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DELTA REPORT

10-Q

YMAB - Y-MABS THERAPEUTICS, INC.

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	3030
CHANGES	192
DELETIONS	1319
ADDITIONS	1519

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

FORM 10-Q

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

For the quarterly period ended September 30, 2023 March 31, 2024

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 43,621,618 43,882,638 shares of Common Stock ($0.0001 par value) outstanding as of November 6, 2023 April 30, 2024.

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FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, about us and our industry 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” 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 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. 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. 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 from those anticipated or implied in the forward-looking statements.

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 made. 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.

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,” "Y-mAbs," "Company," "we," "us," and “our” "our" in this document refer to Y-mAbs Therapeutics, Inc., a Delaware corporation, and, where appropriate, its

subsidiaries. subsidiary.

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.

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These risks are discussed more fully below under “Risk Factors” and include, but are not limited to risks related to, the following:

- We may not be able to successfully implement our business model, including our plans to expand the commercialization of DANYELZA® (naxitamab-gqgk), referred to as DANYELZA, and to develop, obtain regulatory approval of and commercialize our other product candidates;
- Our expectations with respect to the rate and degree of market acceptance and clinical utility for DANYELZA or any current or future product candidate candidates for which we may receive marketing approval may not be realized;

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- Our expectations with respect to the commercial value of any of our product candidates, including antibody constructs based on Self-Assembly Dis-Assembly Pre-targeted Radioimmunotherapy, or SADA PRIT, technology platform, 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, expanding the indications for, and selling DANYELZA and any current or future product candidate candidates for which we may receive marketing approval. This includes 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;
- Our expectations with respect to the pricing, coverage and reimbursement of, and the extent to which patient assistance programs are utilized for DANYELZA or other product candidates for which we may receive marketing approval may not be realized;
- Our expectations with respect to our ongoing and future clinical trials 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 expectations with respect to regulatory submissions and potential regulatory approvals may not be realized on the anticipated timing or at all;
- The SADA PRIT Technology that we use has not been approved for commercial use by the FDA or any other regulatory authority and our clinical effort may not result in approval or marketable products;
- 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 product candidates, such event could adversely affect other clinical trials of our product candidates;
- We may be unable to attract, integrate, manage and retain qualified personnel or key employees;
- Our 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;
- Any collaboration agreement that we may enter into may not be successful, which could adversely affect our ability to develop and commercialize our products or to enter new therapeutic areas;

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- We currently depend on third parties for a portion of our operations, and we may not be able to control their work as effectively as if we performed these functions ourselves. If the third parties fail to comply with regulations, our financial results and financial condition could be adversely affected;
- We are dependent on our relationship with Memorial Sloan Kettering Cancer Center, or MSK, including our ability to maintain our exclusive rights under the 2015 MSK License Agreement (as amended), or the MSK License Agreement, and the 2020 SADA Technology License Agreement, or the SADA License Agreement as well as 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, 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;
- Our 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 health crises, macroeconomic conditions, such as inflation and high interest rates, uncertain global financial markets, supply-chain disruptions, and by geopolitical events, including the invasion of Ukraine by Russia, and sanctions related thereto, which resulted in the suspension of our clinical trial and regulatory activities in

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Russia; as well as the state of the war between involving Israel and Hamas and the related risk of a larger regional more global conflict;

- We currently depend on a small number of third-party contract manufacturing organizations, or CMOs, and expect it would be difficult to find a suitable replacement for the complex and difficult manufacture of DANYELZA and 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 continue to sell DANYELZA or to develop our other product candidates in a timely manner; and
- 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. products;
- Any litigation to which we are a party could result in substantial damages or other adverse consequences to our business and may divert management's time and attention from our business. Any litigation that is successful against us may result in the incurrence of substantial liability if our insurance is inadequate.

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

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PART I – FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements Statements.

Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(in thousands, except share data and per share data)

	As of	
	September 30, 2023	December 31, 2022
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 86,571	$ 105,762
Accounts receivable, net	18,874	12,531
Inventories	7,113	6,702
Other current assets	2,302	5,452
Total current assets	114,860	130,447
Property and equipment, net	296	604
Operating lease right-of-use assets	1,593	1,739
Intangible assets, net	2,720	2,986
Other assets	9,415	5,680
TOTAL ASSETS	$ 128,884	$ 141,456
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 7,610	$ 14,175
Accrued liabilities	13,304	13,241
Operating lease liabilities, current portion	898	868
Total current liabilities	21,812	28,284
Accrued milestone payments	5,375	2,250
Operating lease liabilities, long-term portion	725	899
Other liabilities	822	802
TOTAL LIABILITIES	28,734	32,235
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at September 30, 2023 and December 31, 2022	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at September 30, 2023 and December 31, 2022; 43,621,618 and 43,670,109 shares issued at September 30, 2023 and December 31, 2022, respectively	4	4
Additional paid-in capital	554,779	543,929
Accumulated other comprehensive income	1,849	1,331
Accumulated deficit	(456,482)	(436,043)
TOTAL STOCKHOLDERS' EQUITY	100,150	109,221
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 128,884	$ 141,456

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	March 31, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 75,749	$ 78,637
Accounts receivable, net	20,588	22,454
Inventories	8,448	5,065
Other current assets	3,482	4,955
Total current assets	108,267	111,111
Property and equipment, net	153	224
Operating lease right-of-use assets	1,179	1,412
Intangible assets, net	2,543	2,631
Other assets	11,173	12,491
TOTAL ASSETS	$ 123,315	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 6,728	$ 6,060
Accrued liabilities	9,989	13,166
Operating lease liabilities, current portion	888	902
Total current liabilities	17,605	20,128
Accrued milestone and royalty payments	5,375	5,375
Operating lease liabilities, long-term portion	293	517
Other liabilities	853	864
TOTAL LIABILITIES	24,126	26,884
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2024 and December 31, 2023; 43,852,638 and 43,672,112 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	562,436	558,002
Accumulated other comprehensive income	848	449
Accumulated deficit	(464,099)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	99,189	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 123,315	$ 127,869

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss

(unaudited)

(In thousands, except share and per share data)

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
REVENUES				
Product revenue, net	$ 19,954	$ 12,537	$ 60,956	$ 32,820
License revenue	500	—	500	1,000
Total revenues	20,454	12,537	61,456	33,820
OPERATING COSTS AND EXPENSES				
Cost of goods sold	2,595	2,475	9,327	5,447
License royalties	50	—	50	100
Research and development	15,358	22,453	40,831	71,785
Selling, general, and administrative	10,200	13,626	33,721	50,146
Total operating costs and expenses	28,203	38,554	83,929	127,478
Loss from operations	(7,749)	(26,017)	(22,473)	(93,658)
OTHER INCOME/(LOSS), NET				
Interest and other income/(loss)	189	(1,509)	2,400	(3,067)
LOSS BEFORE INCOME TAXES	(7,560)	(27,526)	(20,073)	(96,725)
Provision for income taxes	187	—	366	—
NET LOSS	$ (7,747)	$ (27,526)	$ (20,439)	$ (96,725)
Other comprehensive income				
Foreign currency translation	806	1,598	518	3,331
COMPREHENSIVE LOSS	$ (6,941)	$ (25,928)	$ (19,921)	$ (93,394)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.63)	$ (0.47)	$ (2.21)
Weighted average common shares outstanding, basic and diluted	43,620,532	43,718,351	43,651,536	43,715,451

	Three months ended March 31,	
	2024	2023
REVENUES		
Product revenue, net	$ 19,431	$ 20,251
License revenue	500	—
Total revenues	19,931	20,251
OPERATING COSTS AND EXPENSES		
Cost of goods sold	2,097	2,083
License royalties	50	—
Research and development	13,267	13,418
Selling, general, and administrative	11,425	12,251
Total operating costs and expenses	26,839	27,752
Loss from operations	(6,908)	(7,501)
OTHER INCOME, NET		
Interest and other income	439	1,111
LOSS BEFORE INCOME TAXES	(6,469)	(6,390)
Provision for income taxes	160	—

NET LOSS	$ (6,629)	$ (6,390)
Other comprehensive income/(loss)		
Foreign currency translation	399	(306)
COMPREHENSIVE LOSS	$ (6,230)	$ (6,696)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.15)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	43,779,456	43,671,589

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

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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, 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
Exercise of stock options	4,000	—	52	—	—	52
Stock-based compensation expense	1,979	—	3,341	—	—	3,341
Retirement of treasury shares – refer to Note 10	(57,887)	—	(963)	—	—	(963)
Foreign currency translation	—	—	—	1,598	—	1,598
Net loss	—	—	—	—	(27,526)	(27,526)
Balance September 30, 2022	43,668,130	$ 4	$ 540,392	$ 4,702	$ (437,200)	$ 107,898

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2022	43,670,109	$ 4	$ 543,929	$ 1,331	$ (436,043)	$ 109,221
Stock-based compensation expense	7,658	—	5,304	—	—	5,304

Foreign currency translation	—	—	—	(306)	—	(306)
Net loss	—	—	—	—	(6,390)	(6,390)
Balance March 31, 2023	43,677,767	$ 4	$ 549,233	$ 1,025	$ (442,433)	$ 107,829
Retirement of treasury shares – refer to Note 10	(58,763)	—	(480)	—	—	(480)
Stock-based compensation expense	1,188	—	3,616	—	—	3,616
Foreign currency translation	—	—	—	18	—	18
Net loss	—	—	—	—	(6,302)	(6,302)
Balance June 30, 2023	43,620,192	$ 4	$ 552,369	$ 1,043	$ (448,735)	$ 104,681
Stock-based compensation expense	1,426	—	2,410	—	—	2,410
Foreign currency translation	—	—	—	806	—	806
Net loss	—	—	—	—	(7,747)	(7,747)
Balance September 30, 2023	43,621,618	$ 4	$ 554,779	$ 1,849	$ (456,482)	$ 100,150

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2022	43,670,109	$ 4	$ 543,929	$ 1,331	$ (436,043)	$ 109,221
Stock-based compensation expense	7,658	—	5,304	—	—	5,304
Foreign currency translation	—	—	—	(306)	—	(306)
Net loss	—	—	—	—	(6,390)	(6,390)
Balance March 31, 2023	43,677,767	$ 4	$ 549,233	$ 1,025	$ (442,433)	$ 107,829

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2023	43,672,112	$ 4	$ 558,002	$ 449	$ (457,470)	$ 100,985
Exercise of stock options	71,550	—	588	—	—	588
Stock-based compensation expense	108,976	—	3,846	—	—	3,846
Foreign currency translation	—	—	—	399	—	399
Net loss	—	—	—	—	(6,629)	(6,629)
Balance March 31, 2024	43,852,638	$ 4	$ 562,436	$ 848	$ (464,099)	$ 99,189

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

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Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Nine months ended September 30,		Three months ended March 31,
	2023	2022	

			2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	$ (20,439)	$ (96,725)	$ (6,629)	$ (6,390)
Adjustments to reconcile net loss to net cash used in operating activities:				
Depreciation and amortization	574	609	159	182
Stock-based compensation	11,330	22,065	3,846	5,304
Foreign currency transactions and other transactions	(369)	3,698		
Foreign currency and other transactions			492	(456)
Changes in assets and liabilities:				
Accounts receivable, net	(6,343)	(1,539)	1,866	(6,171)
Inventories	(411)	(730)	(3,383)	(2,243)
Other current assets	2,671	2,919	1,473	1,722
Other assets	(3,735)	(2,430)	1,318	(2,983)
Accounts payable	(6,196)	171	176	(4,771)
Accrued liabilities and other	3,722	4,702	(2,795)	2,682
NET CASH USED IN OPERATING ACTIVITIES	(19,196)	(67,260)	(3,477)	(13,124)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—	—	—
CASH FLOWS FROM FINANCING ACTIVITIES				
Proceeds from exercised stock options	—	84	588	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	—	84	588	—
Effect of exchange rates on cash and cash equivalents	5	138	1	(9)
NET DECREASE IN CASH AND CASH EQUIVALENTS	(19,191)	(67,038)	(2,888)	(13,133)
Cash and cash equivalents at the beginning of period	105,762	181,564	78,637	105,762
Cash and cash equivalents at the end of period	$ 86,571	$ 114,526	$ 75,749	$ 92,629
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES				
Acquisition of treasury shares upon repayment of secured promissory note – refer to Note 10	$ 480	$ 963		
Intangible assets acquisition in accrued milestones and royalty payments	$ —	$ 1,500		
Right-of-use assets obtained in exchange for lease obligations	$ 636	$ 347		

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

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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 commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. The Company Y-mAbs is leveraging its the Company's proprietary antibody platforms and deep expertise in the field of antibodies to develop a broad portfolio of innovative medicines.

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

NOTE 2—BASIS OF PRESENTATION

The Company has incurred losses in almost all quarters every year 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 FDA approval in the United States and regulatory approval in other jurisdictions; marketing or sales capability or experience; uncertainty in getting adequate payor 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) received accelerated approval 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. become profitable. 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 $456,482,000 $464,099,000 as of September 30, 2023, March 31, 2024 and $436,043,000 $457,470,000 as of December 31, 2022 December 31, 2023. Through September 30, 2023 March 31, 2024, the Company has funded its the operations primarily through proceeds from sales of shares of its the Company's common stock, including its the initial public offering in September 2018 and its the Company's 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 Company's Priority Review Voucher ("PRV") obtained upon FDA approval of DANYELZA.

As of September 30, 2023, the The Company had cash and cash equivalents of $86,571,000, $75,749,000 and $78,637,000 as of December 31, 2022 March 31, 2024 and December 31, 2023, the Company had cash and cash equivalents of $105,762,000. respectively. As of the issuance date of the consolidated financial statements for the third quarter ended September 30, 2023 March 31, 2024, the Company expects that its the cash and cash equivalents at September 30, 2023, as of March 31, 2024 will be sufficient to fund its the Company's operating expenses and capital expenditure requirements as currently planned through at least the next 12 months. months from the date of the financial statements are issued.

The Company may raise additional capital to fund future operations through the sale of its the Company's equity securities, incurring debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. These potential financing sources are in addition to the successful commercialization of DANYELZA and our product candidates, for which the Company may obtain regulatory approval and marketing authorization. The Company's commercialization strategy may include working with a collaborator or distributor. Sufficient funds may not

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strategy may include working with a collaborator or distributor. Sufficient funds may not be available to the Company on attractive terms or at all when needed from equity, debt or debt other financing. If 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. programs in addition to other measures.

The accompanying unaudited consolidated financial statements reflect the accounts of the Company and its the Company's wholly-owned subsidiaries subsidiary and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information, Accounting Standards Codification ("ASC") Topic 270-10 and the instructions to 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 nine-month periods three-month period ended September 30, 2023 March 31, 2024, are not necessarily indicative of the results that may be expected for the year ending December 31, 2023 December 31, 2024, any other interim periods, or any future year or period. The December 31, 2022, consolidated balance sheet data as of December 31, 2023 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, 2022 December 31, 2023.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are detailed in its our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Use of Estimates

The preparation of consolidated 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 consolidated financial statements and the reported amounts of revenues and 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, the valuation of stock options and asset impairments. 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.

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 a loss 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's cash and cash equivalents are held at a large major federal, national bank. 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 loss with respect to such cash balances.

Accounts Receivable, Net

The Company's accounts receivable, net balance consists of amounts due from sales of our approved product, DANYELZA. Receivables from product sales are recorded net of allowances which generally include chargebacks, doubtful accounts, rebates, returns, and discounts. The 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

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expected future write-offs. The Company has not historically experienced any significant credit losses. All customer accounts are actively managed, and no losses are currently expected.

The Company has not experienced any write-offs related to customer accounts receivable and has not recognized any allowance for doubtful accounts nor reversed any allowances in the three months ended March 31, 2024 and 2023.

Concentration of Credit Risk

The Company's product sales are made through arrangements primarily with three national specialty distributors in the United States of America. ("U.S.") specialty distributors. As of September 30, 2023 March 31, 2024, the accounts receivable balances from such distributors totaled 69% 76% of the Company's outstanding accounts receivable. See *NOTE 4 – PRODUCT REVENUE, NET*, for details of product sales to certain customers that accounted for more than 10% of total product revenue, net. The remainder of the Company's accounts receivable as of September 30, 2023 March 31, 2024 represented balances from international distribution partners. The Company has contractual payment terms with each of its customers customer 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.

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Inventories

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. inventories. Amounts in inventory inventories 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 inventories at the receipt of FDA approval.

The Company performs an assessment of the recoverability of capitalized inventory inventories 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. The Company had No material inventory write-downs totaling $375,000 and $831,000 occurred in the three and nine months ended September 30, 2023, respectively, March 31, 2024 and $1,200,000 in the three and nine months ended September 30, 2022, which were each recorded in cost of goods sold on the Consolidated Statements of Net Loss and Comprehensive Loss. 2023.

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;

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- 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.

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

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

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

	Fair Value Measurements at September 30, 2023 Using:				Fair Value Measurements as of March 31, 2024			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash equivalents:								
Money market funds	$ —	$ 82,964	$ —	$ 82,964	$ —	$71,466	$ —	$71,466
Total	$ —	$ 82,964	$ —	$ 82,964	$ —	$71,466	$ —	$71,466

	Fair Value Measurements at December 31, 2022 Using:				Fair Value Measurements as of December 31, 2023			
	Level 1	Level 2	Level 3	Total	Level 1	Level 2	Level 3	Total
Cash equivalents:								
Money market funds	$ —	$ 86,965	$ —	$ 86,965	$ —	$75,501	$ —	$75,501
Total	$ —	$ 86,965	$ —	$ 86,965	$ —	$75,501	$ —	$75,501

During the three quarter ended March 31, 2024 and nine months ended September 30, 2023, 2023, there were no transfers between Level 1, Level 2, and Level 3. 3.

Operating Lease Right-of-Use Assets and Operating Lease Liabilities

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 the Company's 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 an 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 the Company 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 a lease which are is included in the lease term when it is reasonably certain that it the Company 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. The Company also elects the practical expedient to not separate lease and non-lease components for all of our leases. The Company has made an accounting policy election to account for each separate lease component of a contract and its associated non-lease components as a single lease component. See the Lease Agreements section in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* for the related disclosures.

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

Revenue Recognition

To determine revenue recognition for product revenue and license revenue arrangements that the Company determines are within the scope of ASC 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 Company satisfies a performance obligation. The company 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 Company will collect the consideration it the Company 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 Company assesses the goods or services promised

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within each contract, determines those that are performance obligations, and assesses whether each promised good or service is distinct. The company Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied.

Under the practical expedient permitted under Topic 606, the Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less. If there are multiple distinct performance obligations, the Company allocates the transaction price to each distinct performance obligation based on its relative standalone selling price. 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 the Company identifies a bundle of goods or services that is distinct. The standalone selling price is generally determined based on the prices charged to customers.

Product revenue, net

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

to the distributors for sales in the international territories.

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 the Company 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 the Company's 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 ensure that DANYELZA will 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 inventories in the wholesale or retail channel.

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- 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 the distributors to earn these discounts and fees and deduct the full amount of these discounts and fees from its the Company's gross product revenue at the time such revenues are recognized.

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- 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 accounts receivable.

In December 2022, the Company announced a distribution agreement with WEP Clinical Ltd., or WEP, in connection with an early access program for DANYELZA in Europe. There are no regulatory-based or sales-based milestone payments or royalty arrangements under this distribution agreement. The Company recognizes revenue when WEP obtains control of the product upon delivery. The Company invoices WEP based on the terms of the distribution agreement, where a portion is billed upon shipment of product and the unbilled portion is billed at a later date based on terms of the distribution agreement. The Company has an unconditional right to the unbilled portion of the receivable and the Company estimates that the receivable will be collected within one year and therefore has recorded the balance at September 30, 2023 March 31, 2024, within accounts receivable on the Consolidated Balance Sheets.

License revenue

The Company's license agreements include regulatory-based milestone payments and sales-based milestone payments, in addition to royalties. The Company determines whether the achievement of each regulatory-based milestone within the agreement is constrained as they are contingent upon regulatory approvals, which are not within the control of the Company and therefore not deemed probable. The Company expects that the sales-based milestones and royalty payments will be recognized when the milestone is achieved or the related sales occur. The Company re-evaluates the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur, it the Company assesses whether this resolves the constraint and when it is appropriate to recognize revenue.

In December 2020, the Company entered into a development and commercialization arrangement with SciClone International Pharmaceuticals Ltd., or SciClone, for certain indications of DANYELZA and omburtamab for Greater China, including Mainland China, Taiwan, Hong Kong and Macau. Based on the terms of the agreement, the Company may receive regulatory-based milestone payments up to $40,000,000, of which $15,000,000 has already been recognized and received in December 2022 for the conditional approval of DANYELZA in China, and sales-based milestone payments up to $60,000,000 and is entitled to royalties based upon the net sales generated by SciClone related to the product indications in the territory. The Company expects that the remaining regulatory-based and sales-based milestones will be recognized when each milestone is achieved.

In November 2020, the Company entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly-owned wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, the West Bank and the Gaza Strip. Based on the terms of the arrangement, the Company may receive regulatory-based milestone payments up to $750,000, of which $250,000 has already been recognized, and sales-based milestone payments up to $500,000 and is entitled to royalties based upon the net sales generated by Takeda related to the product in the territory. The Company expects that the remaining regulatory-based and sales-based milestones will be recognized when the milestone is achieved, or the related sales occur.

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In December 2020, the Company 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. There are no regulatory-based or sales-based milestone payments or royalty arrangements under this distribution agreement.

In May 2021, the Company entered into an exclusive distribution agreement with Adium Pharma S.A. ("Adium") for Adium to be the exclusive distributor of DANYELZA in Latin America of the Company's antibodies omburtamab, if approved, and DANYELZA. America. Under the terms of the agreement, the Company may receive regulatory-based milestone payments up to an aggregate of $3,000,000, of which $1,000,000 $2,000,000 has already been recognized, and received prior to 2023. In addition, the Company is entitled to royalties based upon DANYELZA net sales generated by Adium in Latin America. The agreement with Adium does not contain a regulatory-based milestone related to In April 2022, the Brazilian Health Regulatory Agency's approval Company received $1,000,000 upon the submission of the updated FDA Biologics License Applications ("BLA") dossier for marketing authorization, which was granted DANYELZA. In addition, during the three months ended June 30, 2023. During the three and nine months ended September 30, 2023, third quarter of 2023, the Company recognized $500,000 in regulatory-

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based regulatory-based license revenue from Adium pursuant to the distribution agreement in connection with the September 2023 achievement of marketing authorization for DANYELZA in Mexico. Lastly, in January 2024, the Company accepted the price approval for the first product in Brazil from the Brazilian Medicines Market Regulation Chamber, or CMED. The Company received $500,000 regulatory-based payment from Adium in connection with the price approval from CMED in the three months ended March 31, 2024. The Company expects that the sales-based milestones and royalty payments will be recognized when and if the milestones are achieved or the related sales occur.

In December 2022, the Company announced a distribution agreement with WEP Clinical Ltd., or WEP, in connection with an early access program for DANYELZA in Europe. There are no regulatory, or sales-based milestone payments or royalties under this distribution agreement.

Stock-Based Compensation

The Company measures stock options granted to employees and directors based on the fair value on the date of the grant and recognizes compensation expense of those awards, over the requisite service period, which for employees and directors is the vesting period of the respective award. Forfeitures are accounted for as they occur. The Company issues stock options with only service based and records 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 grant date using the Black Scholes option pricing model. The Company's public trading commenced in September 2018, and, as a result, there is limited available historical volatility experience. Therefore, the Company estimates expected stock volatility based on the weighting of the Company's historical volatility with the historical volatility of a group of publicly traded peer companies, and the Company expects to continue to do so until there is adequate historical data regarding the volatility of the Company's traded stock prices. 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 common shares and does not expect to pay any cash dividends in the foreseeable future.

The fair value of restricted stock units is determined at the grant-date price of the Company's common stock.

The fair value of performance-based restricted stock units ("PRSU") is determined using a Monte-Carlo simulation model. The vesting of each tranche of the award depends on the fulfillment of both a service condition and the achievement of a stock price hurdle at the end of each tranche's performance period, based on an average of the closing stock price over the 30 consecutive trading days immediately preceding each tranche's vesting date. The stock price volatility is simulated using the Company's historical volatility calculated from daily stock returns over a lookback term which equals the remaining service period from the grant date. The risk-free rate is determined using the zero-coupon risk-free interest rate derived from the Treasury Constant Maturities yield curve on the grant date. The expected dividend yield is based on the fact that the Company has never paid cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

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Earnings Per Share

The Company reports net earnings per share in accordance with ASC 260, Earnings 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. Similarly, securities that could potentially dilute basic EPS in the future are not included in the computation of diluted EPS because to do so would have been antidilutive.

Segment Information

The Company is engaged solely in operations related to the discovery, development, distribution and commercialization of novel antibody-based therapeutic products for the treatment of cancer. Accordingly, cancer, which the Company has determined that it operates in defines as one operating segment.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, and are adopted by the Company as of the specific effective date. The Company adopted ASU 2021-01 (as amended by ASU 2022-06), ASU 2020-06, ASU 2022-03, ASU 2022-04, ASU 2022-02, 2023-01, ASU 2022-01 2023-02 and ASU 2021-08 2023-07 effective January 1, 2023 January 1, 2024, and the adoption of these new standards did not have a material impact on the Company's consolidated financial statements or disclosures.

In December 2023, the FASB issued ASU 2023-09, Improvement to income tax disclosures (Topic 740). ASU 2023-09 addresses annual disclosures related to the income tax rate reconciliation and the income taxes paid within the tax note. ASU 2023-09 requires consistent categories and greater disaggregation of information in the income tax rate reconciliation as well as a disaggregation of taxes paid by jurisdiction for the income taxes paid. ASU 2023-09 is required to be adopted by the Company for annual periods beginning after December 15, 2024. Early adoption is permitted for annual consolidated financial statements that have not yet been issued or made available for issuance. The Company is evaluating the impact of this update on the Company's disclosures.

The Company has evaluated all other 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, NET

The Company's product revenue, net was generated from sales of DANYELZA and totaled $19,954,000 and $12,537,000 for consists of the three months ended September 30, 2023 and 2022, respectively. following (in thousands):

	Three months ended March 31,	
	2024	2023
United States	$ 18,610	$ 16,833
Other countries	821	3,418
Total product revenue, net	$ 19,431	$ 20,251

The geographic breakout for majority of the Company's product revenue, net between sales were in the United States with additional sales in China, Europe, Latin America, and other countries for the three months ended September 30, 2023, were $16,072,000 Israel through sublicenses and $3,882,000, respectively. The geographic breakout for the product revenue, net between the United States and other countries for the three months ended September 30, 2022, was $12,420,000 and $117,000, respectively. distribution agreements. The Company's product revenue, net from other countries for the three months ended September 30, 2023, March 31, 2023 included $3,048,000 of product revenue from the Company's distribution partner, WEP.

The Company's product revenue, net was generated from sales of DANYELZA and totaled $60,956,000 and $32,820,000 for the nine months ended September 30, 2023 and 2022, respectively. The geographic breakout for the product revenue, net between the United States and other countries for the nine months ended September 30, 2023, were $48,756,000 and $12,200,000, respectively. The geographic breakout for the product revenue, net between the United States and other countries for the nine months ended September 30, 2022 was $30,872,000 and $1,948,000, respectively. The Company's product revenue, net from other countries for the nine months ended September

30, 2023, included $3,535,000 of product revenue and related royalties for the commercial launch initial inventory stocking order from the Company's distribution partner, SciClone, which launched commercial sales in China in June 2023. The Company's product revenue, net from other countries for the nine months ended September 30, 2023, also included $5,579,000 $2,516,000 of product revenue, net from the Company's distribution partner, WEP.

Under WEP, in connection with the Company's distribution agreement with WEP, the Company early access program for DANYELZA in Europe. There is entitled to receive all payments based on the net product sales and pays WEP a service fee in exchange for its services. The Company recorded $3,048,000 and $5,579,000 product revenue, net from WEP in the three and nine months ended September 30, 2023. There was no product revenue, net from WEP in the three and nine months ended September 30, 2022 March 31, 2024. The Company

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recognized royalty revenue from the distribution partners of $462,000 and $658,000 in the three months ended March 31, 2024 and 2023, respectively.

The Company had product sales to certain customers that accounted for more than 10% of total product revenue, net for the three months ended March 31, 2024 and 2023. McKesson, AmerisourceBergen and Cardinal Health, accounted for 51%, 25%, and 22%, respectively, of the Company's product revenue, net for the three months ended March 31, 2024. McKesson, AmerisourceBergen, Cardinal Health and WEP accounted for 45%, 29%, 13% and 12%, respectively, of the Company's product revenue, net for the three months ended March 31, 2023.

As of September 30, 2023 March 31, 2024, the Company has had recorded on its the Consolidated Balance Sheets accounts receivable of approximately $4,120,000, $20,588,000, of which $2,241,000 represents an unbilled portion to which the Company has unconditional rights to collect the consideration, and accrued liabilities of $267,000 $198,000 related to product sales to WEP during the nine months year ended September 30, 2023 December 31, 2023.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, discounts, distribution-related fees and other sales-related deductions. Accruals for chargebacks and discounts are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees without contractual right of offset and other sales-related deductions are recorded within accrued liabilities. As of September 30, 2023 March 31, 2024, the Company had recorded accounts receivable allowances of approximately $910,000 $617,000 and accrued liabilities of approximately $3,482,000

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$1,910,000 related to product sales during the nine months ended September 30, 2023. sales. As of December 31, 2022 December 31, 2023, the Company had recorded accounts receivable allowances of approximately $508,000 $492,000 and accrued liabilities of $2,474,000 $2,309,000 related to product sales.

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

	Contractual Allowances and	Contractual Allowances and

	Discounts	Government Rebates	Returns	Total	Discounts	Government Rebates	Returns	Total
		(in thousands)						
Balance December 31, 2022	$ 33	$ 2,905	$ 44	$ 2,982				
Balance December 31, 2023					$ 41	$ 2,694	$ 66	$ 2,801
Current provisions relating to sales in current year	179	7,296	519	7,994	94	2,667	3	2,764
Payments/credits relating to sales in current year	(164)	(5,445)	(220)	(5,829)	(54)	(2,690)	—	(2,744)
Change in estimate related to sales in the prior year	—	(755)	—	(755)	—	(294)	—	(294)
Balance September 30, 2023	$ 48	$ 4,001	$ 343	$ 4,392				
Balance March 31, 2024					$ 81	$ 2,377	$ 69	$ 2,527

The vast majority of the Company's product sales were in the United States with additional sales in China, Europe, Latin America and Israel through sublicenses and distribution agreements. The Company had product sales to certain customers that accounted for more than 10% of total product revenue, net, for the three and nine months ended September 30, 2023 and September 30, 2022, respectively. McKesson, AmerisourceBergen, WEP and Cardinal Health accounted for 48%, 18%, 15% and 14% respectively, of the Company's product revenue, net, for the three months ended September 30, 2023. McKesson and AmerisourceBergen accounted for 78% and 14%, respectively, of the Company's product revenue, net, for the three months ended September 30, 2022. McKesson, AmerisourceBergen and Cardinal Health accounted for 45%, 22% and 13%, respectively, of the Company's product revenue, net, for the nine months ended September 30, 2023. McKesson and AmerisourceBergen accounted for 69% and 16%, respectively, of the Company's product revenue, net, for the nine months ended September 30, 2022. The Company recognized royalty revenue from its distribution partners of $427,000 and $58,000 in the three months ended September 30, 2023 and 2022, respectively, and $3,814,000 and $1,412,000 in the nine months ended September 30, 2023 and 2022, respectively.

During the quarter and nine months ended September 30, 2023, the Company recorded a change in estimate related to assessed Medicaid claims data experience and reserves for historical earned periods. The change in estimate resulted in a benefit of $1,586,000 to the quarter ended September 30, 2023, of which $755,000 related to the deductions for sales occurring in the prior year.

NOTE 5—NET LOSS PER SHARE

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

	Three months ended September 30,		Nine months ended September 30,		Three months ended March 31,	
	2023	2022	2023	2022		
	(in thousands, except per share amounts)				2024	2023
Net loss (numerator)	$ (7,747)	$ (27,526)	$ (20,439)	$ (96,725)	$ (6,629)	$ (6,390)
Weighted-average shares (denominator), basic and diluted	43,621	43,718	43,652	43,715	43,779	43,672
Basic and diluted net loss per share	$ (0.18)	$ (0.63)	$ (0.47)	$ (2.21)	$ (0.15)	$ (0.15)

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options and unvested restricted stock share units outstanding which totaled 9,015,719 11,226,739 shares and 7,119,332 8,894,258 shares as of September 30, 2023 March 31, 2024 and September 30, 2022, 2023, respectively.

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NOTE 6—INVENTORIES

Inventories consist of the following (in thousands):

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
Raw Material			$ 261	$ —
Work In Progress	$ 13,745	$ 11,317	16,550	14,021
Finished Goods	2,219	666	2,378	2,992
Total Inventories	$ 15,964	$ 11,983	$ 19,189	$ 17,013

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

	September 30, 2023	December 31, 2022	March 31, 2024	December 31, 2023
CURRENT ASSETS				
Inventories	$ 7,113	$ 6,702	$ 8,448	$ 5,065
Total recorded in Current Assets	7,113	6,702	8,448	5,065
NONCURRENT ASSETS				
Other assets	8,851	5,281	10,741	11,948
Total recorded in Noncurrent Assets	8,851	5,281	10,741	11,948
Total Inventories	$ 15,964	$ 11,983	$ 19,189	$ 17,013

As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the Company has classified $8,851,000 $10,741,000 and $5,281,000, $11,948,000, respectively, of work in progress work-in-progress inventories as noncurrent assets based on its the Company's current demand schedule and expectation that such inventory inventories will be utilized after one year from the balance sheet date.

During the three months ended September 30, 2023 and 2022, the Company recorded charges to write-off inventory of $375,000 and $1,200,000, respectively. During the nine months ended September 30, 2023 and 2022, the Company recorded charges to write-off inventory of $831,000 and $1,200,000, respectively.

Changes in noncurrent assets are reflected on the Consolidated Statements of Cash Flows within the caption of other assets.

During the three months ended March 31, 2024 and 2023, the Company did not record any material charges to write off inventories.

NOTE 7—INTANGIBLE ASSETS, NET

The Company's intangible assets, net as of September 30, 2023 totaled $2,720,000, which were net of $580,000 of accumulated amortization, and related to capitalized milestone payments made following FDA and other regulatory approvals, and commercialization of DANYELZA.

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The Company's intangible assets, net as of December 31, 2022 totaled $2,986,000, which were net of $314,000 of accumulated amortization, March 31, 2024 and related to capitalized milestone payments made following FDA and other regulatory approvals and commercialization of DANYELZA. December 31, 2023 are as follows (in thousands):

	March 31, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
DANYELZA	$ 3,300	$ 757	$ 2,543	$ 3,300	$ 669	$ 2,631

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 $355,000 each year for the five-year -period year period from 2023 2024 to 2027 2028, and $945,000 $768,000 thereafter.

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NOTE 8—ACCRUED LIABILITIES

Accrued liabilities as of September 30, 2023 March 31, 2024 and December 31, 2022, December 31, 2023 are as follows (in thousands):

	September 30, 2023	December 31, 2022	March 31,	December 31,

			2024	2023
Accrued licensing, milestone and royalty payments	$ 2,137	$ 4,002	$2,459	$ 3,452
Accrued clinical costs	1,049	932	794	597
Accrued compensation and board fees	2,805	2,445	2,165	3,858
Accrued manufacturing costs	3,086	2,977	1,948	2,531
Accrued sales reserves	3,482	2,474	1,910	2,309
Other	745	411	713	419
Total	$ 13,304	$ 13,241	$9,989	$13,166

NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS

The Company has entered into three license agreements and certain other agreements with Memorial Sloan Kettering Cancer Center ("MSK"). The license agreements are include the MSK License Agreement, dated August 20, 2015, between the Company and MSK (the "MSK License"), and the CD33 License Agreement, dated November 13, 2017, between the Company and MSK (the "CD33 License Agreement" License"). Through the Settlement and Assumption and Assignment of the MSK License and Y-mAbs Sublicense Agreement, dated December 2, 2019, among MabVax Therapeutics Holdings, Inc. and MabVax Therapeutics, Inc., (together "MabVax"), the Company and MSK (the "SAAA"), 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.

In addition, the Company entered into the License Agreement, a license agreement, dated April 15, 2020, with MSK and Massachusetts Institute of Technology ("MIT") (the "SADA License Agreement"). 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 payments are contingent milestone and royalty payments, as disclosed in the table below. Amounts disclosed in *NOTE 8—ACCRUED LIABILITIES* for accrued licensing, milestone and royalty payments are inclusive of obligations under the MSK License Agreement, CD33 License Agreement, MabVax/MSK MabVax License Agreement and SADA License Agreement, collectively.

In the past, the Company had defined MSK as a related-party under the Company's related-party policy. During the nine months ended September 30, 2023, the Company updated the related-party policy to remove MSK as a related-party as MSK does not participate on the Company's Board of Directors, does not have a significant ownership in the Company and MSK is not in a position to exert decision making power. The Company has entered into several agreements with MSK, which include the MSK License Agreement, the SADA License Agreement, the CD33 License Agreement, and the MabVax Agreement, all as noted above.

The Company's material license agreements are detailed in *NOTE 9— LICENSE AGREEMENTS AND COMMITMENTS* to the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

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MSK License Agreement

The MSK License Agreement relates to intellectual property for DANYELZA and requires the Company to pay to MSK mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by the Company and the Company's affiliates and sublicensees. The Company is required to pay annual minimum royalties of $80,000 over the royalty term, which amounts are non-refundable but are creditable against royalty payments otherwise due thereunder. The Company is also obligated to pay to MSK certain clinical, regulatory and sales-based milestone payments under the MSK License, which payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License.

SADA License Agreement

Pursuant to the SADA License Agreement, the Company was granted an exclusive worldwide, sublicensable license to MSK's and MIT's rights to certain patent and intellectual property to develop, make, and commercialize

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licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics and cancer treatments using the SADA-BiDE Pre-targeted Radioimmunotherapy Platform ("SADA Technology"). PRIT Technology.

The SADA License Agreement requires the Company to pay MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by the Company and its affiliates and sublicensees. The Company is obligated to pay non-refundable 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, which are creditable against royalty payments otherwise due under the SADA License Agreement. Pursuant to the SADA License Agreement, the Company is also obligated to pay MSK and MIT certain clinical, regulatory and sales-based milestone payments, which become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. The Company may terminate the SADA License Agreement with prior written notice.

The Company's Company did not recognize any expense related to milestones under the SADA License Agreement is detailed in *NOTE 9— LICENSE AGREEMENTS AND COMMITMENTS* in during the Company's Consolidated Financial Statements included in its Annual Report on Form 10-K for the year three months ended December 31, 2022.

March 31, 2024 and 2023, respectively. The Company recognized an expense of $4,125,000 related to clinical milestones under the SADA License Agreement during the three and nine months year ended September 30, 2023 December 31, 2023, as the Company determined certain time-based clinical milestones within the agreement are probable based on the availability of necessary data and the assessment of clinical progress in the third quarter of 2023. The Company did not recognize any expense related to milestones under the SADA License Agreement during the three and nine months year ended September 30, 2022 December 31, 2023. The Company had $4,125,000 and $605,000 in accrued liabilities as of September 30, 2023 March 31, 2024 and December 31, 2022, respectively. December 31, 2023. The Company made a payment of $605,000 in the nine months year ended September 30, 2023 December 31, 2023 related to achievement of the milestone for dosing the first patient in the Phase 1 trial of GD2-SADA in April 2023. The Company did not make any payments under SADA License Agreement in the three months ended March 31, 2024.

For the MSK License Agreement and the SADA License Agreement, in addition to any milestone payments, to the extent the Company enters into sublicense arrangements, it is obligated to pay to MSK, as indicated in MSK License Agreement, and MSK and MIT, as indicated in SADA License Agreement, a percentage of certain payments received from sublicensees of the rights licensed to it by MSK, or MSK and MIT, which percentage will be based upon the achievement of certain clinical milestones. See *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* for sublicense agreements related to MSK License Agreements by the Company.

Failure by the Company to meet certain conditions under each arrangement could cause the related licenses to such licensed products to be canceled and could result in termination of the respective arrangement with MSK, or MSK and MIT.

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Summary of Significant License Agreements and Related Commitments

The Company has below table represents the following maximum clinical, regulatory or sales-based milestones as reflected within the significant license agreements, and related commitments certain of which include have been paid in prior periods or are accrued as presented in the table below (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

The below table represents all obligations pertaining to the significant license agreements that have been paid, expensed, or accrued for during the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, and as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023 (in thousands):

Agreements	Cash paid Nine months ended September 30, 2023	Cash paid Nine months ended September 30, 2022	Expense Three months ended September 30, 2023	Expense Nine months ended September 30, 2023	Expense Three months ended September 30, 2022	Expense Nine months ended September 30, 2022	Accrued liabilities Current as of September 30, 2023	Accrued liabilities Non-current as of September 30, 2023	Accrued liabilities Current as of December 31, 2022	Accrued liabilities Non-current as of December 31, 2022	Cash paid three months ended March 31, 2024	Cash paid three months ended March 31, 2023	Expense three months ended March 31, 2024	Expense three months ended March 31, 2023	Accrued liabilities current as of March 31, 2024
MSK	$ 6,027	$ 2,871	$ 1,142	$ 3,844	$ 753	$ 2,513	$ 1,137	$ 1,950	$ 3,397	$ 1,950	$ 2,377	$ 3,245	$ 1,348	$ 1,223	$ 1,459
CD33	—	—	—	—	—	—	—	300	—	300	—	—	—	—	—
MabVax	10	—	10	10	10	10	—	—	—	—					
SADA	605	1,000	4,125	4,125	—	—	1,000	3,125	605	—	—	—	—	—	1,000

Minimum royalties and certain clinical, regulatory and sales milestones that become due based upon the passage of time under the MSK License Agreement, CD33 License Agreement, the MabVax Agreement, and the SADA License Agreement are excluded from the above table as the Company does not consider such obligations to be probable as of March 31, 2024 and December 31, 2023.

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 License Agreement as well as the MabVax/Y-mAbs Sublicense 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.

Minimum royalties and certain clinical and regulatory milestones that become due based upon the passage of time under the CD33 License Agreement, the SADA Agreement and the MabVax/MSK License Agreement are excluded from the above table as the Company does not consider such obligations to be probable as of September 30, 2023.

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

Lease Agreements

In February 2019, the Company entered into a lease agreement in connection with its the Company's 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 was to expire in January 2024, which the Company exercised and had included in the determination of the related lease liability. In July 2023, the Company entered into a lease amendment to extend the term to February 2025. Fixed rent payable under the lease is approximately $177,000 per annum and is payable in equal monthly installments of approximately $15,000 per month.

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In January 2018, the Company entered into a lease agreement in connection with its the Company's corporate headquarters in New York. The term of the lease was six years from the date the Company began to occupy the premises and the lease was to expire in April 2024. In August 2023, the Company entered into a lease amendment to extend the

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term to April 2025. Fixed rent payable under the lease is approximately $408,000$408,000 per annum and is payable in equal monthly installments of approximately $34,000.

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 that expires in November 2025. The lease is payable in monthly installments of approximately $41,000. In January 2023, the Company notified the landlord of its the intention to reduce the leased premise as a result of the Company's strategic restructuring. The lease modification resulted in an immaterial charge in the nine months year ended September 30, 2023 December 31, 2023.

Total operating lease costs were $229,000 $246,000 and $721,000 $340,000 for the three months ended September 30, 2023 March 31, 2024 and 2022, respectively. Total operating lease costs were $789,000 and $2,127,000 for the nine months ended September 30, 2023 and 2022, 2023, respectively.

For During the three months ended September 30, 2023 March 31, 2024, the operating lease expenses were recorded as $161,000 $168,000 in research and development expense and $68,000 $78,000 in selling, general, and administrative expense. For During the three months ended September 30, 2022 March 31, 2023, the expenses were recorded as $657,000 $283,000 in research and development expense and $64,000 $57,000 in selling, general, and administrative expense. For the nine months ended September 30, 2023, the expenses were recorded as $607,000 in research and development expense and $182,000 in selling, general and administrative expense. For the nine months ended September 30, 2022, the expenses were recorded as $1,937,000 in research and development expense and $190,000 in selling, general and administrative expense.

Cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2023, March 31, 2024 and 2023 was $266,000 $251,000 and $791,000, $259,000, respectively, and cash paid for amounts included in the measurement of lease liabilities for the three and nine months ended September 30, 2022, was $481,000 and $1,689,000, 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 as of September 30, 2023, March 31, 2024 and December 31, 2023 were as follows (in thousands):

	Operating Leases as of September 30, 2023
Remainder of 2023	$ 264
Years ending December 31,	
2024	978
2025	510
Total lease payments	1,752
Less: Imputed interest	(129)
Total operating lease liabilities as of September 30, 2023	$ 1,623

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Maturities of operating leases liabilities as of December 31, 2022, were as follows (in thousands):

	Operating Leases as of December 31, 2022	March 31, 2024	December 31, 2023
Remainder of 2024		$ 730	$ —
Years ending December 31,			
2023	$ 997		
2024	490	—	996
2025	419	525	526
Total lease payments	1,906	1,255	1,522
Less: Imputed interest	(139)	(74)	(103)
Total operating lease liabilities as of December 31, 2022	$ 1,767		
Total operating lease liabilities as of period end		$ 1,181	$ 1,419

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 estimates the incremental borrowing rate based on the information available at the lease commencement date. As of September 30, 2023 March 31, 2024, the weighted average remaining lease term is 1.85 was 1.37 years and the weighted average discount rate used to determine the operating lease liability was 8.3%. As of December 31, 2022 December 31, 2023, the weighted average remaining lease term was 2.36 is 1.61 years and the weighted average discount rate used to determine the operating lease liability was 8.3%.

*Former Chief Executive Officer Contractual Severance Related Benefits*22

On April 27, 2022, the Company announced certain executive management changes. Effective April 22, 2022, Dr. Claus Juan Møller San Pedro stepped down from his positions as Chief Executive Officer and as a memberTable of the Company's Board of Directors. There were no disagreements with the Company expressed by Dr. Møller on any matters relating to the Company's operations, policies or practices. Dr. Møller's contractual severance related benefits provided for cash compensation of $1,589,000, which included salary and certain benefits continuation. All of the cash compensation had been paid as of September 30, 2023. 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 charge of $9,286,000 in the nine months ended September 30, 2022, as there was no longer a service condition related to such awards. The total charge of $10,875,000 related to the executive management change was recorded in selling, general and administrative expenses during the nine months ended September 30, 2022. There was no financial impact in the three and nine months ended September 30, 2023, and in the three months ended September 30, 2022. Contents

Legal Matters

Donoghue vs. Y-mAbs Therapeutics, Inc., and Gad

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 one of the Company's stockholders, Deborah Donoghue (Case No. 1:21-cv-07182). The suit names the Company's Chief Business Officer, and Vice Chairman of the Company's 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. The parties have completed documentary discovery and depositions. The action is currently stayed through November 30, 2023. On February 1, 2024, both the Plaintiff and Mr. Gad filed their respective motions for summary judgment. The Company is of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company 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.

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In re Y-mAbs Therapeutics, Inc. Securities Litigation

On January 18, 2023, a putative class-action lawsuit was filed against the Company and certain of its the Company's current and former officers for alleged violations of the U.S. federal securities laws in the United States District Court, Southern District of New York (Case No.: 1:23-cv-00431). The amended complaint filed on May 23, 2023, asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, on behalf of a proposed class consisting of those who acquired the Company's common stock between October 6, 2020 and October 28, 2022. The amended complaint alleges that there were material misrepresentations and/or omissions regarding the FDA's consideration of the Company's BLA for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma firstly submitted in 2020 and resubmitted in 2022. The amended complaint seeks unspecified damages, and costs and expenses, including attorneys' fees. On April 4, 2023 September 29, 2023, the Court appointed a lead plaintiff for the putative class. On July 11, 2023, the defendants filed a defendants' motion to dismiss the amended complaint. complaint was fully briefed. On August 29, 2023 February 5, 2024, the plaintiff filed his opposition to Court granted in part and denied in part the motion to dismiss. On September 29, 2023, the defendants filed their reply in support of the defendants' motion to dismiss. The Court dismissed the plaintiff's claims relating to three of four categories of challenged statements and dismissed in part plaintiff's claims relating to the fourth category of challenged statements. The Court also dismissed one of the individual defendants from the case. The Company believes that these the remaining claims are without merit and intends to vigorously defend against these claims. The Company has not established a liability for this claim as of September 30, 2023 March 31, 2024 as the Company does not consider a loss on the claim to be probable.

Hazelton vs. Y-mAbs Therapeutics Inc., and Gad, et al.

The Company has been named a nominal defendant in a lawsuit filed in the Court of Chancery of the State of Delaware, on February 8, 2023, by a purported stockholder, Jeffrey Hazelton (Case No. 2023-0147-LWW). The amended complaint filed on May 12, 2023, purports to bring claims on behalf of the Company against current and former members of the Company's board of directors for allegedly awarding themselves excessive compensation for fiscal years 2020 and 2021. The amended complaint seeks, among other things, recovery of alleged excessive compensation, an order directing the Company to undertake certain corporate governance reforms, and an award of costs and expenses, including attorneys' fees. On June 22, 2023, the defendants filed a Defendants' motion to dismiss the amended complaint. complaint

was fully briefed as of September 8, 2023. On August 11, 2023 April 3, 2024, the plaintiff filed his opposition parties informed the Court that they had agreed to resolve the motion matter on mootness grounds and hoped to dismiss. On September 8, 2023, the defendants filed their reply brief in support of the motion to dismiss. The Company is of the opinion that the claims are without merit and intends to maintain this position in the proceedings. reach agreement on formal documentation. The Company has not established a liability for this claim as of September 30, 2023 March 31, 2024 as the Company does not consider a loss on the claim to be probable. estimable.

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NOTE 10—STOCKHOLDERS' EQUITY

Authorized Stock

As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, the Company had 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 43,621,618 43,852,638 shares and 43,672,112 shares of its common stock as of September 30, 2023, March 31, 2024 and 43,670,109 shares of its common stock as of December 31, 2022 December 31, 2023.

Preferred Stock

Preferred stock may be issued from time to time in one or more series with such designations, preferences and relative participating, optional or other special rights and qualifications, limitations or restrictions as approved by the Company's Board of Directors. No preferred stock has been issued as of September 30, 2023 March 31, 2024 or December 31, 2022.

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Stock Grant Agreements with Non-Employees

In April 2020, in connection with the SADA License Agreement, the Company entered into two stock grant agreements with 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 in consideration for their respective prior service. The agreements dated April 2020 are detailed in NOTE 10— STOCKHOLDERS' EQUITY in the Company's Consolidated Financial Statements included in its Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023.

Pursuant to the stock grant agreements, the Company 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 were evidenced by a Secured Promissory Note, which had respective maturity dates in April 2023 and June 2023. In July 2022, one of the researchers repaid their loan, which had a maturity date in April 2023, and

accrued interest, which resulted in a de minimis loss compared to the amortized cost of the loan, in exchange for 57,887 shares that remained pledged as part of its security. Upon receipt, the Company recorded treasury shares at an acquisition cost of $963,000, based on the share price on the settlement date. The Company subsequently cancelled the acquired treasury shares resulting in a reduction of outstanding common stock and a reduction of additional paid-in-capital totaling $963,000. During the fourth quarter of 2022, the Company concluded that the other loan receivable, with a maturity date of June 2023, was impaired, which resulted in a $1,051,000 charge for the year ended December 31, 2022. In June 2023, the other researcher repaid his loan, which resulted in a de minimis gain compared to the book value of the loan, which included the impact of the previous impairment charge. The loan was repaid in exchange for 58,763 shares that remained pledged as part of its security. Upon receipt, the Company recorded treasury shares at an acquisition cost of $480,000, based on the closing price of the Company's common stock on the settlement date. The Company subsequently cancelled the acquired treasury shares, which resulted in a reduction of outstanding common stock and a reduction of additional paid-in-capital totaling $480,000.

NOTE 11—STOCK-BASED COMPENSATION

2015 Equity Incentive Plan

The Company's board of directors and stockholders approved and adopted the Amended and Restated 2015 Equity Incentive Plan (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 the Company's 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 Equity Incentive Plan (the "2018 Plan") in connection with the Company's initial public offering in September 2018. However, options outstanding under the 2015 Plan continue to be governed by the 2015 Plan. The 2018 Plan 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, including performance-based restricted stock units ("PRSUs"), 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 were initially 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 through 2029, equal to 4% of the outstanding shares of common stock as of the last day of the Company's immediately preceding fiscal year or by a lesser amount determined by the board of directors. The exercise price of options granted

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directors. As of March 31, 2024, the Company had 3,106,029 shares available for grant under the 2018 Equity Incentive Plan.

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 between one and four years and generally become immediately exercisable upon the occurrence of a change in control, as defined in the Plan Agreement.

Stock Options Stock-Based Compensation Expense

During the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company recognized the following stock-based compensation expense (in thousands):

	Three months ended March 31,	
	2024	2023
Stock-based compensation by type of award		
Restricted stock units (excluding PRSUs)	$ 421	$ 187
PRSUs	53	—
Stock options	3,372	5,117
Total stock-based compensation expense	$ 3,846	$ 5,304
Stock-based compensation by type of expense		
Research and development expenses	$ 1,872	$ 2,306
Selling, general and administrative expenses	1,974	2,998
Total stock-based compensation expense	$ 3,846	$ 5,304

The expense for stock option grants were $2,229,000 and $3,257,000, respectively, for options granted to employees and directors. During the three months ended September 30, 2023, the expenses were recorded as $1,175,000 in research and development expense and $1,054,000 in selling, general, and administrative expense. For the three months ended September 30, 2022, the expenses were recorded as $1,801,000 in research and development expense and $1,456,000 in selling, general, and administrative expense.

During the nine months ended September 30, 2023 and 2022, stock-based compensation for stock option grants were $10,793,000 and $21,822,000, respectively, for options granted to employees and directors. The expense for the nine months ended September 30, 2023, March 31, 2023 was inclusive of an acceleration of stock-based compensation of $1,706,000, as described further in *NOTE 14—RESTRUCTURING CHARGE*. Stock-based compensation during There is no financial impact from the nine restructuring in the three months ended September 30, 2022 March 31, 2024.

Unrecognized Stock-Based Compensation Expense

The following table sets forth the Company's unrecognized stock-based compensation expense as of March 31, 2024, also includes $9,286,000 related by type of award and the weighted-average period over which the Company expects to recognize the departure expense (in thousands):

	March 31, 2024	
	Unrecognized compensation expense	Weighted average recognition period (years)
Type of award		
Restricted stock units (excluding PRSUs)	$ 4,872	2.4
PRSUs	605	1.9
Stock options	23,991	3.0
Total unrecognized stock-based compensation expense	$ 29,468	

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Restricted Stock Unit (Excluding PRSU) Activity

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 as of December 31, 2023	351,407	$ 5.06	1.99
Granted	400,277	10.96	
Vested	(108,976)	4.82	
Forfeited	(39,934)	7.35	
Outstanding and expected to vest as of March 31, 2024	602,774	$ 8.87	2.41

During the three months ended March 31, 2024, 4,660 shares of RSUs were granted to a new non-executive director, which will vest equal quarterly installments until the third anniversary of the former Chief Executive Officer, which was recorded upon his separation date of grant, provided that the recipient remains as non-executive director through vesting date. The remaining 395,617 shares of RSUs granted in the second quarter of 2022 based on the terms of his service agreement and is further described in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*. For the nine three months ended September 30, 2023, March 31, 2024 will vest annually over the expenses were recorded as $4,629,000 next 3 years, provided in research each case that the recipient remains an employee of the Company through each vesting date.

Performance-based Restricted Stock Unit (PRSUs) Activity

The following table summarizes restricted stock units issued and development expense and $6,164,000 outstanding:

	Performance Restricted Stock Units	Weighted average grant price	Weighted average remaining vesting life (years)
Outstanding and expected to vest as of December 31, 2023	—	$ —	—
Granted	54,000	12.19	
Vested	—	—	
Forfeited	—	—	
Outstanding and expected to vest as of March 31, 2024	54,000	$ 12.19	1.87

The PRSUs of 54,000 shares issued in selling, general, and administrative expense. For the nine three months ended September 30, 2022, March 31, 2024 vest in three equal tranches over a three-year period. The assumptions that the expenses Company used to determine the fair value of the PRSUs granted in the three months ended March 31, 2024 using a Monte-Carlo simulation model were recorded as $5,582,000 follows:

	Three months ended March 31, 2024
Risk-free interest rate	4.2 %
Expected volatility	101.0 %
Expected dividend yield	— %

The Company did not issue any PRSUs in research and development expense and $16,240,000 in selling, general, and administrative expense. the three months ended March 31, 2023.

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Stock Options

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)	Options	Weighted average exercise price	Aggregate intrinsic value (in thousands)	Weighted average remaining contractual life (years)
Outstanding and expected to vest at December 31, 2022	7,079,767	$ 21.27	$ 3,112	6.45				
Outstanding and expected to vest as of December 31, 2023					9,307,330	$ 17.26	$ 10,012	6.44
Granted	1,821,000	5.00			1,450,790	11.23		
Exercised	—				(71,550)	8.22		
Forfeited	(243,679)	11.22			(116,605)	6.34		
Outstanding and expected to vest at September 30, 2023	8,657,088	$ 18.13	$ 5,243	6.38				
Exercisable at September 30, 2023	5,766,863	20.48	4,096	5.19				
Outstanding and expected to vest as of March 31, 2024					10,569,965	$ 16.61	$ 60,339	6.63
Exercisable as of March 31, 2024					6,453,371	$ 20.29	$ 31,312	5.06

The weighted average fair value of stock options granted for the three months ended September 30, 2023 and 2022 was $3.69 and $10.14, respectively. There were 76,100 and 210,000 stock options granted for the three months ended September 30, 2023 and 2022, respectively.

The weighted average fair value of stock options granted for the nine months ended September 30, 2023 and 2022 was $3.65 and $7.88, respectively. There were 1,821,000 and 635,000 stock options granted for the nine months ended September 30, 2023 and 2022, respectively.

There were 1,105,500 options granted in the nine months ended September 30, 2023 under the Company's retention program, which were granted to the continuing employees that were not subject to the Company's strategic restructuring plan.

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All of the options granted in the three months ended September 30, 2023 March 31, 2024, have a maximum contractual term of ten years years. During the three months ended March 31, 2024, 1,422,890 options were granted and 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 remains an employee of the Company through each vesting date. The expected term remaining 27,900 options were granted to a new non-executive director, which will vest equal monthly installments until the third anniversary of the date of grant, provided that the recipient remains as non-executive director through vesting date.

The weighted average fair value of stock options granted for these the three months ended March 31, 2024 and 2023 was $8.24 and $3.40, respectively. The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors in the three months ended September 30, 2023 was 6.25 years, March 31, 2024 and 2023 are set forth in the volatility was 83.0% table below and the risk-free interest rate was approximately 4.38%.

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 expected share price volatility based presented 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 it 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 the Company does not expect to pay any cash dividends in the foreseeable future. weighted average basis. There were no significant changes to the inputs included in the Black-Scholes option pricing model during the period ended September 30, 2023.

As of September 30, 2023, the Company had $16,052,000 of unrecognized compensation expense related to employee stock options that are expected to vest over a period of 2.59 years.

Subsequent to September 30, 2023, on November 6, 2023 the Company granted 690,240 stock options in connection with the start date of the Company's new President and Chief Executive Officer and transition of the Company's Interim Chief Executive Officer to Chief Business Officer.

Restricted Stock Unit Activity

For the three months ended September 30, 2023 and 2022, stock-based compensation for restricted stock unit grants was $181,000 and $84,000, respectively. During the three months ended September 30, 2023, the expenses were recorded as $96,000 in research and development expense and $85,000 in selling, general, and administrative expense. During the three months ended September 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 nine months ended September 30, 2023 and 2022, stock-based compensation for restricted stock unit grants was $537,000 and $242,000, respectively. For the nine months ended September 30, 2023, the expenses were recorded as $320,000 in research and development expense and $217,000 in selling, general, and administrative expense. For the nine months ended September 30, 2022, the expenses were recorded as $215,000 in research and development expense and $27,000 in selling, general, and administrative expense.

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The following table summarizes restricted stock units issued and outstanding: March 31, 2024:

	Three months ended March 31,	
	2024	2023
	Weighted average	Weighted

	Restricted Stock Units	average grant price	remaining vesting life (years)		
Outstanding and expected to vest at December 31, 2022	33,355	$ 17.77	1.77		
Granted	380,636	4.81			
Vested	(10,272)	18.00			
Forfeited	(45,088)	9.15			
Outstanding and expected to vest at September 30, 2023	358,631	$ 5.09	2.22		
Risk-free interest rate				4.1 %	3.60 %
Expected term (in years)				6.3	6.3
Expected volatility				84.0 %	82.6 %
Expected dividend yield				— %	— %

The table above includes 380,636 restricted stock units granted in the nine months ended September 30, 2023, under the Company's retention program, which were granted to the continuing employees that were not subject to the Company's strategic restructuring plan.

As of September 30, 2023, the Company had $1,379,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 2.22 years.

NOTE 12—INCOME TAXES

During the three months ended September 30, 2023 March 31, 2024 and 2022, 2023, the Company experienced pre-tax net losses of $7,560,000 $6,469,000 and $27,526,000. $6,390,000. The Company's Company's current income tax provision was $187,000 $160,000 during the three months ended September 30, 2023 March 31, 2024, and the Company did not not have a current income tax provision during the three months ended September 30, 2022 March 31, 2023. There was were no deferred income tax provisions during the three months ended September 30, 2023 March 31, 2024 and 2022.

During the nine months ended September 30, 2023 and 2022, the Company experienced pre-tax net losses of $20,073,000 and $96,725,000. The Company's current income tax provision was $366,000 during the nine months ended September 30, 2023, and the Company did not have a current income tax provision during the nine months ended September 30, 2022. There was no deferred income tax provisions during the nine months ended September 30, 2023 and 2022. 2023.

The Company's tax returns for the years 2017 to 2022 are all open for tax examination by U.S. federal and state, and the 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 the release of the corresponding reserve. The release did not have a material impact on 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

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is given to evidence that can be objectively verified. In its evaluation, the Company considered its cumulative losses historically and in recent years and its forecasted losses in the near term as significant negative evidence. Based upon review of available positive and negative evidence, the Company determined that the negative evidence outweighed the positive evidence and a full valuation allowance on its U.S. and foreign deferred tax assets will be maintained. The Company will continue to assess the realizability of its deferred tax assets and will adjust the valuation allowance as needed.

NOTE 13—OTHER BENEFITS

The Company has adopted a defined contribution 401(k) savings plan (the "401(k) plan") covering all U.S. employees. Participants may elect to defer a percentage of their pretax or after-tax compensation to the 401(k) plan,

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subject to defined limitations. The plan allows for a discretionary match by the Company. The Company made no matching contributions to the plan during the three and nine months ended September 30, 2023 March 31, 2024 and 2022. 2023.

The Company has established a retirement program for employees of its our Danish subsidiary pursuant to which all such employees can contribute an amount at their election from their base compensation and may receive contributions from our Danish subsidiary. The Danish subsidiary made no contributions during the three and nine months ended September 30, 2023 March 31, 2024 and 2022. 2023. In addition, health insurance benefits for our Danish employees are fully paid for by such employees. Our Danish subsidiary does not incur any costs for these health insurance benefits.

NOTE 14 —RESTRUCTURING—RESTRUCTURING CHARGE

On January 4, 2023, following Board approval, the Company announced a strategic restructuring plan designed to extend its cash resources and prioritize resources for the commercialization and potential label extension of DANYELZA and on the development of the SADA technology PRIT Technology platform. The Company completed the restructuring in May 2023, which resulted in an approximately 35% reduction to its the Company's workforce. Affected employees were offered separation benefits, including severance and outplacement services along with temporary healthcare coverage assistance. As a result, during the nine three months ended September 30, 2023 March 31, 2023, the Company recognized restructuring expenses of $4,482,000 based on the currency rate for the period. For the nine three months ended September 30, 2023 March 31, 2023, the Company recorded $3,346,000 and $1,136,000, respectively, within research and development and selling, general, and administrative, on the Consolidated Statements of Net Loss and Comprehensive Loss. The restructuring expenses primarily related to severance benefits of $2,776,000, which were paid as of September 30, 2023, and acceleration of stock-based compensation of $1,706,000, which was recognized in the nine three months ended September 30, 2023 March 31, 2023 as there is was no longer a service condition related to such awards.

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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 unaudited consolidated financial statements and related notes thereto included elsewhere in this Quarterly Report on Form 10-Q and in our audited consolidated financial statements and related notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023, 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 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. You should carefully read the information under "Forward-Looking Statements" in this Quarterly Report on Form 10-Q. 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) (naxitamab gqgk) received accelerated approval by the United States Food and Drug Administration, or the 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 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 in February 2021. In December 2022, we announced a distribution agreement with WEP Clinical Ltd., or WEP, in connection with an early access program for DANYELZA in Europe.

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DANYELZA has been evaluated in a Phase 2 clinical study in front-line front line NB, a pilot study of chemoimmunotherapy for high-risk NB, and is currently being evaluated in a pivotal-stage multicenter trial (Study 201) which is designed to satisfy the accelerated approval confirmatory study and post-marketing requirements of the FDA, as well as a Phase 2 clinical study in second-line second line relapsed osteosarcoma patients.

We are using our proprietary SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA PRIT Technology, a concept we also refer to as Liquid Radiation™, to advance a series of antibody constructs, using a 2-step two-step pre-targeting approach. The bispecific antibody fragments bind to the tumor before a radioactive payload is subsequently injected. The aim is specifically to deliver the radioactive payload to the tumor while minimizing exposure to normal tissue as indicated in non-clinical studies.

GD2-SADA for potential use in GD2-positive solid tumors is our first SADA PRIT construct, and we had our first clinical patients dosed in April 2023 in our Phase 1, dose-escalation, single-arm, open-label, non-randomized, multicenter trial, for the treatment of certain solid tumor cancers, including small cell lung cancer, sarcoma, and malignant melanoma. We currently have six active treatment sites and expect another three sites to be activated during the fourth quarter 2023. as of March 31, 2024. We are pleased with our observations so far and in particular that patients dosed with the GD2-SADA protein have not experienced treatment related pain, dose limiting toxicities or related severe adverse events or serious adverse events. Based on the SPECT/CT scans performed, we believe that we have demonstrated proof of concept for GD2-SADA by demonstrating that the GD2-SADA molecules can find and bind to tumors and that the radionuclide targets the SADA molecules. At this point, we are in cohort three, have completed cohorts 1, 2 and 3, using a radioactive payload of 200 mCi and a two to five days interval between the SADA protein and the payload. The initial blood PK profile of the construct in these patients dosed with the 0.3 mg/kg and 1 mg/kg of protein dose appears to match our pre-clinical models in terms of clearance data, and the blood PK profiles from patients are comparable and support supportive of the current dose interval of 2-5 two to five days. We are currently treating patients at 3.0 mg/kg in cohort 4.

The IND for our first hematological target, the CD38-SADA construct for the treatment of patients with Relapsed or Refractory Non-Hodgkin Lymphoma was cleared in October 2023, and we expect to dose the first patient in 2024. We Further, we plan to submit an IND to the FDA for a Phase 1 multicenter study of GD2-SADA for the potential

treatment of neuroblastoma in 2024.We believe the SADA PRIT Technology could potentially improve the efficacy of immunological therapeutics, e.g., naked monoclonal antibodies, in tumors that have not historically demonstrated meaningful responses to immunological agents.

In January 2023, following receipt of a complete response letter in November 2022 from the FDA for our Biologics License Application for radiolabeled ^{131}I-omburtamab for central nervous system leptomeningeal metastases, or CNS-LM, we announced a strategic restructuring plan designed to extend our cash resources and prioritize resources on the commercialization and potential label extension of DANYELZA and development of the SADA technology PRIT Technology platform. In addition to deprioritizing the omburtamab program for all indications and product candidates, we have deprioritized other pipeline programs, including activities relating to the GD2-GD3 Vaccine and CD33 bispecific antibody constructs by delaying trial initiation and overall timelines as part of the restructuring plan. We completed the restructuring in May 2023, which resulted in an approximately 35% reduction to our workforce.

We have further determined to cease all development work on radiolabeled omburtamab for CNS-LM, and to suspend the development work on our GD2-GD3 Vaccine and CD33 bispecific antibody constructs to continue focusing our development resources on additional indications for DANYELZA and potential applications for our SADA/PRIT platform. As a result of the decrease in operating expenses from the 2023 restructuring and our current business strategy, we estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, will should support our operations into 2027.

This estimate reflects our current business plan, including our development plans and business strategy following the restructuring, that is supported by assumptions that may prove to be inaccurate, such that we could use our available capital resources sooner than we currently expect. This estimate assumes no income from new partnerships or other new business development activities, and no further development of the omburtamab program. program, the GD2-GD3 Vaccine and the CD33 bispecific antibody constructs. We cannot provide any assurance that we will be able to obtain additional capital from additional equity or debt financings, financing, collaborations, licensing arrangements, or other sources.

Since our inception on April 30, 2015, we have devoted substantially all of our resources to organizing and staffing our company, business planning, identifying potential product candidates, conducting pre-clinical studies of our product candidates and clinical trials of our lead product candidates, commercializing our approved product, raising capital, and acquiring and developing our technology platform among other matters. We developed DANYELZA and our product candidates based on intellectual property subject to several license agreements with MSK, and one agreement with the Massachusetts Institute of Technology. These agreements are important to our business; for a more

detailed discussion of their terms and conditions, see further details in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* in Consolidated the notes to the consolidated financial statements included in Item 1. Financial Statements included in our Annual Report on this Form 10-K for the year ended December 31, 2022. 10-Q.

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, product and license revenues generated from DANYELZA, and the proceeds from our sale of our the Priority Review Voucher, or PRV, obtained upon FDA approval of DANYELZA.

As of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, we had an accumulated deficit of $456.5 million $464.1 million and $436.0 million $457.5 million, respectively. We experienced net losses of $7.7 $6.6 million and $20.4 million $6.4 million for the three and nine months ended September 30, 2023, March 31, 2024 and our net loss was $27.5 million and $96.7 million for the three and nine months ended September 30, 2022. 2023, respectively. We have incurred significant net operating losses in every year since our inception and inception. We expect to continue to incur our net operating losses to decrease in the future as our DANYELZA product

revenue grows to help fund our significant research and significant expenses for the foreseeable future. development expenses. 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 process both in the U.S. and internationally;
- continue to advance our other product candidates through pre-clinical and clinical development;

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- continue to identify additional research programs and additional product candidates, as well as additional indications for existing product candidates;
- initiate pre-clinical studies and clinical trials for any additional product candidates we identify;
- develop, maintain, expand and protect our intellectual property portfolio; and
- hire additional research, sales force, commercialization, clinical and scientific personnel.

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

Recent Developments and Other Developments

New Chief Executive Officer and Executive Officer Transition

On November 6, 2023, our new President and Chief Executive Officer started at the Company. As part of the transition, our President, Interim Chief Executive Officer and Head of Business Development and Strategy transitioned to the position of Chief Business Officer.

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Omburtamab BLA and Advisory Committee Meeting

In August 2016, the FDA granted Orphan Drug Designation, or ODD, to omburtamab for NB, and in June 2017, the compound received breakthrough designation for the treatment of pediatric patients with R/R NB who have central nervous system, or CNS,

leptomeningeal metastases, or LM, from NB. We submitted a BLA to the FDA for 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 following a series of meetings with the FDA, and in May 2022, the agency accepted our BLA for priority review. In October 2022, we met with the FDA's Oncologic Drugs Advisory Committee, or ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In December 2022, we received a complete response letter, or CRL, for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and have requested an 18 month extension of the BLA in October 2023. We can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

DANYELZA Regulatory Developments

On September 26, 2022, we announced that our partner Adium Pharma S.A. ("Adium") submitted a regulatory filing for DANYELZA for the treatment of patients with R/R high-risk NB to the Brazilian Health Regulatory Agency. On May 23, 2023, the Brazilian Health Regulatory Agency granted marketing authorization for DANYELZA. Our distribution agreement with Adium contains no regulatory license revenue milestones related to the Brazilian Health Regulatory Agency marketing authorization. In September 2023, DANYELZA received marketing authorization in Mexico. We recognized $0.5 million of regulatory-based license revenue from Adium pursuant to our distribution agreement with Adium for the three and nine months ended September 30, 2023 in connection with the achievement of the marketing authorization in Mexico.

We entered into a license separation agreement with our Chief Scientific Officer, Steen Lisby. The search for DANYELZA and omburtamab a new Chief Scientific Officer is ongoing with SciClone Pharmaceuticals International Ltd., or SciClone, for Greater China, including Mainland China, Taiwan, Hong Kong and Macau in December 2020. For focus on the nine months ended September 30, 2023, we recorded $3.5 million of product revenue and related royalties from the commercial launch inventory stocking order from our distribution partner, SciClone.

Known Trends, Geopolitical Events and Uncertainties

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 and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia, and we 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 and energy 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 continued advancement of our common stock, which may adversely impact our ability to raise capital on favorable terms or at all.

novel radiopharmaceutical platform. 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 Separation Agreement did not result in disruptions to trade, commerce, pricing stability, credit availability and supply-chain

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continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets.

In addition, on October 7, 2023, Hamas militants infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Following the attack, Israel's security cabinet declared war against Hamas. It is currently not possible to predict the duration or severity of the ongoing conflict, whether it will develop into a wider regional conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing and may have a material adverse impact on to our business and/or our partners. For example, it may have an adverse impact on Takeda Israel's ability to sell our products and/or collect receivables from customers consolidated financial statements included in the State of Israel pursuant to the exclusive licensing and distribution agreement we entered into with Takeda Israel Item 1. Financial Statements in November 2022, or the Takeda Licensing agreement, as well as on Takeda Israel's ability to pursue the development, marketing and/or commercialization of DANYELZA in the State of Israel, West Bank and Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement. this Form 10-Q.

The recent trends towards rising inflation may also materially affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates and overhead costs have and may continue to adversely affect our operating results. Rising interest rates also present a recent challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect demand for our product and our operations. Furthermore, such economic conditions have produced downward pressure on share prices. We may experience increases in our operating costs, including our labor costs and research and development costs, due to supply-chain constraints, the ongoing conflict between Russia and Ukraine, the state of war between Israel and Hamas, and employee availability and wage increases, which may result in additional stress on our working capital resources.

In addition, the closures of Silicon Valley Bank and Signature Bank earlier in 2023 have resulted in broader financial institution liquidity risk and concerns, and future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or corporate development or delay our ability to access such funds. Any such future bank failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. To help guard against that risk, our cash and cash equivalents are held at a large major federal, national bank. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents may be threatened and our ability to borrow or raise additional capital when needed to operate our business could be substantially impaired.

Components of Our Results of Operations

Product Revenue, Net

Product revenue consists of sales of DANYELZA, and royalty revenue generated from the sales of DANYELZA.

License Revenue

License revenue consists of payments received for the licensing rights to DANYELZA and omburtamab. DANYELZA. Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* for additional details. in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q.

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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, third-party royalties payable on our net product revenues and charges for excess and obsolete inventory reserves and inventory write-offs.

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Licensing License royalties

We have incurred certain third party License royalties include third-party royalty expenses related to third party licensing license revenues which are included in Licensing royalties. that have been recognized by the Company.

Research and development

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 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 or any other 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;

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- 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;

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- 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, and European Commission, or any other non-U.S. regulatory authority;
- any requirement by the FDA, the EMA and the European Commission, 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, in its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of a potential trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. profile, and we have determined to discontinue our radiolabeled omburtamab development program for CNS-LM. If we are required and we determine to conduct additional clinical trials of a product candidate, including if we determine to resume development of omburtamab, 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 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. Our research and development expenses include personnel costs, including stock-based compensation, and the costs of conducting clinical trials and potentially preparing regulatory submissions for our pipeline candidates, including supplementary regulatory submissions for DANYELZA. In January 2023, we announced a strategic restructuring plan designed to extend our cash resources and prioritize resources, and we are currently focused on the continued commercialization and potential label extension of DANYELZA and development of the SADA technology PRIT Technology platform. In addition to deprioritizing the discontinuing development of omburtamab program for all indications and product candidates, CNS-LM, we have deprioritized other pipeline programs, including activities relating suspended further work related to the GD2-GD3 Vaccine and CD33 bispecific antibody constructs by delaying trial initiation and overall timelines as part of constructs. Following the January 2023 restructuring, plan. Our our research and development expenses have decreased

as a result of our January 2023 restructuring. from historic averages. Our Research and Development expenses have stayed consistent for the three months ended March 31, 2024 and 2023.

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Selling, general, and administrative

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

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development expenses or cost of goods sold, legal fees relating to corporate matters, and fees for patent, accounting, tax, and consulting services.

Our selling, general, and administrative, or SG&A, expenses decreased in the nine months ended September 30, 2023 due to our January 2023 restructuring. SG&A, expenses include administrative costs to support continued research and development activities, potential commercialization of additional product candidates and additional indications 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.

Other Income / (Loss), Net income, net

Other income, / (loss), net primarily consists of interest income earned on our money market fund and foreign currency transaction gains and losses. Other income, / (loss), net can vary quarter-to-quarter based on interest rates and foreign currency fluctuations.

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 consolidated 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 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 A summary of critical accounting policies and significant judgements and estimates are described included in more detail *NOTE 3— SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the notes to our the consolidated financial statements appearing elsewhere included in Item 1. Financial Statements in this Quarterly Form 10-Q.

For a discussion of critical accounting policies, see the section entitled “Critical Accounting Policies and Significant Judgments and Estimates” in Part II. Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report on Form 10-Q, we believe 10-K for 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 revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, net product revenues, the accrual for research and development expenses, the accrual of milestone and royalty payments, the valuation of stock options and asset impairments. 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 macroeconomic conditions will directly or indirectly impact our business, results of operations and financial condition, including revenues, 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 the economic impact on local, regional, national and international markets. fiscal year ended December 31, 2023.

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Product Revenue, Net

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 for sales in the United States, and upon delivery to the distributors for sales in the international territories.

The vast majority of our product sales were in the United States with additional sales outside the United States in China, Europe, Latin America and Israel through sublicenses and distribution agreements. The Company had product sales to certain customers that accounted for more than 10% of total product revenue, net for the three and nine months ended September 30, 2023 and 2022. McKesson, AmerisourceBergen, WEP and Cardinal Health accounted for 48%, 18%, 15% and 14%, respectively, of our product revenue, net, for the three months ended September 30, 2023. McKesson and AmerisourceBergen accounted for 78% and 14%, respectively, of our product revenue, net, for the three months ended September 30, 2022. McKesson, AmerisourceBergen and Cardinal Health accounted for 45%, 22% and 13%, respectively, of our product revenue, net, for the nine months ended September 30, 2023. McKesson and AmerisourceBergen accounted for 69% and 16%, respectively, of our product revenue, net, for the nine months ended September 30, 2022. We recognized royalty revenue from our distribution partners of $0.4 million and $58 thousand in the three months ended September 30, 2023 and 2022, respectively, and $3.8 million and $1.4 million in the nine months ended September 30, 2023 and 2022, respectively.

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

License Revenue

To determine revenue recognition for arrangements that we determine are within the scope of Topic 606, we perform 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. We only apply 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, we assess the goods or services promised within each contract, determine those that are performance obligations, and assess whether each promised good or service is distinct. We 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, we consider factors such as the research, manufacturing and commercialization capabilities of the licensing partner and the availability of the associated expertise in the general marketplace. We also consider 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, we combine 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

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-party CMOs and CROs for additional product manufacturing and development, and consumables and other materials used in research and

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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/Y-mAbs 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.

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- Expected Dividend Yield: The expected dividend yield assumption is based on the fact that we have never paid cash dividends and have no present intention to pay cash dividends. Consequently, we used an expected dividend of zero.
- Expected Volatility: The expected stock price volatility is estimated by taking the average historic price volatility of the share price of our common stock and industry peers, and adjusting for differences in life cycle and financing leverage. Our industry peers consist of several public companies in the biopharmaceutical industry.
- Expected Term: We determine the average expected life of stock options based on the simplified method in accordance with SEC Staff Accounting Bulletin Nos. 107 and 110. We expect to continue to use the simplified method until we have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

The following table summarizes our results of operations for the three months ended September 30, 2023 March 31, 2024 and 2022: 2023:

	Three Months Ended September 30,		Amount Change	Percentage Change	Three Months Ended March 31,		Change	
	2023	2022	2023 vs. 2022	2023 vs. 2022	2024	2023	Amount	Percent
	(in thousands)		(in thousands)					
(in thousands)								
(in thousands)								
(in thousands)								
(in thousands)								
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(in thousands)								
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(in thousands)								
(in thousands)								
REVENUES								
Product revenue, net	$ 19,954	$ 12,537	$ 7,417	59 %	$19,431	$20,251	$ (820)	(4)%
License revenue	500	—	500	100	500	—	500	N/A
Total revenues	20,454	12,537	7,917	63	19,931	20,251	(320)	(2)
OPERATING COSTS AND EXPENSES								
Cost of goods sold	2,595	2,475	120	5	2,097	2,083	14	1
License royalties	50	—	50	100	50	—	50	N/A
Research and development	15,358	22,453	(7,095)	(32)	13,267	13,418	(151)	(1)
Selling, general, and administrative	10,200	13,626	(3,426)	(25)	11,425	12,251	(826)	(7)
Total operating costs and expenses	28,203	38,554	(10,351)	(27)	26,839	27,752	(913)	(3)
Loss from operations	(7,749)	(26,017)	18,268	(70)	(6,908)	(7,501)	593	(8)
OTHER INCOME / (LOSS), NET								
Interest and other income/(loss)	189	(1,509)	1,698	(113)				
OTHER INCOME, NET								
Interest and other income					439	1,111	(672)	(60)
LOSS BEFORE INCOME TAXES	(7,560)	(27,526)	19,966	(73)	(6,469)	(6,390)	(79)	1
Provision for income taxes	187	—	187	—	160	—	160	N/A
NET LOSS	$ (7,747)	$ (27,526)	$ 19,779	(72) %	$ (6,629)	$ (6,390)	$ (239)	4 %

Revenues

Product revenue, net

The Company's product revenue, net was generated from sales of DANYELZA and consists of the following (in thousands):

	Three months ended March 31,		Change	
	2024	2023	Amount	Percent
(in thousands)				
United States	$ 18,610	$ 16,833	$ 1,777	11 %
Other countries	821	3,418	(2,597)	(76)
Total product revenue, net	$ 19,431	$ 20,251	$ (820)	(4)%

Revenues

We recorded $20.0 million and $12.5 million The $0.8 million, or 4%, decrease was the net impact of a decrease in international markets, partially offset by increased product revenue, net, of 11% in the United States. Our product revenue, net from the United States for the three months ended September 30, 2023 and 2022, respectively. The $7.5 million increase was primarily driven March 31, 2024 increased by an increase in new US patients and an incremental benefit from expanding into international markets as discussed further in *NOTE 4—PRODUCT REVENUE, NET*. The geographic breakout for the product revenue, net between $1.8 million due to increased volume in the United States and other countries for the three months ended September 30, 2023 was $16.1 million and $3.9 million, respectively. The geographic breakout for the product revenue, net between in the United States and other countries for the three months ended September 30, 2022, was $12.4 million and $0.1 million, respectively. States. Our product revenue, net from other countries for the three months ended September 30, 2023 included $3.1 million March 31, 2024 decreased by $2.6 million, or 76%, due to $2.5 million of product revenue in the three months ended March 31, 2023 from our distribution partner, WEP. WEP, in connection with the initiation of an early access program for DANYELZA in Europe. We recognized did not have any product revenue from WEP in the three months ended March 31, 2024. Volumes in early access programs can vary quarter to quarter and we expect the volume to resume in future quarters in 2024.

royalty*License revenue*

In January 2024, we accepted the price for DANYELZA in Brazil from our distribution partners the Brazilian Medicines Market Regulation Chamber, or CMED. We received a $0.5 million regulatory-based milestone payment in connection with the price approval from CMED in the first quarter of $0.4 million and $58,000 2024. There was no license revenue in the three months ended September 30, 2023 and 2022, respectively.

In addition, we recorded $0.5 million in license revenue for the three months ended September 30, 2023 March 31, 2023. The license revenue was recognized upon the September 2023 achievement of marketing authorization for DANYELZA in Mexico within the terms of the non-refundable license milestone under our sublicense agreement with Adium. There is no license revenue recognized for the three months ended September 30, 2022.

Cost of Goods Sold

Cost of goods sold was $2.6 million and $2.5 million for the three months ended September 30, 2023 and 2022, respectively. The increased cost of goods sold was primarily driven by increased product revenue and an inventory charge of $0.4 million in the three months ended September 30, 2023, partially offset by a $1.2 million charge related to a batch that did not meet our quality specifications recognized in the three months ended September 30, 2022. Excluding the $1.2 million charge recognized in the three months ended September 30, 2022, our gross margin decreased in the three months ended September 30, 2023, compared to 2022, as a result of increased revenues from geographic areas outside of the United States, which were at a lower gross margin. Our cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, indirect labor costs, for personnel involved in the manufacturing process, third-party royalties for approved products, and indirect overhead costs. Cost of goods sold was $2.1 million for each of the three months ended March 31, 2024 and 2023.

Our gross margin was relatively unchanged at 89% for the three months ended March 31, 2024, compared to 90% for the three months ended March 31, 2023. We define gross margin as net product revenues less cost of goods sold divided by net product revenues.

License Royalties

License royalties include third-party royalty expenses related to license revenues that have been recognized. During the three months ended March 31, 2024, license royalties were related to MSK's share of licensing revenues. We incurred license royalty expenses expense of $50,000 during the three months ended September 30, 2023, related to licensing revenues recognized upon March 31, 2024 in connection with the September 2023 achievement of marketing authorization for DANYELZA price approval from CMED in Mexico within the terms of the non-refundable license milestone under our sublicense agreement with Adium. which are included in Licensing Revenue on the Consolidated Statements of Net Loss and Comprehensive Loss. January 2024. We did not incur record any license royalty expenses during expense for the three months ended September 30, 2022 March 31, 2023.

Research and Development

We do not record our research and development expenses on a program by program 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. below:

	Three Months Ended September 30,		Change		Three Months Ended March 31,		Change	
	2023	2022	Amount	Percentage	2024	2023	Amount	Percent
	(in thousands)		(in thousands)					
(in thousands)								
(in thousands)								
(in thousands)								
(in thousands)								
(in thousands)								
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Outsourced manufacturing	$ 2,809	$ 8,459	$ (5,650)	(67)%	$ 2,636	$ 2,055	$ 581	28 %
Clinical trials	2,293	2,560	(267)	(10)	3,086	540	2,546	471
Outsourced research and supplies	188	2,158	(1,970)	(91)	88	364	(276)	(76)
Milestones and license acquisition costs	4,125	—	4,125	100				
Personnel costs	2,745	4,214	(1,469)	(35)	3,653	5,812	(2,159)	(37)
Professional and consulting fees	136	872	(736)	(84)	362	443	(81)	(18)
Stock-based compensation	1,356	1,875	(519)	(28)	1,818	2,306	(488)	(21)
Information technology expenses					712	672	40	6
Other	1,706	2,315	(609)	(26)	912	1,226	(314)	(26)
	$ 15,358	$ 22,453	$ (7,095)	(32)%	$13,267	$13,418	$ (151)	(1)%

Research and development expenses were $15.4 million $13.3 million for the three months ended September 30, 2023 March 31, 2024, as compared to $22.5 million $13.4 million for the three months ended September 30, 2022 March 31, 2023. The $7.1 million $0.1 million decrease was primarily mainly due to the a $2.6 million decrease in spending on deprioritized programs, which resulted in a $5.7 million decrease in outsourced manufacturing, decreased personnel related costs, inclusive of stock-based compensation, of $2.0 million, a $2.0 million decrease in outsourced research and supplies, and a $0.3 million decrease in clinical trials, partially offset by a $4.1 million $2.5 million increase in milestones and license acquisition costs related clinical trial expenses due to our increased investment in SADA License Agreement, as we determined PRIT Technology programs in 2024. The $2.6 million decrease in personnel related costs includes the impact of our $3.4 million restructuring charge recorded in the three months ended March 31, 2023, partially offset by an increase in personnel costs in the three months ended March 31, 2024. Please refer to *NOTE 14— RESTRUCTURING CHARGE* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q.

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certain time-based clinical milestones within the agreement are probable based on the availability of necessary data Selling, General, and the assessment of clinical progress in the third quarter of 2023. Please refer to Administrative*NOTE 9— LICENSE AGREEMENTS AND COMMITMENTS* in the consolidated financial statements in this Quarterly Report on Form 10-Q for further discussion on our SADA License Agreement. Outsourced manufacturing decreased by $5.7 million primarily related to $2.0 million of naxitamab inventory vials that

Selling, general, and administrative expenses were designated $11.4 million for use in clinical trials during the three months ended September 30, 2022 March 31, 2024, $1.7 million decreased SADA production in as compared to $12.2 million for the three months ended September 30, 2023, compared March 31, 2023. The $0.8 million decrease in selling, general, and administrative expenses was primarily attributable to the corresponding period a decrease in 2022, and $1.0 million decreased omburtamab production in the three months ended September 30, 2023, compared to the corresponding period in 2022.

Personnel personnel related costs, inclusive of stock-based compensation, decreased to $4.1 million driven by the impact of our $1.1 million restructuring charge recorded in the three months ended September 30, 2023, a $2.0 million decrease compared to the corresponding period in 2022, due to the impact of the strategic restructuring plan we announced in January 2023. March 31, 2023. Please refer to *NOTE 14 — RESTRUCTURING CHARGE* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Quarterly Report on Form 10-Q for further discussion.

Selling, General, and Administrative

Selling, general, and administrative expenses were $10.2 million for the three months ended September 30, 2023, as compared to $13.6 million for the three months ended September 30, 2022. The $3.4 million decrease in SG&A expenses was primarily attributable to a $1.9 million decrease in commercial expense, primarily due to costs incurred in 2022 for the preparation of a potential omburtamab launch. 10-Q.

Interest and Other Income / (Loss)

Interest and other income for the three months ended September 30, 2023 March 31, 2024 was $0.2 million as $0.4 million compared to interest and other loss of $1.5 million $1.1 million for the three months ended September 30, 2022 March 31, 2023. Our interest and other income increased decreased by $1.7 million $0.7 million primarily due to a $0.8 million $0.6 million decrease in foreign currency transaction losses, and a $0.5 million increase from our money market fund investment income. gains.

Provision for Income Taxes

Provision for income taxes was $0.2 million for the three months ended September 30, 2023 March 31, 2024. We did not record any provision for income taxes for the three months ended September 30, 2022 March 31, 2023. The increase in provision for income taxes was primarily driven by certain U.S. state jurisdictions.

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Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

	Nine Months Ended September 30,		Amount Change	Percentage Change
	2023	2022	2023 vs. 2022	2023 vs. 2022
	(in thousands)		(in thousands)	
REVENUES				
Product revenue, net	$ 60,956	$ 32,820	$ 28,136	86 %
License revenue	500	1,000	(500)	(50)
Total revenues	61,456	33,820	27,636	82
OPERATING COSTS AND EXPENSES				
Cost of goods sold	9,327	5,447	3,880	71
License royalties	50	100	(50)	(50)
Research and development	40,831	71,785	(30,954)	(43)
Selling, general, and administrative	33,721	50,146	(16,425)	(33)
Total operating costs and expenses	83,929	127,478	(43,549)	(34)
Loss from operations	(22,473)	(93,658)	71,185	(76)
OTHER INCOME / (LOSS), NET				
Interest and other income/(loss)	2,400	(3,067)	5,467	(178)
LOSS BEFORE INCOME TAXES	(20,073)	(96,725)	76,652	(79)
Provision for income taxes	366	—	366	100
NET LOSS	$ (20,439)	$ (96,725)	$ 76,286	(79) %

Revenues

We recorded $61.0 million and $32.8 million in product revenue, net for the nine months ended September 30, 2023 and 2022, respectively. The $28.2 million increase was primarily driven by an increase in new US patients and an incremental benefit from expanding into international markets as discussed further in *NOTE 4— PRODUCT REVENUE, NET*. The geographic breakout for the product revenue, net

between in the United States and other countries for the nine months ended September 30, 2023 was $48.8 million and $12.2 million, respectively. The geographic breakout for the product revenue, net between the United States and other countries for the nine months ended September 30, 2022 was $30.9 million and $1.9 million, respectively. Our product revenue, net from other countries for the nine months ended September 30, 2023, included $3.5 million of product revenue and related royalties for the commercial launch initial inventory stocking order from our distribution partner, SciClone, which launched commercial sales in China during the nine months ended September 30, 2023. We do not anticipate recurring product revenue, net from SciClone at this level each quarter. Our revenue from other countries for the nine months ended September 30, 2023, also included $5.6 million of product revenue, net from the Company's distribution partner, WEP. We recognized royalty revenue from our distribution partners of $3.8 million and $1.4 million in the nine months ended September 30, 2023 and 2022, respectively.

In addition, we recorded $0.5 million and $1.0 million in license revenue for the nine months ended September 30, 2023, and 2022, respectively. The license revenue for the nine months ended September 30, 2023, was recognized upon September 2023 achievement of marketing authorization for DANYELZA in Mexico under the terms of the non-refundable license milestone within our sublicense agreement with Adium. The license revenue of $1.0 million for the nine months ended September 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.

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Cost of Goods Sold

Cost of goods sold was $9.3 million and $5.5 million for the nine months ended September 30, 2023 and 2022, respectively. The increase in cost of goods sold was primarily driven by increased product revenue and an inventory charge of $0.8 million in the nine months ended September 30, 2023, partially offset by a $1.2 million charge related to a batch that did not meet our quality specifications recognized in the nine months ended September 30, 2022. Excluding the above two inventory charges, our gross margin decreased in the nine months ended September 30, 2023, compared to 2022, as a result of increased revenues from geographic areas outside of the United States, which were at a lower gross margin. 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.

License Royalties

We incurred license royalty expenses of $0.1 million during the nine months ended September 30, 2023 related to licensing revenues recognized upon the September 2023 achievement of marketing authorization for DANYELZA in Mexico within the terms of the non-refundable license milestone under our sublicense agreement with Adium, which are included in Licensing Revenue on the Consolidated Statements of Net Loss and Comprehensive Loss. We incurred license royalty expense of $0.1 million during the nine months ended September 30, 2022, related to the license revenue 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.

Research and Development

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

	Nine Months Ended September 30,		Change	
	2023	2022	Amount	Percentage
	(in thousands)		(in thousands)	
Outsourced manufacturing	$ 9,529	$ 27,433	$ (17,904)	(65) %

Clinical trials	4,614	7,741	(3,127)	(40)
Outsourced research and supplies	825	7,585	(6,760)	(89)
Milestones and license acquisition costs	4,125	—	4,125	100
Personnel costs	10,903	14,207	(3,304)	(23)
Professional and consulting fees	1,003	2,351	(1,348)	(57)
Stock-based compensation	5,034	5,797	(763)	(13)
Other	4,798	6,671	(1,873)	(28)
	$ 40,831	$ 71,785	$ (30,954)	(43) %

Research and development expenses were $40.8 million for the nine months ended September 30, 2023, as compared to $71.8 million for the nine months ended September 30, 2022. The $31.0 million decrease was primarily due to the decrease in spending on deprioritized programs, which resulted in a $17.9 million decrease in outsourced manufacturing, a $6.8 million decrease in outsourced research and supplies, a $3.1 million decrease in clinical trials, and decreased personnel related costs, inclusive of stock-based compensation, of $4.1 million, partially offset by a $4.1 million increase in milestones and license acquisition costs related to our SADA License Agreement, as we determined certain time-based clinical milestones within the agreement are probable based on the availability of necessary data and the assessment of clinical progress in the third quarter of 2023. Please refer to *NOTE 9— LICENSE AGREEMENTS AND COMMITMENTS* in the consolidated financial statements in this Quarterly Report on Form 10-Q for further discussion on our SADA License Agreement. Outsourced manufacturing decreased by $17.9 million primarily related to a $5.2 million decrease in SADA production in the nine months ended September 30, 2023, compared to the corresponding period in 2022, a $4.7 million charge for naxitamab inventory vials that were designated for clinical use

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during the nine months ended September 30, 2022 and a $3.4 million decrease in omburtamab production in the nine months ended September 30, 2023, compared to the corresponding period in 2022.

Personnel related costs, inclusive of stock-based compensation, decreased to $15.9 million in the nine months ended September 30, 2023, a $4.1 million decrease compared to the corresponding period in 2022, due to the impact of the strategic restructuring plan we announced in January 2023. Please refer to *NOTE 14— RESTRUCTURING CHARGE* in the consolidated financial statements in this Quarterly Report on Form 10-Q for further discussion.

Selling, General, and Administrative

SG&A expenses were $33.7 million for the nine months ended September 30, 2023, as compared to $50.1 million for the nine months ended September 30, 2022. The $16.4 million decrease in SG&A expenses was primarily attributable to an $10.9 million charge for severance and share-based compensation expense in the nine months ended September 30, 2022, related to our former Chief Executive Officer as discussed further in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*, jurisdictions, and, to a lesser extent, a $2.9 million decrease in commercial expense, primarily due to costs incurred in 2022 for the preparation limitation on utilization of a potential omburtamab launch, and a $1.6 million decrease in insurance costs, partially offset by a $1.6 million increase in legal expense.

Interest and Other Income / (Loss)

Interest and other income/(loss) resulted in income of $2.4 million for the nine months ended September 30, 2023, as compared to, a loss of $3.1 million for the nine months ended September 30, 2022. Our interest and other income/(loss) experienced a favorable increase of $5.5 million which was primarily due to a $2.6 million decrease in foreign currency transaction losses and a $2.3 million increase from our money market fund investment income.

Provision for Income Taxes

Provision for income taxes was $0.4 million for the nine months ended September 30, 2023. We did not record any provision for income taxes for the nine months ended September 30, 2022. The increase in provision for income taxes was primarily driven by certain U.S.

state jurisdictions.federal net operating losses.

Liquidity and Capital Resources

Overview

Each year we We have experienced a significant use of cash to fund our net operating losses since inception and expect to continue to fund net operating losses. inception. We expect our use of cash to fund our net operating losses to decrease in the future as a result of revenues from our restructuring plan only approved product, DANYELZA, grow and announced in January 2023 and as sales of DANYELZA increase overtime. contribute to funding our significant research expenses. 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 September 30, 2023, primarily through gross proceeds from the aggregate sales of our common stock of $493.8 million in the years 2015 through 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 September 30, 2023 March 31, 2024 and December 31, 2023, we had cash and cash equivalents of $86.6 million. As a result of the expected decrease in forecasted operating expenses, we $75.7 million and $78.6 million, respectively. We estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, will should support our operations into 2027. This estimate is based on our current business plan, including our restructuring, and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. This estimate assumes no income from new partnerships or other new business development activities, and no further development of the omburtamab program. program, the GD2-GD3 Vaccine and the CD33 bispecific antibody constructs. We cannot provide any assurance that we will be able to obtain additional capital from additional equity or debt financings, financing, collaborations, licensing arrangements, or other sources.

For an analysis of the type of contractual obligation obligations 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 see refer to *NOTE 9 —LICENSE AGREEMENTS AND COMMITMENTS* in the section entitled “Contractual Obligations and Commitments” notes to the consolidated financial statements included in Part II. Item 7. *Management’s Discussion and Analysis of* 1. Financial Statements in this Form 10-Q.

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Financial Condition and Results of Operations in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022.

Cash Flows

The following table provides information regarding our cash flows for the nine three months ended September 30, 2023 March 31, 2024 and 2022: 2023:

	Nine Months Ended September 30,		Change		Three Months Ended March 31,		Change	
	2023	2022	Amount	Percentage	2024	2023	Amount	Percent
	(in thousands)		(in thousands)					
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Net cash used in operating activities	$ (19,196)	$ (67,260)	$ 48,064	(71)%	$ (3,477)	$ (13,124)	$ 9,647	(74)%
Net cash provided by investing activities	—	—	—	NA				
Net cash provided by financing activities	—	84	(84)	(100)				
Net cash from investing activities					—	—	—	NA
Net cash from financing activities					588	—	588	NA
Effect of exchange rates on cash and cash equivalents	5	138	(133)	(96)	1	(9)	10	(111)
Net decrease in cash and cash equivalents	$ (19,191)	$ (67,038)	$ 47,847	(71)%	$ (2,888)	$ (13,133)	$10,245	(78)%

Net Cash Used in 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 $19.2 million $3.5 million for the nine three months ended September 30, 2023 March 31, 2024, as compared to net cash used in operating activities of $67.3 million $13.1 million for the nine three months ended September 30, 2022 March 31, 2023. The $48.1 million $9.6 million decrease in cash used in operating activities during the nine months ended September 30, 2023, compared to the corresponding period in 2022, was primarily due to a $61.5 million improvement in our net loss, net of non-cash adjustments, which was partially offset by an increase decrease in cash used for working capital of $13.4 million $10.3 million, which was primarily driven by $8.0 million of increased accounts receivable collections, during the nine three months ended September 30, 2023, March 31, 2024 compared to the corresponding period in 2022. The $13.4 million increase in cash used for working capital was driven by lower accounts payable of $6.4 million due to the impact of deprioritized programs, higher accounts receivable from increased sales activity of $4.8 million for the nine months ended September 30, 2023, and lower accrued liabilities and other of $1.0 million, as compared to the nine months ended September 30, 2022. 2023.

Net Cash Provided by From Investing Activities

We did not generate or use cash for investing activities during the nine three months ended September 30, 2023 March 31, 2024 and 2022. 2023.

Net Cash Provided by From Financing Activities

Net cash provided by financing activities was $0.6 million for the three months ended March 31, 2024, which resulted from proceeds from exercised stock options. We did not generate or use cash for financing activities during the nine three months ended September 30, 2023 March 31, 2023. Net cash provided by financing activities was $84,000 for the nine months ended September 30, 2022, which was proceeds from exercised stock options.

Funding Requirements

We plan to advance the development of our pipeline programs, initiate new research and pre-clinical development efforts and seek marketing approval for any additional product candidates and indications that we successfully develop. If we obtain approval for any additional product candidates and indications, 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. 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.

As a result

Our cash and cash equivalents were $75.7 million as of the realized decrease in operating expenses after the restructuring program we announced in January 2023, we March 31, 2024. We estimate that our cash and cash equivalents, of $86.6 million as of September 30, 2023, when combined with anticipated DANYELZA revenues, will should support operations as currently planned into 2027. This estimate is based on our current business plan and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. This estimate assumes no new partnerships or other new business

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development and no further development of the omburtamab program. program, the GD2-GD3 Vaccine and the CD33 bispecific antibody constructs. We cannot provide any assurance that we will be able to obtain additional capital from new equity or debt financings, financing, collaborations, licensing arrangements, or other sources. As a result of the reduction in workforce and revised business plan, we incurred restructuring expenses of $4.5 million, consisting predominantly of cash related to notice and severance payments of $2.8 million, which were paid as of September 30, 2023, and acceleration of stock-based compensation of $1.7 million. The restructuring expenses were recognized in the first quarter of 2023.

Because of the numerous risks and uncertainties associated with the further development and commercialization of DANYELZA, 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 DANYELZA, and conducting pre-clinical studies and clinical trials for our SADA PRIT constructs;
- 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;

- our headcount and associated costs as we focus our research and development efforts on additional indications for DANYELZA and our SADA technology PRIT Technology and expand our 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

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- 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 additional marketing approval and achieve additional product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, financing, 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

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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 financing 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.

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 in the notes to the consolidated financial statements. statements included in Item 1. Financial Statements in this Form 10-Q.

For a discussion of our material license agreements, see the section entitled "Contractual Obligations and Commitments" in Part II. Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 December 31, 2023.

Research and development is inherently uncertain and, should such research and development fail, the MSK License Agreement, the CD33 License Agreement, and SADA License Agreement 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, for which the percentage varies based upon the nature of the clinical or development milestone. To date, we have not entered into any sublicenses related to the CD33 License, the SADA License or the MabVax/Y-mAbs Sublicense. We have entered into sublicenses and distribution agreements with Swixx, SciClone and Takeda in 2020, and Adium in 2021, and WEP in 2022, 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.

Known Trends, Geopolitical Events and Uncertainties

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 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 and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia, and we 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 and energy 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 and supply-chain

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continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets.

In addition, on October 7, 2023, Hamas militants infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Following the attack, Israel's security cabinet declared war against Hamas. It is currently not possible to predict the duration or severity of the ongoing conflict, whether it will develop into a wider conflict or its effects on our business, operations and financial condition. The ongoing conflict is rapidly evolving and developing and may have a material adverse impact on our business and/or our partners. For example, it may have an adverse impact on Takeda Israel's ability to sell our products and/or collect receivables from customers in the State of Israel pursuant to the exclusive licensing and distribution agreement we entered into with Takeda Israel in November 2022, or the Takeda Licensing agreement, as well as on Takeda Israel's ability to pursue the development, marketing and/or commercialization of DANYELZA in the State of Israel, West Bank and Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement.

Inflation may also materially affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates and overhead costs have and may continue to adversely affect our operating results. High interest rates also present a recent challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect demand for our product and our operations. Furthermore, such economic conditions have produced downward pressure on share prices. We may experience increases in our operating

costs, including our labor costs and research and development costs, due to supply-chain constraints, the ongoing conflict between Russia and Ukraine, the state of the war involving Israel, and employee availability and wage increases, which may result in additional stress on our working capital resources.

In addition, the closures of Silicon Valley Bank and Signature Bank in 2023 have resulted in broader financial institution liquidity risk and concerns, and future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages. The failure of any bank in which we deposit our funds could reduce the amount of cash we have available for our operations or corporate development or delay our ability to access such funds. Any such future bank failure may increase the possibility of a sustained deterioration of financial market liquidity, or illiquidity at clearing, cash management and/or custodial financial institutions. To help guard against that risk, our cash and cash equivalents are held at a large major federal, national bank. In the event we have a commercial relationship with a bank that has failed or is otherwise distressed, we may experience delays or other issues in meeting our financial obligations. If other banks and financial institutions fail or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our cash and cash equivalents may be threatened and our ability to borrow or raise additional capital when needed to operate our business could be substantially impaired.

Recent Accounting Pronouncements

Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the accompanying notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q for a discussion of recent accounting pronouncements.

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Item 3. Quantitative and Qualitative Disclosures About Market Risk.

As a “smaller reporting company” as defined by Item 10 of Regulation S-K, we are not required to provide the information required by this item.

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Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Quarterly Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a 13(a) 15(e) and 15d 15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of September 30, 2023 March 31, 2024.

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

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting, (as defined in Rules 13a 15(f) and 15d 15(f) under the Exchange Act) during the quarter ended September 30, 2023 March 31, 2024, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings.

Donoghue vs. Y-mAbs Therapeutics, Inc., and Gad

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 one of the Company's stockholders, Deborah Donoghue (Case No. 1:21-cv-07182). The suit names the Company's Chief Business Officer, and Vice Chairman of the Company's 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. The parties have completed documentary discovery and depositions. The action is currently stayed through November 30, 2023. On February 1, 2024, both the Plaintiff and Mr. Gad filed their respective motions for summary judgement. The Company is of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company 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.

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In re Y-mAbs Therapeutics, Inc. Securities Litigation

On January 18, 2023, a putative class-action lawsuit was filed against the Company and certain of its the Company's current and former officers for alleged violations of the U.S. federal securities laws in the United States District Court, Southern District of New York (Case No.: 1:23-cv-00431). The amended complaint filed on May 23, 2023, asserts claims under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended, on behalf of a proposed class consisting of those who acquired the Company's common stock between October 6, 2020 and October 28, 2022. The amended complaint alleges that there were material misrepresentations and/or omissions regarding the FDA's consideration of the Company's BLA for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma firstly submitted in 2020 and resubmitted in 2022. The amended complaint seeks unspecified damages, and costs and expenses, including attorneys' fees. On April 4, 2023 September 29, 2023, the Court appointed a lead plaintiff for the putative class. On July 11, 2023, the defendants filed a defendants' motion to dismiss the amended complaint. complaint was fully briefed. On August 29, 2023 February 5, 2024, the plaintiff filed his opposition to Court granted in part and denied in part the motion to dismiss. On September 29, 2023 the defendants filed their reply in support of the defendants' motion to dismiss. The Court dismissed the plaintiff's claims relating to three of four categories of challenged statements and dismissed in part plaintiff's claims relating to the fourth category of challenged statements. The Court also dismissed one of the individual defendants from the case. The Company believes that these the remaining claims are without merit and intends to vigorously defend against these claims. The Company has not established a liability for this claim as of September 30, 2023 March 31, 2024 as the Company does not consider a loss on the claim to be probable.

Hazelton vs. Y-mAbs Therapeutics Inc., and Gad, et al.

The Company has been named a nominal defendant in a lawsuit filed in the Court of Chancery of the State of Delaware, on February 8, 2023, by a purported stockholder, Jeffrey Hazelton (Case No. 2023-0147-LWW). The amended complaint filed on May 12, 2023, purports to

bring claims on behalf of the Company against current and former members of the Company's board of directors for allegedly awarding themselves excessive compensation for fiscal years 2020 and 2021. The amended complaint seeks, among other things, recovery of alleged excessive compensation, an order directing the Company to undertake certain corporate governance reforms, and an award of costs and expenses, including attorneys' fees. On June 22, 2023, the defendants filed a Defendants' motion to dismiss the amended complaint. complaint was fully briefed as of September 8, 2023. On August 11, 2023 April 3, 2024, the plaintiff filed his opposition parties informed the Court that they had agreed to resolve the motion matter on mootness grounds and hoped to dismiss. On September 8, 2023 the defendants filed their reply brief in support of the motion to dismiss. The Company is of the opinion that the claims are without merit and intends to maintain this position in the proceedings. reach agreement on formal documentation. The Company has not established a liability for this claim as of September 30, 2023 March 31, 2024 as the Company does not consider a loss on the claim to be probable.

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 you might lose all or part of your investment.

Risks Related to Our Financial Condition and Need for Additional Capital

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

We are a commercial-stage biopharmaceutical company with a limited operating history. Since our inception in 2015, we have incurred significant losses each year. As of September 30, 2023, March 31, 2024 our accumulated deficit was approximately $456.5 million $464.1 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, the proceeds from the sales of DANYELZA and the sale of the PRV granted to us upon FDA approval of DANYELZA.

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To date, we have devoted substantially all our efforts to research and development, and more recently, commercialization of DANYELZA, which is our only approved product to date and omburtamab. to development of omburtamab and SADA PRIT Technology. On November 25, 2020, DANYELZA was approved by the FDA for the treatment, in combination with GM-CSF, of pediatric patients one 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.

Although in May 2022 our biologic license application, or BLA, for omburtamab was accepted for priority review by the FDA, in November 2022 the FDA issued a complete response letter, or CRL, for the BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. As part of our strategic restructuring plan announced in January 2023, we deprioritized the omburtamab program for all indications and product candidates. We are currently considering candidates, following CRL from the future FDA for the BLA for omburtamab in November 2022. While we received an 18-month extension for the BLA of omburtamab, which expires on May 30, 2025, we have further determined to discontinue our radiolabeled omburtamab development program for CNS-LM.

We are using our proprietary Self-Assembly and Dis-Assembly Pre-targeted, or SADA PRIT, technology platform, a concept we also refer to as Liquid Radiation™, to advance a series of antibody constructs, using a two-step pre-targeting approach. The bispecific antibody fragments bind to the tumor before a radioactive payload is subsequently injected. GD2-SADA for potential use in GD2-positive solid tumors is our first SADA PRIT construct, and we can provide no assurance that had our first clinical patients dosed in April 2023 in our Phase 1, dose-escalation, single-arm, open-label, non-randomized, multicenter trial, for the treatment of certain solid tumor cancers, including small cell lung cancer, sarcoma, and malignant melanoma. The IND for our first hematological target, the CD38-SADA construct for the treatment of patients with Relapsed or Refractory Non-Hodgkin Lymphoma was cleared in October 2023, and we expect to dose the first patient in 2024. We are still in early stages of development of omburtamab will continue or SADA PRIT technology platform. We may not be successful in our efforts to use the SADA PRIT Technology to build a pipeline of product candidates. Our investment in developing SADA PRIT Technology may contribute to the risk that omburtamab will ultimately receive FDA approval. we may never achieve profitability.

Our other product candidates development programs 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 additional product candidates approved and ready for commercialization.

We expect to continue to incur significant expenses and 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 received FDA accelerated approval on November 25, 2020. We began limited sales and shipments of DANYELZA in February 2021 and the revenue generated from product sales does not fully fund our operating expenses. We do not anticipate generating revenue that will fully fund our operating expenses 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 and maintaining 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, among others, or establishing our own manufacturing capabilities and infrastructure;
- obtaining market acceptance of DANYELZA and our other product candidates as viable treatment options;

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- 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;

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- 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. products. For example, we continue to run clinical studies on our currently marketed product DANYELZA to fulfill the regulatory requirement from the accelerated approval of the product by FDA. 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 is designed to enroll a minimum of 80 evaluable 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. We anticipate completing the study no later than by March 31, 2027.

Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, authorities, 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, 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 other products 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 multiple pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors as we continue to develop and commercialize DANYELZA and our other product candidates.

We may not realize the expected benefits from our recent business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties.

In January 2023, we announced a restructuring plan and implemented a workforce reduction. The objective of these initiatives is to focus the organization and its resources on key near and long-term potential growth drivers, namely the DANYELZA franchise and development of our SADA platform. We believe these changes were needed to streamline our organization and reallocate our resources in light of the omburtamab CRL from the FDA.

However, the changes to our business strategy and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our technology roadmap, and results of operations or financial condition. We incurred restructuring expenses of $4.5 million, consisting predominantly of cash related notice and severance payments of $2.8 million and acceleration of stock-based compensation of $1.7 million in the first half of 2023.

We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the revised business plan and reduction in workforce. For example, we recorded an impairment charge of $0.6 million to write-off the net book value of fixed assets that were

related to the production of omburtamab in 2022. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees.

We may also discover that the reductions in workforce and cost cutting measures will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. Moreover, there is no assurance we will be successful in our pursuit of any of our new goals. Our failure to successfully accomplish any of the above activities and goals may have a material adverse impact on our business, financial condition, and results of operations.

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 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 PRIT 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 in 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 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, if achieved, 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, we may be required to use our existing cash, incur debt obligations or issue additional equity securities, any of 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 sales of DANYELZA and conduct clinical trials of, and seek marketing approval for 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. Our ability to raise additional capital may be adversely impacted by worsening global economic conditions, with disruptions to, and volatility in, the credit and financial markets in the U.S. and worldwide resulting from the effects of inflationary pressures, health crises, such as the COVID-19 pandemic, the military conflict between Ukraine and Russia, the state of the war between involving Israel and Hamas and the threat of a greater regional more global conflict, current and potential future bank failures, and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted, which could in the future negatively affect our capacity for certain corporate development transactions or our ability to make other important, opportunistic investments. 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, financing, 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

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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

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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 Historically, we have focused 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 more, recently, SADA for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB. solid tumors and Non-Hodgkin Lymphoma. 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. For example, in November 2022 the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022. In its CRL for

omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. As part of our strategic restructuring plan announced in January 2023, While we deprioritized have since determined to discontinue the radiolabeled omburtamab program for all indications CNS-LM, we have historically allocated a large portion of our resources to the development of this product candidate.

We depend on a limited number of customers for a high percentage of our revenue. If we cannot maintain our current relationships with customers, fail to sustain recurring sources of revenue with our existing customers, or if we fail to enter into new relationships, our future financial condition and results of operations will be adversely affected. Moreover, the financial difficulties or insolvency of one or more of our major customers or their lack of willingness and ability to distribute our approved product, candidates. DANYELZA, could adversely affect our financial position and results of operations.

We are currently considering had product sales to certain customers that accounted for more than 10% of total product revenue, net for the three months ended March 31, 2024 and 2023. McKesson, AmerisourceBergen and Cardinal Health, accounted for 51%, 25%, and 22%, respectively, of the Company's product revenue, net for the three months ended March 31, 2024. McKesson, AmerisourceBergen, Cardinal Health and WEP accounted for 45%, 29%, 13% and 12%, respectively, of the Company's product revenue, net for the three months ended March 31, 2023. Our future for success depends on our omburtamab development program ability to maintain these relationships, to increase our penetration among these existing customers and we to establish new relationships. We engage in conversations with other companies and institutions regarding potential commercial opportunities on an ongoing basis, which can provide be time consuming. There is no assurance that any of these conversations will result in a commercial agreement, or if an agreement is reached, that the development resulting relationship will be successful. In addition, if our customers order our approved product, DANYELZA, but fail to pay on time or at all, our liquidity, financial condition, results of omburtamab will continue operations, cash flows and prospects could be materially and adversely affected.

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Moreover, our product sales are made through arrangements primarily with three national specialty distributors in the United States. As of March 31, 2024, the accounts receivable balances from such distributors totaled 76% of the Company's outstanding accounts receivable. A default by any of these customers on their amounts owed to us could have a material adverse effect on our financial position. Future sales and our ability to collect accounts receivable depend, in part, on the financial strength of our customers and our distributors' willingness and ability to successfully market our approved product, DANYELZA. We estimate an allowance for doubtful accounts based on our assessment of specific identifiable customer accounts considered at risk or that omburtamab will ultimately receive FDA approval. uncollectible, as well as an analysis of current receivables aging and expected future write-offs and this allowance adversely impacts our results of operations. In the event customers experience greater than anticipated financial difficulties, insolvency, or difficulty marketing DANYELZA, we expect our financial position and results of operations to be further adversely impacted by our failure to collect accounts receivable in excess of the amount due, net of the estimated allowances.

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. 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. 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. The nature of the patient populations that we study in our clinical trials means that the treatment effect of our product candidates has to be demonstrated despite being the second or third-line of treatment, and in some cases, despite concomitant treatment with radiation or chemotherapy. Some of our target indications may also be difficult to assess via current imaging technology and other testing methods, which may lead to in conclusory in-conclusory or equivocal data regarding treatment effect. Furthermore, because our study populations are small, statistical analyses may not fully adjust for these and other potential bias in the data. As was the case for omburtamab, any or all of these factors may mean that we are unable to demonstrate substantial evidence of the effectiveness of or our product candidates to the satisfaction of the FDA or other comparable foreign regulatory authorities.

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.

DANYELZA and 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. On November 25, 2020, DANYELZA received regulatory approval by the FDA in the United States for the treatment in combination with GM-CSF of high-risk R/R NB. The FDA has issued a post-marketing commitment to provide data on PFS, supporting the efficacy of the product. We are currently performing clinical studies, such as Study 201, aimed to

fulfill the requirements. There can be no assurance that these studies will generate data sufficient to support the efficacy of the product.

Although the FDA accepted our BLA for omburtamab for priority review, in November 2022 the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. As part of our strategic restructuring plan announced in January 2023, we deprioritized the omburtamab program for all indications and product candidates. We are currently considering While we received an 18-month extension for the future for BLA, which expires on May 30, 2025, we have further determined to discontinue our the radiolabeled omburtamab development program and there for CNS-LM.

The SADA PRIT Technology is no assurance that we will continue to develop omburtamab still in the early stages of clinical development or receive approval of our BLA for omburtamab. pre-clinical research. We may never be able to develop a marketable product other than DANYELZA. 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. 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;

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- 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;

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- 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 product candidates are based on similar technologies. Therefore, if one product candidate encounters safety or efficacy problems, developmental delays, regulatory issues, or other problems, our other development plans and business could be significantly harmed.

The SADA PRIT Technology that we use is unproven still in early stages of clinical development or pre-clinical research and may not result in approvable or marketable products, which exposes us to unforeseen risks and makes it difficult for us to predict the time and cost of product development and potential for regulatory approval, and we may not be successful in our efforts to use the SADA PRIT Technology to build a pipeline of product candidates.

We are seeking to identify and develop a broad pipeline of product candidates using the SADA PRIT Technology. We have only recently begun not yet completed dosing patients in our Phase 1 trial of GD2-SADA. The scientific research that forms the basis of our efforts to develop product candidates with the SADA PRIT Technology is still ongoing. We are not aware of any FDA-approved therapeutics utilizing a similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on the SADA PRIT Technology is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates using the SADA PRIT Technology. For example, before the first dosing in our Phase 1 trial of GD1-SADA, we had not tested any of the product candidates being developed using the SADA PRIT platform in humans, and most of our current data is limited to animal models and pre-clinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates based on the SADA PRIT Technology in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates. In addition, the SADA PRIT Technology has potential safety risks related to, but not limited to, the radiation stemming from the delivery of radioactive payloads. As a result, it is possible that safety events or concerns could

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negatively affect the development of our product candidates developed using the SADA PRIT Technology, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of the SADA PRIT Technology, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates developed using the SADA PRIT Technology, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using the SADA PRIT Technology, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products developed using the SADA PRIT Technology, alone or in combination with other therapies.

Additionally, an element of our strategy is to use and expand the SADA PRIT Technology to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different cancers. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building a pipeline of product candidates developed using the SADA PRIT Technology, the

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potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop, get approval for and begin to commercialize any product candidates developed using the SADA PRIT Technology, we will face difficulty in obtaining product revenue therefrom in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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 conditions in the region, we terminated our clinical trials of DANYELZA in Russia and suspended our regulatory activities to obtain marketing authorization for DANYELZA in Russia. We have been able to make DANYELZA available in Russia on a compassionate (unapproved) use basis for a limited number of patients. Although we are considering expanding the compassionate use of DANYELZA in Russia through our partnership with Swixx BioPharma AG, the sanctions have 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 or that we will be able to expand our collaboration with Swixx BioPharma AG. 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

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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 commercially launched 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:

- continue to develop and expand our sales and marketing efforts;
- 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;

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- 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 limited experience in operating as a commercial company and the marketing and selling biopharmaceutical products. sale of DANYELZA or any future approved products may be unsuccessful or less successful than anticipated. 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 While we have commercially launched DANYELZA in the United States and in several other countries, 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 marketing and selling the biopharmaceutical products. industry. 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, 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.

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, or authorization is lost, we would have prematurely or

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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:

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- our inability to recruit and retain adequate numbers of effective sales and marketing personnel; personnel, and continue to develop and expand our sales and marketing efforts;
- 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 our failure to educate physicians on the benefits of physicians to prescribe prescribing DANYELZA or any future approved products;
- 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; offerings, and the lack of accurately forecast demand for our products and scale manufacturing to meet that demand;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and
- our inability to obtain sufficient coverage and reimbursement from third-party payors and governmental agencies. agencies;

- our inability to establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our products and any future products;
- our inability to maintain or to gain regulatory authorization for the development and commercialization of our product candidates;
- our inability to develop and maintain successful strategic alliances; and
- our inability to develop and maintain successful strategic alliances.

Conversely, 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. In addition, 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, Adium Pharma S.A. and WEP Clinical Ltd.) 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, biotechnology and pharmaceutical industries generally, and the market for developing antibody-based products in particular, is cancer drug sector specifically, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and rapid innovation. Our competitors may be able to develop other compounds or drugs a

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strong emphasis on intellectual property. While we believe that are able to achieve similar or better results. Our actual our product candidates and our knowledge and experience provide us with competitive advantages, we face substantial potential competitors include major multinational competition from many different sources, including large and specialty pharmaceutical companies, established and biotechnology companies, specialty pharmaceutical companies, universities, academic research institutions and other governmental agencies and public and private 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, 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.

In addition to the current standard of care for patients, commercial and academic clinical trials are being pursued by a number of parties in the field of immunotherapy. Early results from these trials have fueled continued interest in immunotherapy, which is being pursued by several biotechnology companies as well as by large pharmaceutical companies. Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, pre-clinical studies, conducting clinical trials, and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established

companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

With respect to DANYELZA, which targets GD2-positive tumors, United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin Unituxin® (dinutuximab), an antibody against GD2, in the United States, Canada and Japan. Although United Therapeutics has discontinued its efforts to investigate Unituxin's Unituxin®'s potential activity against adult cancerous tumors, it has maintained its efforts to develop a humanized version of Unituxin Unituxin® and plans to develop Unituxin Unituxin® within R/R NB, NB. DANYELZA also 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

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to Qarziba® (dinutuximab beta), and it is currently being commercialized in Europe European Union and was approved by the EMA European Commission 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, or NMPA, had granted Qarziba® (dinutuximab beta) conditional marketing 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. EUSA was acquired by Recordati in March 2022. In addition, Renaissance Pharma Ltd in the United Kingdom has announced in August 2023 a development program focused on Hu14.18, a humanized anti-GD2 monoclonal antibody, licensed from St. Jude Children's Research Hospital for the treatment of newly diagnosed high-risk neuroblastoma neuroblastoma. Essential Pharma acquired Renaissance Pharma Ltd in August 2023. US April 2024. U.S. WorldMeds has submitted a New Drug Application, or NDA, in late 2022, and is seeking also received FDA approval of eflornithine hydrochloride, or DFMO, to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma who have completed multiagent, multimodality therapy.

The SADA PRIT Technology, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach faces competition from a range of companies developing comparable approaches, involving one-step, two-step or three-step models to bind antibody constructs to the tumor and radiate the tumor. Perspective Therapeutics, Inc. has a two-step pre-targeting platform, where an antibody is first administered via intravenous injection and binds to the tumor. The antibody accumulates over time at the tumor site. Second, a radionuclide is administered and binds to the antibody to deliver radiation to the tumor sites. Clarity Pharmaceuticals Ltd is developing a platform, through which a bifunctional cage retaining copper isotopes is linked to a targeting molecule, which then finds and binds tumor specific receptors on cancer cells. Once the targeting molecule has found the tumor, the radioisotope can act in that location and emit radiation. Together with the targeting molecule and the isotope, the technology may enable the development of radiopharmaceuticals for diagnosis and therapy in oncology. In mainland China, DANYELZA addition, OncoOne Research & Development GmbH is not developing several constructs under their PreTarg-it® technology, which is a modular platform utilizing bispecific antibodies for delivery of payloads, where the first approved bispecific antibody treatment for R/R NB. If approved is first

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injected and accumulated on the tumor, while unbound antibodies are decomposed and excreted. Subsequently, a payload is administered through a second infusion and binds to the bispecific antibody in Europe, DANYELZA will not be the first approved antibody treatment for R/R

NB in Europe. 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. tumor.

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.

MacroGenics, Inc. and Daiichi Sankyo Co. are developing antibodies against the B7-H3 molecule that is the target of omburtamab.

The market opportunities for DANYELZA and our other 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 populations are based on our beliefs and estimates regarding the incidence or prevalence of certain types of cancers that may be addressable by DANYELZA, 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.

Our current target patient populations are small as we have so far focused our clinical development efforts on rare pediatric cancers. By way of example, only approximately 800 700 children are diagnosed with NB in the United States each year. Even if we obtain significant market share for DANYELZA, 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. Even if we would seek approval as front-line or third-line therapy for DANYELZA 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.

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The indications we seek to treat have low prevalence and it may be difficult to identify and enroll patients with these diseases. 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 have experienced and may continue to 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;

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- 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.

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DANYELZA or any current or future product candidates, including those based on the SADA PRIT Technology, 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, variation or suspension 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,, including those based on the SADA PRIT Technology,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. 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.

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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 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 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, suspend or vary 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 of, or withdraw the approval for such product based on the outcome of post-marketing testing and safety or efficacy of the product, 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;

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- we, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, or comparable foreign strategies, 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 in the United States. or achieving additional approvals, 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.

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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 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 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 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 currently ongoing or planned. In the event that an adverse safety issue, clinical hold or other adverse finding occurs in

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one or more of our clinical trials of the same product candidate, such event could adversely affect our other clinical trials of 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 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 convened an Advisory Committee, which met on October 28, 2022, and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. population . In November 2022, the FDA issued a CRL for our BLA for omburtamab indicating that the FDA determined that it was unable to approve the BLA in its current form since it did not provide substantial evidence of effectiveness of omburtamab for the proposed indication. We have determined to discontinue our radiolabeled omburtamab development program for CNS-LM.

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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.

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

In the November 2022 CRL for our BLA for omburtamab, the FDA determined that it was unable to approve the BLA in its current form since it did not provide substantial evidence of effectiveness of omburtamab for the proposed indication. Further, the FDA stated that comparisons of overall survival between our Study 101 and the external control could not be used to estimate the treatment effect of omburtamab on survival and support claims of effectiveness. Additionally, the FDA held that response rate data from our study 101 were not reliable to verify the anti-tumor activity of omburtamab. This was consistent with the outcome of the ODAC Meeting held in October 2022. In its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. profile, and we have determined to discontinue our radiolabeled omburtamab development program for CNS-LM. If we are required and we determine to conduct additional clinical trials of a product candidate, including if we determine to resume development of omburtamab, 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.

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. For example, as was the case for our BLA for omburtamab, analysis of the clinical data may rely on external control comparator populations to demonstrate efficacy, rather than blinded, placebo-controlled comparator populations. Data from our clinical trials may therefore be subject to heightened scrutiny regarding potential sources of bias such as treatment-center selection bias or differences in treatment patterns between countries and over time. Furthermore, because our clinical trials typically enroll a small number of patients, statistical analyses may only partially adjust to account for

such potential bias. For example, FDA identified key review issues with our BLA for omburtamab, stating that the external control population for our omburtamab BLA is not fit-for-purpose as a comparator and limits the ability to reliably attribute survival differences to omburtamab treatment, that the

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BLA application does not include reliable response rate data to provide supportive evidence of the treatment effect of omburtamab, and that differences in survival cannot be reliably attributed to omburtamab and provide a large degree of uncertainty regarding whether the observed differences in overall survival between patients treated with omburtamab and external control populations are due to omburtamab or whether they are due to differences in other anticancer treatment, supportive care regimens, unknown differences between the two populations, or a combination of these factors.

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. 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.

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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. Our only approved product DANYELZA was only approved in late 2020 by the FDA and launched in the United States in early 2021. Further, DANYELZA was only approved by the Israeli Ministry of Health in Israel, in August 2022, by the NMPA in China in December 2022, by Anvisa in Brazil in April 2023, and by COFEPRIS in Mexico in September 2023. 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 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' 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

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- 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, the Israeli Ministry of Health in Israel for Israel and NMPA in China for China, Anvisa in Brazil and COFEPRIS in Mexico, no assurance can be given that it will be successfully commercialized, widely accepted in the any marketplace or more effective than other commercially available alternatives.

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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, the MabVax Sublicense MabVax/MSK License Agreement 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. 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 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, 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;

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- 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 parties 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

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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 third party or any current or potential future collaborator that cause the delay or termination of the research, development or commercialization of our products or product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- such third parties 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 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 have used Lutetium-177, Iodine-131 and Iodine-124 label and conjugated 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 foreign countries governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third-parties' 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

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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

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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 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, foreign 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, varied 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 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 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 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

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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.

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We rely on third parties to manufacture DANYELZA for commercial supply and our product candidates, including our antibody constructs based on the SADA technology, PRIT Technology, for our ongoing and planned pre-clinical studies and clinical studies. Our business could be harmed if third parties fail to provide us with sufficient quantities of DANYELZA or our other product candidates, including our antibody constructs based on the SADA technology, PRIT Technology, or fail to do so at acceptable quantities, quality levels or prices or fail to maintain adequate compliance with CMC guidelines of the FDA. FDA and comparable

foreign regulatory authorities. Our third party third-party manufacturers have in the past and may in the future experience manufacturing difficulties, and any such difficulties could harm our business.

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, including our antibody constructs based on the SADA technology, PRIT Technology, for pre-clinical studies and clinical trials. 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 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 from a limited number of third-party manufacturers. We have engaged a separate third-party manufacturer to conduct fill-and-finish fill and finish and labeling services, as well as for the storage and distribution of DANYELZA 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.

If we determine to resume development of omburtamab, we expect to continue to be 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 liters) 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 are subject to the following additional risks with respect to the third party third-party manufacture of our antibody-based cancer treatments:

- If we need to qualify any new manufacturer of DANYELZA or other product candidates, 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 or comparable foreign regulatory authorities.

- If we need to qualify any new manufacturer of DANYELZA or other product candidates, 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.

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

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

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- We are exposed to the risk of cross-contamination from other drug substances if more than one product is manufactured at a third party third-party manufacturer's production facilities.
- Our third party third-party manufacturers are subject to ongoing periodic unannounced inspection by the FDA, and corresponding state agencies and comparable foreign regulatory authorities to ensure strict compliance with cGMPs and other government regulations and corresponding foreign standards. We do not have limited control over third party third-party manufacturers' compliance with these and or any other applicable regulations and standards, and any of our third party 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 third-party manufacturers in the manufacturing process for our products.
- Any of our third party 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 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 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 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 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, or comparable foreign submission and approvals by the competent regulatory authorities, 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, or comparable foreign regulatory authorities, result in higher costs or adversely impact commercialization of our product candidates. For example, in the past, we experienced a shortage in the supply of Iodine-131, one of the components of ^{131}I-omburtamab product candidate, from our single-source supplier.

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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, or comparable foreign regulatory authorities could place significant restrictions on us until deficiencies are remedied.

The facilities used by our CMOs to manufacture DANYELZA and our product candidates, including our antibody constructs based on the SADA technology, PRIT Technology, must be approved by the FDA pursuant to inspections conducted after submittal of a BLA to the FDA. Comparable requirements are applicable outside the United States. We

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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. For example, we have had to scrap batches of DANYELZA due to our third-party manufacturer's discontinuation of the batch manufacture. As a result, during the nine months years ended September 30, 2023 December 31, 2023 and 2022, the Company recorded charges to write-off inventory of $831,000 $0.8 million and $1,170,000, $1.2 million, respectively. We do not currently have arrangements in place for redundant supply of DANYELZA or other product candidates, and we currently use only a single third-party manufacturer for fill-and-finish services for DANYELZA and other product candidates. 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 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 pre-clinical research but we also rely on third-party research institutions for both clinical trial and pre-clinical research.

Currently, MSK is conducting a clinical trial to address relapsed osteosarcoma using DANYELZA. Under the terms of the MCTA, we are obligated to pay for costs associated with this clinical trial. A clinical trial at MSK for CNS/LM from NB for omburtamab has completed accrual and no new patients are enrolled but we are performing follow-up activities on already-treated patients.

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

The outside scientists who conduct the clinical testing of DANYELZA and our other current product candidates, and who conduct the research and development upon which our product candidate pipeline depends, are not our employees; rather they serve as either independent contractors or the primary investigators under research and other agreements that we have entered into with MSK. Such scientists and collaborators may have other commitments that 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

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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

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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, including those based on the SADA PRIT Technology, are biologics and the manufacture of DANYELZA and our product candidates, including those based on the SADA PRIT Technology, is complex. We, or any of our third-party manufacturers, may encounter difficulties in production, particularly with respect to process development or scaling-up 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, including those based on the SADA PRIT Technology, 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, including those based on the SADA PRIT Technology, 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, including those based on the SADA PRIT Technology, 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 changes 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

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applicable FDA, EMA EU 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 and European Commission 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 and European Commission 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.

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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 wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, the West Bank and the Gaza Strip. The ongoing and rapidly evolving conflict between war involving Israel and Hamas may have a material adverse impact on

Takeda Israel's ability to sell our products and/or collect receivables from customers in the State of Israel as well as on Takeda Israel's ability to pursue the development, marketing and/or commercialization of DANYELZA in the State of Israel, the West Bank and or in the Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement. 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. For additional risks relating to our collaborations with entities operating in China, see "Risks related to government regulation; market approval and other legal compliance matters — 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." In May 2021, we entered into an exclusive distribution agreement with Adium Pharma S.A., or Adium, for Latin America. Finally, in December 2022, we entered into a distribution agreement with WEP Clinical Ltd. in connection with an early access program for DANYELZA in Europe. 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:

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- 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

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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 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 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

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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.

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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 and comparable foreign regulatory authority approval process is processes are lengthy, time-consuming, 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, Europe, China, Israel, Brazil and Mexico 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. States and foreign countries. 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 or in foreign countries, until we receive a Biologics License from the FDA. FDA or foreign equivalent in other countries. 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.

The FDA standard for regular approval of a BLA generally requires two well-controlled well controlled Phase 3 studies or one large and robust, well-controlled 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 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 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 is the case with DANYELZA in the United States, as a condition of accelerated approval, the FDA may require a sponsor to perform post-marketing 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 ultimately require one or multiple Phase 3 clinical trials prior to approval of any product candidates for which we seek accelerated approval.

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. Our BLA for DANYELZA was approved, but we received a CRL for our BLA for omburtamab. omburtamab and we have determined to discontinue our omburtamab program for CNS-LM. 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 and the small size of our target patient populations, to create further challenges in obtaining regulatory approval from the FDA and other regulatory authorities. For example, for product candidates targeting ultra-rare diseases, such as CNS/LM -LM from NB, where the very small patient population makes it difficult or impossible to conduct two traditional, adequate and well-controlled studies, the FDA or comparable foreign regulatory authorities may need to exercise flexibility in approving therapies for such diseases. Even flexibility from the FDA may not be sufficient to obtain approval. For instance, in its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the

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CRL, the FDA made recommendations for us to consider in terms of adequate and well-controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile.

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, and the use of control groups to support licensure. For example, in connection with our BLA for omburtamab, the FDA convened an Advisory Committee that met in October 2022, which voted 16 to

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0 that the BLA did not provide sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. The opinion of this and any other Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure our product candidates based on the completed clinical trials, such as was the case for with omburtamab. 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 and the European Commission 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 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; IRB or positive opinions from Ethics Committees;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up; 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 pandemics or other public-health emergencies;

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- impact of the Russian invasion of Ukraine;
- impact of the state of the war between involving Israel, and Hamas; the related risk of a more global conflict; or

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- 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*. affected." for additional information on risks related to patient enrollment. Further, a clinical trial may be suspended or terminated by us, the IRBs or Ethics Committees 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 could fail to receive marketing approval for many reasons, including the following:

- the FDA, EMA, European Commission 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, European Commission 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, European Commission 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, European Commission 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 European Commission, national competent authorities of EEA countries 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, or the legal manufacturer may fail to CE mark companion diagnostics, which is an acronym for the French "Conformite Europeenne" that certifies that a product has met EU health, safety, and environmental requirement, that may be required in connection with approval of our therapeutic product candidates; and

- the approval policies or regulations of the FDA, EMA European Commission 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 resulted in our failure to obtain marketing approval to market omburtamab. The same factors may also result in a failure for us to obtain marketing approval to market any of our other product candidates, which would further 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, the European Commission 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 from the European Commission, or our other product candidates, which would prevent DANYELZA, 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. In December 2022, the European Committee for Medicinal Products for Human Use, or EMA's CHMP, adopted a negative opinion recommending a refusal of the MAA. CHMP determined that it was not possible to conclude on the effectiveness of omburtamab as the main study did not have a randomized comparator. We are assessing the implications of the negative opinion and have determined to discontinue our plans radiolabeled omburtamab development program for the omburtamab program. CNS-LM.

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 European Commission 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 "conditional" marketing authorization subject to certain specific obligations to be reviewed annually, which is referred to as in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional marketing authorization. This may apply to authorization for a medicinal products for human use product if it is demonstrated that fall under the jurisdiction all 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. following criteria are met:

- the risk benefit balance of the medicinal product is positive;

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;
- the medicinal product fulfills an unmet medical needs will be fulfilled; need; 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 subject 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 conditions to be used in emergency situations in response to public-health threats.

Conditional marketing authorizations are fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year on a renewable basis. The holder will and must be required to complete ongoing renewed annually until all related conditions have been fulfilled. Once any pending studies or to conduct new studies with a view to confirming that are provided, 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 can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the marketing authorization will allow medicines cease 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. renewed.

Although we may seek a conditional marketing authorization for one or more of our product candidates by the EMA, European Commission, the EMA or CHMP the European Commission 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 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.

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 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

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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.

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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 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 November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB. In February 2017, the European Commission granted OMPD orphan medicinal product designation to omburtamab for the treatment of NB. We have determined to discontinue our radiolabeled omburtamab development program for CNS-LM.

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 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, and 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. If development of omburtamab continues and the BLA for omburtamab is not approved prior to September 30, 2026, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will not be eligible for a PRV.

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

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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

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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 evaluable 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. 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 and comparable foreign regulatory authorities may also impose requirements for costly post-marketing 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, or comparable foreign strategies, 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 and comparable foreign regulatory 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 and comparable foreign regulatory authorities 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 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 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.

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The FDA and other agencies, including the Department of Justice, or the DOJ, as well as comparable foreign regulatory authorities closely regulate and monitor the post-approval 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 and comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding off-label 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 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.

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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.

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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

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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. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. 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.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to two percent (2%) per fiscal year, which went into effect in April 2013 and will remain in effect until 2032 unless additional Congressional action is taken.

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. 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

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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

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reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness 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 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 post marketing testing and other requirements.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. As an example, the regulatory landscape related to clinical trials in the EU has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU Member State, leading to a single decision for each EU Member State. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU Member States in which the trial is to be conducted, and a separate assessment by each EU Member State with respect to specific requirements related to its own territory, including ethics rules. Each EU Member State's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System, or CTIS. The CTR provides a three-year transition period. The extent to which ongoing clinical trials will be governed by the CTR varies. For clinical trials in relation to which an application for approval was made on the basis of the Clinical Trials Directive before January 31, 2023, the CTD will continue to apply on a transitional basis until January 31, 2025. By that date, all ongoing trials will become subject to the provisions of the CTR. The CTR will apply to clinical trials from an earlier date if the related clinical trial application was made on the basis of the CTR or if the clinical trial has already transitioned to the CTR framework before January 31, 2025.

In addition, on April 26, 2023, the European Commission adopted a proposal for a new Directive and Regulation to revise the existing pharmaceutical legislation. If adopted in the form proposed, the recent European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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

Government price controls or other changes in pricing regulation could restrict the amount that we are able to charge for DANYELZA 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. For example, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax

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by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. These provisions take effect progressively starting in fiscal year 2023. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations, although the Medicare drug price negotiation program is currently subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the Centers for Medicare & Medicaid Services Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. In some international markets, the government controls the pricing, which can affect the profitability of drugs. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

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.

In markets outside of the United States, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the EU provides options for EU Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. An EU Member State may approve a specific price for the medicinal product, it may refuse to reimburse a product at the price set by the manufacturer or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Many EU Member States also periodically review their reimbursement procedures for medicinal products, which could have an adverse impact on reimbursement status. We expect that legislators, policymakers and healthcare insurance funds in the EU Member States will continue to propose and implement cost-containing measures, such as lower maximum prices, lower or lack of reimbursement coverage and incentives to use cheaper, usually generic, products as an alternative to branded products, and/or branded products available through parallel import to keep healthcare costs down.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU Member States, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This Health Technology Assessment ("HTA") of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU Member States, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the individual country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU Member States. In December 2021, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, was adopted in the EU. This Regulation, which entered into force in January 2022 and will apply as of January 2025, is intended to boost cooperation among EU Member States in assessing health technologies, including new medicinal products, and providing the basis for cooperation at EU level for joint clinical assessments in these areas. The Regulation foresees a three-year transitional period and will permit EU Member States to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of

the innovative health technologies with the most potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other

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areas. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU Member States for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

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 Privacy Provisions—as amended by the Health Information Technology for Economic and Clinical Health Act (“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 and subcontractors 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 (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as ownership and investment interests held by physicians 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.

Outside the United States, interactions between pharmaceutical companies and health care professionals are also governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

Some state and foreign 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.

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, disgorgement, imprisonment, exclusion of drugs from government-funded healthcare programs, such as Medicare and Medicaid, or comparable foreign programs, and the curtailment or restructuring of our operations. We have established internal policies and procedure procedures 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 government funded healthcare programs.

We are subject to stringent and evolving U.S. and foreign laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of business, we and our collaborators and third-party providers may collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process) personal data and other sensitive information, such as proprietary and confidential business data, trade secrets, intellectual property, and data we collect about trial participants in connection with our clinical trials. Our data processing activities may subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of sensitive information by us and on our behalf. In the United States, federal, state, and local laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), govern the collection, use, disclosure and protection of health-related and other personal data and could apply to our operations or the operations of our collaborators and third-party providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under HIPAA, as amended by HITECH, which imposes specific

requirements relating to the privacy, security, and transmission of individually identifiable health information. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

States are In the past few years, numerous U.S. states—including California, Virginia, Colorado, Connecticut, and Utah—have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal information. As applicable, such rights may include the right to access, correct, or delete certain personal information, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. These state laws also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, collectively the CCPA, imposes obligations on covered businesses. These obligations include, without limitation, providing applies to personal information of consumers, business representatives, and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and affording honor requests of California residents to exercise certain privacy rights related to their personal data. . The CCPA allows provides for statutory fines for noncompliance (up of up to $7,500 per violation) intentional violation and a allows private right of action for litigants affected by certain data breaches. Although breaches to seek to recover potentially significant statutory damages. While the CCPA exempts some data processed in the context and many of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, in 2020 the CCPA expanded to add a new right for individuals to correct their personal data and establish a new regulatory agency to implement and enforce the law. Other states have also enacted data privacy these state laws including Virginia, Colorado, Utah, and Connecticut, all of which differ from the CPRA and become effective in 2023. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely. We expect more states to pass similar laws in the future.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data. In particular, the EU GDPR applies to any company established in the European Economic Area, or EEA, and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The obligations from the EU GDPR and UK GDPR, together referred to as GDPR, may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; complying with specific requirements to process health-related data; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. Under the GDPR, companies may face temporary or

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definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR (17.5 million British Pounds under the UK GDPR) or 4% of annual global revenue, in each case, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy and security laws they generally believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's EU's standard contractual clauses, the UK's International Data Transfer Agreement/Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers for relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms may be subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or

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transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe

for allegedly violating the EU GDPR's cross-border data transfer limitations. In addition to data privacy and security laws, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers.

We publish privacy policies, marketing materials and other statements, such as confirmation of compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources, which may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf. In addition, these obligations may require us to change our business model.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) claims and mass arbitration demands; demands); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management's attention; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. In particular, plaintiffs have become more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations.

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Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; interruptions or stoppages in our business operations (including, as relevant, clinical trials); interruptions or stoppages of data collection needed to train our algorithms; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we process proprietary, confidential, and sensitive data, including personal data (such as health-related data), intellectual property and trade secrets (collectively, sensitive information).

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely, including our current and future CROs, CMOs, other contractors and consultants. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors,

personnel (such as through theft or misuse), sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, (such as credential stuffing), stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats. In particular, severe ransomware attacks are becoming increasingly prevalent – particularly for companies like ours in the medical field – and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, communication systems, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third-parties' third parties' information security practices is limited, and

these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third-parties' third parties' infrastructure in our supply-chain supply chain or our third-party partners' supply-chains supply chains have not been compromised.

We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive information or our information technology systems, or those of the third parties upon whom we rely, including our research partners or collaborators. We may expend significant resources or modify our business activities (including our clinical trial activities or product development) to try to protect against security incidents.

Certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be

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able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. incidents, including affected individuals, customers, regulators, and investors. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we, or a third-party third party upon whom we rely, experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive information (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversions of management's attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our products, deter new customers from using our products, and negatively impact our ability to grow and operate our business. 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. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or disclosure of confidential or proprietary information, further development and commercialization of our product candidates could be delayed.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition, third parties may gather, collect, or infer competitively sensitive information about us from public sources, data brokers, or by other means that could be used to undermine our competitive advantage or market position. Additionally, any sensitive information (including confidential, competitive, proprietary, or personal data) that we input

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into a third-party generative AI platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI model.

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;

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- 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 time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness 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, there is no guarantee that third-party providers will establish coverage policies or provided reimbursement for any of our other product candidates, if approved. The reimbursement payment rates for DANYELZA or any other product we commercialize 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. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services, and imposing controls to manage costs. Our rebate payments may increase, or our prices may be adjusted under value-based purchasing arrangements based on evidence-based measures or outcomes-based measures for a patient or beneficiary based on use of DANYELZA or any other product we commercialize. 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 long term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or

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biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

To date DANYELZA has been approved for sale in the United States, Israel, China and Brazil only, but we intend to seek approval to market our products in both the United States as well as in additional selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we or our partner holding the approval such as Takeda Israel, holding the approval of DANYELZA in Israel 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 authorities. Off label uses are common across medical specialties. Although the FDA and other regulatory agencies authorities do not regulate a physician's choice of treatments, the FDA and other regulatory agencies authorities regulate a manufacturer's communications regarding off-label off label use and prohibit off-label off label promotion, as well as the dissemination of false or misleading labeling or promotional materials. Manufacturers may not promote drugs for off-label 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

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regulations prohibiting promotion of off-label 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 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.

Due to the nature of radioactive isotopes in radioimmunotherapy product candidates, the product shelf life is limited and susceptible to spoilage and/or 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. For commercial manufacture and supply these product candidates require reliable transportation and 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 handling 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.

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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 waste. 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 a 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 the United States as well as 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,

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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

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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.

In addition, certain Chinese biotechnology companies and contract development and manufacturing organizations may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially having an adverse impact on our development and commercialization efforts and potential revenues, including potential payments to us based on regulatory and commercial activities in China. For example, the recently proposed BIOSECURE Act introduced in the U.S. House of Representatives, as well as a substantially similar bill in the U.S. Senate, target U.S. government contracts, grants, and loans for entities that use equipment and services from certain named Chinese biotechnologies companies and authorizes the U.S. government to name additional Chinese biotechnology companies of concern. If these bills become law, or similar laws are passed, they would have the potential to severely restrict the ability of companies to work with certain Chinese biotechnology companies of concern without losing the ability to contract with, or otherwise receive funding from, the U.S. government. Such disruption could have adverse effects on the development and commercialization of our product candidates and products, and our business and financial results.

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 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 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, 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

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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

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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 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 in licensed products or processes.

We may be unable to acquire or in-license 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

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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 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, time consuming, divert the attention of key personnel from business operations or otherwise have a material adverse effect on our business.

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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 in licensed patent rights are highly uncertain. Our pending and future patent applications and in-licensed 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 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 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 ex-partes 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

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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

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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 regard to any in-licensed 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 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;

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- it is possible that others may circumvent our owned or in-licensed 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 in licensed issued patents or patent applications, if and when issued, may not cover our product candidates or products;

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- our owned or in-licensed 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 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; parties;
- 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' 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, 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. 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 2024 2026 through 2039, 2042, 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

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as patents are expected to expire from 2031 through 2042, 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 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

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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 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 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 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 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 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 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 ex parte re exam or post-grant 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 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,

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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. know how.

Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time-consuming, 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.

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If we are sued for infringing patents or other intellectual property rights of third parties, it will be costly and time-consuming, 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 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 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 in licensed to us, we or, in the case of in-licensed 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 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

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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.

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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 ex-partes re-exam, inter partes review or post-grant 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,

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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.

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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. 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. It is important to our success that our new Chief Executive Officer Rossi, as well as any other key employees that join us in the future, quickly adapt to and excel in their new roles.

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.

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In April 2022 we announced the departure of our then Chief Executive Officer and in October 2023, we announced additional management transitions, including the appointment of a new President and Chief Executive Officer and transition of our President and Interim Chief Executive Officer to Chief Business Officer. In addition, in March 2024, we announced the resignation of our Executive Vice President, Chief Financial Officer, Secretary and Treasurer, effective as of the date we appoint his successor and such successor commences employment with us. We cannot assure you that these management changes or any future management change changes will not have an adverse impact on our business operations. The loss of the services of 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.

Our President and Chief Executive Officer Michael Rossi, joined us in November 2023. It is important to our success that Mr. Rossi, our President and Chief Executive Officer, as well as any other key employees that join us in the future, quickly adapt to and excel in their new roles. If they are unable to do so, our business and financial results could be materially adversely affected.

Furthermore, the reduction in workforce that we announced in January 2023 may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, employee attrition beyond our intended reduction in force, a reduction in morale among our remaining employees, greater-than-anticipated costs incurred in connection with implementing the restructuring, and the risk that we may not achieve the benefits from the restructuring to the extent or as quickly as we anticipate, all of which may have a material adverse effect on our business, results of operations or financial condition. These restructuring initiatives could place substantial demands on our management and employees, which could lead to the diversion of our management's and employees' attention from other business priorities. In addition, we may discover that the workforce reduction and other restructuring efforts will make it difficult for us to pursue new opportunities and initiatives and require us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel remains critical to our success. We currently conduct a significant portion of our operations in the New York City metropolitan

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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 may need to increase the size of our organization in the future, and we may experience difficulties managing growth. If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be adversely affected.

We may need to expand the size of our organization in the future. The growth we may experience in the future may provide challenges to our organization, requiring us to also rapidly expand other aspects of our business, including our manufacturing operations. Rapid expansion in personnel may result in less experienced people producing and selling our products, which could result in unanticipated costs and disruptions to our operations. If we cannot scale and manage our business appropriately, our potential growth may be impaired and our financial results will suffer.

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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 September 30, 2023 April 30, 2024, our executive officers, directors and our stockholders, who own more than 5% of our outstanding common stock in the aggregate beneficially, own shares representing approximately 21.9% 22.5% 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 chose 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

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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.

Our ability to utilize our net operating loss carry forwards carry-forwards and certain other tax attributes depends on many factors, including our future income, which cannot be assured, and the impact of any tax reform legislation or proposals. Under current law, U.S. federal net operating loss carryforwards generated in tax years beginning before January 1, 2018 may be carried forward for 20 tax years. U.S. federal net operating loss carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such net operating loss carryforwards is limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to U.S. federal income tax law.

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), an annual limitation is imposed on the corporation's use of its pre change net operating loss carryforwards carry-forwards and certain other pre change pre-change tax attributes to offset its post change post-change taxable income or taxes. Based on our analysis of our Section 382 ownership changes through December 31, 2022, we believe that it is more likely than not that none of our net operating loss carryforwards will expire because of existing limitations under Section 382 of the Code, due to the large size of such limitations. We may experience Section 382 ownership changes in the future as a result of subsequent shifts in our equity ownership, many of which are outside our control. State net operating loss carryforwards may be similarly limited, and there may be periods during which the use of such net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase our state taxes owed.

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Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition, or results of operations.

New income, sales and use, or other tax laws or regulations could be enacted at any time, and existing tax laws and regulations could be interpreted, modified, or applied adversely to us. These events could require us to pay additional taxes on a prospective or retroactive basis, as well as penalties, interest, and other costs for past amounts deemed to be due. New laws, or laws that are changed, modified, or interpreted or applied differently also could increase our compliance, operating, and other costs, as well as the costs of our products. Recent legislation in the United States, commonly referred to as the Inflation Reduction Act, enacts a 15% minimum tax on the adjusted financial statement income of certain large U.S. corporations for tax years beginning after December 31, 2022, as well as a 1% excise tax on stock repurchases made by public corporations after December 31, 2022. Further, the Tax Cuts and Jobs Act of 2017, or the Tax Act, enacted many significant changes to U.S. tax laws, some of which were further modified by the Coronavirus Aid, Relief, and Economic Security Act, and may be modified in the future by the current or a future presidential administration. Among other changes, the Tax Act amended the Code to require that certain research and experimental expenditures be capitalized and amortized over five years if incurred in the United States or fifteen years if incurred in foreign jurisdictions for tax years beginning after December 31, 2021. Although the U.S. Congress has considered legislation that would defer, modify, or repeal the capitalization and amortization requirement, there is no assurance that such changes will be made. If the requirement is not deferred, repealed, or otherwise modified, it may increase our cash taxes and effective tax rate. In addition, it is uncertain if and to what extent various states will conform to current federal law, or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net operating losses and other deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses could have a material impact on the value of our deferred tax assets and could increase our future tax expense.

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.

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Future sales of common stock by us or our stockholders may cause substantial dilution to our existing stockholders and 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 43,621,618 43,882,638 shares of common stock outstanding as of November 6, 2023 April 30, 2024. 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. In addition, we have issued stock options and other equity awards under our equity compensation

plans. The shares underlying these awards are registered on a registration statement on Form S-8. As a result, upon vesting, these shares can be freely exercised, as applicable, and sold in the public market upon issuance, subject to volume limitations applicable to affiliates.

As of November 6, 2023, holders of 2,005,347 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 14,278,887 16,025,771 shares of our common stock that we may issue under our equity compensation plans as of November 6, 2023 April 30, 2024, and we plan to increase that number further.

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.

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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.

We currently have on file with the SEC a shelf registration statement, which allows us to offer and sell certain registered securities, such as common stock, preferred stock, debt securities, warrants and units, from time to time pursuant to one or more offerings at prices and terms to be determined at the time of sale. We may sell common stock, convertible securities or other equity or debt securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity or debt securities in more than one transaction, investors may be materially diluted by subsequent sales. These sales may also result in material dilution to our existing stockholders, and new investors could gain rights superior to our existing stockholders.

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

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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.

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 $2.70 per share and as high as $55.22 per share through November 6, 2023April 30, 2024. In the last 12 months, our stock has traded at prices as low as $4.60 per share and as high as $20.90 per share through April 30, 2024. 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;

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- 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;

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- 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 supply chain disruptions and uncertain global financial markets, and geopolitical events, such as the conflict between Ukraine and Russia and related sanctions and the state of war between Israel and Hamas and the threat of a larger regional conflict; sanctions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class-action litigation has often been instituted against companies following periods of volatility in the price of their common stock. For example, following volatility in the price of our common stock

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following the ODAC meeting in October 2022, one of our stockholders filed a putative class action lawsuit suit in the federal district court for alleged violations of the Securities Exchange Act of 1934, as amended. Litigation could result in substantial costs and divert our management's attention and resources, which could have a material and adverse effect on our financial condition, business, and the per share trading price of our common stock.

We, our Chief Business Officer and Vice Chairman Mr. Thomas Gad, and our former Chief Executive Officer, Dr. Claus Juan Møller San Pedro, and our Chief Medical Officer Dr. Vignesh Rajah, have been named as defendants in a lawsuit that could result in substantial costs and divert management's attention, and we have also been named in other lawsuits. Any of these lawsuits could result in substantial costs and divert management's attention.

As described elsewhere in this report in "Part II, Item 1—Legal Proceedings," we and our Chief Business Officer and Vice Chairman Mr. Thomas Gad, and our former Chief Executive Officer Dr. Claus Juan Møller San Pedro, and our Chief Medical Officer Dr. Vignesh Rajah, have been named as defendants in a class-action lawsuit that alleges that we and the individuals named in the lawsuit violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. Further, as also described elsewhere in this report in "Part II, Item 1—Legal Proceedings," on February 8, 2023, Jeffrey Hazelton, a purported Y-mAbs stockholder, filed a putative stockholder derivative action. These complaints seek, among other things, unspecified damages, and reasonable costs and expenses, including attorneys' fees.

As of the date of this report, we are unable to predict the outcome of these matters. Although we have insurance, it provides for a substantial retention of liability and is subject to limitations and may not cover a significant portion, or any, of the expenses or liabilities we may incur or be subject to in connection with the class-action lawsuit or other litigation to which we are party. Moreover, any conclusion of these matters in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business. In addition, the litigation has caused and will continue to cause our management and board of directors to divert time and attention to the litigation and could adversely impact our

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reputation and further divert management and our board of directors' attention and resources from other priorities, including the execution of our business plan and strategies that are important to our ability to grow our business and advance our product candidates, any of which could have a material adverse effect on our business. In addition, additional lawsuits may be filed, the conclusion of which in a manner adverse to us and for which we incur substantial costs or damages not covered by our directors' and officers' liability insurance would have a material adverse effect on our financial condition and business.

General risk factors

Our business, financial condition and results of operations have been and may in the future be adversely affected by pandemics or similar health crises, macroeconomic conditions and by geopolitical events, including the 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, and as well as the state of the war between Israel and Hamas. involving Israel.

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.

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

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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 although we may still provide drug to be used on a compassionate use basis. 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. business.*"

In addition, on October 7, 2023, Hamas militants infiltrated Israel's southern border from the Gaza Strip and conducted a series of attacks on civilian and military targets. Following the attack, Israel's security cabinet declared war against Hamas. It is currently not possible to predict the duration or severity of the ongoing conflict, whether it will develop into a wider regional conflict or its effects on our business, operations and financial conditions. The ongoing conflict is rapidly evolving and developing and may have a material adverse impact on Takeda

Israel's ability to sell our products and/or collect receivables from customers in the State of Israel pursuant to the Takeda Licensing Agreement as well as on Takeda Israel's ability to pursue the development, marketing and/or commercialization of DANYELZA in the State of Israel, West Bank and Gaza Strip, which may ultimately have an adverse impact on the amount of royalties we receive pursuant to the Takeda Licensing Agreement.

There can be no assurance that further deterioration in credit and financial markets, global banking stability, 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

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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, partnerships, or other strategic transactions, 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, partnerships or other strategic transaction, transactions, 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;

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- 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.

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

We have obtained and plan to continue to seek regulatory approval of our product candidates outside of the United States. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone, Takeda Israel, Swixx Biopharma AG, Adium, and WEP Clinical Ltd. Takeda Israel obtained regulatory approval for DANYELZA in Israel in August 2022 and we obtained regulatory approval for DANYELZA in China in December 2022. In May 2023, we obtained regulatory approval for DANYELZA in Brazil and in September 2023, Adium we obtained regulatory approval for DANYELZA in Mexico. 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;

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- 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 and the state of the war between Hamas and involving Israel and a potential larger regional

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more global conflict, 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 COVID-19, 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 DANYELZA, and our other product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption. Damage or extended periods of interruption to our third-party collaborators', including MSK's, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we intend to maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. The ultimate extent of the impact of any epidemic, pandemic or other global health crisis 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:

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- 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;

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- 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 EU and other similar foreign regulatory bodies; requirements; provide true, complete and accurate information to the FDA, the EMA, the European Commission, 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

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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

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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 downgrades 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.

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If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely consolidated 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.

We qualified as a smaller reporting company and as a non-accelerated filer for the year ended December 31, 2022, and as of the last business day of our second fiscal quarter of 2023, we determined that we requalify as a smaller reporting company and as a non-accelerated filer for the year ending December 31, 2023. As a public company we are required to provide management's attestation on internal controls pursuant to Section 404 of the Sarbanes-Oxley Act. However, as a smaller reporting company and as a non-accelerated filer, we were are not required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm in our this Annual Report on Form 10-K for the fiscal year ended December 31, 2022, and will not be required to include such an attestation report in our Annual Report on Form 10-K for the fiscal year ending December 31, 2023.

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.

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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, we continue to incur significant legal, accounting and other expenses. In addition, the Sarbanes-Oxley 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 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.

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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.

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

None.

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Item 3. Defaults on Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

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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.

Exhibit Number	Exhibit description
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 3.4 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities and Exchange Commission on September 26, 2018)
10.1* 10.1†	Amendment dated August 16, 2023, to Lease Employment Agreement dated January 10, 2018, for Dr. Vignesh Rajah, effective as of January 1, 2024 (incorporated by and between the Registrant and RXR HB Owner LLC reference to Exhibit 10.34 to Registrant's Form 10-K filed, February 29, 2024)
10.2†	Employment Form of Performance Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement entered into on October 17, 2023, between Michael Rossi and under the Company 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 10.46 to the Registrant's Current Report on Form 8-K (File No. 001-38650) 10-K filed, with the Securities and Exchange Commission on October 18, 2023 February 29, 2024)
10.3†*	Employee Confidential Information and Inventions Assignment Severance Agreement dated October 17, 2023, March 21, 2024 between Michael Rossi Y-mAbs Therapeutics A/S and the Company (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities Steen Lisby (filed herewith)
10.4†*	Amended and Exchange Commission on October 18, 2023 Restated Non-Employee Director Compensation Policy, effective April 26, 2024 (filed herewith)

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.

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+* Furnished Filed herewith.

†+ Furnished herewith.

† Indicates management contract or compensatory plan.

++ 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.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In

particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

The agreements and other documents filed as exhibits to this report are not intended to provide factual information or other disclosure other than with respect to the terms of the agreements or other documents themselves, and you should not rely on them for that purpose. In particular, any representations and warranties made by us in these agreements or other documents were made solely within the specific context of the relevant agreement or document and may not describe the actual state of affairs as of the date they were made or at any other time.

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SIGNATURES

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

Y-MABS THERAPEUTICS, INC.

Dated: November 13, 2023 May 7, 2024

By: /s/ Michael Rossi
Name: Michael Rossi
Title: President, Chief Executive Officer
(Principal Executive Officer)

Dated: November 13, 2023 May 7, 2024

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

Exhibit 10.1 10.3

AMENDMENT TO LEASE Graphic

This AMENDMENT TO LEASE (this "Amendment" The following severance agreement (the "Agreement") dated as of August 16th, 2023 (the "Effective Date") between **RXR HB OWNER LLC**, having an office c/o RXR Realty LLC, 625 RXR Plaza, Uniondale, New York 11556 ("Landlord"), and **Y-MABS THERAPEUTICS, INC.,** having an office at 230 Park Avenue, New York, New York 10169 ("Tenant").

W I T N E S E T H:

WHEREAS, Landlord and Tenant has been entered into that certain Lease dated as of January 10, 2018 (the "Existing Lease" by

Y-mAbs Therapeutics A/S
CVR No. 37053678
Agern Allé 11
DK – 2970 Hørsholm
(hereinafter the "Company") pursuant to which Tenant leases

and

Steen Lisby
Vibevang 2
DK – 2970 Hørsholm
(hereinafter the "Employee")

(The Company and the Employee each a portion of "Party" and together the thirty-third (33rd "Parties") floor (the "Premises") of the building known as 230 Park Avenue, New York, New York (the "Building"), all as more particularly described in the Existing Lease; and

SEVERANCE AGREEMENT

1. BACKGROUND

1.1 The Employee has been employed with the Company since July 1, 2017. Subject to the terms of this Agreement, the Parties agree that by his signature to this Agreement, the Employee resigns from his position with the Company effectively from March 31, 2024 (the "Effective Date of Termination").

1.2 This Agreement is subject to the following terms and conditions.

2. JOB OBLIGATIONS UNTIL THE EFFECTIVE DATE OF TERMINATION

2.1 The Employee is not obliged to perform any work for the Company, except upon request from CEO, Mike Rossi. The requests will be kept to a minimum level and will primarily consist of telephone calls.

WHEREAS, Landlord and Tenant desire to modify the Existing Lease to (i) extend the term of the Existing Lease, and (ii) otherwise modify the terms and conditions of the Existing Lease, all as hereinafter set forth (the Existing Lease, as modified by this Amendment, the "3. Lease").**SALARY, BENEFITS, BONUS AND SEVERANCE PAY**

3.1 The Employee will receive his usual pay and keep all his benefits (incl. mobile phone and paid internet) until the Effective Date of Termination. The Company laptop must, however, be returned immediately.

3.2 The bonus for the fiscal year 2024 will be settled according to the bonus agreement and the ordinary payment terms. For the fiscal year 2024, the Employee will be entitled to 3/12 of an eventual bonus, corresponding the 3 months of employment in 2024, cf. the Act on Salaried Employees.

3.3 The Parties have agreed that the Employee will keep his warrants according to the Company's Equity Incentive Plan vested on March 31, 2024, at latest. The Employee is not entitled to warrants granted but not vested after March 31, 2024.

3.4 A severance payment of 6 month's salary, corresponding DKK 1,205,016.48 will be paid as a lump sum with the last salary payment in March 2024.

3.5 The severance payment may be subject to tax under section 7U of the Tax Assessment Act, meaning that an amount of DKK 8,000 is exempt from tax while the remaining amount is subject to tax as ordinary earned income. However, The Employee carries the risk of the tax assessment of the severance payment.

4. HOLIDAYS

4.1 Obtained and unspent holiday and holiday allowance will be paid to FerieKonto in accordance with the rules laid down in the Act on Holiday with Pay.

5. INTELLECTUAL PROPERTY

5.1 During the term of employment, the Employee may have created, discovered and/or developed inventions, creations, works, designs, concepts, data, methods, software, information, brands, etc. ("IP Assets"). Such IP Assets may be protected and/or be protectable by one or more intellectual property rights and/or similar rights, including but not limited to patents, utility models, rights in inventions/creations, design rights, trademark rights, copy rights, rights under marketing practices acts, rights protecting trade secrets, etc. ("IP Rights"). Any and all IP Rights that pertain to IP Assets created during the Employee's employment at the Company are automatically assigned from the Employee to the Company. The Employee acknowledges that the Employee's salary has been negotiated to fully cover such full assignment, and that the Employee therefore is not entitled to any separate renumeration under the Danish Act on Inventions made by Employees.

5.2 The Employee undertakes a perpetual obligation to sign any document as may be deemed necessary or desirable by the Company and/or any group company with a view to obtain registration of IP Rights and/or to enforce IP Rights. The Employee further undertakes a perpetual obligation to provide the Company with information regarding the IP Assets to e.g., enable the Company and/or any group company to apply for or register IP Rights.

5.3 Subject to reimbursement of out-of-pocket costs, the Employee is obligated to assist the Company in prosecuting, defending and enforcing the Company's and/or any group company's IP Rights. This assistance may encompass activities such as providing information and participating in legal proceedings (e.g.as a witness in litigation). The Employee acknowledges and agrees that this obligation remains in effect perpetually unless explicitly terminated by mutual agreement in writing between the Company and the Employee.

5.4 The Company has the exclusive right to and is entitled to exploit and dispose of the IP Assets and IP Rights in any way, including but not limited to development, changes, production, reproduction, assignment, sale, licensing, etc. The Company is not obliged to exploit any of the IP Rights.

6. EFFECTS BELONGING TO THE COMPANY

6.1 No later than at the Effective Date of Termination, the Employee shall return all effects, including keys/access cards, payment cards, etc. and all other materials which belong to the Company, or which concern the Company's affairs including handwritten notes (whether in lab notebooks, composition notebooks, or otherwise), and which are kept at the Employee's address or elsewhere. The above applies to all material in a paper-based or electronic form and irrespective of whether the material was prepared by the Employee or others.

6.2 The Employee declares that, after the return as described above, he is not in possession of any other materials, effects, documents (neither originals nor copies irrespective of medium) or any other effects, including electronic or physical copies or versions thereof, that belong to the Company.

(c) Each reference in the Existing Lease to "this Lease", "herein", "hereunder" or words of similar import shall be deemed to refer to the Lease.**7. CONFIDENTIALITY – TRADE SECRETS**

7.1 The Employee is aware of his duties under section 4 of the Danish Trade Secrets Act and potentially also section 3 of the Danish Marketing Practices Act on good marketing practices, according to which the Employee may not bring-along, store, use or share the Company's confidential information, such as confidential information regarding customers, business methods, know-how or other proprietary information (collectively "Trade Secrets").

7.2 The Employee acknowledges and agrees that he will not bring along, store, use or share any of the Company's Trade Secrets.

4.**8.** Brokerage. Each of Landlord and Tenant represents and warrants to the other that it has not dealt with any broker in connection with this Amendment, except RXR Property Management LLC (the "Broker") and that to the best of its knowledge, no other broker negotiated this Amendment or is entitled to any fee or commission in connection herewith. Each of Landlord and Tenant shall indemnify, defend, protect and hold the other party harmless from and against any and all losses, liabilities, damages, claims, judgments, fines, suits, demands, costs, interest and expenses of any kind or nature (including reasonable attorneys' fees and disbursements) incurred in connection with any claim, proceeding or judgment and the defense thereof which the indemnified party may incur by reason of any claim of or liability to any broker, finder or like agent (except the Broker) arising out of any dealings claimed to have occurred between the indemnifying party and the claimant in connection with this Amendment, and the above representation being false. The provisions of this Section 4 shall survive the expiration or earlier termination of the term of the Lease.**DUTY OF PROFESSIONAL SECRECY AND LOYALTY**

8.1 The Parties agree to keep the content of this Agreement and all matters relating to its conclusion confidential.

8.2 It has been agreed between the Parties that communication about the resignation to the Company's stakeholders, employees, customers, suppliers, and other working relationships etc. solely will be handled by the Company.

8.3 Further, the Parties agree that the Employee shall be prohibited from making any contact, whether verbally or in writing to any of the Company's employees. The prohibition does not apply to situations where the Employee's contact to a Company employee is of a private nature.

8.4 Notwithstanding the resignation, the Employee shall observe his duty of professional secrecy and loyalty towards the Company.

5.**9.** Miscellaneous. (a)Except as set forth herein, nothing contained in this Amendment shall be deemed to amend or modify in any respect the terms of the Existing Lease and such terms shall remain in full force and effect as modified hereby. If there is any inconsistency between the terms of this Amendment and the terms of the Existing Lease, the terms of this Amendment shall be controlling and prevail.**FULL AND FINAL SETTLEMENT**

(c) Tenant represents and warrants to Landlord that as of the Effective Date, there are no defaults existing under the Lease.

(d) This Amendment may be executed in duplicate counterparts, each of which shall be deemed an original and all of which, when taken together, shall constitute one and the same instrument. Transmission of a facsimile or by email of a pdf copy of the signed counterpart of this Amendment shall be deemed the equivalent of the delivery of the original, and any party so delivering a facsimile or pdf copy of the signed counterpart of this Amendment by email transmission shall in all events deliver to the other parties an original signature promptly upon request.

(e) This Amendment shall not be binding upon Landlord or Tenant unless and until Landlord shall have delivered a fully executed counterpart of this Amendment to Tenant.

(f) This Amendment shall be binding upon and inure to the benefit of Landlord and Tenant and their successors and permitted assigns.

(g) This Amendment shall be governed by the laws of the State of New York without giving effect to conflict of laws principles thereof.

(h) The captions, headings, and titles in this Amendment are solely for convenience of reference and shall not affect its interpretation.

[NO FURTHER TEXT ON THIS PAGE]

9.1 The terms and payments stipulated in the Agreement are in full discharge of any claims and rights that the Employee may have against the Company and the Company's employees. The discharge include any claims for the Employee under the employment relationship, another agreement, legislation or otherwise in relation to the Employee's employment with the Company and the expiry of the employment, including without limitation, claims for salary, pension, other pay elements and claims under the Act on Salaried Employees ("Funktionærloven"), the Act on Holiday with Pay (Ferieloven), the Employment Certificate Act (Ansættelsesbevisloven) and the Act on Discrimination ("Forskelsbehandlingsloven").

9.2 Notwithstanding anything to the contrary herein, the Parties acknowledge that should circumstances apply, nothing herein releases Employee from potential liability under the Company's Claw back Policies and that the terms of any claw back provisions of applicable laws and regulations applicable to the Company would still apply to Employee.

9.3 The Employee declares that he has been able to consider the terms of the Agreement thoroughly and seek legal advice thereon before the conclusion of the Agreement.

9.4 The Agreement shall be governed by and construed in accordance with the laws of Denmark.

9.5 This Agreement will expire in its entirety and without prejudice if not signed by the Employee and returned to the Company before 4pm on Thursday March 21, 2024.

IN WITNESS WHEREOF, Landlord and Tenant have executed this Amendment as of the day and year first above written.

LANDLORD:

RXR HB OWNER LLC **SIGNATURES**

9.6 The Agreement is signed digitally via DocuSign.

By: /s/ Steen Lisby

Chief Scientific Officer

Date: March 21, 2024

By: /s/ Michael Rossi

President and Chief Executive Officer

Date: March 21, 2024

Exhibit 10.4

Y-MABS THERAPEUTICS, INC.

By:/s/ THOMAS GAD**AMENDED AND RESTATED NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

Name: The Board of Directors (the "Board") of Y-mAbs Therapeutics, Inc. (the "Company") has approved the following Amended and Restated Non-Employee Director Compensation Policy (the "Policy"), which establishes compensation to be paid to Non-Employee Directors (as defined below) of the Company, as an inducement to obtain and retain the services of qualified persons to serve as members of the Board. This Policy, as hereby amended and restated, is effective as of April [•], 2024 (the "Effective Date") and replaces and supersedes any and all compensation policies or programs previously established or maintained by the Company with respect to Non- Employee Directors; provided, however, that any equity awards outstanding on the Effective Date shall not be affected by this Policy and shall continue to be governed by the applicable terms set forth in the Company's amended and restated 2015 Equity Incentive Plan or the Company's 2018 Equity Incentive Plan (each a "Plan") and in the applicable grant agreements relating to such awards.

1. Applicable Persons

Title: CEO, interim This Policy shall apply to each director of the Company who is not also an employee of the Company or any Affiliate (each, a "Non-Employee Director"). "Affiliate" shall mean an entity which is a direct or indirect parent or subsidiary of the Company, as determined pursuant to Section 424 of the Internal Revenue Code of 1986, as amended.

2. Equity Grants

Date: Aug 20, 2023 All share amounts set forth herein shall be subject to automatic adjustment in the event of any stock split or other recapitalization affecting the Company's common stock, par value $0.0001 per share (the "Common Stock").

(a) Annual Equity Grants

Without any further action of the Board or the compensation committee of the Board (the "Compensation Committee"), each year, at the earlier of the close of business of (i) each annual meeting of the Company's stockholders following the Effective Date (an "Annual Meeting"), or (ii) if the Annual Meeting for a given year has not yet occurred by such date, June 30 (or the next trading day immediately thereafter, if such date falls on a non- trading day), each Non-Employee Director shall automatically be granted (1) a non-qualified stock option with an aggregate grant date fair value equal to $127,500 (the "Annual Option Grant"); and (2) restricted stock units ("RSUs") with an aggregate grant date fair value equal to $42,500 (the "Annual RSU Grant"). Subject to the continued service of each Non-Employee Director through each applicable vesting date, each Annual Option Grant shall vest in equal monthly installments until the first anniversary of the date of grant, and each Annual RSU Grant shall vest in full on the earlier of the first anniversary of the date of grant or the date immediately preceding the date of the following Annual Meeting.

(b) Initial Equity Grants For Newly Appointed or Elected Directors

With respect to any Non-Employee Director who is first appointed or elected to the Board after the Effective Date, without any further action of the Board or the Compensation Committee, on the date on which such new Non-Employee Director commences service in such position pursuant to his or her initial appointment or election to the Board (or, if the date of such commencement of service is not a trading day, the first trading day following the date of such commencement of service), each such new Non-Employee Director shall be granted (1) a non-qualified stock option with an aggregate grant date fair value equal to $255,000 (the "Initial Option Grant"); and (2) RSUs with an aggregate grant date fair value equal to $85,000 (the "Initial RSU Grant"). Subject to the continued service of each Non-Employee Director through each applicable vesting date, each Initial Option Grant shall vest in equal monthly installments until the third anniversary of the date of grant, and each Initial RSU Grant shall vest in equal quarterly installments (i.e., every three months on the same day of the month as the date of grant) until the third anniversary of the date of grant.

(c) Terms for All Equity Grants

All options granted under this Policy shall (i) have an exercise price equal to the fair market value of the Company's Common Stock as determined in the applicable Plan on the date of grant; (ii) terminate on the tenth anniversary of the date of grant and (iii) contain such other terms and conditions as set forth in the form of option agreement approved by the Board or the Compensation Committee. All RSUs granted under this Policy shall contain such other terms and conditions as set forth in the form of RSU agreement approved by the Board or the Compensation Committee. The number of shares of Common Stock subject to an option granted under this Policy will be determined based on a Black Scholes model calculated using the average closing price per share of Common Stock over the 30-calendar day period immediately preceding the grant date. The number of shares of Common Stock subject to RSUs granted under this Policy will be determined based on the average closing price per share of Common Stock for the 30-calendar day period immediately preceding the grant date.

3. Annual Fees

Each Non-Employee Director serving on the Board and the Company's duly appointed audit committee of the Board (the "Audit Committee"), the Compensation Committee and/or duly appointed nominating and corporate governance committee of the Board (the "Nominating and Corporate Governance Committee"), as applicable, shall be entitled to the following annual amounts (the "Annual Fees"):

Board of Directors and Board Committee	Annual Retainer Amount for Member	Additional Annual Retainer Amount for Chair
Board Member	$ 50,000	$ 35,000
Audit Committee	$ 10,000	$ 20,000
Compensation Committee	$ 7,500	$ 15,000
Nominating and Governance Committee	$ 5,000	$ 10,000

TENANT: Except as otherwise set forth in this Policy, all Annual Fees shall be paid for the period from January 1 through December 31 of each year. Such Annual Fees shall be paid in cash. Amounts payable to Non-Employee Directors shall be made quarterly in arrears promptly following the end of each fiscal quarter, provided that (i) the amount of such payment shall be prorated for any portion of such quarter that such director was not serving on the Board or a committee and (ii) no fee shall be payable in respect of any period prior to the date such director was elected to the Board or a committee.

4. Expenses

Upon presentation of documentation of such expenses reasonably satisfactory to the Company, each Non- Employee Director shall be reimbursed for his or her reasonable out-of-pocket business expenses incurred in connection with attending meetings of the Board and committees thereof or in connection with other business related to the Board.

5. Amendments

The Compensation Committee shall periodically review this Policy to assess whether any amendments in the type and amount of compensation provided herein should be made and shall make recommendations to the Board for its approval of any amendments to this Policy. Notwithstanding anything herein to the contrary, the equity and cash retainer amounts set forth in this Policy are subject to periodic review and modification by the Compensation Committee and the limit on non-employee director compensation set forth in Section 5.5 of the Company's 2018 Equity Incentive Plan.

Y-MABS THERAPEUTICS, INC.

By:/s/ BO KRUSE
Name: Bo Kruse
Title: CFO
Date: Aug 10, 2023

Exhibit 31.1

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

I, Michael Rossi certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2023 May 7, 2024

By: /s/ Michael Rossi

Name: Michael Rossi

Title: President, Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Bo Kruse, certify that:

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

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Dated: November 13, 2023 May 7, 2024

By: /s/ Bo Kruse
Name: Bo Kruse
Title: EVP, Executive Vice President, 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 March 31, 2024 (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

September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 13, 2023 May 7, 2024

By: /s/ Michael Rossi
Name: Michael Rossi
Title: President, Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2024 (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

September 30, 2023 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: November 13, 2023 May 7, 2024

By: /s/ Bo Kruse

Name: Bo Kruse

Title: EVP, Executive Vice President, Chief Financial Officer (Principal Financial Officer)

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