2015 Plan, which provided for the grant of incentive stock options, within the meaning of Section 422 of the Code (the Internal Revenue Code), to our employees and any parent and subsidiary corporations' employees, and for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock and restricted stock units to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants. A total of 4,500,000 shares of our common stock were reserved for issuance pursuant to the 2015 Plan. Options granted under the 2015 Plan vest according to the schedule specified in the grant agreements, which is generally a four-year period and generally become immediately exercisable upon the occurrence of a change in control, as defined. Upon the 2018 Equity Incentive Plan (the "2018 Plan') becoming effective in September 2018, no further grants are allowed under the 2015 Plan.

2018 Equity Incentive Plan

Our board of directors and stockholders approved and adopted the 2018 Plan, which became effective upon the Company's initial public offering in September 2018 and which provides for the grant of incentive stock options, within the meaning of Section 422 of the Code (the Internal Revenue Code), to our employees and any parent and subsidiary corporations' employees, and for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock and restricted stock units to our employees, directors and consultants and our parent and subsidiary corporations' employees and consultants. A total of 5,500,000 shares of our common stock, inclusive of the awards previously granted under the 2015 Equity Incentive Plan, are reserved for issuance pursuant to the 2018 Plan. In addition, the number of shares available for issuance under the 2018 Plan will also include an annual increase on the first day of each fiscal year beginning in 2019, equal to 4% of the outstanding shares of common stock as of the last day of our immediately preceding fiscal year. The exercise price of options granted under the plans must at least be equal to the fair market value of our common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of our outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. Options granted under the 2018 Plan vest according to the schedule specified in the grant

agreements, which is generally a four-year period and generally become immediately exercisable upon the occurrence of a change in control, as defined.

Stock Option Valuation

For the three month periods ended September 30, 2021 and 2020, stock-based compensation for stock option grants were $4,829,000 and $3,083,000, respectively, for options granted to employees and directors. For the three months ended September 30, 2021, the expenses were recorded as $1,827,000 in research and development expense and $3,002,000 in selling, general, and administrative expense. For the three months ended September 30, 2020, the expenses were recorded as $686,000 in research and development expense and $2,397,000 in selling, general, and administrative expense.

For the nine month periods ended September 30, 2021 and 2020, stock-based compensation for stock option grants were $14,209,000 and $7,676,000, respectively, for options granted to employees and directors. For the nine months ended September 30, 2021, the expenses were recorded as $5,271,000 in research and development expense and $8,938,000 in selling, general, and administrative expense. For the nine months ended September 30, 2020, the expenses were recorded as $1,712,000 in research and development expense and $5,964,000 in selling, general, and administrative expense.

The following table summarizes common stock options issued and outstanding:

	Options	Weighted average exercise price	Aggregate intrinsic value (in thousands)	Weighted average remaining contractual life (years)
Outstanding and expected to vest at December 31, 2020	5,674,100	$ 22.55	$ 156,726	7.51
Granted	311,000	33.02		
Exercised	(140,492)	3.48		
Forfeited	(39,063)	39.46		
Outstanding and expected to vest at September 30, 2021	5,805,545	$ 23.46	$ 62,545	6.97
Exercisable at September 30, 2021	3,526,547	$ 13.09	$ 59,260	5.83

The weighted average fair value of stock options granted for the three months ended September 30, 2021 and 2020 was $20.19 and $23.72, respectively. There were 102,000 and 155,000 stock options granted for the three months ended September 30, 2021 and 2020, respectively.

The weighted average fair value of stock options granted for the nine months ended September 30, 2021 and 2020 was $20.85 and $20.72, respectively. There were 311,000 and 1,196,000 stock options granted for the nine months ended September 30, 2021 and 2020, respectively.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company’s common stock for those stock options that had exercise prices lower than the fair value of the Company’s common stock. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. We estimate our expected share price volatility based on the historical volatility of a group of publicly traded peer companies and we expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of our stock options has been determined utilizing the “simplified” method for awards issued to employees as we have limited historical data to support the expected term assumption. The risk free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that we have never paid cash dividends on shares of our common stock and do not expect to pay any cash dividends in the foreseeable future.

As of September 30, 2021, we had $44,357,000 of unrecognized compensation expense related to employee stock options that are expected to vest over a period of 2.61 years. As of September 30, 2020, we had $33,036,000 of unrecognized compensation expense related to employee stock options that are expected to vest over a period of 2.85 years.

Restricted Stock Unit Activity

For the three months ended September 30, 2021 and September 30, 2020, stock-based compensation for restricted stock unit grants was $72,000 and $53,000, respectively. For the three months ended September 30, 2021, the expenses were recorded as $63,000 in research and development expense and $9,000 in selling, general, and administrative expense. For the three months ended September 30, 2020, the expenses were recorded as $48,000 in research and development expense and $5,000 in selling, general, and administrative expense.

For the nine months ended September 30, 2021 and September 30, 2020, stock-based compensation for restricted stock unit grants was $217,000 and $123,000, respectively. For the nine months ended September 30, 2021, the expenses were recorded as $194,000 in research and development expense and $23,000 in selling, general, and administrative expense. For the nine months ended September 30, 2020, the expenses were recorded as $112,000 in research and development expense and $11,000 in selling, general, and administrative expense.

The following table summarizes restricted stock units issued and outstanding:

	Restricted Stock Units	Weighted average grant price	Weighted average remaining vesting life (years)
Outstanding and expected to vest at December 31, 2020	30,146	$ 25.45	2.18
Granted	10,092	33.86	
Vested	(10,099)	22.76	
Forfeited	(3,367)	26.33	
Outstanding and expected to vest at September 30, 2021	26,772	$ 29.53	1.91

As of September 30, 2021, we had $631,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 1.91 years. As of September 30, 2020, we had $524,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 2.40 years.

NOTE 11—RELATED PARTY TRANSACTIONS

MSK is a shareholder of the Company. Under the MSK License Agreement, the SADA License Agreement, the CD33 License Agreement, and various other supporting agreements with MSK, we have expensed costs in the total amount of $1,154,000 and $1,050,000 in the three months ended September 30, 2021 and 2020, respectively, for milestones, minimum royalties, and research and development costs. We expensed costs in the total amounts of $3,259,000 and $7,626,000 in the nine months ended September 30, 2021 and 2020, respectively, under these agreements with MSK. Please refer to Note 8—License Agreements and Commitments for additional details on our agreements with MSK. As of September 30, 2021, we had a total of $472,000 recorded as accounts payable, $4,804,000 as accrued liabilities, thereby totaling $5,276,000 due to MSK. As of December 31, 2020, we had a total of $833,000 recorded as accounts payable, $7,161,000 as accrued liabilities, thereby totaling $7,994,000 due to MSK.

NOTE 12—INCOME TAXES

The Company provided no current and deferred income taxes on net losses of $28,858,000 and $32,832,000 for the three month periods ended September 30, 2021 and 2020, respectively, and the net loss of $18,382,000 and $99,404,000 for the nine month periods ended September 30, 2021 and 2020, respectively.

The Company recognizes income tax benefits for tax positions determined more likely than not to be sustained upon examination, based on the technical merits of the positions. The Company's tax returns for the years 2015 to 2020 are open for tax examination by U.S. federal and state, and the Danish tax authorities. Our Danish tax returns for 2016-2019 are currently under review by the Danish Tax authorities. As of September 30, 2021 and December 31, 2020, the Company has determined that there were no uncertain tax positions.

The Company maintains a full valuation allowance on its U.S. and foreign deferred tax assets. The valuation allowance related primarily to net U.S. deferred tax assets from operating losses, and research and development tax credit carryforwards. The assessment regarding whether a valuation allowance is required considers both positive and negative evidence when determining whether it is more likely than not that deferred tax assets are recoverable. In making this assessment, significant weight is given to evidence that can be objectively verified. In its evaluation, the Company considered its cumulative losses historically and in recent years and its forecasted losses in the near term as significant negative evidence. Based upon review of available positive and negative evidence, the Company determined that the negative evidence outweighed the positive evidence and a full valuation allowance on its U.S. and foreign deferred tax assets will be maintained. The Company will continue to assess the realizability of its deferred tax assets and will adjust the valuation allowance as needed.

NOTE 13—OTHER BENEFITS

The Company has adopted a defined contribution 401(k) savings plan (the 401(k) plan) covering all U.S. employees of the Company. Participants may elect to defer a percentage of their pretax or after-tax compensation to the 401(k) plan, subject to defined limitations. The plan allows for a discretionary match by the Company. The Company made no matching contributions to the plan for the three or nine months ended September 30, 2021 and 2020.

The Company has established a retirement program for employees of the Company's Danish subsidiary pursuant to which all such employees can contribute an amount at their election from their base compensation and may receive contributions from our Danish subsidiary. No contributions from Danish subsidiary were made for three and nine months ended September 30, 2021 and 2020. In addition, health insurance benefits for our Danish employees are fully paid for by such employees. Our Danish subsidiary does not incur any costs for these health insurance benefits.

NOTE 14 —GAIN FROM SALE OF PRIORITY REVIEW VOUCHER

On December 28, 2020, the Company announced that it entered into a definitive agreement to sell its DANYELZA Priority Review Voucher to United Therapeutics Corporation for $105,000,000. The PRV was granted in conjunction with the approval by the U.S. Food and Drug Administration ("FDA") of DANYELZA, for the treatment of refractory/relapsed high-risk neuroblastoma. Under the terms of the Company's license agreement with MSK, Y-mAbs retained 60% of the net proceeds received from the sale, and the remaining 40% was paid to MSK. The transaction closed on January 21, 2021 and the Company recognized a net gain of $62,010,000 during the nine months ended September 30, 2021 related to the sale.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations together with our accompanying financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2020 on file with the SEC. 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 and related financing, includes forward-looking statements that involve substantial risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section 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. For convenience of presentation some of the numbers have been rounded in the text below.

Overview

We are a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody based therapeutic products for the treatment of cancer. We are leveraging our proprietary antibody platforms and deep expertise in the field of antibodies to develop a broad portfolio of innovative medicines.

On November 25, 2020, DANYELZA® (naxitamab-gqgk) was approved by the United States Food and Drug Administration, or the FDA, for the treatment, in combination with Granulocyte-Macrophage Colony-Stimulating Factor, or GM-CSF, of pediatric patients one year of age and older and adult patients with relapsed or refractory, or R/R, high-risk neuroblastoma, or NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. DANYELZA is currently being investigated in three Phase 2 clinical studies for the treatment of patients with first-line NB, third-line NB, and in relapsed osteosarcoma. We are commercializing DANYELZA in the United States. In addition, we have an ongoing Phase 2 clinical trial at Memorial Sloan Kettering Cancer Center, or MSK, with our GD2-GD3 Vaccine for the treatment of Stage 4 high-risk NB. We believe the GD2-GD3 Vaccine can potentially serve as an add-on treatment to DANYELZA.

We submitted a Biologics License Application, or BLA, to the FDA in August 2020 for radiolabeled 131I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB, and received a Refusal to File letter from the FDA in October 2020. We held a Type B meeting with the FDA in September 2021, and have requested a pre-BLA meeting with the FDA. Subject to timing of and positive feedback at such pre-BLA meeting, we aim to initiate resubmission of the omburtamab BLA shortly thereafter, and to complete the submission during the course of the first quarter 2022. We plan to commercialize omburtamab as soon as possible after obtaining FDA approval, if such approval occurs.

In April 2021, we submitted a European Marketing Authorization Application, or MAA, for omburtamab. Additionally, we are conducting clinical studies with omburtamab in diffuse intrinsic pontine glioma, or DIPG, and desmoplastic small round cell tumor, or DSRCT. We also have an omburtamab follow-on product candidate, ^{177}Lu-omburtamab-DTPA, in Phase 1 for the treatment of medulloblastoma, and in Phase 1 for treatment targeting B7-H3 positive CNS/LM tumors in adults.

We are advancing a new generation of T cell engaging bispecific antibodies, or BsAbs, that may destroy tumor cells by recruitment of host T cells. Our Y-BiClone format contains two binding arms for the tumor target and two binding arms for T cells. This format was designed to have the minimal binding affinity necessary to recruit T cells. We have a Phase 2 clinical trial ongoing with nivatrotamab, our GD2 BsAb product candidate, in Small Cell Lung Cancer, or SCLC. In addition, a Phase 1/2 clinical trial with nivatrotamab, for the treatment of refractory GD2 positive adult and pediatric solid tumors is ongoing. Our nivatrotamab program thus addresses large patient populations. We are also advancing a CD33 BsAb for the treatment of hematological cancers expressing CD33, a transmembrane receptor expressed on cells of myeloid lineage, for which we have filed an IND, and expect to enter clinical testing in the next six months. We are advancing a pipeline of other novel BsAbs through late pre-clinical development. We believe our BsAbs have the potential to result in improved tumor binding, longer serum half-life and significantly greater T cell mediated killing of tumor cells without the need for continuous infusion.

We are using the SADA technology, our proprietary radioimmunotherapy platform to advance a series of antibody constructs, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach. We also refer to the SADA technology as Liquid Radiation™. We have designated GD2-SADA for potential use in GD2 positive solid tumors, and expect to file an IND for GD2-SADA by the end of 2021. We have additional SADA constructs under development, for potential use in prostate cancer, colon cancer, breast cancer and a number of additional indications. We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.

Our mission is to become the world leader in developing better and safer antibody-based pediatric oncology products addressing clear unmet medical needs and, as such, have a transformational impact on the lives of patients. We intend to continue to advance and expand our product pipeline into certain adult cancer indications either independently or in collaboration with potential partners.

Since our inception on April 30, 2015, we have devoted substantially all of our resources to organizing and staffing our company, business planning, identifying potential product candidates, conducting pre-clinical studies of our product candidates and clinical trials of our lead product candidates, commercializing our approved product, raising capital, and acquiring and developing our technology platform among other matters. We have not generated substantial revenues from sales of DANYELZA which is currently our only approved product.

To date, we have financed our operations primarily through private placements of our securities, proceeds from our initial public offering and proceeds from our two subsequent public offerings, and our product and license revenue from DANYELZA.

On February 22, 2021, we completed our most recent follow-on public offering of our common stock pursuant to which we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share, which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from this offering of $115.0 million, with aggregate net proceeds of approximately $107.7 million after deducting underwriting discounts and commissions and offering expenses.

As of September 30, 2021, we had an accumulated deficit of $303.6 million. Our net loss was $28.9 million for the three months ended September 30, 2021 and $32.8 million for the three months ended September 30, 2020. Our net loss was $18.4 million for the nine months ended September 30, 2021 and $99.4 million for the nine months ended September 30, 2020. We have incurred significant net operating losses in every year since our inception and expect to continue to incur net operating losses and significant expenses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We anticipate that our expenses will increase significantly as we:

- continue to advance our lead product candidates through the regulatory approval process both in the U.S. and internationally;
- continue to advance our other product candidates through pre-clinical and clinical development;
- continue to identify additional research programs and additional product candidates, as well as additional indications for existing product candidates;
- initiate pre-clinical studies and clinical trials for any additional product candidates we identify;
- develop, maintain, expand and protect our intellectual property portfolio;
- hire additional research, sales force, commercialization, clinical and scientific personnel; and
- incur additional costs associated with operating as a public company, including expanding our operational, finance and management teams.

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a Priority Review Voucher, or PRV, which we subsequently sold to United Therapeutics Corporation. We were obligated to pay, and paid 40% of the net proceeds from the sale of the PRV to MSK as required under the terms of the MSK license. We intend to use the remaining proceeds to fund further research and development and other operational programs. The transaction closed in January 2021 upon the resolution of the substantive closing conditions, and was recognized as part of "Other Income, Net" in the Consolidated Statements of Net Loss and Comprehensive Loss for the nine months ended September 30, 2021. Upon the potential FDA approval of omburtamab, we expect to receive another PRV, and upon monetization thereof we will be obligated to pay 33% of the net proceeds from such sale to MSK.

In August 2015, we entered into a license agreement, or the MSK License, with MSK pursuant to which we have obtained exclusive rights to MSK's rights in our current antibody product candidates. Under the MSK License, we have committed to funding scientific research at MSK as well as conducting certain clinical trial activities at MSK. As these product candidates progress through clinical development, regulatory approval and commercialization, certain milestone payments will come due to MSK either as a result of the milestones having been met or the passage of time even if the milestones have not been met. Also, we owe MSK customary royalties on commercial sales of our approved products. In addition, we have committed to obtain certain personnel and laboratory services at MSK under our Master Data Services Agreement, or MDSA, and two separate Core Facility Service Agreements, or CFSAs. Also, under our Investigator-Sponsored Master Clinical Trial Agreement, or MCTA, with MSK, we will provide drug product and funding for certain clinical trials at MSK.

On April 15, 2020, we entered into a license agreement, or the SADA License Agreement, with MSK and Massachusetts Institute of Technology, or MIT, that grants us an exclusive, worldwide, sublicensable license to certain patent and intellectual property rights developed by MSK and MIT to develop, manufacture, and commercialize licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics and cancer treatments using SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA Technology, a concept we also refer to as Liquid Radiation™. The patents and patent applications covered by the SADA License Agreement are directed, in part, to the SADA Technology, as well as a number of SADA constructs developed by MSK. Upon entering into the SADA License Agreement in April 2020 and in exchange for the licenses, we paid MSK and MIT a cash upfront payment and issued an aggregate of 42,900 shares of our common stock to them. During the nine months ended September 30, 2021, we paid a payment in the amount of $1.0 million to MSK and MIT under the agreement.

As required under the SADA License Agreement, in October 2020, we entered into a Sponsored Research Agreement with MSK to fund at least $1,500,000 in scientific research at MSK over the next three years.

Further, the SADA License Agreement requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay minimum annual royalties of $40,000, which shall increase to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License Agreement. As of September 30, 2021, we have determined that payment of the minimum royalties is not probable, and accordingly have not accrued for them at September 30, 2021.

Under the SADA License Agreement, we are also obligated to pay MSK and MIT certain clinical, regulatory and sales-based milestone payments. Certain of the clinical and regulatory milestone payments become due at the earlier of either the completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestones potentially due under the SADA License Agreement are $4,730,000 and $18,125,000, respectively. Sales-based milestones payments, totaling $23,750,000, become due should the Company achieve certain amounts of sales. In addition, for each of the SADA constructs generated by MSK and sold on behalf of the Company by a sublicensee, the Company may make sales-based milestone payments in the total amount up to $60,000,000 based on the achievement of various cumulative net sales made by the sub-licensee. Finally, under the terms of the SADA License, MSK is entitled to receive 25% of any income generated from the sale of any PRV or the sale of other comparable incentives provided by any non-U.S. jurisdiction.

These MSK agreements are important to our business. For a more detailed discussion of the terms and conditions of certain of these agreements, see Note 8 - License Agreements and Commitments.

For DANYELZA, and for any other product candidates for which we obtain regulatory approval, we expect to incur significant milestone costs, as well as commercialization expenses related to product sales, marketing, manufacturing and distribution. Accordingly, we may continue to fund our operations through public or private equity or debt financings or other sources, including strategic collaborations. We may, however, be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our current product candidates, or any additional product candidates. Because of the numerous risks and uncertainties associated with the development of our existing product candidates and any future product candidates, our platform and technology and because the extent to which we may enter into collaborations with third parties for development of any of our product candidates is uncertain, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, product candidates or grant licenses on terms that may not be favorable to us and could have a negative impact on our financial condition.

Recent Developments

Since it was first reported to have emerged in December 2019, a novel strain of coronavirus, which causes COVID-19, has spread around the world, including the New York metropolitan area and Copenhagen, Denmark, where our primary office and laboratory spaces are located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third-party partners, including our preclinical studies, clinical trials, manufacturing operations and commercialization efforts, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus, the emergence of new variants of the virus such as the Delta variant and the actions to contain the coronavirus or treat its impact, among others. We have taken precautionary measures intended to help minimize the risk of the virus to our employees which could negatively affect our business. We cannot presently predict the scope and severity of the planned and potential shutdowns or disruptions of businesses and government agencies, such as the Securities and Exchange Commission, or SEC, the FDA or other domestic and international regulatory authorities.

Components of Our Results of Operations

Product Revenue

Product revenue consists of sales of DANYELZA.

License Revenue

License revenue consists of payments received for the licensing rights of DANYELZA and omburtamab in Latin America.

Operating Costs and Expenses

Cost of goods sold

Cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of DANYELZA, including materials, third-party manufacturing costs, packaging services, freight, labor costs for personnel involved in the manufacturing process, indirect overhead costs and third-party royalties payable on our net product revenues.

Licensing Royalties

The Company has incurred certain third-party royalty expenses related to third-party licensing revenues, which are included in Licensing Royalties.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. We expense research and development costs as incurred. These expenses include, but are not limited to:

- sponsored research, laboratory facility services, clinical trial and data service at MSK under the Sponsored Research Agreements, or the SRAs, the two CFSAs, the MCTA, and the MDSA, with MSK;
- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our non-clinical and pre-clinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical studies and clinical trial materials, including manufacturing validation batches;
- upfront, milestone and other non-revenue related payments due under our third-party licensing agreements;
- employee-related expenses, which include salaries, benefits, travel and stock-based compensation;
- expenses related to regulatory activities, including filing fees paid to regulatory agencies;
- outsourced professional scientific development services; and
- allocated expenses for utilities and other facility-related costs, including rent, insurance, supplies and maintenance expenses, and other operating costs.

The successful development and regulatory approval of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the remainder of the development of DANYELZA and omburtamab or any future product candidates we may develop. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of clinical trials, which vary significantly over the life of a project as a result of many factors, including, but not limited to:

- the number of clinical sites included in the trials;
- the availability and length of time required to enroll a sufficient number of suitable patients in our clinical trials;
- the actual probability of success for our product candidates, including the safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the performance of our existing and any future collaborators;
- the number of doses patients receive;
- the duration of patient follow-up;

- the results of our clinical trials and pre-clinical studies;
- the establishment of commercial manufacturing capabilities;
- adequate ongoing availability of raw materials and drug substance for clinical development and any commercial sales;
- the terms and timing of regulatory approvals, including the timing of our BLA submissions and their acceptance;
- the receipt of marketing approvals, including a safety, tolerability and efficacy profile that is satisfactory to the FDA or any non-U.S. regulatory authority;
- any requirement by the FDA or any non-US regulatory authority to conduct post market surveillance or safety studies;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the success of commercialization of approved products.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development. We may also never succeed in achieving regulatory approval for omburtamab or any other product candidates we may develop.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to increase significantly over the next several years as we increase personnel costs, including stock-based compensation, conduct clinical trials and potentially prepare regulatory submissions for our pipeline candidates, including supplementary regulatory submissions for DANYELZA.

Selling, General, and Administrative Expenses

Selling, general and administrative expenses consist primarily of employee related expenses, including salaries, bonus, benefits, and stock-based compensation expenses for personnel in executive, commercial, finance and administrative functions. Other significant costs include facility costs not otherwise included in research and development expenses or cost of goods sold, legal fees relating to corporate matters, and fees for patent, accounting, tax, and consulting services.

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of additional product candidates and costs associated with operating as a public company, including expenses related to services associated with maintaining compliance with exchange listing and the SEC requirements, director and officer insurance costs and investor and public relations costs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses.

Other Income, Net

On December 28, 2020, the Company announced that it entered into a definitive agreement to sell its DANYELZA PRV to United Therapeutics Corporation for $105.0 million. The PRV was granted in conjunction with the approval by the FDA of DANYELZA®, for the treatment of refractory/relapsed high-risk NB. Under the terms of the MSK License, Y-mAbs retained 60% of the net proceeds received from the sale, and the remaining 40% was paid to MSK. The net proceeds of this sale to the company was $62.0 million. The transaction closed on January 21, 2021 when the substantive closing conditions included within the agreement were resolved.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles, or GAAP. We believe that several accounting policies are significant to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing elsewhere in this Quarterly Report on Form 10-Q, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, net product revenues, the accrual for research and development expenses, the accrual of milestone and royalty payments, and the valuation of stock options. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition, including expenses, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain it or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

Revenue Recognition - Product revenue

We recognize revenue from sales of DANYELZA at a point in time when our customer is deemed to have obtained control of the product, which generally occurs upon receipt at the end-user hospital.

The amount of revenue we recognize from sales of DANYELZA varies due to rebates, chargebacks and discounts provided under governmental and other programs, distribution related fees and other sales-related deductions. In order to determine those deductions, we estimate, utilizing the expected value method, the amount of revenue that we will ultimately be entitled to. This estimate is based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, estimated payor mix, and other relevant factors. Calculating these amounts involves estimates and judgments.

Research and Development Expenses

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of compensation cost for our employees and consultants that perform our research activities, the costs to obtain and maintain our licenses, the payments to third parties for CMOs and CROs and additional product development, and consumables and other materials used in research and development. We record accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, we analyze progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Actual results could differ from our estimates. We are obligated to make certain milestone and royalty payments in accordance with the contractual terms of the MSK License, CD33 License, MabVax Sublicense, and SADA License Agreement based upon the resolution of certain contingencies. Certain of these milestone payments are due and payable with the passage of time whether or not the milestones have actually been met. We record the milestone and royalty payment when the achievement of the milestone (including the passage of time) or payment of the milestone or royalty is probable and the amount of the payment is reasonably estimable.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date (i.e. an exit price). The accounting guidance includes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The three levels of the fair value hierarchy are as follows:

• Level 1 — Unadjusted quoted prices for identical assets or liabilities in active markets;

• Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability; and

• Level 3 — Unobservable inputs for the asset or liability, which include management's own assumption about the assumptions market participants would use in pricing the asset or liability, including assumptions about risk.

The Company’s cash equivalents are carried at fair value, determined according to the fair value hierarchy described above.

Income Taxes

We account for income taxes under the asset and liability approach for the financial accounting and reporting of income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to net operating loss carry forwards and temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. These assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to reverse. A valuation allowance is established when management determines that it is more likely than not that some portion or all of the deferred tax assets will not be realized.

We prepare and file tax returns based on its interpretation of tax laws and regulations. In the normal course of business, our tax returns are subject to examination by various taxing authorities. Such examinations may result in future tax and interest assessments by these taxing authorities. In determining our tax provision for financial reporting purposes, we establish a reserve for uncertain tax positions unless such positions are determined to be more likely than not of being sustained upon examination based on their technical merits. We consider many factors when evaluating and estimating our tax positions and tax benefits, which may require periodic adjustments and which may not accurately anticipate actual outcomes. Accordingly, we will report a liability for unrecognized tax benefits resulting from any uncertain tax positions taken or expected to be taken on a tax return.

Our policy is to recognize, when applicable, interest and penalties on uncertain tax positions as part of income tax expense.

Stock-Based Compensation

We measure stock options granted to employees, directors, and consultants based on the fair value on the date of the grant and recognize compensation expense of those awards, over the requisite service period, which is the vesting period of the respective award for employees and directors. Forfeitures are accounted for as they occur. We issue stock options to employees and directors with only service-based vesting conditions and record the expense for these awards using the straight-line method over the requisite service period.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. Historically, we have been a private company and lack company-specific historical and implied volatility information for our shares. Therefore, we estimate our expected share price volatility based on the historical volatility of a group of publicly-traded peer companies and we expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of our stock options has been determined utilizing the "simplified" method for awards as we have limited historical data to support the expected term assumption. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that we have never paid cash dividends on shares of our common stock and do not expect to pay any cash dividends in the foreseeable future.

Fair Value of Stock Options

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The assumptions used to determine the fair value of the granted stock options were as follows:

- Risk-free interest rate: The risk-free interest rate assumption is based on the U.S. Treasury instruments whose terms were consistent with the expected option term of our stock options.

- Expected Dividend Yield: The expected dividend yield assumption is based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends. Consequently, we used an expected dividend of zero.

- Expected Volatility: The expected stock price volatility is estimated by taking the average historic price volatility of industry peers and adjusting for differences in our life cycle and financing leverage. Our industry peers consist of several public companies in the biopharmaceutical industry.

- Expected Term: We determine the average expected life of stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. We expect to continue to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Results of Operations

Comparison of the Three Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Product revenue, net	$ 8,965	$ —	$ 8,965
Total revenues	8,965	—	8,965
Operating costs and expenses:			
Cost of goods sold	550	—	550
Research and development	23,131	21,005	2,126
Selling, general, and administrative	13,988	11,636	2,352
Total operating costs and expenses	37,669	32,641	5,028
Loss from operations	(28,704)	(32,641)	3,937
Other income, net			
Interest and other loss	(154)	(191)	37
Net loss	$ (28,858)	$ (32,832)	$ 3,974

Revenue

The Company launched DANYELZA in February 2021, and recorded $9.0 million in net product revenues for the three months ended September 30, 2021. Please refer to Note 3—Summary of Significant Accounting Policies Revenue Recognition – Product Revenue.

The Company had no product revenues as we did not have an approved product and no license revenue as we did not enter into any out-licensing agreements during the three months ended September 30, 2020.

Cost Of Goods Sold

The Company began capitalizing inventory costs once DANYELZA was approved by the FDA in November 2020. Cost of goods sold was $550,000 for the three months ended September 30, 2021. The company's cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, third party royalties, and indirect overhead costs. In periods prior to receiving FDA approval for DANYELZA, we recognized inventory and related costs associated with the manufacture of DANYELZA as research and development expenses. This resulted in inventory being sold during the quarter ended September 30, 2021 for which a portion of the costs had been expensed prior to FDA approval. We expect this to continue to impact cost of goods sold through 2022 as such inventory amounts are sold to our customers.

In addition, the Company expensed $1.2 million of minimum royalties related to DANYELZA sales prior to commercial launch which are fully creditable against earned royalties in future periods. If we had not sold previously expensed inventory nor previously expensed minimum royalties, our cost of goods sold would have been approximately $1,256,000.

The Company had no cost of goods sold for the three months ended September 30, 2020.

Research and Development Expenses

We do not record our research and development expenses on a program-by-program or on a product-by-product basis as they primarily relate to personnel, research, manufacturing, license fees and consumable costs, which are simultaneously deployed across multiple projects under development. These costs are included in the table below.

	Three Months Ended September 30,	
	2021	2020
	(in thousands)	
Outsourced manufacturing	$ 7,915	$ 9,331
Clinical trials	3,837	1,892
Outsourced research and supplies	2,636	3,595
Personnel costs	4,092	3,482
Professional and consulting fees	775	834
Stock-based compensation	1,890	734
Other	1,986	1,137
	$ 23,131	$ 21,005

Research and development expenses increased by $2.1 million, from $21.0 million for the three months ended September 30, 2020 to $23.1 million for the three months ended September 30, 2021. This was primarily due to $1.9 million increase in clinical trials and $1.8 million increase in employee-related costs, including salary, benefits and non-cash stock-based compensation for personnel related to our expanding workforce. These increases were partially offset by a decrease $1.4 million outsourced manufacturing costs.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by $2.4 million, from $11.6 million for the three months ended September 30, 2020 to $14.0 million for the three months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily attributable to a $2.1 million increase in employee related costs, including salary, benefits and non-cash stock-based compensation for personnel related to our business activities mainly due to the growth of the commercialization team.

Other Income, Net

Interest and other loss for the three months ended September 30, 2021 was a loss of $154,000 as compared to a loss of $191,000 for the three months ended September 30, 2020. The loss decreased by $37,000 due to decreased foreign currency exchange losses incurred in the current period.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,		
	2021	2020	Change
	(in thousands)		
Revenue:			
Product revenue, net	$ 23,299	$ —	$ 23,299
License revenue	2,000	—	2,000
Total revenues	25,299	—	25,299
Operating costs and expenses:			
Cost of goods sold	843	—	843
Royalties	210	—	210
Research and development	64,488	69,686	(5,198)
Selling, general, and administrative	39,433	30,155	9,278
Total operating costs and expenses	104,974	99,841	5,133
Loss from operations	(79,675)	(99,841)	20,166
Other income, net			
Gain from sale of priority review voucher	62,010	—	62,010
Interest and other income / (loss)	(717)	437	(1,154)
Net loss	$ (18,382)	$ (99,404)	$ 81,022

Revenue

The Company launched DANYELZA in February 2021 and recorded $23.3 million in net revenues for the nine months ended September 30, 2021. Please refer to Note 3—Summary of Significant Accounting Policies Revenue Recognition – Product Revenue. The Company had no product revenues during the nine months ended September 30, 2020 as no products had been approved at the time.

In addition, the Company recorded $2.0 million in license revenues for the nine months ended September 30, 2021. This $2.0 million was attributable to the revenues earned from outlicensing DANYELZA and omburtamab in Latin America. As part of this agreement, we received a nonrefundable up-front fee of $2.0 million for the transfer of the license and know-how related to the constructs. We recognized the revenue as we determined the license to be distinct from other promises within the arrangement.

The company had no revenues during the nine months ended September 30, 2020.

Cost Of Goods Sold

The Company began capitalizing inventory costs once DANYELZA was approved by the FDA in November 2020. Cost of goods sold was $843,000 for the nine months ended September 30, 2021. The company's cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, third party royalties, and indirect overhead costs. In periods prior to receiving FDA approval for DANYELZA, we recognized inventory and related costs associated with the manufacture of DANYELZA as research and development expenses. This resulted in inventory being sold during the nine months ended September 30, 2021 for which a portion of the costs had been expensed prior to FDA approval. We expect this to continue to impact the cost of goods sold through 2022 as such inventory amounts are sold to our customers.

In addition, the Company expensed $1.2 million of minimum royalties related to DANYELZA sales prior to commercial launch which are fully creditable against earned royalties in future periods. If we had not sold previously

expensed inventory nor previously expensed minimum royalties, our cost of goods sold would have been approximately $2,763,000.

The Company had no cost of goods sold for the nine months ended September 30, 2020.

Licensing Royalties

For the nine months ended September 30, 2021, the Company incurred royalty expenses of $210,000 related to licensing revenues which is included in Licensing Royalties on the Consolidated Statements of Net Loss and Comprehensive Loss.

Research and Development Expenses

We do not record our research and development expenses on a program-by-program or on a product-by-product basis as they primarily relate to personnel, research, manufacturing, license fees and consumable costs, which are simultaneously deployed across multiple projects under development. These costs are included in the table below.

	Nine Months Ended September 30,	
	2021	2020
	(in thousands)	
Outsourced manufacturing	$ 22,767	$ 22,837
Clinical trials	7,016	4,555
Outsourced research and supplies	8,960	13,371
Milestones and license acquisition costs	10	13,307
Personnel costs	13,052	9,396
Professional and consulting fees	1,832	1,758
Stock-based compensation	5,465	1,825
Other	5,386	2,637
	$ 64,488	$ 69,686

Research and development expenses decreased by $5.2 million, from $69.7 million for the nine months ended September 30, 2020 to $64.5 million for the nine months ended September 30, 2021. This decrease was primarily due to a $13.3 million decrease in milestones and license acquisition costs. The nine months ended September 30, 2020 includes $13.3 million related to the SADA agreement entered into in April 2020. In addition, outsourced research and supplies expenses decreased by $4.4 million as a result of decreased regulatory affairs costs.

These decreases were partially offset by a $7.3 million increase in employee-related costs, including salary, benefits and non-cash stock-based compensation for personnel related to our expanding workforce, a $2.5 million increase in clinical trials, a $1.4 million increase in expenses primarily related to our manufacturing and supply agreement with SpectronRX which commenced in August 2020, and a $1.0 million increase related to external consulting and software expenses.

Selling, General, and Administrative Expenses

Selling, general, and administrative expenses increased by $9.2 million, from $30.2 million for the nine months ended September 30, 2020 to $39.4 million for the nine months ended September 30, 2021. The increase in selling, general and administrative expenses was primarily attributable to a $8.5 million increase in employee related costs,

including salary, benefits and non-cash stock-based compensation for new hires mainly due to the growth of the commercialization team.

Other Income, Net

On December 28, 2020, the Company announced that it entered into a definitive agreement to sell its DANYELZA PRV to United Therapeutics Corporation for $105.0 million. The PRV was granted in conjunction with the approval by the FDA of DANYELZA, for the treatment of refractory/relapsed high-risk NB. Under the terms of the MSK License, Y-mAbs retained 60% of the net proceeds received from the sale of the PRV, and the remaining 40% was paid to MSK. The transaction closed on January 21, 2021 and the Company recognized a net gain of $62.0 million during the nine months ended September 30, 2021 related to the sale of the PRV.

Interest and other income/loss for the nine months ended September 30, 2021 was a loss of $0.7 million as compared to a gain of $0.4 million for the nine months ended September 30, 2020. Our interest and other income decreased by $1.1 million due to a decrease in interest rates and increased foreign currency exchange losses incurred in the current period.

Liquidity and Capital Resources

Overview

Except for the three months ended March 31, 2021, the Company has incurred quarterly losses since inception, and expects to continue to incur increasing net operating losses and significant expenses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year. We currently have one approved product, DANYELZA, and have started generating revenue from this product's sales in 2021. As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents of $215.7 million and $114.6 million, respectively. We might need additional capital to continue funding our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a PRV, which we sold to United Therapeutics Corporation for $105.0 million in a transaction that closed in January 2021. We were obligated to pay 40% of the net proceeds from the sale of the PRV to MSK. We intend to use the remaining proceeds to fund further research and development and other operational programs.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2021 and 2020:

	Nine Months Ended September 30,	
	2021	2020
Cash used in operating activities	$ (68,693)	$ (73,536)
Cash provided by / (used in) investing activities	61,498	(2,741)
Cash provided by financing activities	108,214	585
Effect of exchange rates on cash and cash equivalents	77	(177)
Net increase / (decrease) in cash and cash equivalents	$ 101,096	$ (75,869)

Net Cash Used in Operating Activities

The use of cash in all periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital.

Net cash used in operating activities was $68.7 million for the nine month period ended September 30, 2021, as compared to net cash used in operating activities of $73.5 million for the nine month period ended September 30, 2020. The $4.8 million decrease in cash usage was primarily due to a $20.2 million reduction in the loss from operations, primarily resulting from $23.2 million of product revenue related to the launch of DANYELZA and $2.0 million of license revenue in the nine month period ended September 30, 2021, partially offset by an increase in operating expenses of $5.1 million during the nine months ended September 30, 2021.

This net increase to operating cash was partially offset by an increase in accounts receivable and inventory of $12.1 million resulting from the launch of DANYELZA in 2021; and a decrease $2.1 million of non-cash stock-based compensation to employees and non-employees due to a $8.7 million equity issuance to MSK and MIT and two inventors in connection with SADA agreement, partially offset by an increase of $6.6 million for non-cash stock-based costs for employees.

Net Cash Provided by /(Used in) Investing Activities

Net cash provided by investing activities was $61.5 million for the nine months ended September 30, 2021, as compared to net cash used in investing activities of $2.7 million for the nine months ended September 30, 2020. The change of $64.2 million was primarily caused by $62.0 million in net proceeds received from the sale of our priority review voucher received from the FDA upon the approval of DANYELZA, partially offset by $0.5 million of investment in property and equipment during the nine months ended September 30, 2021. Net cash used in the nine months ended September 30, 2020 included loans to inventors of $2.6 million. There were no similar loans made by the Company during the nine months ended September 30, 2021.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $108.2 million for the nine months ended September 30, 2021, as compared to $0.6 million for the nine months ended September 30, 2020. The increase of $107.6 million was primarily due to the net proceeds of $107.7 million received from the public offering in February 2021.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we commercialize DANYELZA, continue the development of omburtamab, and advance our BLA resubmission for omburtamab. In addition, we plan to advance the development of other pipeline programs, initiate new research and pre-clinical development efforts and seek marketing approval for any additional product candidates that we successfully develop. If we obtain approval for any additional product candidates, we expect to incur commercialization expenses, which may be significant, related to establishing sales, marketing, manufacturing capabilities, distribution and other commercial infrastructure to commercialize such products. Accordingly, we might 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 would be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts.

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a PRV, which we subsequently sold to United Therapeutics Corporation for $105.0 million. We were obligated to pay 40% of the net proceeds to MSK. We intend to use the remaining proceeds to fund further research and development and other operational programs.

On February 22, 2021, we completed a public offering of our common stock pursuant to which we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share which included the exercise in

full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our third public offering of $115.0 million, with aggregate net proceeds of approximately $107.7 million after deducting underwriting discounts and commissions and offering expenses.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the development and commercialization of naxitamab and omburtamab, and the research, development and commercialization of other potential product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials for developing our lead product candidates, naxitamab and omburtamab, and conducting pre-clinical studies and clinical trials for our other product candidates;
- research and pre-clinical development efforts for any future product candidates that we may develop;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements, distribution agreements or other arrangements;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration or other agreements;
- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the amount and timing of future revenue, if any, received from commercial sales of our current and future product candidates upon any marketing approvals;
- proceeds received, if any, from monetization of any future PRVs;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the costs of operating as a public company.

Identifying potential product candidates and conducting pre-clinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities,

existing ownership interest in our company may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect common stockholders' rights. Debt 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 funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have any off-balance sheet arrangements, as defined under the applicable regulations of the SEC.

Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our material outstanding contractual commitments is included in Note 8 of our enclosed financial statements.

We enter into contracts in the normal course of business with CROs, CMOs, clinical sites and other third parties for clinical trials, preclinical research studies and testing, professional consultants for expert advice and other vendors for clinical supply, manufacturing and other services. These contracts are not considered contractual obligations, as they provide for termination upon prior notice, and, therefore, are cancelable contracts and do not include any minimum purchase commitments. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancellable obligations of our service providers, up to the date of cancellation. These payments are not included in the table of contractual obligations and commitments above.

As further described below, under various licensing and related agreements with third parties, we have agreed to make milestone and royalty payments to third parties. We have not included the contingent payment of certain milestones in the table above, where timing is uncertain. In addition, we have other contingent payment obligations, such as royalties or other third party milestones, which are not included in the table above as the amount, timing and likelihood of such payments are not known.

We have entered into three license agreements and certain other agreements with MSK. The license agreements are further described below as the MSK License, the MSK CD33 License, and the SADA License. Additionally, through the SAAA we have established a direct license with MSK relating to the GD2-GD3 Vaccine.

Under the MSK License and MSK CD33 License we are obligated to (i) make certain payments to MSK, which become due based upon the achievement of the related milestone activities or the passage of time in the event such milestone activities are not achieved, as well as certain sales related milestones, (ii) pay mid to high single digit royalties to MSK, on a product by product and country by country basis, based on net sales of products licensed under the applicable agreement and (iii) pay to MSK a percentage of any sublicense fees received by us. Under the MSK License, we are also obligated to pay annual minimum royalties of $80,000 over the royalty term, which started in 2020. Under the MSK CD33 License, we are obligated to pay annual minimum royalties of $40,000 over the royalty term beginning in 2027, increasing to $60,000 once a patent within the licensed rights is issued. These amounts are nonrefundable but are creditable against royalty payments otherwise due under the respective agreements. The total expensed minimum royalty payments in 2016 under the MSK License were $1,200,000, upon determination that the payment of such minimum royalties was probable and the amount was estimable in 2016. We are also obligated to pay MSK certain clinical, regulatory and sales based milestone payments under the MSK License and MSK CD33 License. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License. Total clinical, regulatory and sales based milestones potentially due under the

MSK License are $2,450,000, $9,000,000 and $20,000,000, respectively. In addition, under the MSK CD33 License, we are obligated to make potential payments of $550,000, $500,000 and $7,500,000 for clinical, regulatory and sales based milestones, respectively. We record milestones in the period in which the contingent liability is probable and the amount is reasonably estimable.

On April 15, 2020, we entered the SADA License Agreement, which requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are nonrefundable but are creditable against royalty payments otherwise due under the SADA License Agreement. Under the SADA License Agreement, we are also obligated to pay MSK and MIT certain clinical, regulatory and sales based milestone payments. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestones potentially due under the SADA License Agreement are $4,730,000 and $18,125,000, respectively. There are also sales based milestones, totaling $23,750,000, that become due should the Company achieve certain amounts of sales of licensed products. In addition, for each SADA construct generated by MSK and sold for the Company by a sublicensee, the Company may pay sales milestones in the total amount of $60,000,000 based on the achievement of various levels of cumulative net sales by the sublicensee. Further, under the SADA License Agreement, we have committed to funding scientific research at MSK for up to $1,500,000 over the next three years, which we will expense as incurred.

On December 2, 2019, we entered into the Settlement and Assumption and Assignment, or SAAA, of MSK License and Y-mAbs Sublicense Agreement, or the MabVax/Y-mAbs Sublicense, between us and MabVax dated June 27, 2018, with MabVax Therapeutics Holdings, Inc. and MabVax Therapeutics, Inc., or together, MabVax, and MSK, which became effective on December 13, 2019. Pursuant to the MabVax/Y-mAbs Sublicense, MabVax sublicensed to us certain patent rights and know-how for development and commercialization of products for the prevention or treatment of NB by means of administering a bi-valent ganglioside vaccine granted to MabVax, pursuant to an exclusive license agreement dated June 20, 2008 between MabVax and MSK, as amended, or the MabVax/MSK License Agreement. We remain responsible for any potential downstream payment obligations by MabVax to MSK related to the GD2-GD3 Vaccine that were specified in the MabVax/MSK License Agreement. This includes the obligation to pay development milestones totaling $1,400,000, annual minimum royalties of $10,000, increasing to $25,000 from approval of the first NDA/BLA for a licensed product, over the royalty term, commencing on the second anniversary of the MabVax/Y-mAbs Sublicense and mid single-digit royalty payments to MSK on sales. Minimum royalties are non-refundable but creditable against royalty payments otherwise due from us to MSK pursuant to the MabVax/MSK License Agreement. In addition, if we obtain FDA approval for the GD2-GD3 Vaccine, then we are obligated to file with the FDA for a PRV. The SAAA stipulates that, if we are granted a PRV from the FDA covering a licensed product under the MabVax/Y-mAbs Sublicense and the PRV is subsequently sold, we will pay directly to MabVax and to MSK, respectively, a percentage of the proceeds from the sale thereof in order that MabVax and MSK each receive the same amount therefrom as envisaged under the MabVax/MSK License Agreement. The MabVax/MSK License Agreement will expire with effect for us, on a country by country basis, on the later of the expiration of (i) 10 years from the first commercial sale of the licensed product in such country or (ii) the last to expire valid claim covering such licensed product rights at the time of and in the country of sale.

Research and development is inherently uncertain and, should such research and development fail, the MSK License, the MSK CD33 License, and SADA License are cancelable at our option. We have also considered the development risk and each party’s termination rights under the three license agreements when considering whether any contingent payments, certain of which also contain time based payment requirements, were probable. In addition, to the extent we enter into sublicense arrangements, we are obligated to pay to MSK a percentage of certain payments that we receive from sublicensees of the rights licensed to us by MSK, which percentage will be based upon the achievement of certain clinical milestones. To date, we have not entered into any sublicenses related to the MSK CD33 License, the SADA License or the MabVax License. We have entered sublicenses with SciClone, Takeda and Adium as allowed under the MSK License in 2020. Our failure to meet certain conditions under such arrangements could cause the related license to such licensed product to be canceled and could result in termination of the entire respective arrangement with

MSK. In addition, we may terminate the MSK License, the MSK CD33 License, or the SADA License with prior written notice to MSK.

Recent Accounting Pronouncements

Refer to Note 3 “Summary of Significant Accounting Policies,” in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

We are exposed to market risk related to changes in interest rates. As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents of $215.7 million and $114.6 million, respectively. Due to the nature of our investments in money market funds, the carrying value of our cash equivalents approximate their fair value at September 30, 2021. We currently have, and may, from time to time in the future, cash in banks in excess of FDIC insurance limits. We have not experienced any losses to date. We mitigate our risk by maintaining the majority of our cash and equivalents with high quality financial institutions. Our exposure to changes in the general level of U.S. interest rates is considered immaterial, particularly because our cash equivalents are primarily held in highly rated securities including a Treasury money market fund. Due to the short term nature of such balances, an immediate 100 basis point change in interest rates would not have any significant effect on the fair market value of cash balances.

Foreign Currency Exchange Risk

Our primary exposure to market risk is foreign exchange rate sensitivity to the Danish Krone (DKK), the currency used in the Kingdom of Denmark, where our wholly owned subsidiary, Y-mAbs Therapeutics A/S, is located. As of September 30, 2021 and December 31, 2020, we had cash and cash equivalents denominated in DKK of $0.5 million and $(0.5) million, respectively, and an immediate 3% change, respectively, in DKK exchange rate would not have any material effect on the fair market value of cash balances with the subsidiary.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2021.

In designing and evaluating the disclosure controls and procedures, management recognized that controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. Further, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within the Company will be detected.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended September 30, 2021, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

The Company has been named a nominal defendant in a lawsuit instigated by a stockholder against our Chairman of the Board and President, Mr. Thomas Gad, seeking to compel Mr. Gad to disgorge alleged short swing profits stemming from a certain transaction involving the Company's common stock undertaken by Mr. Gad on March 10, 2021. The Company is of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company had been informed by Mr. Gad that he also believes the claim is without merit, that he has strong defenses against such claim and that he intends to vigorously defend the action.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q, including our financial statements and the related notes, and in our other filings with the SEC. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In such event, the trading price of our common stock could decline and you might lose all or part of your investment.

Risks Related to Our Financial Condition and Need for Additional Capital

We have a limited operating history and have incurred significant losses since inception. Our only product approved for sale is DANYELZA, which only recently received approval and we have never generated any substantial revenue from product sales. We expect to incur significant losses for the foreseeable future. We may never achieve or maintain profitability, which may cause the market value of our common stock to decline significantly.

We are a commercial-stage biopharmaceutical company with a limited operating history. Since our inception in 2015, we have incurred significant losses each year. As of September 30, 2021 our accumulated deficit was approximately $303.6 million. We have financed our operations principally through private placements, the initial public offering of our common stock in 2018 as well as our public offerings in November 2019 and February 2021.

To date, we have devoted substantially all our efforts to research and development of DANYELZA our only approved product and our other lead product candidate omburtamab. On November 25, 2020, DANYELZA was approved by the FDA for the treatment, in combination with GM-CSF, of pediatric patients 1 year of age and older and adult patients R/R high-risk NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. While our lead product candidate omburtamab is in registration stage clinical development, no assurance can be given that we will receive regulatory approval for the sale of omburtamab or other product candidates in the near term, if at all. Our other product candidates are in the early stages of clinical development or pre-clinical research. As a result, we expect that it will be a number of years, if ever, before we have any of these other product candidates approved and ready for commercialization.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. Our only product approved for sale is DANYELZA, which only recently received approval and we have never generated any substantial revenue from product sales. We have only begun limited sales and shipments of DANYELZA since February 2021 and we do not anticipate generating any substantial revenue from product sales until DANYELZA has been on the market for a period of time. No assurance can be given that we will ever receive regulatory approval for any of our product candidates other than

DANYELZA. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

- the successful launch and commercialization of DANYELZA and our product candidates for which we may obtain regulatory approvals and marketing authorizations, either directly or with a collaborator or distributor;
- completing research regarding, and non-clinical and clinical development of, our product candidates;
- obtaining regulatory approvals, marketing authorizations and coverage and reimbursements from payors for DANYELZA and other product candidates for which we complete clinical studies;
- developing and maintaining a sustainable and scalable manufacturing process for DANYELZA and our other product candidates, including establishing and maintaining commercially viable supply relationships with third parties including Patheon/Thermo Fisher and EMD/Merck or establishing our own manufacturing capabilities and infrastructure;
- obtaining market acceptance of DANYELZA and our product candidates as viable treatment options;
- addressing any competing products, product candidates, related technologies and/or market developments;
- identifying, assessing, acquiring and/or developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, distribution or other arrangements into which we may enter;
- maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how;
- attracting, hiring, and retaining qualified personnel; and
- adequately financing our operations at acceptable terms.

We anticipate incurring research, development, clinical trial, manufacturing and marketing costs associated with commercializing even approved products such as DANYELZA. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, non-clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market more of our product candidates, such as DANYELZA in the US, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for the product, the ability to obtain reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable disease patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably expected population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of DANYELZA or any other approved products, we may never become profitable.

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.

We were incorporated and began our operations on April 30, 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting clinical trials of DANYELZA and our lead product candidates and conducting pre-clinical studies and clinical trials of our other product candidates, and identifying additional potential product candidates. Typically, it takes about six to 10 years to develop a new drug from

the time it is in Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. 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 or a history of successfully developing and commercializing pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors as we continue to develop and commercialize DANYELZA and our other product candidates.

Our payment obligations to MSK and MIT may be a drain on our cash resources, or may cause us to incur debt obligations or issue additional equity securities to satisfy such payment obligations, which may adversely affect our financial position and results of operations.

Under the MSK License, we have committed to funding scientific research as well as conducting certain clinical trial activities at MSK. As licensed product candidates progress through clinical development and commercialization, certain milestone payments will come due, and we will owe MSK customary royalties on commercial sales of our approved products, if any. These milestone payments become due upon achievement of the related clinical, regulatory or sales-based milestone set forth in the MSK License and all milestones are accrued for when they are probable and estimable. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License, whether or not the milestone activity has been achieved. Total clinical and regulatory milestones potentially due under the MSK License are $2,450,000 and $9,000,000, respectively. There are also sales-based milestones that become due should we achieve certain amounts of sales of licensed products with total sales-based milestones potentially due of $20,000,000. Under the MSK CD33 License, we are obligated to make potential payments of $550,000, $500,000 and $7,500,000 for clinical, regulatory and sales-based milestones, respectively.

In addition, we have committed to acquire certain personnel and laboratory services at MSK under a Master Data Services Agreement, or MDSA, and two separate Core Facility Service Agreements, or CFSAs. We have also entered into an Investigator-Sponsored Master Clinical Trial Agreement, or the MCTA, with MSK under which we will provide drug product and funding for certain clinical trials at MSK under separate appendices to be executed. Additionally, we have entered into a Sponsored Research Agreement, or the SRA, with MSK pursuant to which we paid MSK to conduct certain research projects over a period of five years related to the intellectual property licensed under the MSK License. The SRA was amended on September 13, 2019, and will expire five years from the date of the amendment. We entered into a Manufacturing Agreement with MSK's Radiochemistry and Molecular Imaging Probes Core Facility, or RMIP, pursuant to which RMIP will complete specified manufacturing activities related to ^{131}I-omburtamab in connection with Study 101. We also remain responsible for any potential downstream payment obligations to MSK related to the GD2-GD3 Vaccine. This includes our obligation to make development and regulatory milestone payments totaling $1,400,000, annual minimum royalties of $10,000, increasing to $25,000 from approval of the first NDA/BLA for a licensed product over the royalty term, and mid single-digit royalty payments to MSK on sales.

In April 2020, we entered into the SADA License Agreement which requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the SADA License. These amounts are nonrefundable but are creditable against royalty payments otherwise due under the SADA License. We are also obligated to pay to MSK and MIT certain clinical, regulatory and sales-based milestone payments under the SADA License Agreement. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestone payments potentially due under the SADA License Agreement are $4,730,000 and $18,125,000, respectively. Additionally, we are also obligated to make sales-based milestones payments totaling $23,750,000, that become due should the Company achieve certain amounts of sales of licensed products under the SADA License. In addition, for each of the SADA constructs generated by MSK and sold for the Company by a sublicensee of the Company, the Company may pay sales-based milestone payments in the total amount of $60,000,000 based on the achievement of various levels of cumulative net sales by the sublicensee. Under the SADA License Agreement, we have also committed to fund scientific research at MSK under a Sponsored Research Agreement for up to $1,500,000 over three years.

These payments could be significant and in order to satisfy our obligations to MSK and MIT, if and when they are triggered, we may use our existing cash, incur debt obligations or issue additional equity securities, which may materially and adversely affect our financial position and results of operations.

We will need substantial additional funding until at least such time as we can generate substantial revenue from product sales. If we fail to obtain such additional funding, we may be forced to delay, reduce or eliminate our research and drug development programs or current or future commercialization efforts and our license and other agreements may be terminated.

Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials and commercialization of any approved products, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we commence sales and marketing of DANYELZA and conduct clinical trials of, and seek marketing approval for our lead product candidate omburtamab and our other product candidates. We expect to incur commercialization expenses, which may be significant, related to product sales, marketing, manufacturing and distribution of DANYELZA or our product candidates to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of any collaborator that we may have at such time for any such product candidate. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, until at least such time as we can generate substantial additional revenues from sales of DANYELZA or our product candidates, if approved, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient amounts of additional capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and drug development programs or our future commercialization efforts.

Changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We will require additional capital for further development and commercialization of our product candidates and may need to raise additional funds earlier if we choose to expand more rapidly than we presently anticipate.

In addition, we cannot be certain that additional funding will be available on acceptable terms, or at all. We have no firmly committed source of additional capital and if we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of our product candidates or other research and development initiatives. Our licenses and other agreements may also be terminated if we are unable to meet the payment obligations under the agreements. We could be required to seek collaborators for DANYELZA or our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to DANYELZA or our product candidates on terms unfavorable to us.

We expect our expenses to increase in connection with our planned operations. Until such time, if ever, as we can generate substantial additional revenues from the sale of DANYELZA and our product candidates, if approved, we expect to finance our cash needs through a combination of cash on hand, equity offerings, debt financings, collaborations, strategic alliances and/or licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests will be diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect the rights of common stockholders. In addition, debt financing, if available, would result in fixed payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures or acquisitions, limiting our ability to conduct licensing transactions, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our

management's ability to oversee the commercialization of DANYELZA or other products, if approved, or development of our product candidates.

If we raise additional funds through collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights related to our intellectual property, future revenue streams or any of our future product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed, we may be required to delay, reduce and/or eliminate our product development or current or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

We may expand our resources to pursue a particular product or product candidate or indication and fail to capitalize on other products or product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

We intend to focus our efforts and managerial resources on specific products and product candidates and on specific indications such as DANYELZA for the treatment of relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow and omburtamab for central nervous system leptomeningeal metastases from neuroblastoma. As a result, we may forgo or delay pursuit of opportunities with other products or product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates for indications could result in focusing on product candidates for indications with lower market potential, which could harm our business and financial condition. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through partnering, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or product.

Risks related to product development and commercialization

Our only approved product DANYELZA, our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges, and our ability to generate product revenue is dependent on the success of DANYELZA or one or more of our product candidates, which might require additional clinical testing before we can seek regulatory approval and begin commercial sales.

Our only approved product DANYELZA, our product candidates and related technologies represent novel approaches to cancer treatment generally. Developing and commercializing these products therefore subjects us to a number of challenges. To date we have not generated substantial revenues from sales of DANYELZA which is currently our only approved product. We may never be able to develop another marketable product. Our ability to generate product revenue is highly dependent on our ability to successfully commercialize DANYELZA and to obtain additional regulatory approvals of and successfully commercialize additional product candidates including in particular omburtamab. This will require additional clinical and non-clinical development, regulatory review and approval in each jurisdiction in which we intend to market them, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts. We cannot be certain that any other of our product candidates will be successful in clinical studies and they may not receive regulatory approval even if they are successful in clinical studies.

The success of our product candidates in development will depend on several factors, including the following:

- successful and timely completion of our ongoing clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;

- timely receipt of marketing and reimbursement approvals for our lead product candidates from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials and drug product suppliers and manufacturers;
- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;
- successful launch of commercial sales following any marketing approval including the hiring of a direct salesforce and creation of marketing campaigns;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by physicians and patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator.

DANYELZA and our lead product candidate omburtamab are our most advanced product and product candidate. Because our other product candidates are based on similar technology, if DANYELZA or omburtamab encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our development plans and business could be significantly harmed. Further, competitors who are developing products with similar technology may experience problems with their products that could identify problems that would potentially harm our business.

We have limited experience operating as a commercial company and the marketing and sale of DANYELZA or any future approved products may be unsuccessful or less successful than anticipated.

While we have initiated the commercial launch of DANYELZA in the United States, we have limited experience as a commercial company and there is limited information about our ability to successfully overcome many of the risks and uncertainties encountered by companies commercializing drugs in the biopharmaceutical industry. To execute our business plan, in addition to successfully marketing and selling DANYELZA, we will need to successfully:

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our products and any future products;
- obtain adequate pricing and reimbursement for DANYELZA and any future products;
- gain regulatory authorization for the development and commercialization of our product candidates;

- develop and maintain successful strategic alliances;
- accurately forecast demand for our products and scale manufacturing to meet that demand;
- manage our spending as costs and expenses increase due to clinical trials, marketing approvals, and commercialization; and
- maintain and grow our relationship with MSK as a user of DANYELZA and any future products.

If we are unsuccessful in accomplishing these objectives, we may not be able to successfully develop product candidates, commercialize DANYELZA or any future approved products, raise capital, expand our business, or continue our operations.

The commercial success of DANYELZA and of any future approved products, will depend upon the degree of market acceptance by physicians, patients, third-party payors, and others in the medical community.

The commercial success of DANYELZA, and of any future approved products, will depend in part on market acceptance by physicians, patients, third-party payors, and others in the medical community. For example, current cancer treatments like surgery, chemotherapy or radiation therapy are well-established in the medical community, and doctors may continue to rely on these treatments. If DANYELZA or any future approved products do not achieve an adequate level of acceptance, we may not generate significant revenues from sales of drugs and we may not become profitable. The degree of market acceptance of DANYELZA, and of any future product, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- developing processes for the safe administration of our products, including long-term follow-up for all patients who receive the product;
- the potential advantages of the product compared to competitive therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any potential future collaborators, to offer the product for sale at competitive prices;
- the product’s convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions contained in the product’s approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product;
- the willingness of the target patient populations to try new therapies, enroll in ongoing clinical trials, and of physicians to prescribe these therapies;

- relative convenience and ease of administration;
- the requirement for in-patient versus out-patient administration;
- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors; and
- the timing of competitive product introductions and other actions by competitors in the marketplace.

We have only recently established our marketing and sales organization and have only limited experience in marketing and sale of biopharmaceutical products. We may not be successful in commercializing DANYELZA or any future approved product unless we are able to maintain and expand our sales and marketing capabilities or enter into agreements with third parties to sell and market such approved products.

We have only recently established our sales and marketing organization and have only limited experience in marketing and sale of biopharmaceutical products. We began small shipments of DANYELZA in February 2021. Other than our commercialization partnerships for DANYELZA and omburtamab covering certain territories outside the United States with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG and Adium Pharma S.A., we are not currently a party to any strategic collaboration that provides us with access to a collaborator's resources in selling or marketing drugs. To achieve commercial success for any future approved products we must successfully maintain and expand our sales and marketing organization or outsource these functions to strategic collaborators and other third parties. We have built our own focused, specialized sales and marketing organization in the United States. We continue to explore selectively establishing partnerships in markets outside the United States to support the commercialization of our product candidates for which we obtain marketing approval and that can be commercialized with such capabilities, and we are currently initiating the process of building our own sales capabilities in Europe, however, no assurance can be given that we will be successful in our efforts.

There are risks involved with both further establishing our own direct sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training even a small sales force can be expensive and time-consuming and could delay any commercial launch of a product candidate. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our drugs on our own after obtaining any regulatory approval to gain market acceptance include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- our inability to raise financing necessary to maintain and grow our commercialization infrastructure;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe DANYELZA or any future approved products, in particular in light of current reduced in-person access to medical institutions and personnel and other significant disruptions to the healthcare system and community due to COVID-19;
- the lack of complementary drugs to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive drug lines;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and

- inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies.

Our revenues from the sale of drugs or the profitability of these revenues to us are likely to be lower from arrangements that we enter into with third parties to perform sales and marketing service (such as with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG and Adium Pharma S.A.) than if we were to market and sell any drugs that we develop ourselves. In addition, we may not be successful in entering additional arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We have limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our drugs effectively. If we do not maintain and expand our sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we might not be successful in commercializing DANYELZA or any of our product candidates for which we receive marketing approval, if any. In the event that we are unable to effectively deploy our sales organization or distribution strategy on a timely and efficient basis, if at all, the commercialization of DANYELZA or our product candidates, if approved, could be delayed which would negatively impact our ability to generate product revenues.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry, and the market for developing antibody-based products in particular, is characterized by intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs that are able to achieve similar or better results. Our actual and potential competitors include major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, universities, and other research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations as well as established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than DANYELZA or our product candidates or may develop proprietary technologies or secure patent protection that we may need for the commercialization of DANYELZA and development of our product candidates and related technologies.

Specifically, MacroGenics, Inc. and Daiichi Sankyo Co. are developing antibodies against B7-H3. United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin (dinutuximab), an antibody against GD2, in the United States. During the third quarter of 2020, United Therapeutics discontinued its efforts to investigate Unituxin's potential activity against adult cancerous tumors, and its efforts to develop a humanized version of Unituxin, and during the second quarter of 2021 United Therapeutics discontinued development of Unituxin in R/R NB. DANYELZA may face competition from dinutuximab beta, a similar antibody product against GD2 developed by Apeiron Biologics AG, or Apeiron, that was approved in Europe in May 2017 to treat high-risk NB and R/R NB. In October 2016, EUSA Pharma (UK) Ltd., or EUSA, announced that it had acquired global commercialization rights to dinutuximab beta, which is currently being commercialized under the name Qarziba® in Europe. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba® in mainland China and in November 2020 EUSA and BeiGene announced that the BLA for QARZIBA® (dinutuximab beta) was accepted by the China National Medical Products Administration and granted priority review.

We may not be the first to market even with respect to our approved products such as DANYELZA and that may affect the price or demand for DANYELZA and our product candidates. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our products. We may not be able to implement our business plan if the acceptance of our products is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our products, or if physicians switch to other new drug or biologic products or choose to reserve our products for use in limited circumstances. Additionally, a competitor could

obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances.

The market opportunities for DANYELZA and our product candidates, if approved, may be limited to those patients who are ineligible for or have failed prior treatments and may be small. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Also, the market opportunity for DANYELZA and our product candidates, if approved, may be smaller than we expect.

Our current target patient population is based on our beliefs and estimates regarding the incidence or prevalence of certain types of cancers that may be addressable by our DANYELZA and product candidates, which are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, or market research. The total addressable market opportunity for DANYELZA and any other product candidates we may produce, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for our current and future products for sale for these indications, acceptance by the medical community and patient access, drug pricing, and reimbursement. The number of patients in our targeted commercial markets and elsewhere may turn out to be lower than expected, possibly materially, patients may not be otherwise amenable to treatment with our drug, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our results of operations and our business.

Even if we obtain significant market share for DANYELZA or our product candidates, if approved, because the potential target populations are small, we may never achieve profitability without obtaining regulatory approval for additional and broader indications, including use of DANYELZA or our product candidates, if approved, for front-line and third-line therapy.

DANYELZA is approved only as second line treatment for patients with relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow, and we expect to initially seek approval of our product candidate omburtamab also as second-line therapy for patients who have relapsed from systemic disease. Even if we would seek approval as front-line or third-line therapy for DANYELZA, omburtamab or another product candidate there is no guarantee that they would be approved. In addition, we may have to conduct additional clinical trials prior to gaining approval for front-line or third-line therapy.

The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons, including:

- the size and nature of the patient population;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies;

- clinicians' and patients' perceptions as to the potential advantages and side effects of the product candidate being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating;

- our ability to obtain and maintain patient consents; and

- the risk that patients enrolled in clinical trials will not complete a clinical trial.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product 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. 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. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to only use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any future clinical trial.

Even if we are able to enroll a sufficient number of patients in our clinical trials, delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates, submit regulatory filings, obtain marketing approvals and delay the launch of our products, upon approval.

DANYELZA or any current or future product candidates may cause serious adverse events, or SAEs, undesirable side effects or have other properties that could halt their clinical development, prevent, delay, or cause the withdrawal of their regulatory approval, limit their commercial potential, or result in significant negative consequences, including death of patients or cause regulatory authorities to require labeling statements, such as boxed warnings. Even after approval, if we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any potential future collaborators, to market the drug could be compromised.

As with most biological drug products, use of DANYELZA or any current or future product candidates could be associated with undesirable side effects or adverse events which can vary in severity from minor reactions to death and in frequency from infrequent to prevalent. Undesirable side effects or unacceptable toxicities caused by our products or product candidates could cause us or regulatory authorities to interrupt, delay, or halt clinical trials.

Treatment-related undesirable side effects or adverse events could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or could result in potential product liability claims. In addition, these side effects may not be appropriately or timely recognized or managed by the treating medical staff, particularly outside of the research institutions that collaborate with us. We expect to have to educate and train medical personnel using our products and product candidates to understand their side effect profiles, both for our planned clinical trials and upon any commercialization of any product candidates when approved such as DANYELZA. Inadequate training in recognizing or managing the potential side effects of our products or product candidates could result in adverse effects to patients, including death. Any of these occurrences may materially and adversely harm our business, financial condition and prospects.

Undesirable side effects caused by DANYELZA or any other product or product candidate could limit the commercial profile of such product or product candidate or result in significant negative consequences such as a more restrictive label or other limitations or restrictions.

In clinical studies, DANYELZA has been shown to cause serious infusion reactions including anaphylaxis, cardiac arrest, bronchospasm, stridor, and hypotension. The most common adverse events were mainly mild and moderate and included infusion-related reaction, pain, tachycardia, vomiting, cough, nausea, diarrhea, decreased appetite, hypertension, fatigue, erythema multiforme, peripheral neuropathy, urticaria, pyrexia, headache, edema,

anxiety, localized edema and irritability. DANYELZA has been approved with a boxed warning for serious infusion reactions and neurotoxicity.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any potential future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, such as for DANYELZA in the US, a product candidate receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, including during any long-term follow-up observation period recommended or required for patients who receive treatment using our products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such product or seize the product;
- we, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may (such as for DANYELZA) narrow the indications for use or require additional warnings in the labeling, such as a boxed warning or a contraindication, or impose distribution or use restrictions;
- we, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

Any of the foregoing could prevent us from achieving or maintaining market acceptance of DANYELZA or a particular product candidate, if approved, and could significantly harm our business, results of operations, and prospects, and could adversely impact our financial condition, results of operations, ability to raise additional financing or the market price of our common stock.

The outcome of pre-clinical studies and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities, and if an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of our lead product candidates, such event could adversely affect our other clinical trials of our lead product candidates.

Success in pre-clinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through pre-clinical studies and early-stage clinical trials. Product candidates that have shown promising results in pre-clinical studies and early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Additionally, the

outcome of pre-clinical studies and early-stage clinical trials may not be predictive of the success of larger, later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and 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. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available. In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in pre-clinical studies and earlier clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. We have multiple clinical trials of our lead product candidates currently ongoing. In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of our lead product candidates, such event could adversely affect our other clinical trials of our lead product candidates. We have received clinical holds on our IND applications for certain of our product candidates in the past and there is no assurance that we will not be subject to additional clinical holds in the future, which may ultimately delay or otherwise adversely affect the clinical development of our product candidates. Survival and safety data from Study 03-133 will form the primary basis for our planned resubmission of the BLA for omburtamab, which we will compare with data from an external cohort comprising data from the Central German Childhood Cancer Registry (CGCCR) database. Furthermore, interim efficacy, safety and pharmacokinetic data from Study 101 will support the BLA resubmission. If the results of this study fail to demonstrate comparability to the satisfaction of the FDA and other comparable regulatory authorities, this may lead to a delay in the approval process for omburtamab. We do not know what an approval of omburtamab (if approved) will become subject to in terms of postmarketing requirements and commitments, including confirmatory study requirements.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or other pivotal trials. The FDA or non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials or conclude that we do not have adequate manufacturing controls or quality systems. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Before obtaining marketing approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in pre-clinical studies and well-controlled clinical studies, and, with respect to approval in the United States, to the satisfaction of the FDA, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or non-U.S. regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our product candidates for

any indication. The FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective.

If we are required to conduct additional clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

Research and development of biopharmaceutical products is inherently risky. We may not be successful in our efforts to create a pipeline of product candidates and develop commercially successful products. If we fail to develop additional product candidates, our commercial opportunity will be limited.

Other than DANYELZA, the product candidates and related technologies we have licensed have not yet led, and may never lead, to approved products. Further, our only approved product DANYELZA was just recently approved and launched in the United States and hence its commercial potential cannot be judged with accuracy at this point in time. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing our product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and/or become commercially viable. We cannot provide you any assurance that we will be able to successfully advance any of these additional product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

- we may not be successful in identifying additional product candidates;
- we may not be able to assemble sufficient resources to acquire or discover additional product candidates;
- our product candidates may not succeed in pre-clinical or clinical testing;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- competitors may develop alternatives that render our product candidates obsolete or less attractive;
- product candidates we develop may nevertheless be covered by third parties' patents or other exclusive rights;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors, if applicable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. As for DANYELZA, which has been approved by the FDA for the United States market, even if we receive approval to market our product candidates from the FDA, the European Medicines Agency, or EMA, or other regulatory bodies, whether for the treatment of cancers or other diseases, no assurance can be given you that any such product candidates will be

successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

We have entered into several agreements with MSK that are important to our business. We may also form or seek other collaborations or strategic alliances or enter into additional licensing arrangements in the future but may not realize the benefits of such collaborations or strategic alliances. If we are unable to enter into future collaborations, or if such collaborations are not successful, our business could be adversely affected.

We currently have in place several agreements with MSK, including the MSK License, the MSK CD33 License, the SADA License Agreement, that are important and we may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In addition, we anticipate that MSK, due to patients obtaining treatment at the institution, may become a major source for the distribution and administration of DANYELZA. Any disruption of our relationship with MSK could have a material adverse effect on our business, results of operations and financial condition. In addition, any of these relationships may require us to incur other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or because the commercial potential is difficult to predict.

Further, arrangements with third parties, such as our arrangement with MSK or our current or potential future collaborations we may enter into involving our product candidates, are subject to numerous risks, including the following:

- such third parties or any current or potential future collaborators may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- such third parties or any current or potential future collaborators may not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- such third parties or any current or potential future collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- such third parties or any current or potential future collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- product candidates discovered through such arrangements or any potential future collaborations with us may be viewed by such third parties or any potential future collaborators as competitive with their own product candidates or products, which may cause such third parties or collaborators to cease to devote resources to the commercialization of our products or product candidates;
- such third party or any current tor potential future collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- such third parties or any current or potential future collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that

gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and such third party or any current or potential future collaborator that cause the delay or termination of the research, development or commercialization of our products or product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;

- such third parties or any current or potential future collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;

- such arrangements or any current or potential future collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product or product candidate; and

- such third parties or any current or potential future collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

As a result, if we are unable to maintain current arrangements or collaborations or enter into and maintain future arrangements and collaborations, or if such arrangements or collaborations are not successful, our business could be adversely affected. If we enter into certain arrangements or collaboration agreements and strategic partnerships or license our products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our products or product candidates could delay the development and commercialization of our products or product candidates in certain territories for certain indications, which would harm our business prospects, financial condition, and results of operations.

If we or third parties, such as contract research organizations, or CROs, or contract manufacturing organizations, or CMOs, use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us or third parties, such as CROs and CMOs. The use of Iodine-131, Iodine-124 and Lutetium-177-labeled antibody treatments involves the inherent risk of exposure from beta ray emissions, which can alter or harm healthy cells in the body. We and such third parties are subject to federal, state, and local laws and regulations in the United States and Europe governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third-parties' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition, or results of operations. We currently maintain insurance coverage for injuries resulting from the hazardous materials we use; however, future claims may exceed the amount of our coverage. Also, we do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with such federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, they could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts.

Our normal business operations may, directly or indirectly, be adversely impacted by the ongoing global COVID-19 pandemic. COVID-19 and future outbreak of any highly infectious or contagious diseases, could materially and adversely affect our operations and have a material impact on our financial position. Further, the spread of the COVID-19 outbreak has caused business continuity issues of an as yet unknown magnitude and duration.

The COVID-19 pandemic, and preventative measures taken to contain or mitigate this pandemic have caused, and are continuing to cause, business slowdowns or shutdowns in various regions around the world and disruption in the global supply chain and business operations. National, state and local governments in affected regions have implemented and may continue to implement safety precautions, including quarantines, border closures, increased border controls, travel restrictions, shelter in place orders and shutdowns, resulting in business closures, work stoppages, slowdowns and delays, cancellation of events and other measures. These measures may disrupt normal business operations both in and outside of affected areas and may have significant negative impacts on businesses and financial markets worldwide. We continue to monitor our operations and applicable government recommendations, and we have made modifications to our normal operations because of the COVID-19 pandemic, including limiting travel and working from home and also implemented enhanced travel-safe policies for our employees' travel to our clinical sites. Prolonged remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Operating requirements may continually change due to the COVID-19 pandemic and we may experience unpredictability in our expenses, employee productivity and employee work culture. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to security breaches.

The COVID-19 pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. If members of our management and other key personnel in critical functions across our organization are unable to perform their duties or have limited availability due to the COVID-19 pandemic, we may not be able to execute on our business strategy and/or our operations may be negatively impacted.

Our business, operations and clinical development timelines and plans have been and could continue to be adversely affected by COVID-19, and could be adversely impacted by other health epidemics in regions where we have concentrations of clinical trial sites or other business operations, and could cause significant disruption in the operations of CROs, CMOs and other third parties and collaborators upon whom we rely. The COVID-19 pandemic has affected multiple countries worldwide, including those where we have planned and ongoing preclinical studies and clinical trials. Site initiation and patient enrollment could be delayed or suspended due to prioritization of hospital resources toward the COVID-19 pandemic or patients not having a desire to enroll in clinical trials due to concerns regarding COVID-19. In addition, some patients may not be able to comply with clinical trial protocols and the ability to conduct follow up visits with treated patients may be limited if patients do not want to participate in follow up visits due to concerns regarding COVID-19 or if quarantines impede patient movement or interrupt healthcare services. There may be shortages in the raw materials used in the manufacturing of our product candidates or laboratory supplies for our preclinical studies and clinical trials, in each case, because of ongoing efforts to address the outbreak. We cannot assure that the inability to collect such clinical data would not have an adverse impact on our clinical trial results. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 could be adversely impacted.

The response to the COVID-19 pandemic may redirect resources with respect to regulatory matters in a way that would adversely impact our ability to pursue marketing approvals. In addition, we may face impediments to regulatory meetings and potential approvals due to measures intended to limit in-person interactions. Furthermore, third parties, including manufacturers, medical institutions, clinical investigators, CROs and consultants with whom we conduct business, are similarly adjusting their operations and assessing their capacity in light of the COVID-19 pandemic. If these third parties continue to experience shutdowns or business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively impacted.

Further, COVID-19 has severely impacted global economic activity and caused significant volatility and negative pressure in global financial markets. Many experts predict that the outbreak will trigger a period of global economic slowdown or a global recession. We are unable to predict the extent or nature of these impacts at this time.

COVID-19 is adversely affecting, and is expected to continue to adversely affect, our operations, and COVID-19 or another pandemic may result in material and adverse effects on our ability to successfully operate our business, including:

- our ability to successfully launch, commercialize, and generate revenue from DANYELZA and our product candidates, even if approved, may be adversely affected by the impact of the COVID-19 pandemic. For example, limited hospital access for non-patients, social distancing requirements, and precautionary measures due to COVID-19 have impacted the ability of our sales personnel to interact in-person with customers. In response, we have implemented a virtual launch model, which may adversely affect the ability of our sales professionals to effectively market DANYELZA and our product candidates to physicians, which may have a negative impact on our sales and our market penetration. In addition, in the United States we plan to utilize various programs to help patients afford our products, including patient assistance programs for eligible patients. Market disruption and rising unemployment caused by the COVID-19 pandemic may lead to increased utilization of our patient assistance programs, which could reduce revenues;

- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials, including receiving any required investigational new drug applications, or INDs;

- delays or difficulties in enrolling and retaining patients in our clinical trials if patients are affected by the virus or are fearful of visiting or traveling to clinical trial sites because of the outbreak;

- 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;

- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;

- manufacturing disruptions;

- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;

- delays in the transport of clinical trial materials;

- changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;

- 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;

- interruption of or changes in key clinical trial activities, such as clinical trial site monitoring, implementation of virtual monitoring, use of local testing labs, or home delivery of study drugs, due to limitations on travel imposed or recommended by federal or state governments, employers and others, use of new digital technologies for subject visits or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees;

- delays in regulatory approvals for our product candidates due to the FDA focusing on clinical trials related to therapies and vaccines targeting COVID-19;

- refusal of the FDA or other regulatory authorities to accept data, including from clinical trials in affected geographies or failure to comply with updated FDA or other regulatory guidance and expectations related to the conduct of clinical trials during the COVID-19 pandemic;

- the destabilization of the markets and negative impacts on the healthcare system or regulatory authorities globally could negatively impact our ability to obtain approval to market, market and sell our products, including through the disruption of regulatory activities or health care activities in general;

- difficulty accessing the capital and credit markets on favorable terms, or at all, and a severe disruption and instability in the global financial markets, or deteriorations in credit and financing conditions which could affect our access to capital necessary to fund business operations;

- the potential negative impact on the health of our employees, especially if a significant number of them or any of their family members are impacted or if any of our senior leaders are impacted for an extended period of time;

- potential delays in the preparation and submission of applications for regulatory approval of our product candidates, as well as potential interruptions or delays in FDA's ability to review applications in a timely manner consistent with past practices, which may impact review and approval times;

- delays in scheduling manufacturing inspections in connection with BLA approval;

- a general decline in business activity; and

- a deterioration in our ability to ensure business continuity during a disruption.

Despite our efforts to manage and mitigate these impacts to our company, their ultimate impact also depends on factors beyond our knowledge or control, including the duration and severity of this and any other pandemic, as well as third-party actions taken to contain its spread and mitigate its public health effects, and the pace of global economic recovery following containment of the spread. In addition, while we cannot predict the impact that COVID-19 will have on our suppliers, vendors and other business partners and each of their financial conditions, any material adverse effects on these parties could adversely impact us. The ultimate impact of this and any other pandemic on our business is highly uncertain and the continued spread of COVID-19 may have further adverse impacts on our business, operations, any pending regulatory approvals, supply chain, and financial position, and may also exacerbate other risks discussed in this Quarterly Report on Form 10-Q. To the extent the COVID-19 pandemic adversely affects our business, clinical trials, results of operations and financial condition, it may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change.

Any significant disruption in or unauthorized access to our computer systems or those of third parties that we utilize in our operations, including those relating to cybersecurity or arising from cyber-attacks, could result in a loss or degradation of service, unauthorized disclosure of data, including member and corporate information, or theft of intellectual property which could adversely impact our business.

Our business is dependent upon the reliable performance and security of our computer systems and those of third parties that we utilize in our operations. These systems may be subject to damage or interruption from, among other things, earthquakes, adverse weather conditions, other natural disasters, terrorist attacks, state-sponsored attacks, rogue employees, power loss, telecommunications failures, and cybersecurity risks. Interruptions in these systems, or with the internet in general, could hinder our ability to operate. Service interruptions, errors in our software or the unavailability of computer systems used in our operations could diminish the overall attractiveness of our business.

Our computer systems and those of third parties we use in our operations are subject to cybersecurity threats, including cyber-attacks such as computer viruses, denial of service attacks, physical or electronic break-ins and similar disruptions. Additionally, outside parties may attempt to induce or deceive employees or users to disclose sensitive or confidential information in order to gain access to data. Any attempt by hackers to obtain our data (including patient, clinical trial and corporate information) or intellectual property, disrupt our business, or otherwise access our systems, or those of third parties we use, if successful, could harm our business, be expensive to remedy and damage our reputation. We have implemented commercially reasonable systems and processes to thwart hackers and otherwise protect our data and systems, but the techniques used to gain unauthorized access to data and software are constantly evolving, and we may be unable to anticipate or prevent unauthorized access. There is no assurance that hackers may not have a material impact on our business or systems in the future. Efforts to prevent hackers from disrupting our service or otherwise accessing our systems are expensive to develop, implement and maintain. These efforts require ongoing monitoring and updating as technologies change and efforts to overcome security measures become more sophisticated, and such efforts may limit the functionality of or otherwise negatively impact our operations and systems. Any significant disruption to our systems could adversely affect our business and results of operation. Further, a penetration of our systems or a third-party's systems or other misappropriation or misuse of personal information could subject us to business, regulatory, litigation and reputation risk and divert internal resources to respond to such an event, which could have a negative effect on our business, financial condition and results of operations.

We utilize our own communications and computer hardware systems located either in our facilities or in that of a third-party provider. In addition, we utilize third-party "cloud" computing services in connection with our business operations. Problems faced by us or our third-party "cloud" computing or other network providers, including technological or business-related disruptions, as well as natural disasters, cybersecurity threats and regulatory interference, could adversely impact the experience of our members.

Risks related to our dependence on third parties

Third parties have sponsored most clinical trials of DANYELZA and omburtamab so far, and our ability to influence the design and conduct of such clinical trials has been limited. We have incurred significant expenses and are obligated to make significant payments in the future with respect to such clinical trials. We plan to assume control over the future clinical and regulatory development of such product candidates, including obtaining sponsorship of existing INDs or filing new company-sponsored INDs, which will entail substantial additional expenses and may be subject to delay. Any failure by a third party to meet its obligations with respect to the clinical and regulatory development of our product candidates may delay or impair our ability to obtain regulatory approval for our product candidates and result in liability for our company.

We have sponsored only a limited number of clinical trials relating to DANYELZA and omburtamab. Instead, faculty members at our third-party research institution collaborators, or those institutions themselves, have sponsored most of the clinical trials relating to these product candidates, in each case, under their own INDs. We have incurred significant expenses and are obligated to make significant payments in the future with respect to such clinical trials. To date, we have assumed control of only a limited number of such clinical trials and plan to assume control of the overall clinical and regulatory development of DANYELZA and omburtamab for future clinical trials and obtain sponsorship of the INDs or file new company-sponsored INDs, all of which will cause us to incur substantial additional expenses and may be subject to delay. Failure to obtain, or delays in obtaining, sponsorship of INDs or in filing new company-sponsored INDs for DANYELZA or omburtamab or any other product candidates we determine to advance could negatively affect the timing of our potential future clinical trials. Such an impact on timing could increase research and development costs and could delay or prevent obtaining regulatory approval for our most advanced product candidates, either of which could have a material adverse effect on our business.

Further, even in the event that the IND sponsorship is obtained for existing and new INDs, we did not control the design or conduct of the previous trials. It is possible that the FDA will not accept these previous trials as providing adequate support for future clinical trials, whether controlled by us or third parties, for any reason, including the safety, purity, and potency of the product candidate, the degree of product characterization, elements of the design or execution of the previous trials or safety concerns, or other trial results. We may also be subject to liabilities arising from any treatment-related injuries or adverse effects in patients enrolled in these previous trials. As a result, we may be subject to

unforeseen third-party claims and delays in our potential future clinical trials. We may also be required to repeat in whole or in part clinical trials previously conducted by our third-party research institution collaborators, which will be expensive and delay the submission and licensure or other regulatory approvals with respect to any of our product candidates. Any such delay or liability could have a material adverse effect on our business.

Moreover, we have so far been dependent on contractual arrangements with our third-party research institution collaborators and will continue to be until we assume control. Such arrangements provide us certain information rights with respect to the previous trials, including access to and the ability to use and reference the data, including for our own regulatory filings, resulting from the previous trials. However, if the data prove to be inadequate compared to the first-hand knowledge we might have gained had the completed trials been corporate-sponsored trials, then our ability to design and conduct our planned corporate-sponsored clinical trials may be adversely affected. Additionally, the FDA may disagree with the sufficiency of our right to reference the pre-clinical, manufacturing, or clinical data generated by these prior investigator-sponsored trials, or our interpretation of pre-clinical, manufacturing, or clinical data from these clinical trials. Moreover, the FDA may require us to obtain and submit additional pre-clinical, clinical, manufacturing, clinical, toxicology or other in vivo or in vitro data before we may begin our planned trials and/or may not accept such additional data as adequate to begin our planned trials.

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We rely on third parties to conduct our clinical trials under agreements with MSK, universities, medical institutions, CROs, strategic partners, and others. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product 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 these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional non-clinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties 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 or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. We may also rely on investigator-reported interim data in making business decisions. Independent review of the data could fail to confirm the investigator reported interim data, which may lead to revisions in disclosed clinical trial results in the future. Any such revisions that reveal more negative data than previously disclosed investigator-reported interim data could have an adverse impact on our business prospects and the trading price of our common stock. Such revisions could also reduce investor confidence in investigator-reported interim data that we disclose in the future.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and delays and requires management time and focus. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges in the future or that these challenges will not have a material adverse impact on our business, financial condition and prospects.

We rely on third parties to manufacture DANYELZA for commercial sales and our product candidates for our ongoing and planned pre-clinical studies and clinical studies. We also expect to rely on third parties for the manufacturing process of additional product candidates and for commercial supplies of other product candidates than DANYELZA, if approved. Our business could be harmed if those third parties fail to provide us with sufficient quantities of product supplies or product candidates, or fail to do so at acceptable quality levels or prices or fail to maintain adequate compliance with CMC guidelines of the FDA.

We do not currently own any facility that may be used as commercial or clinical-scale manufacturing and processing facility and we rely on outside vendors to manufacture supplies and process DANYELZA and product candidates for pre-clinical studies and clinical trials under the guidance of our management team. DANYELZA and omburtamab have only been manufactured or processed on a limited basis and we may not be able to continue doing so for these or any of our product candidates. Our manufacturing process may be more difficult or expensive than the approaches currently in use. We may make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will not result in significantly different products that may not be as safe and effective as any product candidates deployed by our third-party research institution collaborators.

To date, we have obtained the active pharmaceutical ingredient, or API, of DANYELZA and omburtamab from a limited number of third-party manufacturers. We have engaged a separate third-party manufacturer to conduct fill-and-finish and labeling services, as well as for the storage and distribution of DANYELZA and omburtamab to clinical sites. We do not have a long-term supply agreement with any of these third-party API manufacturers, and we purchase our required drug supplies on a purchase order basis.

We rely also on third-party manufacturers and third-party collaborators for the manufacture of DANYELZA for commercial supply and we expect this also to be the case for any of our product candidates for which we or any of our potential future collaborators obtain marketing approval. We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

We are highly dependent on our current third-party drug substance manufacturer of omburtamab, EMD/Merck, since this manufacturing process uses a hybridoma cell line in a relatively small scale (200 litres) cGMP manufacturing process. Many manufacturers refuse to allow hybridoma cell lines to be used in their facilities due to the risk of contamination and the relatively small scale of the cGMP system may render a collaboration with us less attractive from a third party’s commercial point of view.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the number of potential manufacturers is limited, we would need to qualify any new manufacturers, our BLA submissions would need to be amended and ultimately the FDA must approve any new manufacturers. This approval would require new testing and cGMP, compliance inspections by the FDA. In addition, a new manufacturer would have to be educated in, or develop substantially equivalent processes for, production of our products;

- our third-party manufacturers might be unable to timely manufacture our product or produce the quantity and quality required to meet our clinical and commercial needs, if any;

- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;

- our third-party manufacturers may not perform as agreed, according to our schedule or specifications, or at all, may not devote sufficient resources to our product candidates, may give greater priority to the supply of other products over our product candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products;

- the risk of cross-contamination if more than one product is manufactured at our third-party manufacturer's production facilities;

- our third-party manufacturers are subject to ongoing periodic unannounced inspection by the FDA and corresponding state agencies to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these and or any other applicable regulations and standards;

- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our products;

- our third-party manufacturers could breach, terminate or not renew their agreement with us at a time that is costly or inconvenient for us;

- clinical and, if approved, commercial supplies for the raw materials and components used to manufacture and process our product candidates, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects;

- the possible mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- the possible misappropriation of our proprietary information, including our trade secrets and know-how;

- the possibility of clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales. Our third-party manufacturers and critical reagent suppliers may be subject to inclement weather, as well as natural or man-made disasters; and

- our third-party manufacturers may have unacceptable or inconsistent product quality success rates and yields and may have inadequate quality control systems.

Each of these risks could delay or prevent the completion of our clinical trials, could delay any additional BLA submissions or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. For example, during 2018 we experienced a shortage in the supply of Iodine-131, one of the components of our ^{131}I-omburtamab product candidate, from our single source supplier. We have established a relationship with an additional supplier which we believe will be able to provide us with adequate supplies of Iodine-131. While we have not yet experienced any delays in the research and development of our ^{131}I-omburtamab product candidate to date, any such shortages in the supply of such raw materials used in the manufacture of our product candidates could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. In addition, we will rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on our company until deficiencies are remedied.

The facilities used by our contract manufacturers to manufacture DANYELZA and our product candidates must be approved by the FDA pursuant to inspections conducted after submittal of the BLA to the FDA. We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. DANYELZA and any product candidates that we may develop may compete with product candidates of other companies for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of

product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our drugs and harm our business and results of operations.

Any performance failure on the part of our existing or future manufacturers could adversely affect our commercialization of approved products, such as DANYELZA, and delay clinical development or marketing approval of other product candidates. We do not currently have arrangements in place for redundant supply of our DANYELZA and omburtamab and we only currently use a different single third-party manufacturer for fill-and-finish services for DANYELZA and omburtamab. If our current contract manufacturers cannot perform as agreed, we may be required to replace those manufacturers and we may incur added costs and delays in identifying and qualifying any such replacement. We have been informed that the FDA plans to visit and inspect the site of EMD Millipore Corporation (now part of the Merck KGaA group of companies), or EMD/Merck, in Martillac, France, where the omburtamab drug substance is manufactured and Vela Labs, GmbH, in Austria where an analytical release test of omburtamab drug substance is performed. We estimate that the FDA inspection may occur in the third quarter of 2022 assuming the FDA accepts the omburtamab BLA submission. However, if the FDA is not able to timely conduct an inspection for any reason, including due to COVID-19 travel restrictions or otherwise, there may be adverse consequences to the approval process, and we may not obtain BLA approval on a timely basis or at all. Delays in the approval process or our inability to obtain approval for any reason for omburtamab or any other product candidate would have a material adverse effect upon our business, results of operations and financial condition. The FDA may also decide to inspect the fill and finish site at Patheon/Thermo Fisher in Ferentino, Italy, which may cause similar risks. We also expect EMA to require an inspection of the manufacturing facilities for omburtamab due to our MAA submission for omburtamab. If the EMA is unable to conclude that these manufacturing facilities are in substantial compliance with cGMP there may be adverse consequences to the approval process, and we may not obtain a MA for omburtamab in Europe on a timely basis or at all.

We are and will continue to rely in significant part on outside scientists and their third-party research institutions for research and development and early clinical testing of our product candidates. These scientists and institutions may have other commitments or conflicts of interest, which could limit our access to their expertise and adversely affect the timing of the IND filings and our ability to conduct future planned clinical trials.

We currently have limited internal research and development capabilities and we have not and are not currently conducting any independent clinical trials. Therefore, we currently rely on third-party research institutions for both capabilities.

Currently, MSK is conducting clinical trials to address pediatric high-risk NB and relapsed osteosarcoma using DANYELZA. We are also conducting clinical trials at MSK for CNS/LM from NB, DIPG and DSRCT for our omburtamab product candidate and GD2 positive tumors for our nivatrotamab product candidate. Under the terms of the MCTA, we are obligated to pay for the costs associated with these clinical trials.

We have agreed to fund certain research and development costs under both the MSK License, the MSK CD33 License and the SADA License Agreement. However, the research we have agreed to fund constitutes only a small portion of the overall research of MSK. Other research being conducted by MSK may receive higher priority than research on the programs we may fund.

The outside scientists who conduct the clinical testing of DANYELZA and our other current product candidates, and who conduct the research and development upon which our product candidate pipeline depends, are not our employees; rather they serve as either independent contractors or the primary investigators under research and other agreements that we have entered into with MSK. Such scientists and collaborators may have other commitments that would limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for MSK or another entity arises, we may lose their services. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to, and have a material adverse effect on, our business.

Our existing agreements with MSK may be subject to termination by MSK upon the occurrence of certain circumstances. If MSK terminates the MSK License, the MSK CD33 License, the SADA License Agreement or its other agreements with us, commercialization of any approved product, such as DANYELZA, or the research and development of the relevant product candidates would be suspended, and we would not be able to research, develop, and license our existing and future product candidates as currently contemplated. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us. Switching or adding third parties to conduct our clinical trial would involve substantial costs and delays and require extensive management time and focus, which can materially impact our ability to meet our desired clinical development timelines.

DANYELZA and our product candidates are biologics and the manufacture of DANYELZA and our product candidates is complex. We, or any of our third-party manufacturers, may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities. For some reagents, equipment, and materials, we rely or may rely on sole source vendors or a limited number of vendors. Such difficulties may result in an inadequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

DANYELZA and our product candidates are biologics and the process of manufacturing them is complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process for biologics is less reliable and is more difficult to reproduce. In addition, manufacturing of DANYELZA and our product candidates require many reagents, which are substances used in our manufacturing processes to bring about chemical or biological reactions, and other specialty materials and equipment, some of which are manufactured or supplied by small companies with limited resources and experience to support commercial biologics production. Our manufacturing process may be susceptible to product loss or failure due to interruptions in the manufacturing process variability in product characteristics, quality control, contamination, equipment or reagent failure, improper installation or operation of equipment, product testing, vendor or operator error, availability of qualified personnel, logistics and shipping as well as compliance with strictly enforced federal, state and foreign regulations. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. No assurance can be given that any stability failures or other issues relating to the manufacture of DANYELZA or our product candidates will not occur in the future.

Further, as product candidates are developed through pre-clinical to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. Moreover, as we develop and/or scale-up our manufacturing process, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of that process. We may not be able to obtain rights to such materials on commercially reasonable terms, or at all.

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA and other foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and other foreign regulatory authority requirements on an ongoing basis. If we, or our CMOs, are unable to reliably produce products to specifications acceptable to the FDA, EMA or other foreign regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair

commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Although we are working to develop commercially viable processes, our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. We may ultimately be unable to, among other things, develop a manufacturing process and distribution network that will, reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

We have entered into strategic collaborations for the development, marketing and commercialization of DANYELZA and omburtamab in certain jurisdictions and may do so also in the future for all or some of our product candidates. If those collaborations are not successful, or if we are unable to establish additional collaborations, we may have to alter or delay our development and commercialization plans.

As we further develop our lead product candidates and following potential approval, commercialize our products, we may build a commercial infrastructure with the capability to directly market it to a variety of markets and territories. In November 2020, we entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, West Bank and Gaza Strip. In December 2020, we entered into a distribution agreement for DANYELZA and omburtamab with Swixx BioPharma AG for the Eastern European territories Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia and Slovenia. In December 2020, we entered into a license agreement for DANYELZA and omburtamab with SciClone Pharmaceuticals International Ltd., for Greater China, including Mainland China, Taiwan, Hong Kong and Macau. Finally, in May 2021, we entered into an exclusive distribution agreement with Adium Pharma S.A. for Latin America. We may enter into further strategic collaborations for the development, marketing and commercialization of all or some of our product candidates. Our current and future potential collaborators for any collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We would face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any further collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. We have and will for any future collaborations likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, marketing and/or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our current and future potential collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our current collaborators have and any future collaborators may have, the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

Our current and any future potential collaborations involving our product candidates pose risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development, marketing and/or commercialization of our product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;

- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or product candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to the marketing and distribution of such drug or drugs;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control;
- we may be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and/or commercialization of the applicable product candidates;
- collaborators may learn about our discoveries, data, proprietary information, trade secrets, or compounds and use this knowledge to compete with us in the future; and
- the number and type of our collaborations could adversely affect our attractiveness to potential future collaborators or acquirers.

Our current and any future collaboration agreements, if any, may not lead to development or commercialization of product candidates in the most efficient manner, or at all.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all, if and when we seek to enter into collaborations. If we are unable to do so, we may have to curtail the development of a product 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 any 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 may not be able to further develop our product candidates or bring them to market and generate revenue from sales of drugs.

Coverage and reimbursement decisions by third-party payors may have an adverse effect on pricing and market acceptance. If there is not sufficient coverage and reimbursement for our products, it is less likely that our products will be widely used.

Market acceptance and sales of our products, if approved, such as DANYELZA, will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs they will

reimburse and establish payment levels and, in some cases, utilization management strategies, such as tiered formularies and prior authorization. To date, although a number of third party providers have established coverage policies and provided reimbursement for DANYELZA, no third-party provider has established coverage policies or provided reimbursement for any of our other product candidates and we cannot assure you that coverage and reimbursement will be readily available for DANYELZA or any products that we develop or that the reimbursement level will be adequate to allow us to operate profitably. Also, we cannot be certain that coverage and reimbursement policies will not reduce the demand for, or the price paid for, our products. If coverage and reimbursement is not available or is available on a limited basis, or if the coverage and reimbursement amount is inadequate, we may not be able to successfully commercialize any of our approved products.

Risks related to government regulation; market approval and other legal compliance matters

In October 2020 we received a Refusal to File letter from the FDA regarding our BLA for omburtamab. We plan to resubmit the BLA. The FDA retains discretion to decide again not to file our BLA for omburtamab and may refuse to accept an accelerated approval pathway for omburtamab or our other product candidates which could have a material adverse impact on our development and approval process for these product candidates and our other product candidates.

We initiated submission of a BLA for omburtamab in June 2020 under the FDA's rolling review process and completed the submission in August 2020. In October 2020 we received a Refusal to File letter from the FDA regarding the BLA for omburtamab. The reason for the FDA's Refusal to File was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control (CMC) Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We have been working closely with the FDA to resolve these issues and have discussed the adequacy of the external control reanalysis and supporting data to demonstrate direct anti-tumor effect for a BLA resubmission. We have held three Type B meetings with FDA in 2021 concerning omburtamab, the latest in September 2021. At the September meeting we provided the FDA with additional detailed data and the statistical analysis plan, or SAP. Based on FDA's feedback on these items, we have in October requested a pre-BLA meeting with the FDA in December 2021. Subject to timing of and feed-back at such pre-BLA meeting, we aim to initiate rolling resubmission of the omburtamab BLA by the end of 2021. We plan to commercialize omburtamab as soon as possible after obtaining FDA approval, if such approval occurs. However, there is no assurance that the FDA will accept our proposal and our data as sufficient to allow the BLA resubmission. In addition, the FDA may raise additional issues and pose questions to us that may delay the resubmission of our BLA for omburtamab, the filing of the BLA for omburtamab by the FDA, the approval process and the ultimate issuance of any Marketing Authorization for omburtamab. We may not be able to provide a satisfactory or a timely response to FDA questions or we may not be able to timely gather the required data, or at all, to prepare our BLA submission for omburtamab as planned. If we are unable to address all questions or concerns the FDA has raised or may raise or if we do not have timely access to the data required for the preparations of the BLA, we may not be able to timely submit our BLA and ultimately receive a Marketing Authorization for omburtamab. If the FDA files the BLA and we are delayed or unable to provide data in response to FDA information requests, the PDUFA date for our BLA may be extended or we may receive a Complete Response Letter, which would have a material adverse effect on our business, results of operation and financial condition.

The FDA retains discretion to decide again not to review our BLA for omburtamab. No assurance can be given that we would be able to satisfactorily or timely answer or resolve all the questions and issues the FDA may pose.

In addition, while we are currently pursuing a full approval for our BLA for omburtamab, in the event the FDA finds our data insufficient to support such full approval, it is possible that the FDA would consider whether our clinical data is sufficient for a potential accelerated approval. However, the FDA may not find our data sufficient to support either a full approval or an accelerated approval. Even if the FDA were to find our clinical data sufficient to support an accelerated approval, we would need to conduct a post-marketing study to confirm the clinical benefit of omburtamab. The FDA may also impose other conditions as a result of any accelerated or full approval which we may not be able to

satisfy. Any delay or inability to obtain approval for our BLA for omburtamab would materially adversely affect our ability to generate revenue from commercialization of omburtamab, which would likely result in significant harm to our financial position and adversely impact our stock price. This could also adversely affect the development and approval process for our other product candidates. We can provide no assurance that the FDA will agree with our proposal or that we will be able to resubmit the BLA as planned or at all or that we will ultimately be able to obtain FDA approval for omburtamab.

In addition, as part of the FDA approval process, the FDA requires an inspection of the manufacturing facilities for omburtamab. If the FDA is unable to conclude that these manufacturing facilities are in substantial compliance with cGMP there may be adverse consequences to the approval process, and we may not obtain BLA approval on a timely basis or at all. We estimate that the FDA inspection may occur in the third quarter of 2022 assuming the FDA accepts the omburtamab BLA filing, however, if the FDA is not able to timely conduct an inspection for any reason including due to COVID-19 travel restrictions or otherwise, there may be adverse consequences to the approval process, and we may not obtain BLA approval on a timely basis or at all. We expect EMA to require an inspection of the manufacturing facilities for omburtamab due to our MAA submission for omburtamab. If the EMA is unable to conclude that these manufacturing facilities are in substantial compliance with cGMP there may be adverse consequences to the approval process, and we may not obtain a MA for omburtamab in Europe on a timely basis or at all. Delays in the approval process or our inability to obtain approval for any reason for omburtamab or any other product candidate would have a material adverse effect upon our business, results of operations and financial condition.

Even if we complete the necessary pre-clinical studies and clinical trials, the FDA regulatory approval process is lengthy, time-consuming, and inherently unpredictable, and we or any of our potential future collaborators may experience significant delays in the clinical development and regulatory approval, if any, for the commercialization of our product candidates. To date, we have only obtained regulatory approval to market DANYELZA in the United States for relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow. We cannot predict when or if, and in which other territories, we, or any of our potential future collaborators, will obtain marketing approval to commercialize a product or product candidate.

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. Even if we complete the necessary pre-clinical studies and clinical trials, we will not be permitted to market any biological drug product in the United States until we receive a Biologics License from the FDA as we did for DANYELZA for relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow. We intend to conduct additional clinical trials in the United States and Europe. We intend to discuss with the FDA submission of BLAs for respective approval of DANYELZA and omburtamab as treatments for indications that currently lack FDA-approved treatments.

The FDA standard for regular approval of a BLA generally requires two well-controlled Phase 3 studies or one large and robust, well-controlled Phase 3 study in the patient population being studied that provides substantial evidence that a biologic is safe, pure and potent. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. However, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require a sponsor to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. The FDA may not agree with our accelerated approval strategy with respect to omburtamab. The FDA may ultimately require one or multiple Phase 3 clinical trials prior to approval of omburtamab or other product candidates.

We have some, but only limited, experience in completing a submission of a BLA to the FDA, or similar approval submissions to comparable foreign authorities. A BLA must include extensive pre-clinical and clinical data and supporting information to establish that the product candidate is safe, pure, and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates to create further challenges in obtaining regulatory approval from the FDA and other regulatory authorities. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support licensure. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure of the product candidates based on the completed clinical trials. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

The process of obtaining marketing approvals, both in the United States, the European Union and elsewhere, is a lengthy, expensive and uncertain process. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive pre-clinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. The FDA, EMA or other regulatory authorities have substantial discretion and may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

In addition, clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- obtaining regulatory approval to begin a trial, if applicable;
- the availability of financial resources to begin and complete the planned trials;
- reaching 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;
- obtaining approval at each clinical trial site by an Institutional Review Board or IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCPs, or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites;
- manufacturing qualified materials under cGMPs for use in clinical trials;
- impact of the COVID-19 pandemic; or

- inspection of clinical trial sites and manufacturing facilities by regulatory authorities.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above "—The market opportunities for DANYELZA and our product candidates may be limited to those patients who are ineligible for or have failed prior treatments and may be small. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Also, the market opportunity for DANYELZA and our product candidates may be smaller than we expect." for additional information on risks related to patient enrollment. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or the FDA or other regulatory authorities 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 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 product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate potential future product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Our third-party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. 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 product candidates.

Our product candidates, including omburtamab, could fail to receive marketing approval for many reasons, including the following:

- the FDA, 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, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;

- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;

- the FDA, 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 product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain marketing approval in the United States, the EU or elsewhere;

- the FDA, 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, EMA or comparable foreign regulatory authorities may fail to approve any companion diagnostics that may be required in connection with approval of our therapeutic product candidates; and

- the approval policies or regulations of the FDA, 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 clinical trial results may result in our failing to obtain marketing approval to market omburtamab or any of our other product candidates, which would significantly harm our business, results of operations and prospects. In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted drug application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional pre-clinical studies, clinical trials, toxicology or other in vivo or in vitro data to support the initiation of other studies and testing. In addition, varying interpretations of the data obtained from pre-clinical studies and clinical trials could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any collaborators we may have in the future, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability or that of any collaborators we may have to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

The European Medicines Agency, or the EMA, or comparable foreign regulatory authorities, may disagree with our regulatory plans, including our plans to seek conditional marketing authorization, and we may fail to obtain regulatory approval of DANYELZA, omburtamab or our product candidates, which would prevent DANYELZA, omburtamab or our product candidates from being marketed abroad. Any approval we are granted for our product candidates in the United States, such as the approval of DANYELZA, would not assure approval of our product candidates in foreign jurisdictions.

In order to market and sell our drugs in the European Union and many other jurisdictions, we, and any collaborators we may have in the future, must obtain separate marketing approvals and comply with numerous and varying regulatory requirements.

On April 27, 2021 we submitted a Marketing Authorization Application, or MAA, to the European Medicines Agency for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.

The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside of the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside of the United States, it is required that the drug be approved for reimbursement before the drug can be approved for sale in that country. We, and any collaborators we may have in the future, may not obtain approvals from regulatory authorities outside of the United States on a timely basis, if at all. Approval by the FDA, such as the approval of DANYELZA for relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow, does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside of the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA.

As part of its marketing authorization process, the EMA may grant marketing authorizations on the basis of less complete data than is normally required, when, for certain categories of medicinal products, doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization. This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating diseases or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and efficacy of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data are still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete non-clinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public-health threats.

Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing studies or to conduct new studies with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

The granting of a conditional marketing authorization will allow medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product are generated, submitted, assessed and acted upon. Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, the EMA or CHMP may ultimately not agree that the requirements for such conditional marketing authorization have been satisfied.

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of pre-clinical and clinical studies may not be predictive of the results of later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through pre-clinical studies and initial clinical trials. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that our product candidates' risk-benefit ratios for their proposed indications are acceptable;
- the results of clinical trials may not meet the level of statistical significance required by the FDA, EMA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that the clinical and other benefits of our product candidates outweigh their safety risks;
- the FDA, 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 product candidates may not be sufficient to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities to support the submission of a BLA, MAA or

other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States, the EU or elsewhere;

- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, our own manufacturing facilities, or a third-party manufacturer's facilities with which we contract for clinical and commercial supplies; and

- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Failure to obtain regulatory approval to market any of our product candidates would significantly harm our business, results of operations, and prospects.

We may seek Breakthrough Therapy Designation, or BTD, for one or more of our product candidates. We may not receive such designation, and even if we do, such designation may not lead to a faster development or regulatory review or approval process.

BTD is intended to expedite the development and review of products that treat serious or life-threatening diseases when "preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development." The designation of a product candidate as a breakthrough therapy provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate and ensure collection of appropriate data needed to support approval; more frequent written correspondence from FDA about such things as the design of the proposed clinical trials and use of biomarkers; intensive guidance on an efficient drug development program, beginning as early as Phase 1; organizational commitment involving senior managers; and eligibility for rolling review and priority review.

In June 2017, ^{131}I-omburtamab received BTD for the treatment of pediatric patients with R/R NB who have CNS/LM from NB. We may seek BTD for some or all of our other product candidates, but we may never receive such BTD, or, if received, the development of our product candidates may not be expedited or benefited by such designation. BTD does not change the standards for product approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. Even if we receive BTD, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Our product candidates may not be able to obtain or maintain Orphan Drug Designation, or ODD, or Rare Pediatric Disease Designation, or RPDD.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually 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 September 2021 the FDA granted RPDD for ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma. In July 2021, the European Commission granted orphan medicinal product designation, or OMPD, for ^{177}Lu-omburtamab-DTPA for the treatment of medulloblastoma. In September 2020, the FDA granted ODD and RPDD to nivatrotamab for the treatment of neuroblastoma. In November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB. In

February 2017, the European Commission granted OMPD to omburtamab for the treatment of NB. In August 2016, the FDA granted ODD to ^{131}I-omburtamab for the treatment of NB. In 2013, the FDA granted ODD to DANYELZA for the treatment of NB.

In the United States, ODD 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 that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product may be entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

The Rare Pediatric Disease Priority Review Voucher Program, or PRV Program, is intended to incentivize pharmaceutical sponsors to develop drugs for rare pediatric diseases. A sponsor who obtains approval of a BLA for a rare pediatric disease may be eligible for a PRV, under this program, which may be redeemed by the owner of such PRV to obtain priority review for a marketing application. A PRV is fully transferrable and can be sold to any sponsor, who in turn can redeem the PRV for priority review of a marketing application in six months, compared to the standard timeframe of approximately 10 months.

A drug that receives RPDD before September 30, 2024, will continue to be eligible for a PRV if the drug is approved by the FDA before September 30, 2026.

Even if our product candidates obtain ODD or RPDD in the future, they may not be able to obtain or maintain such status or the associated benefits. We may not be the first to obtain marketing approval of any product candidate that has obtained ODD for the orphan-designated 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 we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. ODD 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.

Even if we, or any collaborators we may have in the future, obtain marketing approvals for our product candidates, the terms of approvals and ongoing regulation of our drugs could require substantial expenditure of resources and may limit how we, or they, manufacture and market our drugs, which could materially impair our ability to generate revenue.

Once marketing approval has been granted, such as for DANYELZA in the United States, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. The accelerated approval of DANYELZA is subject to certain postmarketing requirements and commitments, including a confirmatory postmarketing trial of clinical benefit, that must be completed in order to convert the BLA to full approval and prevent withdrawal of the license by FDA. The confirmatory postmarketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which will enroll a minimum of 80 patients and report overall rate of response, or ORR, duration of response, or DOR, progression free survival, or PFS, or overall survival, or OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint, PFS and OS are secondary endpoints in long-term follow up. As of July 1, 2021 we have enrolled 62 patients and we anticipate completing the study no later than March 31, 2027. Other requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control,

quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We, and any collaborators we may have in the future, must also comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug's approved labeling. Thus, we, and any collaborators we may have in the future, may not be able to promote any drugs we develop for indications or uses for which they are not approved.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. For example, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a Risk Evaluation and Mitigation Strategy, which could include requirements for a restricted distribution system. Manufacturers of approved drugs and those manufacturers' facilities are also required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. Accordingly, assuming we, or our potential future collaborators, receive marketing approval for one or more of our product candidates, we, and our potential future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

If we, and our future potential collaborators, are not able to comply with post-approval regulatory requirements, we, and our potential future collaborators, could have the marketing approvals for our drugs withdrawn by regulatory authorities and our, or our potential future collaborators', ability to market any future drugs could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

The FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted, in a manner that could prevent, limit or delay regulatory approval of our product candidates, which would impact our ability to generate revenue.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, such as for DANYELZA, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

DANYELZA and any of our product candidates for which we, or our potential future collaborators, obtain marketing approval in the future will be subject to substantial penalties if we, or they, fail to comply with regulatory requirements or if we, or they, experience unanticipated problems with our drugs following approval.

DANYELZA and any of our product candidates for which we, or our potential future collaborators, obtain marketing approval in the future, will be subject to continual review by the FDA and other regulatory authorities.

The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of drugs to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we, or our potential future collaborators, do not market any of our product candidates for which we, or they, receive marketing approval for only their approved indications, we, or they, may be subject to warnings or enforcement action for off-label marketing. Violation of the Federal Food, Drug and Cosmetic Act, or FDCA, and other statutes, including the False Claims Act, relating to the

promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our drugs or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- litigation involving patients taking our drug;
- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- restrictions on coverage by third-party payors;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- drug seizure; or
- injunctions or the imposition of civil or criminal penalties.

Current and future legislation, and a change in existing government regulations and policies, may increase the difficulty and cost for us and our potential future collaborators to obtain marketing approval of and commercialize our product candidates and affect the prices we, or they, may obtain.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of our potential future collaborators, to profitably sell any drugs for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or our potential future collaborators, may receive for any approved drugs.

In the United States, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, or ACA, substantially changed the way healthcare is financed by both governmental and private insurers.

New laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. We cannot predict whether these challenges will continue or other proposals will be made or adopted, or what impact these efforts may have on us. Further, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the price of drugs under Medicare and reform government program reimbursement methodologies for drug products. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Some states are also considering legislation and ballot initiatives that would control the prices and coverage and reimbursement levels of drugs, including laws to allow importation of pharmaceutical products from lower cost jurisdictions outside the U.S. and laws intended to impose price controls on state drug purchases.

We expect healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for DANYELZA and any other approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures. The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidates to that of other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

Legislative and regulatory proposals have also been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether the FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of DANYELZA or our other approved products, if any, may be. In addition, increased scrutiny by the Congress of the FDA’s approval process may significantly delay or prevent marketing approval, as well as subject us and any future collaborators to more stringent drug labeling and post-marketing testing and other requirements.

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for DANYELZA and omburtamab, if approved, or any of our other product candidates that may be approved in the future, which would adversely affect our revenue and results of operations.

We expect that coverage and reimbursement of pharmaceutical products may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. In particular, drug pricing by pharmaceutical companies has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. In some international markets, the government controls the pricing, which can affect the profitability of drugs.

Current government regulations and possible future legislation regarding health care may affect coverage and reimbursement for medical treatment by third-party payors, which may render DANYELZA or our other product candidates, if approved, not commercially viable or may adversely affect our anticipated future revenues and gross margins.

We cannot predict the extent to which our business may be affected by these or other potential future legislative or regulatory developments. However, future price controls or other changes in pricing regulation or negative publicity related to the pricing of pharmaceutical drugs generally could restrict the amount that we are able to charge for any our future products, which would adversely affect our anticipated revenue and results of operations.

Our relationships with healthcare providers, physicians and third-party payors are subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to penalties, including criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Our relationships with healthcare providers, physicians and third-party payors are subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Our current and future arrangements with healthcare providers, physicians and third-party payors and patients may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute DANYELZA and other our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- Anti-Kickback Statute—the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under 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;

- False Claims Act—the federal False Claims Act imposes 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, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- HIPAA—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing 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 federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouse as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- HIPAA Privacy Provisions—as amended by HITECH and its implementing regulations, HIPAA also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouse as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and HIPAA, as amended, requires notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- Transparency Requirements—the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the Affordable Care Act, and its implementing regulations, which requires certain manufacturers of drugs, devices, therapeutic biologics and medical supplies reimbursable under Medicare, Medicaid, and Children's Health Insurance Programs to report annually to the Department of Health and Human Services information related to certain payments and other transfers of value, including consulting fees, travel reimbursements, research grants, and other payments or gifts with values over $10 made to physicians, other healthcare providers and teaching hospitals, as well as ownership and investment interests held by physicians and other healthcare providers and their immediate family members;

- FDCA—the FDCA, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices; and

- Analogous State and Foreign Laws—analogous state and foreign fraud and abuse laws and regulations, such as state anti-kickback and false claims laws that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information. State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The collection and processing of personal data—including health data—is governed by the European Union-wide General Data Protection Regulation, or GDPR, which became applicable on May 25, 2018. GDPR applies to us through the activities of our wholly-owned subsidiary Y-mAbs Therapeutics A/S, and also to most businesses, regardless of location, that provides goods or services to residents in the EU, which includes our clinical trial activities in European Union Member States. The GDPR imposes operational requirements for processors and controllers of personal data, including, for example, special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU, expanded disclosures about how personal information is to be used, limitations on retention of information, increased requirements pertaining to health data and pseudonymized

(i.e., key-coded) data, mandatory data breach notification requirements and higher standards for controllers to demonstrate that they have obtained valid consent for certain data processing activities. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. The GDPR provides that European Union Member States may make their own further laws and regulations in relation to the processing of genetic, biometric or health data, which could result in differences between Member States, limit our ability to use and share personal data or could cause our costs to increase, and harm our business and financial condition. We are also subject to evolving and strict rules on the transfer of personal data out of the European Union to the United States. Failure to comply with European Union data protection laws may result in fines and other administrative penalties, which may be onerous and adversely affect our business, financial condition, results of operations and prospects. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations involve substantial costs. It is possible that interpretation of healthcare laws and regulations will vary across jurisdictions, and that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of drugs from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We have established internal policies and procedure to mitigate our compliance risks. However, no assurance can be given that such policies and procedures will be adequate to ensure compliance with applicable laws and regulations. Moreover, although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, it may be costly to us in terms of money, time and resources, and they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Coverage and reimbursement may be limited or unavailable in certain market segments for DANYELZA and our product candidates, which could make it difficult for us to sell DANYELZA and our product candidates profitably.

Successful sales of DANYELZA and our product candidates, if approved, depend on the availability of adequate coverage and reimbursement from third-party payors. In addition, because DANYELZA and our product candidates represent relatively new approaches to the treatment of cancer, we cannot accurately estimate the potential revenue from DANYELZA or our product candidates.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors are critical to new product acceptance.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;

- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. To date, although a number of third party providers have established coverage policies and provided reimbursement for DANYELZA, no third party provider has established coverage policies or provided reimbursement for any of our other product candidates. Even if we obtain coverage for DANYELZA or any other product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products, if approved. Patients are unlikely to use our product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Because our products and product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater.

To date DANYELZA has been approved for sale in the United States only, but we intend to seek approval to market our products in both the United States as well as in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the EU, the pricing of biologics is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures.

We may incur significant liability if enforcement authorities allege or determine that we are engaging in commercial activities or promoting DANYELZA or another product candidate in a way that violates applicable regulations.

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label uses. Accordingly, we may not promote DANYELZA in the United States for use in any indications other than relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

Notwithstanding regulations related to product promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws and regulatory guidance.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations involve the use of hazardous, radioactive and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Laws and regulations governing any international operations we may have in the future may preclude us from developing, manufacturing and selling certain products or product candidates outside of the United States and require us to develop and implement costly compliance programs.

We currently have operations in the United States and Denmark and we maintain relationships with CMOs in other parts of Europe as well as in the United States for the manufacture of our product candidates. If we further expand our operations outside of the United States, we must comply with numerous laws and regulations in each new jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. No assurance can be given that our compliance policies and procedures are or will be sufficient or that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct.

The FCPA prohibits any U.S. individual or business from paying, offering, authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and to devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the DOJ. The Securities and Exchange Commission, or SEC, is involved with enforcement of the books and records provisions of the FCPA.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because, in many countries, hospitals are operated by the government, and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions. Similar laws in other countries, such as the U.K. Bribery Act 2010, may apply to our operations.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States, or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. If we expand our presence outside of the United States, it will require us to dedicate additional resources to comply with these laws, and these laws may preclude us from developing, manufacturing, or selling certain drugs and product candidates outside of the United States, which could limit our growth potential and increase our development costs.

The failure to comply with laws governing international business practices may result in substantial penalties, including suspension or debarment from government contracting. Violation of the FCPA or other export control, anti-corruption, anti-money laundering and anti-terrorism laws or regulations can result in significant civil and criminal penalties. Indictment alone under the FCPA can lead to suspension of the right to do business with the U.S. government until the pending claims are resolved. Conviction of a violation of the FCPA can result in long-term disqualification as a government contractor. The termination of a government contract or relationship as a result of our failure to satisfy any of our obligations under laws governing international business practices would have a negative impact on our operations and harm our reputation and ability to procure government contracts. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

Risks related to our intellectual property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our commercial success will depend in large part on obtaining and maintaining proprietary rights including patent, trademark and trade secret protection of our products, product candidates and related proprietary technologies, their respective components, formulations, methods used to manufacture them and methods of treatment, as well as successfully defending these patents against third-party challenges. Our ability to stop unauthorized third parties from making, using, selling, offering to sell or importing our products, product candidates and related proprietary technologies is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The patenting process is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. In addition, we may not be able to pursue or obtain patent protection in all relevant markets. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Our pending and future patent applications may not result in issued patents that protect our product candidates or related technologies, in whole or in part. In addition, our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing product candidates or products and related technologies.

We currently depend on proprietary technology licensed from MSK and MIT and may depend on other third-party licensors in the future. If we lose our existing licenses or are unable to acquire or license additional proprietary rights from MSK, MIT or other third parties, we may not be able to continue developing our products.

We currently in-license certain intellectual property from MSK and MIT. In the future we may in-license intellectual property from other licensors. We rely on certain of these licensors to file and prosecute patent applications and maintain patents and otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by these licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid, enforceable or sufficient patents and other intellectual property rights. We have limited control over the manner in which our licensors may initiate an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that the licensors' infringement proceedings or defense activities may be less vigorous than had we conducted them ourselves.

The growth of our business may depend in part on our ability to acquire or in-license additional proprietary rights. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our products or product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may develop products containing our compounds and pre-existing pharmaceutical compounds. These pharmaceutical compounds may be covered by intellectual property rights held by others. We may be required by the FDA or comparable foreign regulatory authorities to provide a companion diagnostic test or tests with our products or product candidates. Such diagnostic test or tests may be covered by intellectual property rights held by others. We may not own, or may have to share, the intellectual property rights obtained in collaboration with any other party, or intellectual property rights obtained relating to improvements of in-licensed products or processes.

We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license under such intellectual property rights, any such license may be non-exclusive, which may allow our competitors to access the same technologies licensed to us. Additionally, we sometimes collaborate with academic and other institutions, such as MSK, to accelerate our pre-clinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates, products and related proprietary technologies. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

We are a party to license agreements with MSK, MIT, and others, pursuant to which we in-license key patent and patent applications for our product candidates, products and related proprietary technologies. These existing licenses impose various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations or otherwise materially breach a license agreement, our licensors may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property. In addition, any claims asserted against us by our licensors may be costly and time-consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

Uncertainty as to the issuance, scope, validity, enforceability and value of patents, and the potential for future changes in patent and other intellectual property protections, may result in inadequate protection of our as well as in-licensed intellectual property or may result in alleged or actual infringement of the intellectual property rights of third parties.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and in-licensed patent rights are highly uncertain. Our pending and future patent applications and in-licensed patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our products or product candidates or related technologies or which effectively prevent others from

commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our and in-licensed patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our as well as in-licensed patent rights are highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and in-licensed patent applications and the enforcement or defense of the issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. During examination of our own as well as our in-licensed patent applications third parties may present observations or submit patents, published patent applications or other prior art which may affect the patentability of the claimed inventions. The costs for obtaining patent protection may be increased significantly by the need for appeal proceedings or oral proceedings, which may also result in a patent not being issued. We may become involved in opposition, interference, derivation, post grant review, inter partes review, ex-parte re-examination or other proceedings challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our and in-licensed patent rights, allow third parties to commercialize our products, product candidates and related technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Intellectual property rights do not necessarily address all potential threats.

Even if our owned or in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in the patent claims of our owned or in-licensed patents being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our products, product candidates and technology. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use compounds that are similar to the pharmaceutical compounds used in our products or product candidates but that are not covered by the claims of our patents;
- the APIs in our current products or product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation, method of manufacture or method of use;
- we may not be able to prevent parallel importation of products into the U.S., EU member states and/or other jurisdictions, which may reduce our profit margin;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our products or product candidates and proprietary technologies;
- it is possible that our owned or in-licensed pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- we may not be able to obtain patent term extensions or supplementary protection certificates covering our products;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates, products or technologies similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or products;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- we have engaged in scientific relationships in the past, such as with MSK, and expect to continue to do so with MSK and/or other third parties in the future. Such third parties may develop adjacent or competing

products to ours that are outside the scope of our licensed patents and/or the respective research collaboration/agreement with such third party;

- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that products, product candidates or diagnostic tests we develop may be covered by third parties' patents or other proprietary rights; or
- the patents of others may have an adverse effect on our business.

In addition, during the course of business we have decided not to pursue certain products or processes and we may do so again in the future. If it is later determined that our activities, product or product candidates infringed the intellectual property of any third party, we may be liable for damages, enhanced damages or subjected to an injunction, any of which could have a material adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our licensors, collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors or use such information to compete with us. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and this would have a material adverse effect on our business.

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology products and product candidates. Likewise, our current owned patents and patents in-licensed from MSK relating to our proprietary technologies and our product candidates comprise patents that are expected to expire on various dates from 2021 through 2037, without taking into account any possible patent term adjustments, extensions or supplementary protection. Upon the expiration of our current patents, we may lose the right to exclude others from practicing the relevant inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own or in-license pending patent applications from MSK covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2031 through 2041, without taking into account any possible patent term adjustments, extensions or supplementary protections. However, no assurance can be given that the USPTO or relevant foreign patent offices will grant any of these patent applications. Even if granted, we may fail to obtain patent term extensions or supplementary protection certificates covering our products.

We may incur substantial costs as a result of litigation or other proceedings relating to patents, and we may be unable to protect our rights to our product candidates, products and technologies.

If we or our licensors choose to go to court to stop a third party from using the inventions claimed in our owned or in-licensed patents, that third party may ask the court to rule that the patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we or they, as the case may be, were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we or they, as the case may be, do not have the right to stop others from using the inventions.

There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the third party on the ground that such third party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the

USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents. Similar considerations pertain to patents granted outside of the United States, for which the validity, enforceability and/or scope of protection may be influenced by changing national and/or international legal principles.

We, or our licensors, may not be able to detect infringement against our owned or in-licensed patents, as the case may be, which may be especially difficult for manufacturing processes or formulation patents. Even if we or our licensors detect infringement by a third party of our owned or in-licensed patents, we or our licensors, as the case may be, may choose not to pursue litigation against or settlement with the third party. If we, or our licensors, later sue such third party for patent infringement, the third party may have certain legal defenses available to it, which otherwise would not be available except for the delay between when the infringement was first detected and when the suit was brought. Such legal defenses may make it impossible for us or our licensors to enforce our owned or in-licensed patents, as the case may be, against such third party. If another party questions the patentability of any of our claims in our owned or in-licensed U.S. patents, the third party can request that the USPTO review the patent claims such as in an inter partes review, ex parte re-exam or post-grant review proceedings. These proceedings are expensive and may result in a loss of scope of some claims or a loss of the entire patent. In addition to potential USPTO review proceedings, we may become a party to patent opposition proceedings in the European Patent Office, or EPO, or similar proceedings in other foreign patent offices, where either our owned or in-licensed foreign patents are challenged. The costs of these opposition or similar proceedings could be substantial, and such oppositions may result in a loss of scope of some claims or a loss of the entire patent. An unfavorable result at the USPTO, EPO or other patent office may result in the loss of our right to exclude others from practicing one or more of our inventions in the relevant country or jurisdiction, which could have a material adverse effect on our business.

We may incur substantial costs as a result of litigation or other proceedings relating to intellectual property rights other than patents, and we may be unable to protect our rights to our product candidates, products and technologies.

We may rely on trade secrets and confidentiality or nondisclosure agreements to protect our proprietary technology and know-how, especially where we do not believe patent protection is appropriate or obtainable. Where we enter into agreements imposing confidentiality or nondisclosure obligations upon employees or third parties to protect our proprietary technology and know-how, these confidentiality obligations may be breached or may not provide meaningful protection for our trade secrets or proprietary technology and know-how. Furthermore, despite the existence of such confidentiality and nondisclosure agreements, or other contractual restrictions, we may not be able to prevent the unauthorized disclosure or use of our confidential proprietary information or trade secrets by consultants, vendors, former employees or current employees. In addition, adequate remedies may not be available in the event of an unauthorized access, use, or disclosure of our trade secrets or know-how.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets effectively or to the same extent as the laws of the United States. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful.

Third parties may obtain knowledge of our trade secrets through independent development or other access by legal means. The occurrence of such events could limit or preclude our ability to produce or sell our products in a competitive manner or otherwise have a material adverse effect on our business.

If we are sued for infringing patents or other intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation may have a material adverse effect on our business.

Our commercial success depends upon our ability to develop, manufacture, market and sell our products or product candidates and use our proprietary technologies without infringing the proprietary rights of third parties. U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields relating to our product candidates or products. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that others may assert that our products or product candidates infringe others' patent rights. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs,

products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates or products, technologies or methods.

In addition, because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology related to our products or product candidates, technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may affect technology covered by our owned and in-licensed patent applications or patents, which could require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to those owned by or in-licensed to us, we or, in the case of in-licensed technology, the licensor may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. If we or one of our licensors is a party to an interference proceeding involving a U.S. patent application on inventions owned by or in-licensed to us, we may incur substantial costs, divert management's time and expend other resources, even if we are successful.

There is a substantial amount of litigation involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries generally. We may be subject to, or threatened with litigation by third parties having patent or other intellectual property rights alleging that our product candidates or products and/or proprietary technologies infringe, misappropriate or violate their intellectual property rights.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;
- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates or products, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, it may not be offered on reasonable terms and may require that we pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our products or product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may choose to challenge the patentability of claims in a third party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These

proceedings are expensive and may consume our time or other resources. We may choose to challenge a third party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and such proceedings may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third party alleging that the patent may be infringed by our product candidates or products or proprietary technologies.

We may not be able to protect our intellectual property rights with patents throughout the world.

Filing, prosecuting and defending patents on all of our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technology 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 have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products or product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends upon 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.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force, which would have a material adverse effect on our business.

Failure to secure trademark registrations could adversely affect our business.

If we do not successfully register our trademarks, we may encounter difficulty in enforcing, or be unable to enforce, our trademark rights against third parties, which could adversely affect our business and our ability to effectively compete in the marketplace. When we file registration applications for trademarks relating to our products or product candidates, those applications may be rejected, and registered trademarks may not be obtained, maintained or enforced. During trademark registration proceedings in the United States and foreign jurisdictions, we may receive rejections. We are given an opportunity to respond to those rejections, but we may not be able to overcome such rejections. In addition, in the United States Patent and Trademark Office and in comparable agencies in many foreign jurisdictions, third parties may oppose pending trademark registration applications or seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademark registrations may not survive such proceedings.

In addition, any proprietary name we use, such as DANYELZA, or propose to use with any of our products or product candidates in the United States must be approved by the FDA, regardless of whether we have registered, or applied to register, the proposed proprietary name as a trademark. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable proprietary product name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA.

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, which may have a material adverse effect on our business.

We rely on our trademarks, trade names, service marks, domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We rely on trademark protections to protect our business and our products and services. We generally seek to register and continue to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate. Our registered trademarks or unregistered trademarks, trade names or service marks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Effective trademark protection may not be available or may not be sought in every country in which our products are made available and contractual disputes may affect the use of marks governed by private contract. Similarly, not every variation of a domain name may be available or be registered, even if available. We may not be able to protect our rights to these trademarks, trade names, service marks and domain names, which we need to build brand name recognition in our markets of interest. And while we seek to protect the trademarks we use in the United States and in other countries, we may be unsuccessful in obtaining registrations and/or otherwise protecting these trademarks. If that were to happen, we may be prevented from using our names, brands and trademarks unless we enter into appropriate royalty, license or coexistence agreements. Over the long term, if we are unable to establish name recognition based on our trademarks, trade names, service marks and domain names, then we may not be able to compete effectively, resulting in a material adverse effect on our business.

Risks related to employee matters and managing growth

We have a limited number of employees and depend heavily on our executive officers and consultants. Our future success depends on our ability to retain our senior management and other key executives and to attract, retain and motivate qualified personnel. The loss of their services could materially harm our business.

We are highly dependent on the members of our executive management as well as the other principal members of our management and scientific teams. Our agreements with any of them do not prevent them from terminating their employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. The loss of the services of any of these persons could impede the achievement of our research, development and commercialization objectives.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. We intend to conduct our operations in the New York City metropolitan area, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock option and/or restricted stock grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us.

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

We have expanded and continue to expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of sales and marketing, clinical operations, regulatory affairs and, drug development. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical 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 stock

Our executive officers, directors and principal stockholders have ownership of a significant percentage of our stock and will be able to exercise significant influence over matters subject to stockholder approval.

As of November 2, 2021, our executive officers, directors and our stockholders, which own more than 5% of our outstanding common stock beneficially own shares representing approximately 35.9% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management or members of our board of directors.

Provisions in our amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;

- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and

- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, or DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

An active trading market for our common stock may not be sustained and, as a result, it may be difficult for you to sell your shares of our common stock.

Our shares of common stock began trading on The NASDAQ Global Select Market on September 21, 2018. Given the limited trading history of our common stock, there is a risk that an active trading market for our shares will not be sustained, which could put downward pressure on the market price of our common stock and thereby affect the ability of our stockholders to sell their shares.

Effective as of December 31, 2020, we became a large accelerated filer and were no longer an emerging growth company. We are not able to take advantage of the reduced disclosure requirements applicable to emerging growth companies.

As a result of our public float (the market value of our common shares held by non-affiliates) as of June 30, 2020, we became a large accelerated filer as of December 31, 2020 and therefore no longer qualified as an "emerging growth company," as defined in the JOBS Act. Additionally, due to our public float as of June 30, 2020, we no longer qualified as a "smaller reporting company" as defined in the Exchange Act. As a large accelerated filer, we are subject to certain disclosure and compliance requirements that apply to other public companies but did not previously apply to us due to our status as an emerging growth company. These requirements include, but are not limited to:

- the requirement that our independent registered public accounting firm attest to the effectiveness of our internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act of 2002;

- compliance with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation;

- the requirement that we provide full and more detailed disclosures regarding executive compensation; and

- the requirement that we hold a non-binding advisory vote on executive compensation and obtain stockholder approval of any golden parachute payments not previously approved.

We expect that compliance with the additional requirements of being a large accelerated filer will increase our legal and financial compliance costs and cause management and other personnel to divert attention from operational and other business matters to devote substantial time to public company reporting requirements. In addition, if we are not able to comply with changing requirements in a timely manner, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities, which would require additional financial and management resources.

Our ability to use our net operating loss carryforwards and certain other tax attributes may be limited.

Utilization of net operating loss carry forwards depends on many factors, including our future income, which cannot be assured, and the impact of the Tax Reform Bill. Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. The Company has performed an analysis of its Section 382 ownership changes through March 31, 2021. Due to the large annual limitation, the Company believes that it is more likely than not that none of the net operating loss carryforwards will expire as a result of the limitation from the ownership change under Section 382.

Because we do not anticipate paying any cash dividends on our capital stock for the foreseeable future, capital appreciation, if any, of our common stock will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Future sales of common stock by stockholders may have an adverse effect on the then prevailing market price of our common stock.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, 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.

Sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933, or the Securities Act. There were 43,643,916 shares of common stock outstanding as of November 2, 2021. Of these shares of our common stock, 6,900,000 shares sold in our initial public offering in 2018, 5,134,750 shares sold in our public offering in 2019 and 2,804,878 shares sold in our public offering in February 2021 are freely tradable, without restriction, in the public market. As of November 2, 2021 holders of approximately 2,550,348 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also registered 6,200,000 shares of our common stock that we may issue under our equity compensation plans.

Also, in general under Rule 144, a non-affiliated person who has satisfied a six-month holding period in a company registered under the Exchange Act, as amended, may, sell their restricted common stock without volume limitation, so long as the issuer is current with all reports under the Exchange Act in order for there to be adequate common public information.

Affiliated persons may also sell their common shares held for at least six months, but affiliated persons will be required to meet certain other requirements, including manner of sale, notice requirements and volume limitations. Non-affiliated persons who hold their common shares for at least one year will be able to sell their common stock without the need for there to be current public information in the hands of the public. Future sales of shares of our public float or by restricted common stock made in compliance with Rule 144 may have an adverse effect on the then prevailing market price, if any, of our common stock.

We may issue additional shares of our common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investments or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

Our amended and restated certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against us and our directors, officers and employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware) is the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the DGCL or our amended and restated certificate of incorporation or amended and restated bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. This exclusive forum provision may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our sales of our common stock by us, our insiders or other stockholders.

General risk factors

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our stockholders if we issue equity securities, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integration;
- the diversion of our management’s attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing products or product candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities, which could impair our ability to grow or obtain access to technology or products that may be important to the development of our business.

We expect our operating results to fluctuate in future periods, which may adversely affect our stock price.

Our quarterly operating results have fluctuated in the past, and we believe they will continue to do so in the future. Our operating results may fluctuate due to the level of success of our commercial efforts, as well as the variable nature of our operating expenses as a result of the timing and magnitude of expenditures. In one or more future periods, our results of operations may fall below the expectations of securities analysts and investors. In that event, the market price of our common stock could decline.

Drug development is a lengthy and expensive process, with an uncertain outcome. If clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs, experience delays in completing, or ultimately be unable to complete, the development of our product candidates or be unable to obtain marketing approval. We may encounter substantial delays in our clinical trials, or may not be able to conduct our trials on the timelines we expect.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Failure of one or more clinical trials can occur at any stage of testing. The outcome of pre-clinical studies and early stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial, such as the results of our ongoing clinical trials of our lead product candidates, do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

No assurance can be given that any clinical studies will be conducted as planned or completed on schedule, if at all. In addition, we cannot be sure that we will be able to submit INDs for any of our product candidates in the future and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these clinical studies begin, issues may arise that could suspend or terminate such clinical trials. A failure of one or more clinical studies can occur at any stage of testing, and our future clinical studies may not be successful.

A variety of risks associated with operating our business internationally, including through collaboration partners, could materially adversely affect our business.

We plan to seek regulatory approval of our product candidates outside of the United States, and submitted a MAA for omburtamab to EMA in April 2021 for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG and Adium Pharma S.A. Accordingly, we and our existing and potential collaborators in jurisdictions outside the US, are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including local transfer pricing regulations and withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the Foreign Corrupt Practices Act of 1977, or FCPA, Office of Foreign Assets Control, or OFAC, Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our current and planned international operations may materially adversely affect our ability to attain or maintain profitable operations.

Our internal computer systems, or those used by our third-party research institution collaborators, CROs, CMOs, other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs, CMOs, other contractors and consultants are vulnerable to damage from computer viruses, cyber-attack, malicious intrusion, breakdown or other significant disruption and unauthorized access. Although to our knowledge we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, terrorist activities, other natural or man-made disasters or business interruptions, for which we are predominantly self-insured, and other severe hazards or global health crises, such as an outbreak of Ebola or the ongoing global COVID-19 pandemic, or other actual or threatened epidemic, pandemic, outbreak and spread of a communicable disease or virus, in the countries where we operate or plan to sell our products, if approved, could adversely affect our operations and financial performance. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our DANYELZA and our product candidates.

Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our third-party collaborators', including MSK's, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we intend to maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. The ultimate extent of the impact of any epidemic, pandemic or other global health crisis on our business, financial condition and results of operations will depend on future developments which are highly uncertain and cannot be predicted, including new information that may emerge concerning the duration and severity of such epidemic, pandemic or other global health crisis, actions taken to contain or prevent their further spread and the pace of global economic recovery following containment of the spread.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our product candidates.

We face an inherent risk of product liability as a result of the sale of DANYELZA and clinical testing of our product candidates and will face an even greater risk if we commercialize more products. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during use, clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants and inability to continue clinical trials;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize any product candidate;
- loss of any potential future revenue; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of DANYELZA or any product candidates we develop, alone or with collaborators. The amount of clinical trial and product liability insurance coverage that we may obtain, may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or

replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

Brexit may affect our operations.

On January 31, 2020 the United Kingdom withdrew from and ceased to be part of the European Union, commonly referred to as Brexit. Trade between European Union member states and the United Kingdom is now governed by the EU-UK Trade and Cooperation Agreement, which took effect after the Brexit transition period expired on December 31, 2020. The EU-UK Trade and Cooperation Agreement contains a number of general provisions on regulation and regulatory practice that are intended to facilitate exchange of goods and services between the European Union and the United Kingdom. However, since a significant proportion of the regulatory framework in the United Kingdom is derived from European Union directives and regulations, Brexit could materially impact the regulatory regime with respect to the approval and/or sale of our product candidates in the United Kingdom or the European Union. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. The unavoidable uncertainties and events related to Brexit could cause volatility in currency exchange rates, interest rates, and European, United Kingdom or worldwide political, regulatory, economic or market conditions and contribute to instability in political institutions, regulatory agencies and financial markets. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for our product candidates, which could significantly and materially harm our business. Brexit is likely to lead to legal uncertainty and potentially divergent national laws and regulations as the United Kingdom determines which EU laws to replace or replicate. Any of these effects of Brexit, and others we cannot anticipate, could adversely affect our business, financial condition, and results of operations.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the laws of the FDA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. As we have obtained FDA approval of DANYELZA and have begun commercializing DANYELZA in the United States, our exposure under such laws has increased significantly, and our costs associated with compliance with such laws have increased significantly and are likely to continue to increase. These laws impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for 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 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 these laws or regulations. 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, including the imposition of significant fines or other sanctions.

We may be subject to claims that our licensors, employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their former employers or their clients.

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, 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, it could have a substantial adverse effect on the price of our common stock. This type of litigation or proceeding 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 intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

The increasing use of social media platforms presents new risks and challenges.

Social media is increasingly being used to communicate about our drug, clinical development programs, and the diseases our drug and drug candidates are being developed to treat, and we are utilizing what we believe is appropriate social media in connection with our commercialization efforts for DANYELZA and we intend to do the same for our future products, if approved. Social media practices in the biopharmaceutical industry continue to evolve and regulations relating to such use are not always clear. This evolution creates uncertainty and risk of noncompliance with regulations applicable to our business, resulting in potential regulatory actions against us. For example, patients may use social media channels to comment on their experience in an ongoing blinded clinical study or to report an alleged adverse event, or AE. When such disclosures occur, there is a risk that we fail to monitor and comply with applicable AE reporting obligations or we may not be able to defend our business or the public's legitimate interests in the face of the political and market pressures generated by social media due to restrictions on what we may say about our investigational products. There is also a risk of inappropriate disclosure of sensitive information or negative or inaccurate posts or comments about us on any social networking website. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face regulatory actions, or incur other harm to our business.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock.

Our stock price is likely to be volatile. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Since our common stock began trading on The NASDAQ Global Select Market on September 22, 2018, our stock has traded at prices as low as $14.16 per share and as high as $55.22 per share through November 2, 2021. As a result of this volatility, you may not be able to sell your common stock at or above the price your paid for it.

The market price for our common stock may be influenced by many factors, including:

- our ability to successfully launch and commercialize DANYELZA and any other product candidates, if approved;
- the timing and results of clinical trials of any of our product candidates;
- regulatory actions with respect to our products or product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- establishment or termination of collaborations for our products and product candidates or development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of revenues and expenses related to any of our products, product candidates or development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- our ability to accurately forecast demand for our products, actual or anticipated changes in forecasts of financial performance, or changes in development timelines;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this "Risk Factors" section.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and our resources, which could harm our business.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. We were no longer an "emerging growth company" as of December 31, 2020 as the market value of our common stock held by non-affiliates exceeded $700.0 million as of June 30, 2020.

Our inability to operate controls effectively may not enable us to avoid material weaknesses in our internal control over financial reporting in the future. An adverse report on the effectiveness of our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act in future years, by our independent registered public accounting firm could have a material adverse impact on our company and financial statements and we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

The rules governing the standards that must be met for management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation. In connection with our and our independent registered public accounting firm's evaluations of our internal control over financial reporting, we may need to upgrade systems, including information technology, implement additional financial and management controls, reporting systems, and procedures, and hire additional accounting and finance staff.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third-party litigation, as well as investigations by the SEC, the Nasdaq Global Select Market, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. Further, any delay in compliance with the auditor attestation provisions of Section 404 could subject us to a variety of administrative sanctions, including ineligibility for short-form resale registration, action by the SEC and the suspension or delisting of our common stock, which could reduce the trading price of our common stock and could harm our business.

We will continue to incur costs associated with satisfying our obligations as public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, and as a large accelerated filer we will incur significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and rules subsequently implemented by the SEC and Nasdaq have imposed various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

Recent Sales of Unregistered Equity Securities

During the period covered by this Quarterly Report on Form 10-Q, we did not issue securities that were not registered under the Securities Act.

Use of Proceeds of Our Public Offerings

On September 25, 2018, we completed the initial public offering of our common stock, or IPO pursuant to which we issued and sold 6,900,000 shares of our common stock at a price to the public of $16.00 per share which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our initial public offering of $110.4 million, or aggregate net proceeds of approximately $99.8 million after deducting underwriting discounts and commissions and offering expenses. Merrill Lynch, Pierce Fenner & Smith Incorporated and Cowen and Company, LLC acted as joint book-running managers for the initial public offering. Canaccord Genuity LLC acted as lead manager and BTIG LLC acted as co-manager for the initial public offering.

On November 1, 2019, we completed a secondary public offering of our common stock pursuant to which we issued and sold 5,134,750 shares of our common stock at a price to the public of $28.00 per share which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our secondary public offering of $143.8 million, or aggregate net proceeds of approximately $134.7 million after deducting underwriting discounts and commissions and offering expenses. Morgan Stanley, J.P. Morgan and BofA Securities acted as joint book-running managers for the secondary public offering. Wedbush PacGrow and H.C. Wainwright & Co. acted as co-managers for the secondary public offering.

On February 22, 2021, we completed a secondary public offering of our common stock pursuant to which we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share which included the

exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our secondary public offering of $115.0 million, or aggregate net proceeds of approximately $107.7 million after deducting underwriting discounts and commissions and offering expenses J.P. Morgan, Morgan Stanley and BofA Securities acted as joint book-running managers for the secondary public offering. Kempen & Co. U.S.A. and H.C. Wainwright & Co. acted as co-managers for the secondary public offering.

None of the underwriting discounts and commissions or offering expenses were incurred or paid, directly or indirectly, to directors or officers of ours or their associates or to persons owning 10 percent or more of our common stock or to any of our affiliates, and we have not used any of the net proceeds from the public offerings to make payments, directly or indirectly, to any such persons.

We have invested the net proceeds from the public offerings in cash and cash equivalents. There has been no material change in our planned use of proceeds as described in our final prospectus filed pursuant to Rule 424(b)(5) under the Securities Act with the SEC on February 18, 2021.

As of September 30, 2021, we had cash and cash equivalents of $215.7 million.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibit Index, which Exhibit Index is incorporated herein by reference.

3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities and Exchange Commission on September 26, 2018)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities and Exchange Commission on September 26, 2018)
10.1	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018)
10.2	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018)
10.3	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018)

10.4	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018)
10.5	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018) 2018
10.6	2018 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-226999) filed with the Securities and Exchange Commission on August 24, 2018)
10.7++	Amendment No. 1, dated March 18, 2021 to License Agreement, dated as of August 20, 2015 between Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.7 to Registrant's Form 10-Q filed May 6, 2021)
10.8	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (as amended, employees, consultants and service providers other than directors) (incorporated by reference to Exhibit 10.8 to Registrant's Form 10-Q filed November 5, 2020)
10.9	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (as amended, directors) (incorporated by reference to Exhibit 10.9 to Registrant's Form 10-Q filed November 5, 2020)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	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	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

+ Furnished herewith.

++ Portions of the exhibit have been omitted because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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.

Y-MABS THERAPEUTICS, INC.

Dated: November 4, 2021

By: /s/ Claus Juan Møller San Pedro
Name: Claus Juan Møller San Pedro
Title: Chief Executive Officer
(Principal Executive Officer)

Dated: November 4, 2021

By: /s/ Bo Kruse
Name: Bo Kruse
Title: EVP, Chief Financial Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Claus Juan Møller San Pedro certify that:

1. I have reviewed this quarterly report on Form 10-Q of Y-mAbs Therapeutics, Inc.;

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.

Dated: November 4, 2021

By: /s/ Claus Juan Møller San Pedro
Name: Claus Juan Møller San Pedro
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Bo Kruse, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Y-mAbs Therapeutics, Inc.;

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.

Dated: November 4, 2021

By: /s/ Bo Kruse
Name: Bo Kruse
Title: EVP, Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Y-mAbs Therapeutics, Inc. (the "Company") hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 4, 2021

By: /s/ Claus Juan Møller San Pedro
Name: Claus Juan Møller San Pedro
Title: Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

Pursuant to 18 U.S.C. § 1350, as created by Section 906 of the Sarbanes-Oxley Act of 2002, the undersigned officer of Y-mAbs Therapeutics, Inc. (the "Company") hereby certifies, to his knowledge, that:

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended September 30, 2021 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 4, 2021

By: /s/ Bo Kruse
Name: Bo Kruse
Title: EVP, Chief Financial Officer
(Principal Financial Officer)