Table of Contents

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 June 30, 2022
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 43,719,549 shares of Common Stock ($0.0001 par value) outstanding as of August 3, 2022.

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," "continue," "could," "estimate," "expect," "contemplate," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "will," "would", "goal," "aim" 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 risks, 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, except as required by law.

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 under "Risk Factors" and include, but are not limited to, the following:

- We may not be able 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 or in any other jurisdictions where we may receive marketing approval in the future;

- We may not be able to successfully implement 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;
- Our expectations with respect to 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 may not be realized;
- We may not be successful in obtaining approval of our biological license application, or BLA, for omburtamab, or a priority review voucher, or PRV, for omburtamab and expectations with respect to the commercial value from any such PRV may not be realized;
- We may not be successful in implementing our business strategy, including our ability and plans in continuing to build out our commercial infrastructure and successfully launching, marketing, and selling DANYELZA, omburtamab and any 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, market access and patient support activities of DANYELZA and related assumptions;
- Expectations with respect to the pricing, coverage and reimbursement of, and the extent to which patient assistance programs are utilized for DANYELZA, omburtamab or any current or future product candidate for which we may receive marketing approval may not be realized;
- Expectations with respect to our ongoing and future clinical trials for DANYELZA and our lead product candidate omburtamab and other product candidates, whether conducted by us or by any of our collaborators, may not be realized, including the timing of initiation of these trials, the pace of enrollment, the completion of enrollment, the availability of data from, and the outcome of, these trials, and the expected dates of BLA submission and potential approval by the United States Food and Drug Administration, or FDA, and equivalent foreign regulatory authorities;
- Our ability to manage our business, operations and clinical development plans and timelines have been and could be further adversely affected by the effects of health epidemics, including the COVID-19 pandemic, on the manufacturing, clinical trial and other business activities performed by us or by third parties with whom we conduct business, including our contract manufacturers, or CMOs, contract research organizations, or CROs, shippers and others;
- We may be unable to attract, integrate, manage and retain qualified personnel or key employees;
- Expectations with respect to the timing of and our ability to obtain and maintain regulatory, marketing and reimbursement approvals for our product candidates may not be realized;
- We may be unable to successfully implement our commercialization, marketing and manufacturing capabilities and strategy;
- If we are unable to establish and maintain sufficient intellectual property position, strategy and scope of protection for the intellectual property rights covering our product candidates and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours and our ability to successfully commercialize our products, product candidates and other proprietary technologies, if approved, may be adversely affected;
- We may be unable to identify and develop additional product candidates and technologies with significant commercial potential;
- We may be unable to enter into collaborations or strategic partnerships for the development and commercialization of our product candidates and future operations, and the potential benefits of any such collaboration or partnership may not be realized;
- We are dependent on our ability to continue to maintain and leverage our relationship with Memorial Sloan Kettering Cancer Center, or MSK, including our exclusive rights to the 2015 MSK License Agreement (as amended), or MSK License, the 2020 SADA Technology License Agreement, or SADA License Agreement, and current and future technology and our relationship with MSK as a user of DANYELZA and any future products;

- Our expectations related to the use of our cash and cash equivalents, and how long our cash resources are expected to last, may be inaccurate and we may require additional funding sooner than we expect;
- We will require substantial additional funding to finance our operations, complete the development and commercialization of our product and product candidates and evaluate future product candidates, and programs or other operations;
- The timing and amount of any future financing transaction and our common stock price and other factors may impact our ability to raise additional capital on favorable terms;
- Expectations with respect to our financial performance, including our estimates regarding revenues, expenses, cash flow, and capital expenditure requirements may not be realized;
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more effective than ours;
- Our business, financial condition and results of operations have been and may in the future be adversely affected by the global COVID-19 pandemic, including the pace of commercialization of DANYELZA;
- Our business, financial condition and results of operations have been and may in the future be adversely affected by macroeconomic conditions, such as rising inflation, uncertain global financial markets, supply chain disruptions, and by geopolitical events, including the recent global conflict resulting from the invasion of Ukraine by Russia, and sanctions related thereto, which resulted in the suspension of our clinical trial and regulatory activities in Russia;
- We currently depend on a small number of third-party CMOs and expect it would be difficult to find a suitable replacement for the complex and difficult manufacture of our product candidates. The loss of any of these CMOs or the failure of any of them to meet their obligations to us could affect our ability to develop omburtamab in a timely manner or to continue to sell DANYELZA;
- We are subject to government laws and regulations, and we may be unable to comply with healthcare laws and regulations in the United States and any applicable foreign countries, including, without limitation, those applying to the marketing and sale of pharmaceutical products; and
- Other risks and uncertainties described in the section herein entitled “Risk Factors.”

TABLE OF CONTENTS

You should read this Quarterly Report on Form 10-Q 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)

	June 30, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 133,665	$ 181,564
Accounts receivable, net	7,208	7,712
Inventories	6,794	5,512
Other current assets	6,253	7,473
Total current assets	153,920	202,261
Property and equipment, net	1,554	1,847
Operating lease right-of-use assets	2,381	3,842
Intangible assets, net	1,574	1,663
Other assets	5,749	3,170
TOTAL ASSETS	$ 165,178	$ 212,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 11,291	$ 13,552
Accrued liabilities	17,067	12,540
Operating lease liabilities, current portion	1,092	1,783
Total current liabilities	29,450	27,875
Accrued milestone and royalty payments	2,250	2,100
Operating lease liabilities, long-term portion	1,302	1,851
Other liabilities	780	851
TOTAL LIABILITIES	33,782	32,677
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at June 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2022 and December 31, 2021; 43,720,038 and 43,694,716 shares issued at June 30, 2022 and December 31, 2021, respectively	4	4
Additional paid in capital	537,962	519,206
Accumulated other comprehensive income	3,104	1,371
Accumulated deficit	(409,674)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	131,396	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 165,178	$ 212,783

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Income / (Loss) and Comprehensive Income / (Loss)

(unaudited)

(In thousands, except share and per share data)

	Three months ended June 30,		Six months ended June 30,	
	2022	2021	2022	2021
REVENUES				
Product revenue, net	$ 9,797	$ 8,951	$ 20,283	$ 14,334
License revenue	1,000	2,000	1,000	2,000
Total revenues	10,797	10,951	21,283	16,334
OPERATING COSTS AND EXPENSES				
Cost of goods sold	1,140	200	2,972	293
License royalties	100	210	100	210
Research and development	26,420	19,778	49,332	41,357
Selling, general, and administrative	23,082	13,475	36,520	25,445
Total operating costs and expenses	50,742	33,663	88,924	67,305
Loss from operations	(39,945)	(22,712)	(67,641)	(50,971)
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	—	—	62,010
Interest and other loss	(1,186)	(225)	(1,558)	(563)
NET INCOME / (LOSS)	$ (41,131)	$ (22,937)	$ (69,199)	$ 10,476
Other comprehensive income				
Foreign currency translation	1,422	78	1,733	513
COMPREHENSIVE INCOME / (LOSS)	$ (39,709)	$ (22,859)	$ (67,466)	$ 10,989
Net income / (loss) per share attributable to common stockholders, basic	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.25
Weighted average common shares outstanding, basic	43,718,748	43,569,482	43,713,967	42,724,813
Net income / (loss) per share attributable to common stockholders, diluted	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.23
Weighted average common shares outstanding, diluted	43,718,748	43,569,482	43,713,967	45,080,419

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, 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 loss	—	—	—	—	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

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2021	43,694,716	$ 4	$ 519,206	$ 1,371	$ (340,475)	$ 180,106
Exercise of stock options	16,000	—	32	—	—	32
Stock-based compensation expense	7,449	—	5,091	—	—	5,091
Foreign currency translation	—	—	—	311	—	311
Net loss	—	—	—	—	(28,068)	(28,068)
Balance March 31, 2022	43,718,165	$ 4	$ 524,329	$ 1,682	$ (368,543)	$ 157,472
Stock-based compensation expense	1,873	—	13,633	—	—	13,633
Foreign currency translation	—	—	—	1,422	—	1,422
Net loss	—	—	—	—	(41,131)	(41,131)
Balance June 30, 2022	43,720,038	$ 4	$ 537,962	$ 3,104	$ (409,674)	$ 131,396

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Six months ended June 30,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (69,199)	$ 10,476
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	383	346
Stock-based compensation	18,724	9,525
Foreign currency transactions	1,733	513
Changes in assets and liabilities:		
Accounts receivable, net	504	(8,517)
Inventories	(1,282)	(3,820)
Other current assets	1,220	4,284
Other assets	(2,579)	(1,503)
Accounts payable	(2,261)	(2,569)
Accrued liabilities and other	4,732	2,658
NET CASH USED IN OPERATING ACTIVITIES	(48,025)	(50,617)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	—	(441)
Net proceeds from sale of priority review voucher	—	62,010
NET CASH PROVIDED BY INVESTING ACTIVITIES	—	61,569
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of issuance costs	—	107,725
Proceeds from exercised stock options	32	241
NET CASH PROVIDED BY FINANCING ACTIVITIES	32	107,966
Effect of exchange rates on cash and cash equivalents	94	35
NET INCREASE / (DECREASE) IN CASH AND CASH EQUIVALENTS	(47,899)	118,953
Cash and cash equivalents at the beginning of period	181,564	114,634
Cash and cash equivalents at the end of period	$ 133,665	$ 233,587
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Intangible assets acquisition in accrued milestones and royalty payments	$ 1,500	$ —

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 biopharmaceutical company focused on the development and commercialization of novel, antibody based therapeutic products for the treatment of cancer. The Company is leveraging its proprietary antibody platforms and deep expertise in the field of antibodies to develop a broad portfolio of innovative medicines and has several ongoing clinical trials in progress.

The Company is headquartered in 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 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 the U.S. Food and Drug Administration ("FDA") approval in the United States and regulatory approval in other jurisdictions; marketing or sales capability or experience; uncertainty in getting 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 FDA in November 2020, but there can be no assurance that the Company's other research and development efforts 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 and commercialization 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 consolidated 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 $409,674,000 as of June 30, 2022 and $340,475,000 as of December 31, 2021. Through June 30, 2022, 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, as well as additional funding from the sales of DANYELZA and from the sale of the DANYELZA PRV.

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 June 30, 2022, the Company had cash and cash equivalents of $133,665,000, and as of December 31, 2021 the Company had cash and cash equivalents of $181,564,000. As of the issuance date of the consolidated financial statements for the second quarter ended June 30, 2022, the Company expects that its cash and cash equivalents at June

30, 2022 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 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 any such financing. If successful 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 and 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 the Company's liquidity position which may include significantly reducing the current rate of spending through delaying or 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 ("GAAP") for interim financial information, Accounting Standards Codification ("ASC") Topic 270-10 and the instructions to Quarterly Report on Form 10-Q. Accordingly, these consolidated financial statements do not include all of the information and notes required by GAAP for complete financial statements. The unaudited interim consolidated 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 six month periods ended June 30, 2022 are not necessarily indicative of the results that may be expected for the year ended December 31, 2022, any other interim periods, or any future year or period. The December 31, 2021 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 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, 2021.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are detailed in its Annual Report on Form 10-K for the year ended December 31, 2021.

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 consolidated 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 the Company's 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 or treat COVID-19, as well as the economic impact on local, regional, national and international markets.

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. To date, the Company has not experienced any losses on its cash and cash equivalents. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term and liquid nature. The Company maintains cash balances in excess of insured limits. The Company monitors the financial performance, credit ratings and liquidity of the money market fund to timely assess and respond to any changes in the asset values of the fund. The Company does not anticipate any losses with respect to such cash balances.

Trade Accounts Receivables

The Company's trade accounts receivable balance consists of amounts due from sales of its approved product, DANYELZA. Receivables from product sales are recorded net of allowances which generally include chargebacks, doubtful accounts, rebates, returns, and discounts. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and expected future write-offs. The Company has not historically experienced any significant credit losses. All customer accounts are actively managed, and no material losses are currently expected.

The Company has not experienced any write-offs related to its customers and has not recognized any allowance for doubtful accounts nor reversed any allowances in the six months ended June 30, 2022.

Concentration of Credit Risk

The Company's product sales are made through arrangements primarily with three national specialty distributors in the United States. As of June 30, 2022, the receivables balances from such distributors totaled 91% of the Company's 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 cost includes 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 beginning at the receipt of FDA approval. Prior to FDA approval, the Company expensed such costs as part of research and development expenses.

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 occurs. 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 six months ended June 30, 2022.

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 June 30, 2022 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 111,857	$ —	$ 111,857
Total	$ —	$ 111,857	$ —	$ 111,857

	Fair Value Measurements at December 31, 2021 Using:			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 166,729	$ —	$ 166,729
Total	$ —	$ 166,729	$ —	$ 166,729

During the quarter ended June 30, 2022, there were no transfers between Level 1, Level 2, and Level 3.

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, the Company 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. The Company also elects the practical expedient to not separate lease and non-lease components for all of its 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 9—LICENSE AGREEMENTS AND COMMITMENTS* for the related disclosures.

Revenue Recognition

Product revenue

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

The amount of revenue the Company recognizes 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, the Company estimates, utilizing the expected value method, the amount of revenue that it 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, and the Company reviews these estimates quarterly. If actual results vary from its original estimates, the Company will adjust these estimates quarterly, which would affect net product revenue and earnings in the period such variances occur.

- Rebates and chargebacks

  The Company contracts with United States governmental agencies to enable DANYELZA to be eligible for coverage under the various programs administered by the agencies. The Company estimates the rebates and chargebacks to be provided and deducts these estimated amounts from its gross product revenues. These reserves are recorded in the same period the revenue is recognized, resulting in a reduction of product revenue and the establishment of accrued liabilities for the rebates and a reduction of accounts receivable for the chargebacks. The Company develops estimates for rebates and chargebacks based upon (i) the Company's contracts with these agencies, (ii) the government-mandated discounts applicable to government-funded programs, and (iii) information obtained from hospitals and third party consultants regarding the payor mix. The Company's liability for these rebates and chargebacks mainly consists of claims for which invoices have not yet been received and paid. The Company does not maintain material levels of inventory in the wholesale or retail channel.

- Discounts and distribution-related fees

  The Company provides invoice discounts on DANYELZA sales to its distributors for prompt payment and fees for distribution services and invoice discounts reduce the original accounts receivable balances. The payment terms for sales to distributors generally include a 2% discount for prompt payment or fees for distribution services which are based on contractual rates agreed with the respective distributors. Based on historical data and experiences with the distributors, the Company expects its distributors to earn these discounts and fees and deduct the full amount of these discounts and fees from the Company's gross product revenue at the time such revenues are recognized.

- Returns

  The Company offers its customers limited product return rights for damaged, defective, or expiring products. The Company estimates returns on sales of DANYELZA mainly based on information provided to the Company from the hospitals and distributors. The return reserves are recorded in the

same period the related revenue is recognized, resulting in a reduction of product revenue and an establishment of an accrued liability.

License revenue

In May 2021, the Company entered into an exclusive distribution agreement with Adium Pharma S.A. ("Adium") for Adium to be the exclusive distributor in Latin America of the Company's antibodies omburtamab, if approved, and DANYELZA. As part of this agreement, the Company received and recognized a non-refundable up-front fee of $2,000,000 for the transfer of the license and know-how related to the product indications during the three and six months ended June 30, 2021. The Company may also receive regulatory-based milestone payments up to an aggregate of $3,000,000. In April 2022, the Company received the first of these milestone payments, a non-refundable fee of $1,000,000 that was payable upon submission by the Company for the updated FDA BLA dossier for DANYELZA. In addition, the Company is entitled to royalties based upon the net sales generated by Adium related to the product indications in Latin America. The Company 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. As part of the Company's evaluation of the regulatory milestones constraint, the Company determined that the achievement of such milestones are contingent upon regulatory approvals which are not within the Company's control and therefore not deemed probable. The Company expects that the sales-based milestone payments and royalty arrangements will be recognized when the related sales occur or the milestone is achieved. The Company reevaluates the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur, the Company assesses whether this resolves the constraint and revenue will be recognized.

Segment Information

The Company is engaged solely in the discovery, development, distribution and commercialization 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

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, ("FASB"), and are adopted by the Company as of the specific effective date. The Company adopted ASU 2020-10, ASU 2021-04 and ASU 2020-06 effective January 1, 2022, and the adoption of these new standards did not have a material impact on the Company's consolidated financial statements or disclosures.

The Company has evaluated accounting pronouncements recently issued but not yet adopted and believes that these pronouncements do not apply to the Company's operations and therefore will not have a material impact on the Company's consolidated financial statements or disclosures.

NOTE 4—PRODUCT REVENUE

The Company's product revenues were generated from sales of DANYELZA and totaled $9,797,000 and $20,283,000 for the three and six months ended June 30, 2022, and $8,951,000 and $14,334,000 for the three and six months ended June 30, 2021.

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, discounts and distribution-related fees with contractual right of offset are recorded as a direct reduction to accounts receivable. Accruals for rebates,

distribution-related fees without contractual right of offset and other sales-related deductions are recorded within accrued liabilities. As of June 30, 2022, the Company had recorded accounts receivable allowances of approximately $797,000 and accrued liabilities of $3,082,000 related to product sales during the six months ended June 30, 2022. As of December 31, 2021, the Company had recorded accounts receivable allowances of approximately $486,000 and accrued liabilities of $2,615,000 related to product sales.

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

	Discounts	Contractual Allowances and Government Rebates	Returns	Total
		(in thousands)		
Balance, December 31, 2021	$ 13	$ 3,027	$ 61	$ 3,101
Current provisions relating to sales in current year	46	2,203	253	2,502
Payments/credits relating to sales in current year	(50)	(1,360)	(314)	(1,724)
Balance, June 30, 2022	$ 9	$ 3,870	$ —	$ 3,879

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 six months ended June 30, 2022 and June 30, 2021. Mckesson, AmerisourceBergen, and Cardinal Health accounted for 71%, 10%, and 11%, respectively, of the Company's gross product revenue for the three months ended June 30, 2022. Mckesson and AmerisourceBergen accounted for 75% and 19%, respectively, of the Company's gross product revenue for the three months ended June 30, 2021. Mckesson, AmerisourceBergen, and Cardinal Health accounted for 64%, 17%, and 11%, respectively, of the Company's gross product revenue for the six months ended June 30, 2022. Mckesson and AmerisourceBergen accounted for 77% and 13%, respectively, of the Company's gross product revenue for the six months ended June 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 June 30,		Six months ended June 30,	
	2022	2021	2022	2021
	(in thousands, except per share amounts)			
Net income /(loss) (numerator)	$ (41,131)	$ (22,937)	$ (69,199)	$ 10,476
Weighted-average shares (denominator), basic	43,719	43,569	43,714	42,725
Basic net income / (loss) per share	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.25
Weighted-average shares (denominator), diluted	43,719	43,569	43,714	45,080
Diluted net income / (loss) per share	$ (0.94)	$ (0.53)	$ (1.58)	$ 0.23

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options outstanding and unvested restricted stock units ("RSUs") totaled 6,972,558 shares as of June 30, 2022 and 1,427,850 shares as of June 30, 2021.

NOTE 6—INVENTORIES

Inventories consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw Material	$ 1,500	$ —
Work In Progress	9,306	4,741
Finished Goods	1,276	771
Total Inventories	$ 12,082	$ 5,512

Inventories are classified on the Consolidated Balance Sheets in each respective period (in thousands):

	June 30, 2022	December 31, 2021
CURRENT ASSETS		
Inventories	$ 6,794	$ 5,512
Total recorded in Current Assets	6,794	5,512
NONCURRENT ASSETS		
Other assets	5,288	—
Total recorded in Noncurrent Assets	5,288	—
Total Inventories	$ 12,082	$ 5,512

The Company has classified $1,500,000 of raw material and $3,788,000 of work in progress inventories as noncurrent assets based on its current demand schedule and expectation that such inventory will be utilized in excess of one year from the balance sheet date.

NOTE 7—INTANGIBLE ASSETS, NET

The Company's intangible assets, net as of June 30, 2022 totaled $1,574,000 and related to capitalized milestone payments accrued following FDA approval and commercialization of DANYELZA. The intangible assets net book value as of June 30, 2022 is net of $226,000 of accumulated amortization.

The Company's intangible assets, net as of December 31, 2021 totaled $1,663,000. The intangible assets net book value as of December 31, 2021 is net of $137,000 of accumulated amortization.

Intangible assets are amortized on a straight-line basis based on a 10-year useful life of the assets. Annual amortization expense is expected to be $180,000 each year for the five-year period from 2022 to 2026.

NOTE 8—ACCRUED LIABILITIES

Accrued short-term liabilities at June 30, 2022 and December 31, 2021 are as follows (in thousands):

	June 30, 2022	December 31, 2021
Accrued licensing, milestone and royalty payments	$ 2,438	$ 3,090
Accrued clinical costs	872	915
Accrued compensation and board fees	4,151	1,877
Accrued manufacturing costs	6,251	2,622
Accrued sales reserves	3,082	2,615
Other	273	1,421
Total	$ 17,067	$ 12,540

NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS

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 the Company's 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 8—ACCRUED LIABILITIES* for accrued milestone and royalty payments are inclusive of obligations under the MSK License Agreement, CD33 License Agreement and SADA License Agreement, collectively.

The Company has the following significant license agreements and related commitments which include all obligations that have been paid or accrued as of and for the three and six months ended June 30, 2022 and as of December 31, 2021(in thousands):

Agreements	Cash paid Six months ended June 2022	Cash paid Six months ended June 2021	Expense Three months ended June 2022	Expense Six months ended June 2022	Expense Three months ended June 2021	Expense Six months ended June 2021	Accrued liabilities Current as of June 2022	Accrued liabilities Non-current as of June 2022	Accrued liabilities Current as of December 2021	Accrued liabilities Non-current as of December 2021
MSK	$ 1,263	$ 450	$ 1,083	$ 1,760	$ 210	$ 210	$ 1,683	$ 1,950	$ 1,486	$ 1,650
CD33	—	100	—	—	—	—	150	300	—	450
MabVax	—	—	—	—	10	10	—	—	—	—
SADA	1,000	1,000	—	—	—	—	605	—	1,605	—

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

Research and development is inherently uncertain and should such research and development fail the MSK License Agreement, the CD33 License Agreement, the SADA License 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 respective 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 License Agreement, all time-based milestones coming due within 36 months of the effective date of the agreement, totaling $605,000, have been accrued, as this continues to represent the time period the Company expects 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

The Company has 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 the Company committed to fund certain clinical trials at MSK; two separate core facility service agreements pursuant to which the Company committed to obtaining certain laboratory services from MSK; and in October 2020 the Company entered into a SADA sponsored research agreement pursuant to which the Company 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 the three months ended June 30, 2022 and 2021, the Company incurred research and development expenses of $351,000 and $947,000, respectively, under these agreements. For the six months ended June 30, 2022 and 2021, the Company incurred research and development expenses of $1,047,000 and $1,895,000, 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 established 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, the Company 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 $233,000 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, the Company expanded the space with an additional 235 square feet. The original term of the lease was three years from the date the Company occupied the premises, with an option to extend for an additional two years which the Company exercised 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 into a lease agreement for certain office space in Denmark, which has been amended several times.The lease was renewed on November 1, 2021 with a four year term. The lease is payable in monthly installments of approximately $41,000, which are recognized on a straight line basis.

Total operating lease costs were $701,000 and $646,000 for the three months ended June 30, 2022 and 2021, respectively, and $1,406,000 and $1,291,000 for the six months ended June 30, 2022 and 2021, respectively.

For the three months ended June 30, 2022, the operating lease expenses were recorded as $641,000 in research and development expense and $60,000 in general and administrative expense. For the three months ended June 30, 2021, the expenses were recorded as $587,000 in research and development expense and $59,000 in general and administrative expense. For the six months ended June 30, 2022, the expenses were recorded as $1,279,000 in research and development expense and $127,000 in general and administrative expense. For the six months ended June 30, 2021, the expenses were recorded as $1,174,000 in research and development expense and $117,000 in general and administrative expense.

Cash paid for amounts included in the measurement of lease liabilities for the three and six months ended June 30, 2022 was $601,000 and $1,208,000, respectively, and cash paid for amounts included in the measurement of lease liabilities for the three and six months ended June 30, 2021 was $549,000 and $1,093,000, 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 June 30, 2022 were as follows (in thousands):

	Operating Leases at June 30, 2022
Remainder of 2022	$ 724
Years ending December 31,	
2023	985
2024	509
2025	408
Total lease payments	2,626
Less: Imputed interest	(232)
Total operating lease liabilities at June 30, 2022	$ 2,394

Maturities of operating leases at December 31, 2021 were as follows (in thousands):

Years ending December 31,	Operating Leases at December 31, 2021
2022	$ 1,953
2023	1,025
2024	550
2025	445
Total lease payments	3,973
Less: Imputed interest	(339)
Total operating lease liabilities at December 31, 2021	$ 3,634

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 June 30, 2022, the weighted average remaining lease term is 2.51 years and the weighted average discount rate used to determine the operating lease liability was 6.6%. As of December 31, 2021, the weighted average remaining lease term is 2.62 years and the weighted average discount rate used to determine the operating lease liability was 6.5%.

Former Chief Executive Officer Contractual Severance Related Benefits

On April 27, 2022, the Company announced certain executive management changes. Effective April 22, 2022, Dr. Claus Møller stepped down from his positions as Chief Executive Officer and as a member of the Company's Board of Directors. There were no disagreements with the Company expressed by Dr. Møller on any matters relating the Company's operations, policies or practices. Dr. Møller's contractual severance related benefits provided for cash compensation of $1,428,000, which includes salary and certain benefits continuation. Also, under terms of the equity award agreement, Dr. Møller's outstanding stock option awards will continue to vest as scheduled and become exercisable when vested. This resulted in a non-cash share-based compensation expense charge of $9,286,000 that the Company recognized in three and six months ended June 30, 2022 as there is no longer a service condition related to such awards. The total charge of $10,714,000 related to executive management change was recorded in Selling, General and Administrative expenses during the three and the six months ended June 30, 2022.

Legal Matters

The Company has been named a nominal defendant in a lawsuit filed in the U.S. District Court, Southern District of New York, on August 25, 2021, by a stockholder of the Company, Deborah Donoghue. The suit names the Company's President, Interim Chief Executive Officer and Head of Business Development and Strategy, and member of its board of directors, Mr. Thomas Gad, as an additional defendant and it seeks 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 together with appropriate interest and costs of the lawsuit. On December 17, 2021, Mr. Gad filed a Motion to Dismiss the lawsuit. On August 8, 2022, the Court denied Mr. Gad's Motion to Dismiss the lawsuit. As a result, the lawsuit will enter the discovery phase. The Company continues to be of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company has 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 10—STOCKHOLDERS' EQUITY

Authorized Stock

As of June 30, 2022 and December 31, 2021, 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 43,720,038 shares of its common stock as of June 30, 2022 and 43,694,716 shares of its common stock as of December 31, 2021.

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 June 30, 2022 or December 31, 2021.

Stock grant agreements with non-employees

In April 2020, in connection with the SADA License Agreement, the Company entered into certain stock grant agreements pursuant to which it agreed to issue a total of 213,996 shares to two non-employee researchers who were involved in the development of the SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging antibody system) Pre-targeted Radioimmunotherapy Platform (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 six months ended June 30, 2022, the non-employee researchers vested in an additional 20% of the awards. Therefore, as of June 30, 2022, the two non-employee researchers have vested in 80% of the total grant with the remaining 20% vesting on the anniversary date of the agreement in April 2023. The unvested 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. In April 2020, the Company recognized $7,376,000, the fair value of the issued shares on the grant date, within research and development expense. There is no future expense related to these awards.

In July 2020, pursuant to the stock grant agreements, the Company 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, which matures in April 2023. 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 and the loans are included in other current assets on the Company's Consolidated Balance Sheets.

Issuance of common stock

On February 22, 2021, the Company completed a third public offering of its common stock pursuant to which the Company issued and sold 2,804,878 shares of its 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. The Company received aggregate gross proceeds from the 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 11—SHARE-BASED COMPENSATION

2015 Equity Incentive Plan

The Company's 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 the Company's 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 the Company's employees, directors and consultants and its parent and subsidiary corporations' employees and consultants. A total of 4,500,000 shares of the Company's 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

The Company's 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 the Company's 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 the Company's employees, directors and consultants and the Company's parent and subsidiary corporations' employees and consultants. A total of 5,500,000 shares of the Company's 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 the Company's immediately preceding fiscal year. The exercise price of options granted under the plans must at least be equal to the fair market value of the Company's 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 the Company's 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 June 30, 2022 and 2021, stock-based compensation for stock option grants were $13,549,000 and $4,752,000, respectively, for options granted to employees and directors. Stock-based compensation during the three months ended June 30, 2022 includes $9,286,000 related to the departure of the former Chief Executive Officer as described in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*. For the three months ended June 30, 2022, the expenses were recorded as $2,002,000 in research and development expense and $11,547,000 in selling, general, and administrative expense. For the three months ended June 30, 2021, the expenses were recorded as $1,753,000 in research and development expense and $2,999,000 in selling, general, and administrative expense.

For the six month periods ended June 30, 2022 and 2021, stock-based compensation for stock option grants were $18,566,000 and $9,380,000, respectively, for options granted to employees and directors. Stock-based compensation during the six months ended June 30, 2022 includes $9,286,000 related to the departure of the former Chief Executive Officer as described in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*. For the six months ended June 30, 2022, the expenses were recorded as $3,781,000 in research and development expense and $14,785,000

in selling, general, and administrative expense. For the six months ended June 30, 2021, the expenses were recorded as $3,444,000 in research and development expense and $5,936,000 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, 2021	6,687,128	$ 22.43	$ 26,412	7.21
Granted	425,000	9.51		
Exercised	(16,000)	2.00		
Forfeited	(160,167)	31.03		
Outstanding and expected to vest at June 30, 2022	6,935,961	$ 21.48	$ 25,565	6.87
Exercisable at June 30, 2022	4,350,315	$ 18.19	$ 23,232	5.69

The weighted average fair value of stock options granted for the three and six months ended June 30, 2022 and 2021 was $6.28 and $32.44, respectively. There were 425,000 and 209,000 stock options granted for the three months ended June 30, 2022 and 2021, respectively.

Options granted in the three months ended June 30, 2022, have a maximum contractual term of ten years. There were 425,000 options granted in the three months ended June 30, 2022. During the three months ended June 30, 2022, 255,000 options were granted to senior executives and certain other employees under a retention program for their continued service to the Company over the next two years from the grant date. The options granted under the retention program have a vesting schedule in which 50% vest on the first anniversary of the grant date and the remainder vest on the second anniversary of the grant date, provided in each case that the recipient remains an employee of the Company through each vesting date. The expected term for the options granted under the retention program was 5.75 years and the risk-free interest rate was approximately 2.8%. The remaining 170,000 options granted in the three months ended June 30, 2022, have a vesting schedule in which 25% vest on the first anniversary of the grant date and the remainder vest ratably on a monthly basis over the next 36 months, provided in each case that the recipient remain an employee of the Company through each vesting date. The expected term of those options was 6.25 years and the risk-free interest rate was approximately 2.8%.

The above noted retention program also included a cash bonus payable to the same senior executives and other employees that is payable on the anniversary of the grant date provided that the respective recipient remains an employee of the Company through such date and subject further to the achievement by such date of the Company's product candidate omburtamab having received marketing approval by the FDA. The Company did not record compensation expense related to the cash retention program in the three and six months ended June 30, 2022, as the payment will not be deemed probable until the Company receives FDA approval for omburtamab. The aggregate value of the cash bonus portion of the retention program is $1,091,000 as of June 30, 2022.

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. The Company's public trading commenced in September 2018, and, as a result, there is only limited available historical volatility experience. Therefore, the Company estimates its expected share price volatility based on a combination of the historical volatility of a group of publicly traded peer companies and the historical volatility of the Y-mAbs share price, and the Company expects to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards as the Company has 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 the Company has never paid cash dividends on shares

of its common stock and does not expect to pay any cash dividends in the foreseeable future. There were no significant changes to the inputs included in the Black-Scholes option pricing model during the three and six months ended June 30, 2022.

As of June 30, 2022, the Company had $27,608,000 of unrecognized compensation expense related to employee stock options that are expected to vest over a period of 2.65 years. As of June 30, 2021, the Company had $47,280,000 of unrecognized compensation expense related to employee stock options that are expected to vest over a period of 2.73 years.

Restricted Stock Unit Activity

For the three months ended June 30, 2022 and June 30, 2021, stock-based compensation for restricted stock unit grants was $84,000 and $75,000, respectively. For the three months ended June 30, 2022, the expenses were recorded as $74,000 in research and development expense and $10,000 in selling, general, and administrative expense. For the three months ended June 30, 2021, the expenses were recorded as $68,000 in research and development expense and $7,000 in selling, general, and administrative expense.

For the six months ended June 30, 2022 and June 30, 2021, stock-based compensation for restricted stock unit grants was $158,000 and $145,000, respectively. For the six months ended June 30, 2022, the expenses were recorded as $142,000 in research and development expense and $16,000 in selling, general, and administrative expense. For the six months ended June 30, 2021, the expenses were recorded as $131,000 in research and development expense and $14,000 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, 2021	28,907	$ 28.04	1.82
Granted	18,102	9.66	
Vested	(9,330)	23.89	
Forfeited	(1,082)	29.81	
Outstanding and expected to vest at June 30, 2022	36,597	$ 19.45	2.20

As of June 30, 2022, the Company had $575,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 2.20 years. As of June 30, 2021, the Company had $585,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 1.99 years.

NOTE 12—RELATED PARTY TRANSACTIONS

MSK is a shareholder of the Company. Under the MSK License Agreement, the SADA License Agreement, the CD33 License Agreement, the MabVax Agreement and various other supporting agreements with MSK, the Company has expensed costs in the total amount of $1,434,000 and $1,157,000 in the three months ended June 30, 2022 and 2021, respectively, for milestones, minimum royalties, and research and development costs. The Company expensed costs in the total amounts of $2,808,000 and $2,105,000 in the six months ended June 30, 2022 and 2021, respectively, under these agreements with MSK. Please refer to *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* for additional details on the Company's agreements with MSK. As of June 30, 2022, the Company had a total of $345,000 recorded as accounts payable, $5,341,000 as accrued liabilities, thereby totaling $5,686,000 due to MSK. As of December 31, 2021, the Company had a total of $748,000 recorded as accounts payable, $5,443,000 as accrued liabilities, thereby totaling $6,191,000 due to MSK.

NOTE 13—INCOME TAXES

The Company provided no current and deferred income taxes on net losses of $41,131,000 and $22,937,000 for the three month periods ended June 30, 2022 and 2021, respectively, and the net loss of $69,199,000 and net income of $10,476,000 for the six month periods ended June 30, 2022 and 2021, 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. Unrecognized tax benefits were $0 and $304,000 at June 30, 2022 and December 31, 2021, respectively. As of June 30, 2022 and December 31, 2021, the Company did not have any interest or penalties accrued related to the total amount of unrecognized tax benefits. The Company's tax returns for the years 2020, 2019, 2018, and 2017 are open for tax examination by U.S. federal and state and Danish tax authorities. During 2022, the review of the Company's transfer pricing policies by the Danish Tax Authorities for tax years 2016 through 2020 was completed resulting in no material impacts to the Company's income tax accounts.

The Company maintains a full valuation allowance on its U.S. and foreign deferred tax assets. 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 14—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 six months ended June 30, 2022 and 2021.

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 the Company's Danish subsidiary. No contributions from the Danish subsidiary were made for the three and six months ended June 30, 2022 and 2021. In addition, health insurance benefits for the Company's Danish employees are fully paid for by such employees. The Company's Danish subsidiary does not incur any costs for these health insurance benefits.

NOTE 15 —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, or PRV, to United Therapeutics Corporation for $105,000,000. The PRV was granted in conjunction with the approval by the FDA of DANYELZA, for the treatment of refractory/relapsed high-risk neuroblastoma. Under the terms of the Company's license agreement with MSK, the Company 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 once the substantive closing conditions included within the agreement were resolved the Company recognized a net gain of $62,010,000 during the six months ended June 30, 2021 related to the sale.

The Company did not recognize a corresponding gain during the three and six months ended June 30, 2022.

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 consolidated 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, 2021 filed with the U.S. Securities and Exchange Commission, or 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 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.

Our only approved drug DANYELZA® (naxitamab-gqgk) was approved by the United States Food and Drug Administration, or FDA, in November 2020 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. We are commercializing DANYELZA in the United States and began shipping the product in February 2021.

DANYELZA is also 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. In addition, we have an ongoing Phase 2 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 for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. We completed the resubmission of the BLA for omburtamab in March 2022 and in May 2022, the FDA accepted our BLA for priority review. The FDA set an action date of November 30, 2022 under the Prescription Drug User Fee Act, or PDUFA; however, we can provide no assurance that omburtamab will ultimately receive FDA approval.

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 two omburtamab follow-on product candidates.

We are advancing a new generation of antibody constructs based on the our proprietary SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or SADA Technology, to create SADA constructs. 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 as our first SADA constructs and in December 2021 we filed an IND for GD2-SADA. We obtained clearance for the IND in July 2022, and expect to treat the first patient in the fourth quarter of 2022. We have secured clinical supplies for a medical radioisotope no-carrier-added, or n.c.a., lutetium-177 from ITM Isotope Technologies Munich SE, or ITM, who will provide its n.c.a. 177Lu for phase 1-3 clinical development of GD2-SADA.

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.

Based on the Y-BiClone platform, we have 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 smallest binding affinity necessary to recruit T cells. We are advancing a CD33 BsAb for the treatment of hematological cancers expressing CD33, a transmembrane receptor expressed on cells of myeloid lineage, for which we filed an IND in December 2021 and treated the first patient during the second quarter of 2022. 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. Our Phase 2 trial with nivatrotamab, a GD2 BsAb product candidate, for Small Cell Lung Cancer, or SCLC, and our Phase 1/2 trial for the treatment of refractory GD2 positive adult and pediatric solid tumors are in the process of being wound down in order to allow for reallocation of resources to our SADA constructs.

Our mission is to become a 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. 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 IPO and proceeds from our two subsequent public offerings, revenues generated from DANYELZA, license revenues, and the proceeds from our sale of the Priority Review Voucher, or PRV, obtained upon FDA approval of DANYELZA.

On February 22, 2021, we completed our most recent 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.

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 a purchase price of $105 million. We paid 40% of the net proceeds from the sale of the PRV to MSK as required under the terms of the MSK License. We have and 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 the gain was recognized within "Other Income, Net" on the Consolidated Statements of Net Income / (Loss) and Comprehensive Income / (Loss) for the six months ended June 30, 2021. Upon the potential FDA approval of omburtamab, we expect that we would receive another PRV, and upon a potential sale of such voucher we would be obligated to pay 33% of the net proceeds from such sale to MSK.

As of June 30, 2022, we had an accumulated deficit of $409.7 million. Our net loss was $41.1 million and $69.2 million for the three and six months ended June 30, 2022, and our net loss was $22.9 million for the three months ended June 30, 2021 and net income was $10.5 million for the six months ended June 30, 2021. 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 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 efforts 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; and
- hire additional research, sales force, commercialization, clinical and scientific personnel.

In August 2015, we entered into a license agreement with MSK, or the MSK License, pursuant to which we have obtained exclusive rights to MSK's rights in our current antibody product candidates including DANYELZA and omburtamab. Under the MSK License, we 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 mid-to-high single digit 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. 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 the SADA Technology 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 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 year ended December 31, 2021, we made a cash payment in the amount of $1.0 million to MSK and MIT under the agreement. During the three months ended June 30, 2022 we made another cash 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 $1.5 million in scientific research at MSK over the following 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 June 30, 2022, we have determined that payment of the minimum royalties is not probable, and accordingly have not accrued for such royalties at June 30, 2022.

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 approximately $4.7 million and $18.1 million, respectively. Sales based milestone payments, totaling approximately $23.8 million, 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 is obligated to make sales-based milestone payments in the total amount up to $60.0 million 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. As of June 30, 2022, we have accrued $0.6 million of the clinical based milestones under the SADA License Agreement which we considered to be estimable and probable and we expect to pay this amount in the fourth quarter of 2022.

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 9—LICENSE AGREEMENTS AND COMMITMENTS.*

For DANYELZA, and for any other product candidates for which we obtain regulatory approval, if any, 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 securities 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 business 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

COVID-19, Geopolitical Events and Macroeconomic Conditions

We are subject to additional risks and uncertainties as a result of the continued spread of COVID-19, adverse geopolitical and macroeconomic events, such as the ongoing conflict between Ukraine and Russia and related sanctions, and uncertain market conditions, including higher inflation and supply chain disruptions, which could continue to have a material impact on our business and financial results.

We continue to closely monitor the ongoing COVID-19 pandemic.

The extent to which the COVID-19 pandemic 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 COVID-19 pandemic, the emergence of new variants of the virus 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. At its height, the COVID-19 pandemic was limiting certain commercialization efforts for DANYELZA and also led to slower initiation of new clinical trials and a fluctuating rate of recruitment for ongoing clinical trials, which has delayed our clinical development activities and thereby postponed certain accompanying costs.

Given the continued evolution of the COVID-19 pandemic and the related complexities and uncertainties associated with the additional variants, the future effects of COVID-19 are unknown and the Company’s financial results may be negatively affected in the future. The COVID-19 pandemic may also have long-term effects on the nature of the

office environment and remote working, which may present strategy, operational, talent recruiting and retention and workplace culture challenges that may adversely affect its business.

As global economic conditions recover from the COVID-19 pandemic, business activity may not recover as quickly as anticipated, and it is not possible at this time to estimate the long-term impact that these and related events could have on our business, as the impact will depend on future developments, which are highly uncertain and cannot be predicted. For instance, product demand may be reduced due to an economic recession, prolonged unemployment, rising inflation rates, labor shortages, reduction in consumer confidence, adverse geopolitical and macroeconomic events, or any similar negative economic condition.

On February 24, 2022, Russia launched a wide-ranging attack on Ukraine. The resulting conflict and retaliatory measures by the global community have created global security concerns, including the possibility of expanded regional or global conflict, which have had and are likely to continue to have, short-term and longer-term adverse impacts on Russia, Ukraine and Europe and around the globe. Sanctions issued by the U.S. and other countries against Russia in response to its attack on Ukraine and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia. In light of the continuously evolving and worsening conditions in the region, we have terminated our clinical trials of DANYELZA in Russia and put on hold our regulatory activities to obtain marketing authorization for DANYELZA in Russia. This has negatively impacted our plans to commercialize and sell DANYELZA in Russia and may therefore adversely affect our business. In addition, the war between Russia and Ukraine has had significant ramifications on global financial markets, including volatility in the U.S. and global financial markets, which has led to disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity globally, and has caused and may continue to cause volatility in the price of our common stock, which may adversely impact our ability to raise capital on favorable terms or at all.

The full economic and social impact of the sanctions imposed on Russia and possible future punitive measures that may be implemented, as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

Omburtamab BLA

On May 31, 2022, we announced FDA acceptance of the Biologics License Application, or BLA, for omburtamab (OMBLASTYS®) for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma for Priority Review. The FDA set an action date of November 30, 2022, under the PDUFA. The FDA also indicated in the BLA filing communication letter that it is planning to hold an advisory committee meeting in October 2022 to discuss the application. We do not expect that the preparation for the advisory committee meeting and the potential launch of omburtamab will have a significant impact on the planned spending for 2022.

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 to DANYELZA and omburtamab. Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* for additional details.

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

We have 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 study and clinical trial materials, including manufacturing of 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 potential regulatory approvals, including the timing of any BLA and Marketing Authorization Application, or MAA, submissions and their acceptance;
- the potential receipt of marketing approvals, including a safety, tolerability and efficacy profile that is satisfactory to the FDA, the European Medicines Agency, or EMA, or any other non-U.S. regulatory authority;
- any requirement by the FDA, the EMA or any other 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, the EMA 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 selling, 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 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 / (Loss), Net

On December 28, 2020, we announced that we entered into a definitive agreement to sell our 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 Agreement, we retained 60% of the net proceeds received from the sale, and the remaining 40% was paid to MSK. As a result, we received net proceeds from this sale of $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 consolidated 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 consolidated 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 occur. 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 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.

Substantially all of our product sales have been in the United States. We had product sales to certain customers that accounted for more than 10% of total gross product revenue for the three and six months ended June 30, 2022 and June 30, 2021. Mckesson, AmerisourceBergen, and Cardinal Health accounted for 71%, 10%, and 11%, respectively, of our gross product revenue for the three months ended June 30, 2022. Mckesson and Cardinal Health accounted for 75% and 19%, respectively, of our gross product revenue for the three months ended June 30, 2021. Mckesson, AmerisourceBergen, and Cardinal Health accounted for 64%, 17%, and 11%, respectively, of our gross product revenue for the six months ended June 30, 2022. Mckesson and Cardinal Health accounted for 77% and 13%, respectively, of our gross product revenue for the six months ended June 30, 2021.

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. Such estimate are 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.

License Revenue

To determine revenue recognition for arrangements that the Company determines are within the scope of Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) the entity satisfies a performance obligation. The company only applies the five-step model to arrangements that meet the definition of a contract with a customer under ASC 606, including when it is probable that the entity will collect the consideration it is entitled to in exchange for the goods or services it transfers to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, the company assesses the goods or services promised within each contract, determine those that are performance obligations, and assesses whether each promised good or service is distinct. The company then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on our relative standalone selling price. In assessing whether a promised good or service is distinct in the evaluation of a license arrangement subject to ASC 606, the Company considers factors such as the research, manufacturing and commercialization capabilities of the licensing partner and the availability of the associated expertise in the general marketplace. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company combines that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct.

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 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.

Our cash equivalents are carried at fair value, determined according to the fair value hierarchy described above.

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 a combination of the historical volatility of a group of publicly-traded peer companies and the historical volatility of the Y-mAbs share price, 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 based on a combination of the historical volatility of a group of publicly traded peer companies and the historical volatility of our share price. 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 June 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended June 30, 2022 and 2021:

	Three Months Ended June 30,		Amount Change	Percentage Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
	(in thousands)		(in thousands)	
REVENUES				
Product revenue, net	$ 9,797	$ 8,951	$ 846	% 9
License revenue	1,000	2,000	(1,000)	(50)
Total revenues	10,797	10,951	(154)	(1)
OPERATING COSTS AND EXPENSES				
Cost of goods sold	1,140	200	940	470
License royalties	100	210	(110)	(52)
Research and development	26,420	19,778	6,642	34
Selling, general, and administrative	23,082	13,475	9,607	71
Total operating costs and expenses	50,742	33,663	17,079	51
Loss from operations	(39,945)	(22,712)	(17,233)	76
OTHER INCOME / (LOSS), NET				
Interest and other loss	(1,186)	(225)	(961)	427
NET LOSS	$ (41,131)	$ (22,937)	$ (18,194)	79

Revenues

We launched DANYELZA in February 2021 and recorded $9.8 million and $9.0 million in net revenues for the three months ended June 30, 2022 and 2021, respectively.

In addition, we recorded $1.0 million and $2.0 million in license revenues for the three months ended June 30, 2022 and 2021, respectively. The license revenue of $1.0 million for the three months ended June 30, 2022 was

recognized upon the delivery of the updated FDA BLA Dossier for DANYELZA in accordance with the non-refundable license milestone under our sublicense with Adium, and we received this $1.0 million payment in the second quarter of 2022. The license revenue of $2.0 million for the three months ended June 30, 2021 was attributable to the revenues earned from the entering into of the sublicense agreement with Adium to outlicense DANYELZA and omburtamab in Latin America. As part of this agreement, we received a non-refundable up-front fee of $2.0 million for the transfer of the license and know-how related to the constructs.

We recognized the above license revenue as we determined the license to be distinct from other promises within the arrangement.

Cost of Goods Sold

We began capitalizing inventory costs once DANYELZA was approved by the FDA in November 2020. Cost of goods sold was $1.1 million and $0.2 million for the three months ended June 30, 2022 and 2021, respectively. Our 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 for approved products, and indirect overhead costs. In periods prior to receiving FDA approval for DANYELZA, we recognized inventory and related manufacturing costs of DANYELZA as research and development expenses. This resulted in inventory being sold during the quarter ended June 30, 2021 for which a portion of the costs had been previously expensed prior to FDA approval. All inventory sold in the quarter ended June 30, 2022 had been produced after we had received FDA approval for DANYELZA.

In addition, in 2016, we expensed $1.2 million of minimum royalties related to DANYELZA prior to commercial launch which were fully creditable against earned royalties in future periods. As a result, there was no royalty expense recorded for the three months ended June 30, 2021. If we had not sold previously expensed inventory and if we had not utilized the minimum royalty credit, our cost of goods sold would have been approximately $0.9 million for the three months ended June 30, 2021.

License Royalties

For the three months ended June 30, 2022 and 2021, we incurred royalty expenses of $0.1 million and $0.2 million, respectively, related to licensing revenues which is included in Licensing Revenue 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.

	Three Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
Outsourced manufacturing	$ 11,282	$ 5,995	$ 5,287	% 88
Clinical trials	2,413	1,565	848	54
Outsourced research and supplies	2,746	3,235	(489)	(15)
Milestones and license acquisition costs	300	—	300	NA
Personnel costs	4,857	4,675	182	4
Professional and consulting fees	670	473	197	42
Stock-based compensation	2,075	1,820	255	14
Other	2,077	2,015	62	3
	$ 26,420	$ 19,778	$ 6,642	% 34

Research and development expenses were $26.4 million for the three months ended June 30, 2022, as compared to $19.8 million for the three months ended June 30, 2021. The $6.6 million increase reflects a $5.3 million increase related to outsourced manufacturing, which included $2.9 million of naxitamab inventory vials that were designated for use in clinical trials during the three months ended June 30, 2022, and $0.8 million increase in clinical trials, mainly related to omburtamab.

Selling, General, and Administrative Expenses

Selling, general, and administrative, or SG&A expenses were $23.1 million for the three months ended June 30, 2022, as compared to $13.5 million for the three months ended June 30, 2021. The $9.6 million increase in SG&A expenses was primarily attributable to a $10.7 million charge related to the departure of the Company's former Chief Executive Officer, as discussed further in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* in the consolidated financial statements included within this quarterly report on Form 10-Q.

Other Income / (Loss), Net

Interest and other loss for the three months ended June 30, 2022 was $1.2 million as compared to $0.2 million for the three months ended June 30, 2021. Our interest and other loss increased by $1.0 million mainly due to increased foreign currency exchange losses recognized in the three months ended June 30, 2022.

Comparison of the Six Months Ended June 30, 2022 and 2021

The following table summarizes our results of operations for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Amount Change	Percentage Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
	(in thousands)		(in thousands)	
REVENUES				
Product revenue, net	$ 20,283	$ 14,334	$ 5,949	% 42
License revenue	1,000	2,000	(1,000)	(50)
Total revenues	21,283	16,334	4,949	30
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,972	293	2,679	914
License royalties	100	210	(110)	(52)
Research and development	49,332	41,357	7,975	19
Selling, general, and administrative	36,520	25,445	11,075	44
Total operating costs and expenses	88,924	67,305	21,619	32
Loss from operations	(67,641)	(50,971)	(16,670)	33
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	62,010	(62,010)	(100)
Interest and other loss	(1,558)	(563)	(995)	177
NET INCOME / (LOSS)	$ (69,199)	$ 10,476	$ (79,675)	% (761)

Revenues

We launched DANYELZA in February 2021 and recorded $20.3 million and $14.3 million in net revenues for the six months ended June 30, 2022 and 2021, respectively.

In addition, we recorded $1.0 million and $2.0 million in license revenue for the six months ended June 30, 2022 and 2021, respectively. The license revenue of $1.0 million for the six months ended June 30, 2022 was recognized upon the delivery of the updated FDA BLA Dossier for DANYELZA in accordance with the non-refundable license milestone under our sublicense with Adium, and we received this $1.0 million payment in the second quarter of 2022. The license revenue of $2.0 million for the six months ended June 30, 2021 was attributable to the revenues earned from the entering into of the sublicense agreement with Adium to outlicense DANYELZA and omburtamab in Latin America. As part of this agreement, we received a non-refundable up-front fee of $2.0 million for the transfer of the license and know-how related to the constructs.

We recognized the above license revenue as we determined the license to be distinct from other promises within the arrangement.

Cost of Goods Sold

We began capitalizing inventory costs once DANYELZA was approved by the FDA in November 2020. Cost of goods sold was $3.0 million and $0.3 million for the six months ended June 30, 2022 and 2021, respectively. Our 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 for approved products, and indirect overhead costs. In periods prior to receiving FDA approval for DANYELZA, we recognized inventory and related manufacturing costs of DANYELZA as research and development expenses. This resulted in inventory being sold during the six months ended June 30, 2021 for which a portion of the costs had been previously expensed prior to FDA approval. All inventory sold in the six months ended June 30, 2022, was produced after we had received FDA approval for DANYELZA.

In addition, in 2016, we expensed $1.2 million of minimum royalties related to DANYELZA prior to commercial launch which were fully creditable against earned royalties in future periods. As a result, there was no royalty expense recorded for the six months ended June 30, 2021. If we had not sold previously expensed inventory and if we had not utilized the minimum royalty credit, our cost of goods sold would have been approximately $1.5 million for the six months ended June 30, 2021.

License Royalties

For the six months ended June 30, 2022 and 2021, we incurred royalty expenses of $0.1 million and $0.2 million, respectively, related to licensing revenues which is included in Licensing Revenue 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.

	Six Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)		(in thousands)	
Outsourced manufacturing	$ 18,974	$ 14,853	$ 4,121	% 28
Clinical trials	5,180	3,179	2,001	63
Outsourced research and supplies	5,427	6,324	(897)	(14)
Milestones and license acquisition costs	300	—	300	NA
Personnel costs	9,993	8,960	1,033	12
Professional and consulting fees	1,480	1,057	423	40
Stock-based compensation	3,923	3,575	348	10
Other	4,055	3,409	646	19
	$ 49,332	$ 41,357	$ 7,975	% 19

Research and development expenses were $49.3 million for the six months ended June 30, 2022, as compared to $41.3 million for the six months ended June 30, 2021. The $8.0 million increase reflects a $4.1 million increase related to outsourced manufacturing, which included $2.9 million of naxitamab inventory vials that were designated for clinical use during the six months ended June 30, 2022, a $2.0 million increase in clinical trials, mainly related to omburtamab, and a $1.4 million increase for personnel costs, inclusive of stock-based compensation.

Selling, General, and Administrative Expenses

SG&A expenses were $36.5 million for the six months ended June 30, 2022, as compared to $25.4 million for the six months ended June 30, 2021. The $11.1 million increase in SG&A expenses was primarily attributable to a $10.7 million charge related to the departure of our former Chief Executive Officer, as discussed further in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* in the consolidated financial statements included within this quarterly report on Form 10-Q.

Other Income / (Loss), Net

On December 28, 2020, we announced that we had entered into a definitive agreement to sell our 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, we 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 we recognized a net gain of $62.0 million during the six months ended June 30, 2021 related to the sale of the PRV. There were no PRV sales during the six months ended June 30, 2022.

Interest and other loss for the six months ended June 30, 2022 was a loss of $1.6 million as compared to a loss of $0.6 million for the six months ended June 30, 2021. Our interest and other loss increased by $1.0 million mainly due to increased foreign currency exchange losses.

Liquidity and Capital Resources

Overview

Except for the quarter ended March 31, 2021, we have incurred significant net operating losses since 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 currently have one approved product, DANYELZA, which launched in the first quarter of 2021. We have financed our operations through June 30, 2022 primarily through gross proceeds from the sale of our common stock of $378.8 million in the years 2015 through 2019, and an additional $115.0 million from the sale of our common stock in 2021, as well as additional funding from the proceeds from the sales of DANYELZA and from proceeds from the sale of the DANYELZA PRV. As of June 30, 2022 and December 31, 2021, we had cash and cash equivalents of $133.7 million and $181.6 million, respectively. We expect that we may need to raise 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 subsequently sold to United Therapeutics Corporation in a transaction that closed in January 2021 based on an agreed valuation of $105.0 million. We were obligated to pay 40% of the net proceeds to MSK. We have used and intend to use the remaining proceeds to fund further research and development and other operational programs.

For an analysis of the type of contractual obligation and the relevant time periods for the related cash requirements of such obligations which may have a material impact on our liquidity and capital resources refer to *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2022 and 2021:

	Six Months Ended June 30,		Change	
	2022	2021	Amount	Percentage
	(in thousands)		(in thousands)	
Net cash used in operating activities	$ (48,025)	$ (50,617)	$ 2,592	% (5)
Net cash provided by investing activities	—	61,569	(61,569)	(100)
Net cash provided by financing activities	32	107,966	(107,934)	(100)
Effect of exchange rates on cash and cash equivalents	94	35	59	169
Net increase / (decrease) in cash and cash equivalents	$ (47,899)	$ 118,953	$ (166,852)	% (140)

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 $48.0 million for the six months ended June 30, 2022, as compared to net cash used in operating activities of $50.6 million for the six months ended June 30, 2021. The $2.6 million decrease in cash used in operating activities during the six months ended June 30, 2022, compared to the corresponding period in 2021, was primarily due to working capital changes of $9.8 million, partially offset by a $6.1 million increased use of cash to fund the net loss, net of non-cash adjustments. The $10.9 million decreased cash used for working capital during the six months ended June 30, 2022, as compared to the corresponding period in 2021, was driven by an increase in accounts receivable collections of $9.0 million for the six months ended June 30, 2022. Additionally, there was a $7.2 million increased use of cash to fund the net loss in the six months ended June 30, 2022 of $48.4 million, net of non-cash adjustments, compared to the net loss in the six months ended June 30, 2021 of $41.2 million, net of non-cash adjustments.

Net Cash Provided by Investing Activities

We did not generate or use cash for investing activities during the six months ended June 30, 2022. Net cash provided by investing activities was $61.6 million for the six months ended June 30, 2021. The net change of $61.6 million was primarily the result of the $62.0 million payment related to our share of the gross proceeds received from the sale of our PRV to United Therapeutics Corporation. For additional information on the PRV sale, please refer to the section entitled “Other Income / (Loss), Net”.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.03 million for the six months ended June 30, 2022, which resulted from proceeds from exercised stock options. Net cash provided by financing activities was $108.0 million for the six months ended June 30, 2021, which was driven by the net proceeds of $107.7 million received from our public offering in February 2021 and proceeds from exercised stock options of $0.2 million for the six months ended June 30, 2021.

Funding Requirements

We expect our expenses to increase as we continue to expand our commercialization efforts for DANYELZA, continue the development of omburtamab, and advance our BLA 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 may need to obtain substantial additional funding in connection with our continuing operations. However, global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of COVID-19 and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted. 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 have used and intend to use the remaining net proceeds of $62.0 million 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 had cash and cash equivalents of $133.7 million as of June 30, 2022. We believe our current cash and cash equivalents are sufficient to fund our operations as currently planned through mid-2024, and have based our estimate 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. This assumption includes an incremental benefit from international revenues, including the receipt of approval based licensing milestones. This estimate does not include any assumption for net proceeds received on the anticipated priority review voucher, which we could sell upon the potential approval of omburtamab. This estimate also does not reflect the potential impact of any future acquisitions, mergers, dispositions, licensing agreements, collaborations, joint ventures or investments that we may make. Potential omburtamab revenues upon approval are also excluded, and the DANYELZA revenues are only assumed to increase modestly each year for the purpose of this analysis of runway. 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 may 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 may 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, including the PRV that may be granted by the FDA for omburtamab;
- 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 securities 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 the financial balances related to our material outstanding contractual commitments and the maximum financial impact related to milestones under those contractual obligations are included in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* of our enclosed consolidated financial statements.

We enter into contracts in the normal course of business with CROs, CMOs, clinical sites and other third parties for clinical trials, pre clinical 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 non cancellable obligations of our service providers, up to the date of cancellation.

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 entered into three license agreements and certain other agreements with MSK. The license agreements are further described below as the MSK License, the 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 the 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 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 non-refundable but are creditable against royalty payments otherwise due under the respective agreements. We are also obligated to pay MSK certain clinical, regulatory and sales-based milestone payments under the MSK License and the 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 $2.5 million, $9.0 million and $20.0 million, respectively. In addition, under the CD33 License, we are obligated to make potential payments of $0.6 million, $0.5 million and $7.5 million 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 non refundable 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 $4.7 million and $18.1 million, respectively. There are also sales based milestones, totaling $23.8 million, that become due should we 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, we are obligated to pay sales milestones in the total amount of $60.0 million 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 an aggregate total of $1.5 million 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 $1.4 million, 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 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 CD33 License, the SADA License or the MabVax License. We have entered sublicenses with SciClone and Takeda in 2020 and Adium in 2021 as allowed under the MSK License. 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 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 June 30, 2022 and December 31, 2021, we had cash and cash equivalents of $133.7 million and $181.6 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 June 30, 2022. 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 Kroner (DKK), the currency used in the Kingdom of Denmark, where our wholly owned subsidiary, Y-mAbs Therapeutics A/S, is located. As of June 30, 2022 and December 31, 2021, we had cash and cash equivalents denominated in DKK of $5.6 million and $0.9 million, respectively, and an immediate 10% change, respectively, in the DKK to USD 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 Interim Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report on Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 15(e) and 15d 15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our Interim Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2022.

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 our organization will be detected.

Changes in Internal Control over Financial Reporting

During the three months ended June 30, 2022, we completed the implementation of a new cloud-based accounting and general ledger system. The system change was made to improve the efficiency of our financial close process and related financial reporting. As part of the implementation, we modified internal controls where necessary

due to the system change. There were no other changes in our internal control over financial reporting in the three months ended June 30, 2022 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

We have been named a nominal defendant in a lawsuit filed in the U.S. District Court, Southern District of New York, on August 25, 2021, by one of our stockholders, Deborah Donoghue. The suit names our President, Interim Chief Executive Officer and Head of Business Development and Strategy, and member of our board of directors, Mr. Thomas Gad as an additional defendant, and it seeks to compel Mr. Gad to disgorge alleged short swing profits stemming from a certain transaction involving our common stock undertaken by Mr. Gad on March 10, 2021 together with appropriate interest and costs of the lawsuit. On December 17, 2021, Mr. Gad filed a Motion to Dismiss the lawsuit. On August 8, 2022, the Court denied Mr. Gad's Motion to Dismiss the lawsuit. As a result, the lawsuit will enter the discovery phase. We are of the opinion that the claim is without merit and intend to maintain this position in the proceedings. In addition, we have 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. We have assessed the proceedings and do not believe that it is probable that a gain or a liability will be realized by us. As a result, we did not record any loss or gain contingencies for this matter.

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 consolidated 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 investors may lose all or part of their 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 June 30, 2022 our accumulated deficit was approximately $409.7 million. We have financed our operations principally through private placements, the initial public offering of our common stock in 2018 as well as subsequent public offerings of our common stock in November 2019 and February 2021, and the sale of our PRV granted upon FDA approval of DANYELZA.

To date, we have devoted substantially all our efforts to research and development, and more recently, commercialization of DANYELZA, our only approved product to date 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 with relapsed/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. While our biologic license application, or BLA, for our lead product candidate omburtamab was accepted for priority review by the FDA in May 2022 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. While we will be entitled to receive a PRV upon the potential FDA approval of omburtamab, we may not be successful in selling or otherwise realizing the value of such PRV. 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 approved product for sale is DANYELZA, which only received FDA approval on November 25, 2020 and we have not generated any substantial revenue from product sales. We began limited sales and shipments of DANYELZA in February 2021 and we do not anticipate generating substantial revenue from product sales until DANYELZA has been on the market for a period of time, if ever. 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 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 omburtamab, 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 any such 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 patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably expected populations for treatment are 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, commercializing DANYELZA, conducting clinical trials of DANYELZA and our lead product candidate, omburtamab 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, omburtamab 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 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. Milestone payments become due upon achievement of the related clinical, regulatory or sales-based milestone set forth in the MSK license agreements 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 agreements, whether or not the milestone activity has been achieved. Total clinical and regulatory milestones potentially due under the MSK License are $2.5 million and $9.0 million, 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 $20.0 million. Under the MSK CD33 License, we are obligated to make potential payments of $0.6 million, $0.5 million and $7.5 million for clinical, regulatory and sales-based milestones, respectively.

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 non-refundable 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 $4.7 million and $18.1 million, respectively. Additionally, we are also obligated to make sales-based milestones payments totaling $23.8 million, that become due should we 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 on our behalf by one of our sublicenses, we may pay sales-based milestone payments in the total amount of $60.0 million based on the achievement of various levels of cumulative net sales by the sublicensee. Under the SADA License Agreement, we also committed to fund scientific research at MSK under a Sponsored Research Agreement for $1.5 million. The scientific research took place over a period that commenced in September 2020 and ended at the end of February 2022.

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 are providing drug product and funding for certain clinical trials at MSK under separate executed appendices. 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 $1.4 million, annual minimum royalties of $10,000, increasing to $25,000 from approval of the first new drug application, or NDA, or BLA for a licensed product over the royalty term, and mid single-digit royalty payments to MSK on sales.

These payments could be significant and in order to satisfy our obligations to MSK and MIT, and may require us to 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 grow our sales and marketing team to support sale 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. 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 when needed, 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 such 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, securities 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 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 candidates, if approved, or the 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 R/R high-risk NB in bone and/or bone marrow and omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB. 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

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 investigational new drug applications, or 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.

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. Although the FDA has accepted our BLA for omburtamab for priority review, 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 of our other 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. Further, competitors who are developing product candidates with technology similar to ours may experience problems with their product candidates that could identify problems in the technology that would potentially harm our business.

Many of our other product candidates are based on technology similar to DANYELZA and omburtamab. Therefore, if either DANYELZA or omburtamab encounter safety or efficacy problems, developmental delays, regulatory issues, or other problems, our other development plans and business could be significantly harmed.

Our bispecific antibody product candidates, including nivatrotamab and our CD33-BsAb product candidate, are based on the Y-BiClone platform technology. Therefore, safety or efficacy problems, developmental delays, regulatory issues, or other problems, encountered by one bispecific product candidate may affect all our bispecific product candidates and our other development plans and business could be significantly harmed.

Our normal business operations have and may in the future, directly or indirectly, be adversely impacted by the still ongoing global COVID-19 pandemic and resulting macroeconomic conditions. 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.

The COVID-19 pandemic, and preventative measures taken to contain or mitigate the pandemic 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 working from home. 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 extent to which the COVID-19 pandemic 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 COVID-19 pandemic, the emergence of new variants of the virus such as the Delta and Omicron variants 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. During 2021, the COVID-19 pandemic was limiting certain commercialization efforts for DANYELZA. Limited hospital access for non patients, social distancing requirements, and

precautionary measures due to COVID 19 impacted the ability of our sales personnel to interact in person with customers.

The pandemic also led to slower initiation of new clinical trials and a fluctuating rate of recruitment for ongoing clinical trials, which has delayed our clinical development activities and thereby postponed certain accompanying costs. 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 further adversely impacted. 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.

Our clinical development timelines and plans have been and could further 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. 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 CMOs, 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 any of these third parties with whom we conduct business 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.

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;

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

Furthermore, the COVID-19 pandemic has resulted in significant volatility in the global financial markets, and specifically in the trading prices for our common stock and the shares of other biopharmaceutical and biotechnology

companies. Global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of COVID-19 and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted. A recession or additional market corrections resulting from the impact of the evolving effects of the COVID-19 pandemic could materially affect our business and the value of our ordinary shares. While we expect these effects to adversely affect our business operations and financial results, the extent of the impact on our ability to generate sales of our approved products, execute on new product launches, our clinical development and regulatory efforts, our corporate development objectives and the value of and market for our ordinary shares, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time. The COVID-19 pandemic and macroeconomic conditions may also exacerbate the other risks discussed in this Quarterly Report on Form 10-Q.

Russia's invasion of Ukraine and ancillary developments have had and may continue to have an adverse effect on our business.

On February 24, 2022, Russia launched a wide-ranging attack on Ukraine. The resulting conflict and retaliatory measures by the global community have created global security concerns, including the possibility of expanded regional or global conflict, which have had and are likely to continue to have, short-term and more likely longer-term adverse impacts on Russia, Ukraine and Europe and around the globe. Sanctions issued by the U.S. and other countries against Russia in response to its attack on Ukraine and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia. In light of the continuously evolving and worsening conditions in the region, we have terminated our clinical trials of DANYELZA in Russia and suspended our regulatory activities to obtain marketing authorization for DANYELZA in Russia. This has negatively impacted our plans to commercialize and sell DANYELZA in Russia and may therefore adversely affect our business. At this time, we cannot guarantee that our clinical or regulatory activities will recommence. In addition, the conflict between Russia and Ukraine and related sanctions has had significant ramifications on global financial markets, including volatility in the U.S. and global financial markets experienced, which has led to disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity globally, and has caused and may continue to cause volatility in the price of our common stock, which may adversely impact our ability to raise capital on favorable terms or at all.

The full economic and social impact of the sanctions imposed on Russia and possible future punitive measures that may be implemented, as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia and related sanctions, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict.

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;
- maintain 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 and the prevalence and severity of any side effects;
- 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;
- 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 and any requirement for in-patient versus out-patient administration;
- 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 and enroll in ongoing clinical trials, and of physicians to prescribe these therapies;
- relative convenience and ease of 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. We are currently building our own sales capabilities in Europe, however, no assurance can be given that we will be successful in these efforts.

Risks are involved both with further establishing our own direct sales and marketing capabilities and with 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 approved. 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 marketing approval 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 our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive offerings;

- 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.

Conversely, 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 services (such as with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG and Adium Pharma S.A.) than if we were ourselves to market and sell any drugs that we develop. 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. 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. 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 manufacturing organizations as well as established marketing and 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, omburtamab or our other product candidates or may develop proprietary technologies or secure patent protection that we may need for the commercialization of DANYELZA and the development of our product candidates and related technologies.

Specifically, MacroGenics, Inc. and Daiichi Sankyo Co. are developing antibodies against the B7-H3 molecule that is the target of our lead product candidate, omburtamab. With respect to DANYELZA, which targets GD2 positive tumors, United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin (dinutuximab), an antibody against GD2, in the United States. Although United Therapeutics has discontinued its efforts to investigate Unituxin's potential activity against adult cancerous tumors, its efforts to develop a humanized version of Unituxin, and its plans to develop Unituxin in R/R NB, DANYELZA faces competition from Qarziba® (dinutuximab beta), a similar antibody product against GD2 developed by Apeiron Biologics AG, or Apeiron. EUSA Pharma (UK) Ltd., or EUSA, has acquired global commercialization rights to Qarziba® (dinutuximab beta) and it is currently being commercialized in Europe and was approved by the EMA to treat high-risk NB and R/R NB. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba® in mainland China and in August 2021 EUSA and BeiGene announced that the China National Medical Products Administration had granted Qarziba® conditional approval for the treatment of high-risk NB and R/R NB. EUSA has previously announced plans to file for registration of dinutuximab beta in the United States for the treatment of R/R NB.

Even if approved, in Europe and/or mainland China DANYELZA will not be the first approved antibody treatment for R/R NB in these territories and we may not be the first to market in other geographies, which may affect the price or demand for DANYELZA. Similarly, we may not be the first to market for any of our other future products, if approved. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our DANYELZA or for any other future products, if approved. We may not be able to implement our business plan if the acceptance of DANYELZA or for any other future products, if approved, 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. 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 DANYELZA, omburtamab and our other product candidates, which are derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations, and market research. The total addressable market opportunity for DANYELZA and any other products we may produce, if approved, will ultimately depend upon, among other things, the diagnosis criteria included in the final label for the relevant product, 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 omburtamab or our other product candidates, if approved, because the initial target populations we are seeking to treat 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 R/R high-risk NB 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 any will be approved. In addition, we may have to conduct additional clinical trials prior to gaining approval for front-line or third-line therapy.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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 relevant 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 populations;
- 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 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 use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any of our clinical trials.

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 commercial launch of our product candidates, if approved.

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 withdraw marketing approval or 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 educate and train medical personnel using our products and product candidates to understand their side effect profiles - both for our approved product DANYELZA and our current clinical trials and we anticipate this also to be the case for our future products, if approved, and clinical trials. 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 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 narrow the indications for use or, as the FDA did in its approval of DANYELZA for the treatment of R/R high-risk NB rather than NB that was not R/R
- regulatory authorities may require additional warnings in the labeling, such as a boxed warning, as the FDA did in its approval of DANYELZA, 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 candidate, omburtamab, 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 omburtamab, such event could adversely affect our other clinical trials of omburtamab or our other 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. We submitted a Biologics License Application, or BLA, to the FDA for radiolabeled ^{131}I-omburtamab for CNS LM from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC, Module and the Clinical Module of the BLA required further detail. We completed the resubmission of the BLA for omburtamab in March 2022. Survival and safety data from our pivotal Phase 2 clinical trial 03-133 formed the primary basis for our resubmission of the BLA for omburtamab, and we compared this data with data from an external cohort comprising data from the Central German Childhood Cancer Registry, or CGCCR, database. Furthermore, we believe interim efficacy, safety and pharmacokinetic data from our pivotal Phase 2 clinical trial 101 supported the BLA resubmission. In May 2022, the FDA indicated that our BLA had been accepted for priority review. The FDA has set an action date of November 30, 2022 under the Prescription Drug User Fee Act; however, we can provide no assurance that omburtamab will ultimately receive FDA approval, and if approved, whether it will be subject to onerous post-marketing requirements and commitments.

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 present or future clinical trials to be sufficient to serve as the basis for approval of omburtamab or any of our other 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 only approved in late 2020 and launched in the United States in early 2021 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 other 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 obtain marketing approval for omburtamab or advance any of our other 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, as 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 US market no assurance can be given that it will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

We are dependent on our ability to maintain and continue to leverage our relationship with MSK. 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 CD33 License, and the SADA License Agreement, which are important to us, 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, because it is a hospital where patients are treated, may become a major source for the distribution and administration of DANYELZA and omburtamab, if approved. 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 of strategic collaborations is time consuming and complex. We may not be successful in our efforts to establish a strategic partnership, other than the one we have with MSK, or other alternative arrangements for our product candidates because potential strategic partners may deem our product candidates to be at too early a stage of development for collaborative effort, because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or because the commercial potential of our product candidates is too difficult to predict.

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

- such third parties may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- such third parties 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 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 could independently develop, or develop with others, 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 as competitive with their own product candidates or products, which

may cause such third parties to cease to devote resources to the commercialization of our products or product candidates;

- such third party with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- such third parties 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 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 may infringe the intellectual property rights of others, 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 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. We label an antibody with Iodine-131 to generate our product candidate omburtamab, and we also use Iodine-124 and Lutetium-177-labeled antibody treatments. Our uses involve the inherent risk of exposure from beta ray emissions, which can alter or harm healthy cells in the body. We, our CROs, our CMOs and other 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.

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. We do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with applicable federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, compliance could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts. Furthermore, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks related to our dependence on third parties

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 supply and our product candidates for our ongoing and planned pre-clinical studies and clinical studies. We also are highly dependent on our CMO SpectronRx to perform radiolabelling of our omburtamab product candidate. Our business could be harmed if those third parties fail to provide us with sufficient quantities of DANYELZA or our product candidates, or fail to do so at acceptable quantities, 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 for commercial or clinical-scale manufacturing and processing and we rely on outside vendors to manufacture DANYELZA for commercial supply and for supplies and processing of our product candidates for pre-clinical studies and clinical trials. Omburtamab and our other product candidates have only been manufactured or processed on a limited basis and we and our CMO may not be able to continue manufacturing omburtamab or any of our other product candidates. The manufacturing process that we have developed may be more difficult or expensive than other 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 substances that may not be as safe and effective as any substances 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 and for commercial use. 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 CMOs and third-party collaborators for the manufacture of DANYELZA for commercial supply, and we expect that this will be the manufacturing arrangement for any of our other potential products, if approved. If we are unable to establish agreements with CMOs on acceptable terms, or at all, our business and results of operations may be materially adversely affected.

We are highly dependent on our current CMO, EMD/Merck, for the production of omburtamab 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. In addition, the relatively small scale of the cGMP system required for manufacture of omburtamab may increase the risk that we are unable to establish an alternative manufacturing arrangement on commercially reasonable terms because the small scale may lead to less commercially attractive terms for us. We also are highly dependent on our CMO SpectronRx to perform radiolabelling of our omburtamab product candidate. Our agreement with SpectronRx is due to expire soon and there can be no guarantee that the agreement will be extended or renewed in a timely manner and on favorable terms, or at all, which would require us to amend our BLA for omburtamab which again would delay the omburtamab BLA approval date (if approved at all).

We are subject to the following additional risks with respect to the third-party manufacture of our antibody-based cancer treatments:

- If we need to qualify any new manufacturer of DANYELZA or omburtamab, the respective BLA submissions will need to be amended, and ultimately the FDA must approve any new manufacturer. Any such approval would require new testing, which may include comparability analyses between the biologic substance manufactured for use in prior clinical trials and the biologic substance manufactured by such potential new manufacturer. Any such potential new manufacturer would further need to pass cGMP compliance inspections by the FDA.

- If we need to qualify any new manufacturer, such third party would have to be educated in, or develop substantially equivalent processes for, production of our product and/or product candidates.

- Any of our third-party manufacturers might be unable to timely manufacture our product and/or product candidates or to produce the quantity and quality required to meet our clinical and commercial needs.

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

- Any of our third-party manufacturers may not perform as agreed, according to our schedule or specifications, or at all. Any such third-party manufacturer 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 commercial needs.

- We are exposed to the risk of cross-contamination from other drug substances if more than one product is manufactured at a 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, and any of our third-party manufacturers could fail to comply with applicable government regulations.

- 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.

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

- The raw materials and components used to manufacture and process DANYELZA and 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.

- Any of our third-party manufacturers could potentially mislabel commercial or clinical supplies, which may result in the wrong dose amounts being supplied or active drug or placebo not being properly identified;

- Any of our third-party manufacturers could misappropriate our proprietary information, including our trade secrets and know-how, which could lead to weaker intellectual property protection for our portfolio or potentially increased competition if a competitor were to obtain such proprietary information.

- Our clinical trials may be interrupted if third-party suppliers fail to deliver clinical supplies on time, or we may experience lost sales if drug supplies are not distributed to commercial vendors in a timely manner, in each case because of inclement weather, natural or man-made disasters, or other circumstances beyond our control.

- Any of 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. Any shortage 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 have and will continue to 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 us until deficiencies are remedied.

The facilities used by our CMOs to manufacture DANYELZA and our product candidates must be approved by the FDA pursuant to inspections conducted after submittal of a 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 is 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 commercial product and clinical product candidates 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, such as omburtamab. We do not currently have arrangements in place for redundant supply of DANYELZA and omburtamab and we currently use only a single third-party manufacturer for fill-and-finish services for DANYELZA or omburtamab. If any of our current CMOs cannot perform as agreed, we may be required to replace such manufacturer 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, and Seibersdorf Labor GmbH in Austria where an analytical release test of omburtamab drug substance is performed and manufacture of clinical and commercial supply is planned. We expect that the FDA inspection will occur during the third and fourth quarter of 2022 based on the FDA's May 2022 acceptance of our BLA submission for omburtamab on a priority review basis. 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. Substantial delays in the approval process, or our inability to obtain approval for any reason for omburtamab 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 would include similar risks of delay. We also expect that the EMA will require an inspection of the manufacturing facilities for omburtamab in connection with our Marketing Authorization Application, or MAA, submission for omburtamab. If the EMA is unable to conclude that these manufacturing facilities are in 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. In addition, if the EMA 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 MAA approval on a timely basis or at all.

We are and will continue to be, reliant 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. We conduct independent clinical trials and perform preclinical research but we also rely on third-party research institutions for both clinical trial and preclinical research.

Currently, MSK is conducting a clinical trial to address relapsed osteosarcoma using DANYELZA. MSK is also conducting a clinical trial to address desmoplastic small round cell tumors, or DSRCT for our omburtamab product candidate. Under the terms of the MCTA, we are obligated to pay for costs associated with these clinical trials. We are conducting clinical trials at MSK for CNS/LM from NB and diffuse intrinsic pontine glioma, or DIPG for our omburtamab.

We have agreed to fund certain research and development costs under 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 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 including in the event of our insolvency or bankruptcy, if we are convicted of a felony relating to the manufacture, use, or sale of products licensed from MSK or if we fail to pay amounts owed to MSK under the agreements or other types of breach by us of our obligations under the agreements that remain uncured. 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, manufacture of DANYELZA and our product candidates requires 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 delays 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 contaminants 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 a product candidate progresses from pre-clinical studies 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 such change could cause the product candidate 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 processes, we expect that we will need to obtain rights to and supplies of certain materials and equipment to be used as part of those processes. 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 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.

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. Sanctions issued by the U.S. and other countries against Russia in response to its attack on Ukraine and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia and may have a material adverse impact on our ability to sell our products and/or collect receivables from customers in Russia. In December 2020, we entered into a license agreement for DANYELZA and omburtamab with SciClone Pharmaceuticals International Ltd., or SciClone, 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., or Adium, 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 include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We 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 DANYELZA and any other potential products, if approved, 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. Furthermore, 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 DANYELZA or any of our other potential products, if approved.

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

Even if we complete the necessary non-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 R/R high-risk NB 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 DANYELZA or any of our product candidates.

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. Although we have received a Biologics License for DANYELZA for R/R high-risk NB in bone and/or bone marrow, we intend to discuss with the FDA submission of additional BLAs for approval of DANYELZA to treat additional indications that currently lack an FDA-approved treatment option. We are currently waiting for the FDA to take action on the BLA that we submitted for omburtamab for the treatment of CNS/LM from NB, and if approved for that indication, we intend to discuss with the FDA submission of additional BLAs for approval of omburtamab for the treatment of additional indications with high unmet need.

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. The FDA provided us with a Refusal to File letter regarding our original BLA submission for omburtamab, and there can be no guarantee that we will not receive another Refusal to File letter on any future BLA that we may submit. 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 the Russian invasion of Ukraine; 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 "*—If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected*." 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 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 other product candidates, which would prevent DANYELZA, omburtamab or our other 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 MAA, to the EMA for omburtamab for the treatment of pediatric patients with CNS/LM from NB.

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, 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.

We may decide to voluntarily withdraw our MAA for omburtamab for the treatment of pediatric patients with CNS/LM from NB submitted to EMA, if we determine based on feed-back received from the EMA, that it is unlikely that a continued application process will lead to approval and we, therefore, decide to focus our efforts on pursuing FDA approval of the BLA for omburtamab for the treatment of CNS/LM from NB, in the US.

Failure to obtain regulatory approval to market any of our product candidates outside of the US 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 the 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 the 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 another BTD, or, if received, 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. BTD does not change the standards for product approval nor assure ultimate approval by the FDA

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. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets 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 an indication with 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 November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab (DANYELZA) 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 corresponding 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 we obtain ODD or RPDD for any of our product candidates in the future, we may not be able to maintain such status or enjoy the anticipated associated benefits. We may not be the first to obtain marketing approval of any product candidate that has 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 candidate, 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, as it was 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 post-marketing requirements and commitments, including a confirmatory post-marketing 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 post-marketing 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, and overall survival, or OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint and PFS and OS are secondary endpoints in long-term follow up. As of July 1, 2022 we have enrolled 83 patients and we anticipate completing the study no later than by March 31, 2027. Other post-marketing requirements associated with the approval of DANYELZA 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.

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, or changes in existing FDA and other government regulations and policies, may increase the difficulty and cost for us and our potential future collaborators to maintain or obtain potential 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. 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 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.

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.

In Europe, the collection and processing of personal data—including health data—is governed by the European Union-wide General Data Protection Regulation, or GDPR. 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 related 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.

Our radioimmunotherapy product candidates have very limited shelf lives that make them susceptible to damage and loss, which could adversely affect our business, financial condition and operating results.

Our radioimmunotherapy product candidates have a very limited shelf life once radiolabeled with radioactive elements. These product candidates require reliable transportation or radiolabeling production facilities located in close proximity to our final customers to avoid spoilage, damage and/or loss. The failure of third parties with whom we contract to deliver these product candidates within the scope of their limited shelf lives could result in the loss of a given shipment and the sales associated with it. Any delay in shipment results in a loss of the radioactive dose as a result of radioactive decay, with the risk that the entire useful dose may be lost. Moreover, since each order is made individually and delivered with dedicated transportation in compliance with local regulations applicable to the delivery of radioactive materials, we do not have readily available replacements to substitute for a lost delivery if circumstances beyond our control, such as delays or problems caused by inclement weather or a failure in the transportation system operated by third parties that we hire, prevent the timely delivery of a batch, or if the receiving facility fails to distribute the ordered batch in a timely fashion in accordance with specifications. Such losses or failures could have a material adverse effect on our business, financial condition and results of operations.

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.

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 2041, 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 and others covering our proprietary technologies or our product candidates that if issued as patents are expected to expire from 2021 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 a 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 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.

On April 27, 2022, we announced certain management changes, including that our Chief Executive Officer had stepped down, effective immediately, and that our current Chairman, President and Head of Business Development & Strategy had stepped down as Chairman and had assumed the role of Interim Chief Executive Officer. We cannot assure you that we will be able to identify, attract and hire a suitable replacement for our Chief Executive Officer in a timely fashion or that the loss of our Chief Executive Officer and certain additional management changes will not have an adverse impact on our business operations. The loss of the services of our Chief Executive Officer or other members of our executive management team and the failure to find appropriate replacements in a timely fashion 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 currently 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. We do not maintain “key person” insurance for any of our executives or other employees.

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 July 1, 2022, our executive officers, directors and our stockholders, which own more than 5% of our outstanding common stock beneficially own shares representing approximately 30.11% 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 a stockholder might otherwise receive a premium for their 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.

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. We have performed an analysis of our Section 382 ownership changes through March 31, 2021. Due to the large annual limitation, we believe 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 the source of gain associated with investment in our common stock.

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 the sole source of gain associated with investment in our common stock 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 43,719,549 shares of common stock outstanding as of August 3, 2022. 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 August 3, 2022 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

Our business, financial condition and results of operations have been and may in the future be adversely affected by macroeconomicconditions and by geopolitical events, including the recent global conflict resulting from the invasion of Ukraine by Russia, and sanctions related thereto, which resulted in the suspension of our clinical trial and regulatory activities in Russia.

Our financial condition, results of operations, business and cash flow may be negatively affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy has experienced extreme volatility and disruptions, including as a result of the COVID-19 pandemic, as well as from international conflicts, terrorism or other geopolitical events, such as the Russian invasion of Ukraine, and related sanctions and other economic disruptions or concerns.

For example, during March 2020, a global pandemic was declared by the World Health Organization related to the rapidly growing outbreak of a novel strain of coronavirus (COVID-19). The global spread of COVID-19 has created, and continues to create, significant volatility, uncertainty and economic disruption, including significant volatility in the capital markets. The extent to which the COVID-19 pandemic affects our business, operations, financial results and the trading price of our common stock will depend on numerous evolving factors that we may not be able to accurately predict, including: the duration and scope of the pandemic or possible resurgence of the pandemic or continued emergence of new strains of COVID-19; the availability of an effective vaccine and the speed with which it is administered to the public; governmental and business actions that have been and continue to be taken in response to the pandemic (including mitigation efforts such as stay at home and other social distancing orders) and the impact of the pandemic on economic activity and actions taken in response (including stimulus efforts such as the Families First Coronavirus Act and the Coronavirus Aid, Relief, and Economic Security Act and recent increases to the federal prime interest rate). The ultimate impact of the COVID-19 pandemic on our results of operations and financial condition is dependent on future developments, including the duration of the pandemic and the related extent of its severity, as well as its impact on macroeconomic conditions such as the rate of inflation in the U.S. economy, which are uncertain and cannot be predicted at this time. If the global response to contain the COVID-19 pandemic escalates further or is unsuccessful, or if governmental decisions to ease pandemic related restrictions are ineffective, premature or counterproductive, we could experience a material adverse effect on our business, financial condition, results of operations and cash flows.

Additionally, the global economy and financial markets may also be adversely affected by the current or anticipated impact of military conflict, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, may also adversely impact the financial markets and the global economy, and the economic countermeasures by the affected countries or others could exacerbate market and economic instability. On February 24, 2022, Russia initiated significant military action against Ukraine. In response, the United States and certain other countries imposed significant sanctions and trade actions against Russia and could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. It is not possible to predict the broader consequences of the conflict, including related geo-political tensions, and the measures and retaliatory actions that will be taken by the United States and other countries in respect thereof, as well as any countermeasures or retaliatory actions Russia may take in response, are likely to cause regional instability and geo-political shifts and could materially adversely affect global trade, currency exchange rates, regional economies, and the global economy. While it is difficult to anticipate the ultimate impact of any of the foregoing on our company in particular, the conflict and actions taken in response to the conflict has caused us to terminate our clinical trials and suspend our regulatory activities to obtain marketing authorization for DANYELZA in Russia. Additional actions that we or others may take in response to the conflict could increase our costs, disrupt our supply chain, impair our ability to raise or access additional capital when needed on acceptable terms, if at all, or otherwise adversely affect our business, financial condition, and results of operations. For additional detail regarding this conflict, see the risk factor above "*—Russia's invasion of Ukraine and ancillary developments may have an adverse effect on our business.*"

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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 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.

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 the EMA in April 2021 for the treatment of pediatric patients with CNS/LM from NB. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone, Takeda Israel, Swixx Biopharma AG and Adium. 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 FCPA, 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.

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, droughts, floods, hurricanes, typhoons, fires, extreme weather conditions, climate change events, medical epidemics, terrorist activities, wars or other armed conflicts, geopolitical tensions, such as the ongoing conflict between Russia and Ukraine and related sanctions, cyber security attacks and 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, omburtamab and our other product candidates including SpectronRx to perform radiolabelling of omburtamab. 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, such as COVID-19, 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.

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 regulations of the FDA, the EMA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA, the EMA 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 has been and is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Also, the volatility of our stock price may adversely affect our ability to attract equity funding in the future on reasonable terms or at all.

Our stock price has been and 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 $6.50 per share and as high as $55.22 per share through August 3, 2022. From August 3, 2021 through August 3, 2022 our stock price has ranged from a low of $6.5 to a high of $39.82. As a result of this volatility, investors in our common stock may not be able to sell their shares at or above the prices they paid. Further, as a result of this volatility it may be difficult for us to attract new equity investments, including additional public offerings of our common stock, on terms we consider reasonable, or at all.

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 and investor sentiment in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as an increased rate of inflation, increased cost of goods, supply chain disruptions and uncertain global financial markets, and geopolitical events, such as the conflict between Ukraine and Russia and related sanctions; 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.

As a public company and large accelerated filer for the year ended December 31, 2021, we were required to provide management's attestation on internal controls pursuant to Section 404 of the Sarbanes-Oxley Act, and our independent registered public accounting firm was required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act. However, as of the last business day of our second fiscal quarter, we determined that we requalify as a smaller reporting company and as a non-accelerated filer for the year ended December 31, 2022. We will therefore no longer be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Our inability to operate controls effectively could cause material weaknesses in our internal control over financial reporting in the future, 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. In addition, we may be in the future be required to provide Section 404 of the Sarbanes-Oxley Act, or Section 404, reports by our independent registered public accounting attesting to the effectiveness of our internal control over financial reporting. An adverse report could have a material adverse impact on our company and financial statements, 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, when applicable, 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 conducted by us or our independent registered public accounting firm 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, if and when applicable, 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.

We may be adversely affected by global climate change or by legal, regulatory or market responses to such change.

Increasing stakeholder environmental, social and governance, or ESG, expectations, physical and transition risks associated with climate change, and emerging ESG regulation and policy requirements may pose risk to our market outlook, and reputation, financial outlook, cost of capital, supply chain and production continuity, which may impact our ability to achieve our business objectives. Changes in environmental and climate change laws or regulations could lead to additional operational restrictions and compliance requirements upon us or our third party providers or otherwise could negatively impact our business.

Changes in market dynamics, stakeholder expectations, local, national and international climate change policies, and the frequency and intensity of extreme weather events on critical infrastructure in the United States and abroad, all have the potential to disrupt our business and operations. Such events could result in a significant increase in our costs and expenses and harm our future revenue, cash flows and financial performance. Global climate change is resulting in, and may continue to result, in certain natural disasters and adverse weather events, such as droughts, wildfires, storms, sea-level rise and flooding, occurring more frequently or with greater intensity, which could cause business disruptions and impact employees' abilities to commute or to work from home effectively. Government failure to address climate change in line with the Paris Agreement could result in greater exposure to economic and other risks from climate change and impact our ability to achieve our goals.

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.

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.

We and others are subject to a variety of laws, regulations, or industry standards, including with respect to cybersecurity, that may have a material adverse effect on our business, results of operations, or financial condition

On March 9, 2022, the SEC issued a proposed rule intended to enhance and standardize disclosures regarding cybersecurity risk management, strategy, governance, and cybersecurity incident reporting by public companies, such as us, that are subject to the reporting requirements of the Securities Exchange Act of 1934. The proposed rule would require current reporting about material cybersecurity incidents and periodic disclosures about policies and procedures to identify and manage cybersecurity risks, management's role in implementing cybersecurity policies and procedures, and the board of directors' cybersecurity expertise and its oversight of cybersecurity risk.

To date, we have not experienced a significant compromise, significant data loss or any material financial losses related to cybersecurity attacks, but our systems and those of our customers and third-party service providers are under constant threat and it is possible that we could experience a significant event in the future. Risks and exposures related to cybersecurity attacks are expected to remain high for the foreseeable future due to the rapidly evolving nature and sophistication of these threats, as well as due to the expanding use of Internet banking, mobile banking and other technology-based products and services by us and our customers.

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

None.

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 3.2 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*	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan
10.2*	Retention Bonus Agreement, dated May 30, 2022 by and between EVP and Chief Financial Officer, Bo Kruse and Y-mAbs Therapeutics A/S
10.3*	Form of Retention Bonus Agreement of Y-mAbs Therapeutics A/S
10.4*	Form of Retention Bonus Agreement of Y-mAbs Therapeutics, Inc.
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	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline 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: August 8, 2022

By: /s/ Thomas Gad
Name: Thomas Gad
Title: Founder, President, Interim Chief Executive Officer and Head of Business Development and Strategy
(Principal Executive Officer)

Dated: August 8, 2022

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

Y-MABS THERAPEUTICS, INC.
2018 EQUITY INCENTIVE PLAN
STOCK OPTION GRANT NOTICE

Y-mAbs Therapeutics, Inc. a Delaware corporation, (the "Company"), pursuant to its 2018 Equity Incentive Plan, as may be amended from time to time (the "Plan"), hereby grants to the holder listed below ("Participant"), an option to purchase the number of shares of the Company's Common Stock (the "Shares"), set forth below (the "Option"). This Option is subject to all of the terms and conditions set forth herein, as well as in the Plan and the Stock Option Agreement attached hereto as Exhibit A (the "Stock Option Agreement"), each of which are incorporated herein by reference. Unless otherwise defined herein, the terms defined in the Plan shall have the same defined meanings in this Grant Notice and the Stock Option Agreement.

Participant:	[ ]
Grant Date:	[ ]
Vesting Commencement Date:	[ ]
Exercise Price per Share:	$[ ]
Total Exercise Price:	$[ ]
Total Number of Shares Subject to the Option:	[ ]
Expiration Date:	[ ]
Vesting Schedule:	

Fifty percent (50%) of the Shares subject to the Option shall vest and become exercisable on the twelve (12) month anniversary of the Vesting Commencement Date, and the remaining fifty percent (50%) of the Shares subject to the Option shall vest and become exercisable on the twenty-four (24) month anniversary of the Vesting Commencement Date.

Notwithstanding the foregoing, in the event of a Termination of Service caused by termination by the Company for Cause or termination by the Participant voluntarily (other than for Retirement), such vesting schedule shall terminate immediately, and the Shares subject to the Option which have not vested prior to such Termination of Service shall not vest and shall not become exercisable by the Participant.

In the event of a Termination of Service caused by termination by the Company without Cause or by the Participant for Good Reason, or by the Participant's Retirement, Disability or death, then the Shares subject to the Option shall continue to vest and become exercisable in accordance with the above vesting schedule provided, however, that upon the occurrence of an event constituting a Change of Control, all Shares (100%) subject to the Option shall vest and become immediately exercisable in full so long as the Participant's employment relationship with the Company has not been terminated by the Company for

Cause or by the Participant voluntarily (other than for Retirement) prior to the date of such Change of Control.

This Option will be exercisable with respect to the Shares which have vested as per the above vesting schedule until a date no later than the earlier of (1) the Option's original Term/Expiration Date set forth above, or (2) the 10th anniversary of the original Date of Grant set forth above. Notwithstanding the foregoing sentence, in no event may this Option be exercised after the Term/Expiration Date as provided above and may be subject to earlier termination as provided in the Plan.

Section 3.3 (c) and (d) of the Stock Option Agreement shall not apply to this Option.

“Cause” shall mean: (i) conviction of the Participant of any felony; (ii) conviction of the Participant of any lesser crime or offense involving fraud, misappropriation, theft or embezzlement of the property of the Company or its affiliates; (iii) gross negligence or willful misconduct by the Participant in connection with the performance of any material portion of his or her duties under any employment agreement or arrangement or other agreement between the Participant and the Company; (iv) conviction of a crime involving a violation of federal or state securities laws, a breach of a fiduciary duty or moral turpitude; (v) abuse of alcohol or another drug while performing his or her duties as an employee of the Company; or (vi) a breach of or a failure or refusal by Participant to comply with any material provision of his or her employment agreement or arrangement with the Company if not cured within ten (10) days after written notice thereof from the Company.

“Good Reason” shall mean the occurrence of any of the following, in each case during the term of the Participant’s employment relationship with the Company, without the Participant's written consent: (i) a material reduction in the Participant's base salary or compensation; (ii) a material reduction in the Participant's bonus opportunity; (iii) a relocation of the Participant's principal place of employment by more than 50 miles; (iv) any material breach by the Company of any provision of a Participant’s employment agreement or arrangement, or any material provision of any other agreement between the Participant and the Company; (v) the Company's failure to obtain an agreement from any successor to the Company to assume and agree to perform a Participant’s employment agreement or arrangement in the same manner and to the same extent that the Company would be required to perform if no succession had taken place, except where such assumption occurs by operation of law; (vi) a material, adverse change in the Participant's title, authority, duties, or responsibilities (other than temporarily while the Participant is physically or mentally incapacitated or as required by applicable law); or (vii) a material change in the reporting structure applicable to the Participant.

“Disability” shall mean total and permanent disability as defined in Code Section 22(e)(3), provided that in the case of Awards other than Incentive Stock Options, the Administrator in its discretion may determine whether a permanent and total disability exists in accordance with uniform and non-discriminatory standards adopted by the Administrator from time to time.

Type of Option: ☐ Incentive Stock Option ☐ Nonqualified Stock Option

By his or her signature and the Company's signature below, Participant agrees to be bound by the terms and conditions of the Plan, the Stock Option Agreement, and this Grant Notice. Participant has reviewed the Stock Option Agreement, the Plan and this Grant Notice in their entirety, has had an opportunity to obtain the advice of counsel prior to executing this Grant Notice and fully understands all provisions of this Grant Notice, the Stock Option Agreement and the Plan. Participant hereby agrees to accept as binding, conclusive and final all decisions or interpretations of the Administrator upon any questions arising under the Plan, this Grant Notice or the Stock Option Agreement.

Y-MABS THERAPEUTICS, INC.:		**PARTICIPANT:**	
By:		By:	
Print Name:	[ ]	Print Name:	[ ]
Title:	[ ]		
Address:		Address:	[ ]
	[ ]		

EXHIBIT A

STOCK OPTION AGREEMENT

Pursuant to the Stock Option Grant Notice (the "Grant Notice") to which this Stock Option Agreement (this "Agreement") is attached, Y-mAbs Therapeutics, Inc., a Delaware corporation (the "Company"), has granted to the Participant an Option under the Company's 2018 Equity Incentive Plan, as may be amended from time to time (the "Plan"), to purchase the number of Shares indicated in the Grant Notice.

ARTICLE 1.

GENERAL

1.1 Defined Terms. Wherever the following terms are used in this Agreement they shall have the meanings specified below, unless the context clearly indicates otherwise. Capitalized terms not specifically defined herein shall have the meanings specified in the Plan and the Grant Notice.

1.2 Incorporation of Terms of Plan. The Option is subject to the terms and conditions of the Plan which are incorporated herein by reference. In the event of any inconsistency between the Plan and this Agreement, the terms of the Plan shall control.

ARTICLE 2.

GRANT OF OPTION

2.1 Grant of Option. In consideration of the Participant's past and/or continued employment with or service to the Company or any Subsidiary and for other good and valuable consideration, effective as of the Grant Date set forth in the Grant Notice (the "Grant Date"), the Company irrevocably grants to the Participant the Option to purchase any part or all of an aggregate of the number of Shares set forth in the Grant Notice, upon the terms and conditions set forth in the Plan and this Agreement, subject to adjustments as provided in Article IX of the Plan. Unless designated as a Nonqualified Stock Option in the Grant Notice, the Option shall be an Incentive Stock Option to the maximum extent permitted by law.

2.2 Exercise Price. The exercise price of the Shares subject to the Option shall be as set forth in the Grant Notice, without commission or other charge; *provided*, *however*, that the price per share of the Shares subject to the Option shall not be less than 100% of the Fair Market Value of a Share on the Grant Date. Notwithstanding the foregoing, if this Option is designated as an Incentive Stock Option and the Participant is a Greater Than 10% Stockholder as of the Date of Grant, the exercise price per share of the Shares subject to the Option shall not be less than 110% of the Fair Market Value of a Share on the Grant Date.

2.3 Consideration to the Company. In consideration of the grant of the Option by the Company, the Participant agrees to render faithful and efficient services to the Company or any Subsidiary. Nothing in the Plan or this Agreement shall confer upon the Participant any right to continue in the employ or service of the Company or any Subsidiary or shall interfere with or restrict in any way the rights of the Company and its Subsidiaries, which rights are hereby expressly reserved, to discharge or terminate the services of the Participant at any time for any reason whatsoever, with or without cause, except to the extent expressly provided otherwise in a written agreement between the Company or a Subsidiary and the Participant.

ARTICLE 3.

PERIOD OF EXERCISABILITY

3.1 Commencement of Exercisability.

(a) Subject to Sections 3.2, 3.3, 5.11 and 5.17 hereof, the Option shall become vested and exercisable in such amounts and at such times as are set forth in the Grant Notice.

(b) No portion of the Option which has not become vested and exercisable at the date of the Participant's Termination of Service shall thereafter become vested and exercisable, except as may be otherwise provided by the Administrator or as set forth in a written agreement between the Company and the Participant.

(c) Notwithstanding Section 3.1(a) hereof and the Grant Notice, but subject to Section 3.1(b) hereof, in the event of a Change in Control the Option shall be treated pursuant to Sections 9.2 and 9.3 of the Plan.

3.2 Duration of Exercisability. The installments provided for in the vesting schedule set forth in the Grant Notice are cumulative. Each such installment which becomes vested and exercisable pursuant to the vesting schedule set forth in the Grant Notice shall remain vested and exercisable until it becomes unexercisable under Section 3.3 hereof.

3.3 Expiration of Option. The Option may not be exercised to any extent by anyone after the first to occur of the following events:

(a) The Expiration Date set forth in the Grant Notice, which shall in no event be more than ten (10) years from the Grant Date;

(b) If this Option is designated as an Incentive Stock Option and the Participant, at the time the Option was granted, was a Greater Than 10% Stockholder, the expiration of five (5) years from the Grant Date;

(c) The expiration of three (3) months from the date of the Participant's Termination of Service, unless such termination occurs by reason of the Participant's death or disability; or

(d) The expiration of one (1) year from the date of the Participant's Termination of Service by reason of the Participant's death or disability.

3.4 Special Tax Consequences. The Participant acknowledges that, to the extent that the aggregate Fair Market Value (determined as of the time the Option is granted) of all Shares with respect to which Incentive Stock Options, including the Option (if applicable), are exercisable for the first time by the Participant in any calendar year exceeds $100,000, the Option and such other options shall be Nonqualified Stock Options to the extent necessary to comply with the limitations imposed by Section 422(d) of the Code. The Participant further acknowledges that the rule set forth in the preceding sentence shall be applied by taking the Option and other "incentive stock options" into account in the order in which they were granted, as determined under Section 422(d) of the Code and the Treasury Regulations thereunder. The Participant also acknowledges that an Incentive Stock Option exercised more than three (3) months after the Participant's Termination of Employment, other than by reason of death or disability, will be taxed as a Nonqualified Stock Option.

3.5 Tax Indemnity.

(a) The Participant agrees to indemnify and keep indemnified the Company, any Subsidiary and the Participant's employing company, if different, from and against any liability for or obligation to pay any Tax Liability (a "Tax Liability" being any liability for income tax, withholding tax and any other employment related taxes or social security contributions in any jurisdiction) that is attributable to (1) the grant or exercise of, or any benefit derived by the Participant from, the Option, (2) the acquisition by the Participant of the Shares on exercise of the Option or (3) the disposal of any Shares.

(b) The Option cannot be exercised until the Participant has made such arrangements as the Company may require for the satisfaction of any Tax Liability that may arise in connection with the exercise of the Option and/or the acquisition of the Shares by the Participant. The Company shall not be required to issue, allot or transfer Shares until the Participant has satisfied this obligation.

(c) The Participant hereby acknowledges that the Company (i) makes no representations or undertakings regarding the treatment of any Tax Liabilities in connection with any aspect of the Option and (ii) does not commit to and is under no obligation to structure the terms of the grant or any aspect of any Award, including the Option, to reduce or eliminate the Participant's liability for Tax Liabilities or achieve any particular tax result. Furthermore, if the Participant becomes subject to tax in more than one jurisdiction between the date of grant of an Award, including the Option, and the date of any relevant taxable event, the Participant acknowledges that the Company may be required to withhold or account for Tax Liabilities in more than one jurisdiction.

ARTICLE 4.

EXERCISE OF OPTION

4.1 Person Eligible to Exercise. Except as provided in Section 5.3 hereof, during the lifetime of the Participant, only the Participant may exercise the Option or any portion thereof, unless it has been disposed of pursuant to a DRO. After the death of the Participant, any exercisable portion of the Option may, prior to the time when the Option becomes unexercisable under Section 3.3 hereof, be exercised by the deceased the Participant's personal representative or by any person empowered to do so under the deceased the Participant's will or under the then applicable laws of descent and distribution.

4.2 Partial Exercise. Any exercisable portion of the Option or the entire Option, if then wholly exercisable, may be exercised in whole or in part at any time prior to the time when the Option or portion thereof becomes unexercisable under Section 3.3 hereof. However, the Option shall not be exercisable with respect to fractional Shares.

4.3 Manner of Exercise. The Option, or any exercisable portion thereof, may be exercised solely by delivery to the Secretary of the Company (or any third party administrator or other person or entity designated by the Company; for the avoidance of doubt, delivery shall include electronic delivery), during regular business hours, of all of the following prior to the time when the Option or such portion thereof becomes unexercisable under Section 3.3 hereof:

(a) An exercise notice in a form specified by the Administrator, stating that the Option or portion thereof is thereby exercised, such notice complying with all applicable rules established by the Administrator. The notice shall be signed by the Participant or other person then entitled to exercise the Option or such portion of the Option;

(b) The receipt by the Company of full payment for the Shares with respect to which the Option or portion thereof is exercised, including payment of any applicable withholding tax, which shall be made by deduction from other compensation payable to the Participant or in such other form of consideration permitted under Section 4.4 hereof that is acceptable to the Company;

(c) Any other written representations or documents as may be required in the Administrator's sole discretion to evidence compliance with the Securities Act, the Exchange Act or any other applicable law, rule or regulation; and

(d) In the event the Option or portion thereof shall be exercised pursuant to Section 4.1 hereof by any person or persons other than the Participant, appropriate proof of the right of such person or persons to exercise the Option.

Notwithstanding any of the foregoing, the Company shall have the right to specify all conditions of the manner of exercise, which conditions may vary by country and which may be subject to change from time to time.

4.4 Method of Payment. Payment of the exercise price shall be by any of the following, or a combination thereof, at the election of the Participant:

(a) Cash or check;

(b) With the consent of the Administrator, surrender of Shares (including, without limitation, Shares otherwise issuable upon exercise of the Option) held for such period of time as may be required by the Administrator in order to avoid adverse accounting consequences and having a Fair Market Value on the date of delivery equal to the aggregate exercise price of the Option or exercised portion thereof; or

(c) Other legal consideration acceptable to the Administrator (including, without limitation, through the delivery of a notice that the Participant has placed a market sell order with a broker with respect to Shares then issuable upon exercise of the Option, and that the broker has been directed to pay a sufficient portion of the net proceeds of the sale to the Company in satisfaction of the Option exercise price; *provided* that payment of such proceeds is then made to the Company at such time as may be required by the Company, but in any event not later than the settlement of such sale).

4.5 Conditions to Issuance of Shares. The Shares deliverable upon the exercise of the Option, or any portion thereof, may be either previously authorized but unissued Shares or issued Shares which have then been reacquired by the Company. Such Shares shall be fully paid and nonassessable. The Company shall not be required to issue or deliver any Shares purchased upon the exercise of the Option or portion thereof prior to fulfillment of all of the conditions in Section 10.7 of the Plan and following conditions:

(a) The admission of such Shares to listing on all stock exchanges on which such Shares are then listed;

(b) The completion of any registration or other qualification of such Shares under any state or federal law or under rulings or regulations of the Securities and Exchange Commission or of any other governmental regulatory body, which the Administrator shall, in its absolute discretion, deem necessary or advisable;

(c) The obtaining of any approval or other clearance from any state or federal governmental agency which the Administrator shall, in its absolute discretion, determine to be necessary or advisable;

(d) The receipt by the Company of full payment for such Shares, including payment of any applicable withholding tax, which may be in one or more of the forms of consideration permitted under Section 4.4 hereof; and

(e) The lapse of such reasonable period of time following the exercise of the Option as the Administrator may from time to time establish for reasons of administrative convenience.

4.6 Rights as Stockholder. The holder of the Option shall not be, nor have any of the rights or privileges of, a stockholder of the Company, including, without limitation, voting rights and rights to dividends, in respect of any Shares purchasable upon the exercise of any part of the Option unless and until such Shares shall have been issued by the Company and held of record by such holder (as evidenced by the appropriate entry on the books of the Company or of a duly authorized transfer agent of the Company). No adjustment will be made for a dividend or other right for which the record date is prior to the date the Shares are issued, except as provided in Article IX of the Plan.

ARTICLE 5.

OTHER PROVISIONS

5.1 Administration. The Administrator shall have the power to interpret the Plan and this Agreement and to adopt such rules for the administration, interpretation and application of the Plan as are consistent therewith and to interpret, amend or revoke any such rules. All actions taken and all interpretations and determinations made by the Administrator in good faith shall be final and binding upon the Participant, the Company and all other interested persons. No member of the Committee or the Board shall be personally liable for any action, determination or interpretation made in good faith with respect to the Plan, this Agreement or the Option.

5.2 Whole Shares. The Option may only be exercised for whole Shares.

5.3 Option Not Transferable.

(a) Subject to Section 4.1 hereof, the Option may not be sold, pledged, assigned or transferred in any manner other than by will or the laws of descent and distribution or, subject to the consent of the Administrator, pursuant to a DRO, unless and until the Option has been exercised and the Shares underlying the Option have been issued, and all restrictions applicable to such Shares have lapsed. Neither the Option nor any interest or right therein shall be liable for the debts, contracts or engagements of the Participant or his or her successors in interest or shall be subject to disposition by transfer, alienation, anticipation, pledge, hypothecation, encumbrance, assignment or any other means whether such disposition be voluntary or involuntary or by operation of law by judgment, levy, attachment, garnishment or any other legal or equitable proceedings (including bankruptcy) unless and until the Option has been exercised, and any attempted disposition thereof prior to exercise shall be null and void and of no effect, except to the extent that such disposition is permitted by the preceding sentence.

(b) During the lifetime of the Participant, only the Participant may exercise the Option (or any portion thereof), unless it has been disposed of pursuant to a DRO; after the death of the Participant, any exercisable portion of the Option may, prior to the time when such portion becomes unexercisable under the Plan or this Agreement, be exercised by the Participant's personal representative or by any person empowered to do so under the deceased the Participant's will or under the then-applicable laws of descent and distribution.

(c) Notwithstanding any other provision in this Agreement, the Participant may, in the manner determined by the Administrator, designate a beneficiary to exercise the rights of the Participant and to receive any distribution with respect to the Option upon the Participant's death. A beneficiary, legal guardian, legal representative, or other person claiming any rights pursuant to the Plan is subject to all terms and conditions of the Plan and this Agreement, except to the extent the Plan and this Agreement otherwise provide, and to any additional restrictions deemed necessary or appropriate by the Administrator. If the Participant is married or a domestic partner in a domestic partnership qualified under Applicable Law and resides in a community property state, a designation of a person other than the Participant's spouse or domestic partner, as applicable, as his or her beneficiary with respect to more than 50% of the Participant's interest in the Option shall not be effective without the prior written consent of the Participant's spouse or domestic partner. If no beneficiary has been designated or survives the Participant, payment shall be made to the person entitled thereto pursuant to the Participant's will or the laws of descent and distribution. Subject to the foregoing, a beneficiary designation may be changed or revoked by the Participant at any time provided the change or revocation is filed with the Administrator prior to the Participant's death.

5.4 Tax Consultation. The Participant understands that the Participant may suffer adverse tax consequences as a result of the grant, vesting and/or exercise of the Option, and/or with the purchase or disposition of the Shares subject to the Option. The Participant represents that the Participant has consulted with any tax consultants the Participant deems advisable in connection with the purchase or disposition of such Shares and that the Participant is not relying on the Company for any tax advice.

5.5 Binding Agreement. Subject to the limitation on the transferability of the Option contained herein, this Agreement will be binding upon and inure to the benefit of the heirs, legatees, legal representatives, successors and assigns of the parties hereto.

5.6 Adjustments Upon Specified Events. The Administrator may accelerate the vesting of the Option in such circumstances as it, in its sole discretion, may determine. In addition, upon the occurrence of certain events relating to the Shares contemplated by Article IX of the Plan (including, without limitation, an extraordinary cash dividend on such Shares), the Administrator shall make such adjustments the Administrator deems appropriate in the number of Shares subject to the Option, the exercise price of the Option and the kind of securities that may be issued upon exercise of the Option. The Participant acknowledges that the Option is subject to adjustment, modification and termination in certain events as provided in this Agreement and Article IX of the Plan.

5.7 Notices. Any notice to be given under the terms of this Agreement to the Company shall be addressed to the Company in care of the Secretary of the Company at the Company's principal office, and any notice to be given to the Participant shall be addressed to the Participant at the Participant's last address reflected on the Company's records. By a notice given pursuant to this Section 5.7, either party may hereafter designate a different address for notices to be given to that party. Any notice which is required to be given to the Participant shall, if the Participant is then deceased, be given to the person entitled to exercise his or her Option pursuant to Section 4.1 hereof by written notice under this Section 5.7. Any notice shall be deemed duly given when sent via email or when sent by certified mail (return receipt requested) and deposited (with postage prepaid) in a post office or branch post office regularly maintained by the United States Postal Service.

5.8 Titles. Titles are provided herein for convenience only and are not to serve as a basis for interpretation or construction of this Agreement.

5.9 Governing Law. The laws of the State of Delaware shall govern the interpretation, validity, administration, enforcement and performance of the terms of this Agreement regardless of the law that might be applied under principles of conflicts of laws.

5.10 Conformity to Securities Laws. The Participant acknowledges that the Plan and this Agreement are intended to conform to the extent necessary with all provisions of the Securities Act and the Exchange Act and any and all Applicable Law and regulations and rules promulgated by the Securities and Exchange Commission thereunder, and state securities laws and regulations. Notwithstanding anything herein to the contrary, the Plan shall be administered, and the Option is granted and may be exercised, only in such a manner as to conform to such Applicable Law. To the extent permitted by applicable law, the Plan and this Agreement shall be deemed amended to the extent necessary to conform to such Applicable Law.

5.11 Amendment, Suspension and Termination. To the extent permitted by the Plan, this Agreement may be wholly or partially amended or otherwise modified, suspended or terminated at any time or from time to time by the Administrator or the Board; *provided, however,* that, except as may otherwise be provided by the Plan, no amendment, modification, suspension or termination of this Agreement shall adversely affect the Option in any material way without the prior written consent of the Participant.

5.12 Successors and Assigns. The Company may assign any of its rights under this Agreement to single or multiple assignees, and this Agreement shall inure to the benefit of the successors and assigns of the Company. Subject to the restrictions on transfer herein set forth in Section 5.3 hereof, this Agreement shall be binding upon the Participant and his or her heirs, executors, administrators, successors and assigns.

5.13 Notification of Disposition. If this Option is designated as an Incentive Stock Option, the Participant shall give prompt notice to the Company of any disposition or other transfer of any Shares acquired under this Agreement if such disposition or transfer is made (a) within two (2) years from the Grant Date with respect to such Shares or (b) within one (1) year after the transfer of such Shares to the Participant. Such notice shall specify the date of such disposition or other transfer and the amount realized, in cash, other property, assumption of indebtedness or other consideration, by the Participant in such disposition or other transfer.

5.14 Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan or this Agreement, if the Participant is subject to Section 16 of the Exchange Act, the Plan, the Option and this Agreement shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including any amendment to Rule 16b-3 of the Exchange Act) that are requirements for the application of such exemptive rule. To the extent permitted by applicable law, this Agreement shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

5.15 Not a Contract of Service Relationship. Nothing in this Agreement or in the Plan shall confer upon the Participant any right to continue to serve as an employee or other service provider of the Company or any of its Subsidiaries or interfere with or restrict in any way with the right of the Company or any of its Subsidiaries, which rights are hereby expressly reserved, to discharge or to terminate for any reason whatsoever, with or without cause, the services of the Participant's at any time.

5.16 Entire Agreement. The Plan, the Grant Notice and this Agreement constitute the entire agreement of the parties and supersede in their entirety all prior undertakings and agreements of the Company and the Participant with respect to the subject matter hereof.

5.17 Section 409A. This Option is not intended to constitute "nonqualified deferred compensation" within the meaning of Section 409A of the Code (together with any Department of Treasury regulations and other interpretive guidance issued thereunder, including without limitation any such regulations or other guidance that may be issued after the date hereof, "Section 409A"). However, notwithstanding any other provision of the Plan, the Grant Notice or this Agreement, if at any time the Administrator determines that the Option (or any portion thereof) may be subject to Section 409A, the Administrator shall have the right in its sole discretion (without any obligation to do so or to indemnify the Participant or any other person for failure to do so) to adopt such amendments to the Plan, the Grant Notice or this Agreement, or adopt other policies and procedures (including amendments, policies and procedures with retroactive effect), or take any other actions, as the Administrator determines are necessary or appropriate either for the Option to be exempt from the application of Section 409A or to comply with the requirements of Section 409A.

5.18 Limitation on the Participant's Rights. Participation in the Plan confers no rights or interests other than as herein provided. This Agreement creates only a contractual obligation on the part of the Company as to amounts payable and shall not be construed as creating a trust. Neither the Plan nor any underlying program, in and of itself, has any assets. The Participant shall have only the rights of a general unsecured creditor of the Company with respect to amounts credited and benefits payable, if any, with respect to the Option, and rights no greater than the right to receive the Shares as a general unsecured creditor with respect to options, as and when exercised pursuant to the terms hereof.

* * * * *

Exhibit 10.2

May 30, 2022 **VIA EMAIL**
Bo Kruse

Re: Retention Bonus

Dear Bo

We are pleased to inform you that, in recognition of your contributions to Y-mAbs Therapeutics A/S (the "Company"), you are being offered the opportunity to receive a retention bonus (the "Retention Bonus") on the following terms and conditions:

1. Payment of Retention Bonus. Subject to satisfaction of the conditions set forth below, you will be eligible to receive a Retention Bonus in the amount of DKK 572,068.50 on April 26, 2023 (the "Vesting Date") payable in a lump sum within thirty (30) days following the Vesting Date.

2. Conditions to Payment. To receive the Retention Bonus, all of the following conditions must be satisfied:

(a) You are still employed with the Company through the Vesting Date;

(b) No notice of termination of your employment has been given by either you or the Company for any reason through the Vesting Date; and

(c) Y-mAbs Therapeutics, Inc.'s Biologics License Application for ^{131}I-omburtamab has been approved by the U.S. Food and Drug Administration on or before the Vesting Date.

3. Termination of Employment. If you are not employed with the Company through the Vesting Date for any reason, or if notice of termination of your employment with the Company is made by you or the Company for any reason prior to the Vesting Date (or any other condition set forth in paragraph 2 above is not satisfied), your right to payment of the Retention Bonus will be forfeited in its entirety.

4. Tax Withholding. Payment of the Retention Bonus will be subject to applicable tax withholdings.

5. Effect on Other Benefits/No Performance Requirement. You acknowledge that payment of the Retention Bonus is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, holiday pay, pension or retirement benefits, matching contributions or similar payments. The Retention Bonus does not replace any other bonus arrangement in place between you and the Company and is not dependent on any specific work performance by you.

6. Assignment. The obligation to pay the Retention Bonus is solely that of the Company. You may not assign your right to receive the Retention Bonus.

7. No Right to Continued Employment. The grant of this Retention Bonus opportunity does not give you any right to continue your employment relationship with the Company, and you shall remain subject to discharge to the same extent as if this opportunity were not granted to you.

8. Governing Law. Any dispute arising under this letter shall be decided by applying the laws of Denmark, without regard to conflicts of law principles.

We hope that this arrangement encourages your continued commitment to the Company. Please acknowledge your agreement to the terms of this letter by countersigning it in the space below and returning it to me. Please retain a copy of the letter.

Sincerely,

Y-MABS THERAPEUTICS A/S

By: /s/ THOMAS GAD
Name: Thomas Gad
Title: CEO & Board Member

ACKNOWLEDGED AND AGREED TO
ON MAY 30, 2022
Bo Kruse /s/ BO KRUSE

EXHIBIT 10.3

[ ]
[ ]

VIA EMAIL

Re: Retention Bonus

Dear [ ]

We are pleased to inform you that, in recognition of your contributions to Y-mAbs Therapeutics A/S (the "Company"), you are being offered the opportunity to receive a retention bonus (the "Retention Bonus") on the following terms and conditions:

1. Payment of Retention Bonus. Subject to satisfaction of the conditions set forth below, you will be eligible to receive a Retention Bonus in the amount equal to 25% of your base, cash, salary on April 26, 2023 (the "Vesting Date") payable in a lump sum within thirty (30) days following the Vesting Date.

2. Conditions to Payment. To receive the Retention Bonus, all of the following conditions must be satisfied:

(a) You are still employed with the Company through the Vesting Date;

(b) No notice of termination of your employment has been given by either you or the Company for any reason through the Vesting Date; and

(c) Y-mAbs Therapeutics, Inc.'s Biologics License Application for ^{131}I-omburtamab has been approved by the U.S. Food and Drug Administration on or before the Vesting Date.

3. Termination of Employment. If you are not employed with the Company through the Vesting Date for any reason, or if notice of termination of your employment with the Company is made by you or the Company for any reason prior to the Vesting Date (or any other condition set forth in paragraph 2 above is not satisfied), your right to payment of the Retention Bonus will be forfeited in its entirety.

4. Tax Withholding. Payment of the Retention Bonus will be subject to applicable tax withholdings.

5. Effect on Other Benefits/No Performance Requirement. You acknowledge that payment of the Retention Bonus is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, holiday pay, pension or retirement benefits, matching contributions or similar payments. The Retention Bonus does not replace any other bonus arrangement in place between you and the Company and is not dependent on any specific work performance by you.

6. Assignment. The obligation to pay the Retention Bonus is solely that of the Company. You may not assign your right to receive the Retention Bonus.

7. No Right to Continued Employment. The grant of this Retention Bonus opportunity does not give you any right to continue your employment relationship with the Company, and you shall remain subject to discharge to the same extent as if this opportunity were not granted to you.

8. Governing Law. Any dispute arising under this letter shall be decided by applying the laws of Denmark, without regard to conflicts of law principles.

We hope that this arrangement encourages your continued commitment to the Company. Please acknowledge your agreement to the terms of this letter by countersigning it in the space below and returning it to me. Please retain a copy of the letter.

Sincerely,

Y-MABS THERAPEUTICS A/S
By: [ ]
Name: [ ]
Title: [ ]

ACKNOWLEDGED AND AGREED TO
ON [ ]
[ ]

EXHIBIT 10.4

[ ] VIA EMAIL

[ ]

Re: Retention Bonus

Dear [ ]

We are pleased to inform you that, in recognition of your contributions to Y-mAbs Therapeutics, Inc. (the "Company"), you are being offered the opportunity to receive a retention bonus (the "Retention Bonus") on the following terms and conditions:

1. Payment of Retention Bonus. Subject to satisfaction of the conditions set forth below, you will be paid a Retention Bonus in the amount equal to 25% of your base cash salary on April 26, 2023 (the "Vesting Date") payable in a lump sum within thirty (30) days following the Vesting Date.

2. Conditions to Payment. To receive the Retention Bonus, all of the following conditions must be satisfied:

(a) You are still employed with the Company through the Vesting Date;

(b) No notice of termination of your employment has been given by either you or the Company through the Vesting Date; and

(c) the Company's Biologics License Application for ^{131}I-omburtamab has been approved by the U.S. Food and Drug Administration on or before the Vesting Date.

3. Termination of Employment. If you are not employed with the Company through the Vesting Date for any reason, or if notice of termination of your employment with the Company is made by you or the Company for any reason prior to the Vesting Date (or any other condition set forth in paragraph 2 above is not satisfied), your right to payment of the Retention Bonus will be forfeited in its entirety.

4. Tax Withholding. Payment of the Retention Bonus will be subject to applicable federal, state and local tax withholding.

5. Effect on Other Benefits. You acknowledge that payment of the Retention Bonus is not part of normal or expected compensation for purposes of calculating any severance, resignation, redundancy, end of service payments, bonuses, long-service awards, pension or retirement benefits, matching contributions or similar payments.

6. Assignment. The obligation to pay the Retention Bonus is solely that of the Company. You may not assign your right to receive the Retention Bonus.

7. No Right to Continued Employment. The grant of this Retention Bonus opportunity does not give you any right to continue your employment relationship with the Company, and you shall remain subject to discharge to the same extent as if this opportunity were not granted to you.

8. Governing Law. Any dispute arising under this letter shall be decided by applying the laws of the State of New York, without regard to conflicts of law principles.

We hope that this arrangement encourages your continued commitment to the Company. Please acknowledge your agreement to the terms of this letter by countersigning it in the space below and returning it to me.

Sincerely,

Y-MABS THERAPEUTICS, INC.
By: [ ]
Name: [ ]
Title: [ ]

ACKNOWLEDGED AND AGREED TO
THIS [ ]
[ ]

Exhibit 31.1

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

I, Thomas Gad 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: August 8, 2022

By: /s/ Thomas Gad
Name: Thomas Gad
Title: Founder, President, Interim Chief Executive Officer and Head of Business Development and Strategy
(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: August 8, 2022

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 June 30, 2022 (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: August 8, 2022

By: /s/ Thomas Gad
Name: Thomas Gad
Title: Founder, President, Interim Chief Executive Officer and Head of Business Development and Strategy
(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 June 30, 2022 (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: August 8, 2022

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