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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 June 30, 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 44,569,834 shares of Common Stock ($0.0001 par value) outstanding as of August 5, 2024.

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 I, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and Part II, Item 1A, "Risk Factors" in our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, as supplemented 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 "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" sections, that could cause actual results or events to differ materially from the forward-looking statements that we make. These factors include, without limitation:

- 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 candidates for which we may receive marketing approval 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 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;

- 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;

- 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;

- 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 License Agreement, or the SADA License Agreement as well as our relationship with MSK as a user of DANYELZA and any future 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;

- 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 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;
- 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;
- 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 Russia; as well as the state of the war involving Israel and the related risk of a more global conflict;
- We are subject to government laws and regulations, and we may be unable to comply with healthcare laws and regulations in the United States and any applicable foreign countries, including, without limitation, those applying to the marketing and sale of pharmaceutical products; and
- 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, including product liability claims, that is successful against us may result in the incurrence of substantial liability if our insurance is inadequate.

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

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

PART I – FINANCIAL INFORMATION

Item 1. Consolidated Financial Statements

Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(unaudited)

(in thousands, except share and per share data)

	June 30, 2024	December 31, 2023
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 77,806	$ 78,637
Accounts receivable, net	22,191	22,454
Inventories	8,498	5,065
Insurance recovery receivable related to legal settlement (Note 9)	16,025	—
Other current assets	2,243	4,955
Total current assets	126,763	111,111
Property and equipment, net	87	224
Operating lease right-of-use assets	1,271	1,412
Intangible assets, net	2,454	2,631
Other assets	13,460	12,491
TOTAL ASSETS	$ 144,035	$ 127,869
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 10,190	$ 6,060
Accrued liabilities	12,788	13,166
Accrued legal settlement (Note 9)	19,650	—
Operating lease liabilities, current portion	842	902
Total current liabilities	43,470	20,128
Accrued milestone and royalty payments	3,950	5,375
Operating lease liabilities, long-term portion	432	517
Other liabilities	847	864
TOTAL LIABILITIES	48,699	26,884
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at June 30, 2024 and December 31, 2023; 44,567,334 and 43,672,112 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	4	4
Additional paid-in capital	567,633	558,002
Accumulated other comprehensive income	1,047	449
Accumulated deficit	(473,348)	(457,470)
TOTAL STOCKHOLDERS' EQUITY	95,336	100,985
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 144,035	$ 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 June 30,		Six months ended June 30,	
	2024	2023	2024	2023
REVENUES				
Product revenue, net	$ 22,798	$ 20,751	$ 42,229	$ 41,002
License revenue	—	—	500	—
Total revenues	22,798	20,751	42,729	41,002
OPERATING COSTS AND EXPENSES				
Cost of goods sold	3,014	4,649	5,111	6,732
License royalties	—	—	50	—
Research and development	12,341	12,055	25,608	25,473
Selling, general, and administrative	17,232	11,270	28,657	23,521
Total operating costs and expenses	32,587	27,974	59,426	55,726
Loss from operations	(9,789)	(7,223)	(16,697)	(14,724)
OTHER INCOME, NET				
Interest and other income	640	1,100	1,079	2,211
LOSS BEFORE INCOME TAXES	(9,149)	(6,123)	(15,618)	(12,513)
Provision for income taxes	100	179	260	179
NET LOSS	$ (9,249)	$ (6,302)	$ (15,878)	$ (12,692)
Other comprehensive income/(loss)				
Foreign currency translation	199	18	598	(288)
COMPREHENSIVE LOSS	$ (9,050)	$ (6,284)	$ (15,280)	$ (12,980)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.21)	$ (0.14)	$ (0.36)	$ (0.29)
Weighted average common shares outstanding, basic and diluted	44,022,356	43,663,112	43,900,639	43,667,385

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Changes in Stockholders' Equity

(unaudited)

(In thousands, except share data)

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 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	(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

	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
Exercise of stock options	699,497	—	1,758	—	—	1,758
Stock-based compensation expense	15,199	—	3,439	—	—	3,439
Foreign currency translation	—	—	—	199	—	199
Net loss	—	—	—	—	(9,249)	(9,249)
Balance June 30, 2024	44,567,334	$ 4	$ 567,633	$ 1,047	$ (473,348)	$ 95,336

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Six months ended June 30,	
	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (15,878)	$ (12,692)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	312	406
Stock-based compensation	7,285	8,920
Foreign currency and other transactions	724	(774)
Changes in assets and liabilities:		
Accounts receivable, net	263	(6,587)
Inventories	(3,433)	1,515
Insurance recovery receivable related to legal settlement	(16,025)	—
Other current assets	2,712	1,402
Other assets	(969)	(6,570)
Accounts payable	3,406	(6,149)
Accrued liabilities and other	(1,226)	2,671
Accrued legal settlement	19,650	—
NET CASH USED IN OPERATING ACTIVITIES	(3,179)	(17,858)
CASH FLOWS FROM INVESTING ACTIVITIES	—	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	2,346	—
NET CASH PROVIDED BY FINANCING ACTIVITIES	2,346	—
Effect of exchange rates on cash and cash equivalents	2	5
NET DECREASE IN CASH AND CASH EQUIVALENTS	(831)	(17,853)
Cash and cash equivalents at the beginning of period	78,637	105,762
Cash and cash equivalents at the end of period	$ 77,806	$ 87,909
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Right-of-use assets obtained in exchange for lease obligations	$ 320	$ —
Acquisition of treasury shares upon repayment of secured promissory note	$ —	$ 480

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(unaudited)

NOTE 1—ORGANIZATION AND DESCRIPTION OF BUSINESS

Y-mAbs Therapeutics, Inc. ("we," "us," "our," the "Company," or "Y-mAbs") is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer. Y-mAbs is leveraging 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 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 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 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 $473,348,000 as of June 30, 2024 and $457,470,000 as of December 31, 2023. Through June 30, 2024, the Company has funded the operations primarily through proceeds from sales of shares of the Company's common stock, including the initial public offering in September 2018 and 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.

The Company had cash and cash equivalents of $77,806,000 and $78,637,000 as of June 30, 2024 and December 31, 2023, respectively. As of the issuance date of the consolidated financial statements for the three and six months ended June 30, 2024, the Company expects that the cash and cash equivalents as of June 30, 2024 will be sufficient to fund the Company's operating expenses and capital expenditure requirements as currently planned through at least the next 12 months from the issuance of such financial statements.

The Company may raise additional capital to fund future operations through the sale of the Company's 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

be available to the Company on attractive terms or at all when needed from equity, debt or 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 rate of spending through delaying or scaling back operations or suspending certain research and development programs and other operational programs in addition to other measures.

The accompanying unaudited consolidated financial statements reflect the accounts of the Company and the Company's wholly-owned 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 a normal recurring nature) necessary in the judgment of management for a fair statement of the results for the periods presented. All intercompany balances and transactions have been eliminated. The Company has evaluated subsequent events through the date of this filing. Operating results for the three and six months ended June 30, 2024, are not necessarily indicative of the results that may be expected for the year ending December 31, 2024, any other interim periods, or any future year or period. The 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, 2023.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are described in the Company's Annual Report on Form 10-K for the year ended December 31, 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;
- Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability; and
- Level 3 — Unobservable inputs for the asset or liability, which include management's own assumption about the assumptions market participants would use in pricing the asset or liability, including assumptions about risk.

Cash equivalents held in money market funds are valued using other significant observable inputs, which represent a Level 2 measurement within the fair value hierarchy. There is no change in the valuation methodology for the six months ended June 30, 2024. The Company has no other cash equivalents.

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

	Fair Value Measurements as of June 30, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 72,387	$ —	$ 72,387
Total	$ —	$ 72,387	$ —	$ 72,387

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

During the three and six months ended June 30, 2024, there were no transfers between Level 1, Level 2, and Level 3.

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.

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 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 and accounting standard updates recently issued but not yet adopted and believes that these pronouncements 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 consists of the following (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
	(in thousands)			
Product revenue, net by geographical location:				
United States	$ 15,226	$ 15,851	$ 33,836	$ 32,685
International:				
Western Europe	2,076	—	2,076	2,516
Eastern Asia	3,415	4,553	3,466	5,304
Latin America	1,749	—	2,257	—
Other regions	332	347	594	497
Total international	7,572	4,900	8,393	8,317
Total product revenue, net	$ 22,798	$ 20,751	$ 42,229	$ 41,002

The Company recognized royalty revenue from the distribution partners of $2,756,000 and $2,620,000 in the three months ended June 30, 2024 and 2023, respectively. The Company recognized royalty revenue from the distribution partners of $3,218,000 and $3,387,000 in the six months ended June 30, 2024 and 2023, respectively.

Product sales to certain customers that accounted for more than 10% of total product revenue, net, for the three and six months ended June 30, 2024 and 2023 consists of the following:

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
McKesson	38 %	46 %	43 %	44 %
Cardinal Health	18	12	19	12
AmerisouceBergen	11	18	17	23
SciClone	15	20	8	12

As of June 30, 2024, the Company had recorded on the Consolidated Balance Sheets accounts receivable of approximately $22,191,000, of which $3,431,000 represents an unbilled portion to which the Company has unconditional rights to collect the consideration, and accrued liabilities of $300,000 both related to product sales to the Company's distributor in Western Europe, WEP.

Revenue from product sales is recorded as 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 June 30, 2024, the Company had recorded accounts receivable allowances of approximately $613,000 and accrued liabilities of approximately $1,681,000 related to product sales. As of December 31, 2023, the Company had recorded accounts receivable allowances of approximately $492,000 and accrued liabilities of $2,309,000 related to product sales.

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

	Discounts	Contractual Allowances and Government Rebates	Returns	Total
Balance December 31, 2023	$ 41	$ 2,694	$ 66	$ 2,801
Current provisions relating to sales in current year	187	5,223	7	5,417
Payments/credits relating to sales in current year	(156)	(5,386)	—	(5,542)
Change in estimate related to sales in the prior year	—	(382)	—	(382)
Balance June 30, 2024	$ 72	$ 2,149	$ 73	$ 2,294

NOTE 5—NET LOSS PER SHARE

The calculations of basic and diluted net loss per share are as follows (in thousands, except per share amounts):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Net loss (numerator)	$ (9,249)	$ (6,302)	$ (15,878)	$ (12,692)
Weighted-average shares (denominator), basic and diluted	44,022	43,663	43,901	43,667
Basic and diluted net loss per share	$ (0.21)	$ (0.14)	$ (0.36)	$ (0.29)

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options and unvested restricted stock units outstanding, which totaled 10,805,426 shares and 8,975,495 shares as of June 30, 2024 and 2023, respectively.

NOTE 6—INVENTORIES

Inventories consist of the following (in thousands):

	June 30, 2024	December 31, 2023
Raw Material	$ 224	$ —
Work In Progress	17,198	14,021
Finished Goods	4,108	2,992
Total Inventories	$ 21,530	$ 17,013

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

	June 30, 2024	December 31, 2023
CURRENT ASSETS		
Inventories	$ 8,498	$ 5,065
Total recorded in Current Assets	8,498	5,065
NONCURRENT ASSETS		
Other assets	13,032	11,948
Total recorded in Noncurrent Assets	13,032	11,948
Total Inventories	$ 21,530	$ 17,013

As of June 30, 2024 and December 31, 2023, the Company has classified $13,032,000 and $11,948,000, respectively, of work in progress inventories as noncurrent assets based on the Company's current demand schedule and expectation that such inventory will be utilized after one year from the balance sheet date. Changes in noncurrent assets are reflected on the Consolidated Statements of Cash Flows within the caption of other assets.

During the three and six months ended June 30, 2024, the Company did not record any charges to write-off inventory. During the three and six months ended June 30, 2023, the Company recorded charges to write-off inventory of $456,000.

NOTE 7—INTANGIBLE ASSETS, NET

The Company's intangible assets, net related to capitalized milestone payments made following FDA and other regulatory approvals, and commercialization of DANYELZA. The Company's intangible assets, net as of June 30, 2024 and December 31, 2023 are as follows (in thousands).

	June 30, 2024			December 31, 2023		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
DANYELZA	$ 3,300	$ 846	$ 2,454	$ 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 from 2024 to 2028, and $679,000 thereafter.

NOTE 8—ACCRUED LIABILITIES

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

	June 30, 2024	December 31, 2023
Accrued licensing, milestone and royalty payments	$ 4,522	$ 3,452
Accrued clinical costs	551	597
Accrued compensation and board fees	3,184	3,858
Accrued manufacturing costs	2,078	2,531
Accrued sales reserves	1,681	2,309
Other	772	419
Total	$ 12,788	$ 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 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"). 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 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 License Agreement and SADA License Agreement, collectively.

The Company's material license agreements are described 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, 2023.

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 licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics and cancer treatments using the SADA 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.

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.

Summary of Significant License Agreements and Related Commitments

The below table represents the maximum clinical, regulatory or sales-based milestones as reflected within the significant license agreements, certain of which 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 six months ended June 30, 2024 and 2023, and as of June 30, 2024 and December 31, 2023 (in thousands)

Agreements	Cash paid six months ended June 30, 2024	Cash paid six months ended June 30, 2023	Expense three months ended June 30, 2024	Expense six months ended June 30, 2024	Expense three months ended June 30, 2023	Expense six months ended June 30, 2023	Accrued liabilities current as of June 30, 2024	Accrued liabilities non-current as of June 30, 2024	Accrued liabilities current as of December 31, 2023	Accrued liabilities non-current as of December 31, 2023
MSK	$ 2,377	$ 3,245	$ 1,503	$ 2,887	$ 1,479	$ 2,702	$ 2,962	$ 1,950	$ 2,452	$ 1,950
CD33	—	—	—	—	—	—	—	300	—	300
MabVax	—	—	10	10	—	—	10	—	—	—
SADA	875	605	—	—	—	—	1,550	1,700	1,000	3,125

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 June 30, 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.

Lease Agreements

In February 2019, the Company entered into a lease agreement in connection with 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 and the lease has been amended twice extending the term to February 2027. 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 until February 2025. The fixed rent payable will increase to $182,000 per annum from February 2025 to February 2026, and will further increase to approximately $188,000 per annum payable in equal monthly installments of approximately $16,000 per month, from February 2026 to the end of the lease term.

In January 2018, the Company entered into a lease agreement in connection with 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 term to April 2025. Fixed rent payable under the lease is approximately $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 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 six months ended June 30, 2023.

Total operating lease costs were $246,000 and $220,000 for the three months ended June 30, 2024 and 2023, respectively. Total operating lease costs were $492,000 and $560,000 for the six months ended June 30, 2024 and 2023, respectively.

During the three months ended June 30, 2024, the operating lease expenses were recorded as $170,000 in research and development expense and $76,000 in selling, general and administrative expense. During the three months ended June 30, 2023, the expenses were recorded as $163,000 in research and development expense and $57,000 in selling, general and administrative expense. During the six months ended June 30, 2024, the expenses were recorded as $338,000 in research and development expense and $154,000 in selling, general and administrative expense. During the six months ended June 30, 2023, the expenses were recorded as $446,000 in research and development expense and $114,000 in selling, general and administrative expense.

Cash paid for amounts included in the measurement of lease liabilities for the three and six months ended June 30, 2024, was $245,000 and $496,000, respectively, and cash paid for amounts included in the measurement of lease liabilities for the three and six months ended June 30, 2023, was $266,000 and $525,000, 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 June 30, 2024 and December 31, 2023 were as follows (in thousands):

	June 30, 2024	December 31, 2023
Remainder of 2024	$ 491	$ —
Years ending December 31,		
2024	—	996
2025	681	526
2026	187	—
2027	16	—
Total lease payments	1,375	1,522
Less: Imputed interest	(101)	(103)
Total operating lease liabilities as of period end	$ 1,274	$ 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 estimates the incremental borrowing rate based on the information available at the lease commencement date. As of June 30, 2024, the weighted average remaining lease term is 1.69 years and the weighted average discount rate used to determine the operating lease liability was 8.5%. As of December 31, 2023, the weighted average remaining lease term was 1.61 years and the weighted average discount rate used to determine the operating lease liability was 8.3%.

Legal Matters

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

The Company was 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 named 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 sought 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 based on the record at the time. The parties have since completed documentary discovery and depositions. On February 1, 2024, both the Plaintiff and Mr. Gad filed their respective motions for summary judgment. On August 5, 2024 the Court granted the defendants motion to dismiss the case and issued a judgment order releasing all claims and terminating the case. As a result of this decision, the Company considers this case closed.

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 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 February 5, 2024, the Court granted in part and denied in part the defendants' motion to dismiss the amended complaint. 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. On June 26, 2024, without admitting any liability, the remaining defendants entered into a Stipulation and Agreement of Settlement ("Stipulation") that, if approved, is expected to resolve the lawsuit. Under the terms of the Stipulation, in exchange for the release and dismissal with prejudice of all claims against all defendants in the action, the Company has agreed to a settlement amount of $19,650,000, which must be paid into an escrow account by the Company and the Company's insurance carriers by August 13, 2024. Based upon the retention limits of the Company's Directors & Officers Insurance Policy, the Company is limited to a maximum liability relating to this matter of $5,000,000, inclusive of legal defense fees, of which the Company has paid approximately $1,375,000. The Company has recorded the settlement amount of $19,650,000 within accrued legal settlement and a corresponding insurance recovery receivable of $16,025,000 within insurance recovery receivable related to legal settlement on the consolidated balance sheet as of June 30, 2024. The Company has recorded the settlement amount of $19,650,000 and the corresponding insurance recovery receivable of $16,025,000, with net impact of $3,625,000, within selling, general and administrative expense on the consolidated statements of net loss and comprehensive loss. The determination that the recorded insurance recovery receivable is probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. The proposed settlement under the Stipulation does not constitute an admission of fault or wrongdoing by the Company or any of the individual defendants. On July 1, 2024, the Court entered an order that, among other things, granted preliminary approval of the proposed settlement, approved plaintiffs' proposed form of notice of the proposed settlement, and scheduled a settlement fairness hearing to be held on October 28, 2024. The proposed settlement remains subject to final approval by the Court and certain other conditions.

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. Defendants' motion to dismiss the amended complaint was fully briefed as of September 8, 2023. On April 3, 2024, the parties informed the Court that they had agreed to resolve the matter on mootness grounds and hoped to reach agreement on formal documentation. On July 22, 2024, the parties executed a settlement agreement. As part of the resolution reached on mootness grounds, the Company agreed to: (i) cancel 5,000 shares of stock options issued to each of the Company's non-employee directors as compensation for the years 2020 and 2021; (ii) amend the Company's Compensation Committee Charter to provide that the Compensation Committee shall meet at least quarterly, or more frequently as necessary, to undertake its duties; and (iii) disclose in the annual proxy statements the constituents of the Company's peer group and relevant financial and business metrics considered in establishing the peer group, including market capitalization, and a reasonably detailed description of the process for determining and approving such peer group. As part of the settlement executed on July 22, 2024, the Company agreed to pay $225,000 in attorney's fees and expenses in full satisfaction of any and all claims by the plaintiff and his counsel for fees and expenses in the action. On July 24, 2024, the parties submitted a stipulation and proposed order, which, if entered by the court, would result in the dismissal of the action following a court-approved form of notice of the

resolution reached on mootness grounds. The Company has recorded the fee and expenses to be paid to the plaintiffs' counsel of $225,000 within accrued liabilities on the consolidated balance sheet as of June 30, 2024, and within selling, general and administrative expense on the consolidated statements of net loss and comprehensive loss for the three and six months ended June 30, 2024.

NOTE 10—STOCKHOLDERS' EQUITY

Authorized Stock

As of June 30, 2024 and December 31, 2023, the Company had 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 44,567,334 shares and 43,672,112 shares of common stock as of June 30, 2024 and 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 June 30, 2024 or December 31, 2023.

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 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. However, options outstanding under the 2015 Plan continue to be governed by 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 September 2018. 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 and ending in 2028, 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. As of June 30, 2024, the Company had 2,812,646 shares available for grant under the 2018 Equity Incentive Plan. Options granted under the 2018 Plan vest according to the schedule, which generally ranges from one to four years, specified in the grant agreements, and generally become immediately exercisable upon the occurrence of a change in control, as defined in the Plan Agreement.

Stock-Based Compensation Expense

During the three and six months ended June 30, 2024 and 2023, the Company recognized the following stock-based compensation expense (in thousands):

	Three months ended June 30,		Six months ended June 30,	
	2024	2023	2024	2023
Stock-based compensation by type of award				
Restricted stock units (excluding PRSUs)	$ 502	$ 169	$ 923	$ 356
PRSUs	99	—	152	—
Stock options	2,838	3,447	6,210	8,564
Total stock-based compensation expense	$ 3,439	$ 3,616	$ 7,285	$ 8,920
Stock-based compensation by type of expense				
Research and development expenses	$ 1,267	$ 1,372	$ 3,139	$ 3,678
Selling, general and administrative expenses	2,172	2,244	4,146	5,242
Total stock-based compensation expense	$ 3,439	$ 3,616	$ 7,285	$ 8,920

The expense for the six months ended June 30, 2023 was inclusive of an acceleration of stock-based compensation of $1,706,000, as described further in *NOTE 14— RESTRUCTURING CHARGE*. There was no expense related to the restructuring in the three and six months ended June 30, 2024

Unrecognized Stock-Based Compensation Expense

The following table sets forth the Company's unrecognized stock-based compensation expense as of June 30, 2024, by type of award and the weighted-average period over which the Company expects to recognize the expense (in thousands):

	June 30, 2024	
	Unrecognized compensation expense	Weighted average recognition period (years)
Type of award		
Restricted stock units (excluding PRSUs)	$ 4,523	2.2
PRSUs	506	1.6
Stock options	23,955	3.0
Total unrecognized stock-based compensation expense	$ 28,984	

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	423,378	11.01	
Vested	(124,175)	5.38	
Forfeited	(50,034)	8.33	
Outstanding and expected to vest as of June 30, 2024	600,576	$ 8.92	2.17

During the six months ended June 30, 2024, 20,970 shares of RSUs were granted to non-executive directors, which will vest on the earlier of the first anniversary of the date of grant and the date immediately preceding the Company's annual meeting of stockholders in 2025, provided that in each case the recipient remains as a non-executive director through the vesting date. In addition, 4,660 shares of RSUs were granted to a new non-executive director, which will vest in equal quarterly installments until the third anniversary of the date of grant, provided that the recipient remains as non-executive director through the vesting date. The remaining 397,748 shares of RSUs granted in the six months ended June 30, 2024 will vest annually over the next 3 years, provided in each case that the recipient remains an employee of the Company through each vesting date.

Performance-based Restricted Stock Unit (PRSU) Activity

The following table summarizes PRSUs issued and 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 June 30, 2024	54,000	$ 12.19	1.62

The PRSUs of 54,000 shares issued in the six months ended June 30, 2024 vest in three equal tranches over a three-year period. The assumptions that the Company used to determine the fair value of the PRSUs granted in the six months ended June 30, 2024 using a Monte-Carlo simulation model were as follows:

	Six months ended June 30, 2024
Risk-free interest rate	4.2 %
Expected volatility	101.0 %
Expected dividend yield	— %

The Company did not issue any PRSUs in the six months ended June 30, 2023.

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)
Outstanding and expected to vest as of December 31, 2023	9,307,330	$ 17.26	$ 10,012	6.44
Granted	1,812,760	11.37		
Exercised	(771,047)	3.04		
Forfeited	(198,193)	7.14		
Outstanding and expected to vest as of June 30, 2024	10,150,850	$ 17.48	$ 27,367	6.84
Exercisable as of June 30, 2024	6,123,559	$ 22.11	$ 13,405	5.40

All of the options granted in the six months ended June 30, 2024, have a maximum contractual term of ten years. During the six months ended June 30, 2024, 1,697,590 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, 27,900 options were granted to a new non-executive director, which will vest in equal monthly installments until the third anniversary of the date of grant, provided that the recipient remains as non-executive director through vesting date, and 87,270 options were granted to non-executive directors, which will vest in equal monthly installments until the first anniversary of the date of grant, provided that in each case the recipient remains a non-executive director through vesting date.

The weighted average fair value of stock options granted for the six months ended June 30, 2024 and 2023 was $8.36 and $3.65, respectively. The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors in the six months ended June 30, 2024 and 2023 are set forth in the table below and presented on a weighted average basis. There were no significant changes to the inputs included in the Black-Scholes option pricing model during the six months ended June 30, 2024.

	Six months ended June 30,	
	2024	2023
Risk-free interest rate	4.2 %	3.6 %
Expected term (in years)	6.2	6.2
Expected volatility	84.3 %	82.8 %
Expected dividend yield	— %	— %

Subsequent to June 30, 2024, on July 12, 2024 the Company granted 170,000 stock options and 46,000 RSUs in connection with the start date of the Company's new Chief Financial Officer. The fair value of the stock options and RSUs granted is approximately $2,150,000.

NOTE 12—INCOME TAXES

During the three months ended June 30, 2024 and 2023, the Company experienced pre-tax net losses of $9,149,000 and $6,123,000. The Company's income tax provision was $100,000 and $179,000 during the three months ended June 30, 2024 and 2023. There were no deferred income tax provisions during the three months ended June 30, 2024 and 2023.

During the six months ended June 30, 2024 and 2023, the Company experienced pre-tax net losses of $15,618,000 and $12,513,000. The Company's current income tax provision was $260,000 and $179,000 during the six months ended June 30, 2024 and 2023. There were no deferred income tax provisions during the six months ended June 30, 2024 and 2023.

The Company's tax returns for the years 2017 to 2022 are open for tax examination by U.S. federal and state, and the Danish tax authorities.

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

NOTE 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, 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 six months ended June 30, 2024 and 2023.

The Company has established a retirement program for employees of its 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 six months ended June 30, 2024 and 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 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 PRIT Technology platform. The Company completed the restructuring in May 2023, which resulted in an approximately 35% reduction to its then workforce. Affected employees were offered separation benefits, including severance and outplacement services along with temporary healthcare coverage assistance. As a result, during the six months ended June 30, 2023, the Company recognized restructuring expenses of $4,482,000. For the six months ended June 30, 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, and acceleration of stock-based compensation of $1,706,000, which was recognized in the six months ended June 30, 2023 as there was no longer a service condition related to such awards.

NOTE 15 —SUBSEQUENT EVENTS

Bo Kruse Separation Agreement

On July 16, 2024, in connection with the previous announcement that Bo Kruse was resigning from his position as Chief Financial Officer of the Company, the Company entered into a separation agreement with Mr. Kruse and a consultancy agreement with Investeringsselskabet GH ApS, pursuant to which Mr. Kruse will provide consulting services to the Company. The terms of the separation agreement resulted in modifications to vesting and expiration terms of his awards, which resulted in a non-cash stock-based compensation expense of approximately $718,000 to be recorded in the Company's financial statements for the third quarter of 2024 as there is no longer a service condition related to such awards. Also included in the separation agreement, Mr. Kruse is entitled to a bonus payment for the first seven months of 2024. On July 31, 2024, the Company paid the bonus amount of approximately $150,000, of which the amount related to the first six months of 2024 was included in the accrued liabilities on the consolidated balance sheet as of June 30, 2024. Under the terms of the consultancy agreement, which commenced on August 1, 2024, the Company

will pay approximately $520,000 over one year period upon the commencement of the agreement, and will recognize in the third quarter of 2024 as there is no longer a service condition related to such payments.

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, 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 statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of our Annual Report on Form 10-K for the year ended December 31, 2023 and our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, as supplemented by 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) 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 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.

DANYELZA in combination with GM-CSF has been evaluated in a Phase 2 clinical study in front-line high-risk NB, or HR NB, for patients in first complete remission, including those that did not undergo autologous stem cell transplant. DANYELZA plus GM-CSF in combination with chemotherapy (irinotecan + temozolamide) was also evaluated and shown to be effective in patients with refractory or multiple relapsed HR-NB disease. DANYELZA is currently being evaluated in an ongoing pivotal-stage multicenter trial (Study 201) which is designed to satisfy the accelerated approval confirmatory study and post-marketing requirements of the FDA. In addition, a Phase 2 clinical study in second line relapsed osteosarcoma patients with pulmonary-only recurrence and with complete surgical remission, has completed enrolment and is undergoing evaluation of results.

In late June 2024, we received a preliminary draft abstract of certain results from MSK's investigator-initiated Phase 2 study of naxitamab in second line relapsed osteosarcoma patients (Study 15-096; NCT02502786). For the 39 patients in the study with pulmonary-only recurrence, the summary stated that there were 14 event-free patients at 12 months, rather than MSK's primary endpoint of 16 event-free patients at 12 months. Analysis of the full study results is still under way. Once we obtain the full data set, we plan to undertake further analysis to evaluate tumor GD2 expression in the study subjects, efficacy, and the degree of correlation with clinical response in both primary and secondary endpoints. We intend to use the results of such further analysis to inform our determinations with respect to further development of naxitamab-based immunotherapy in patients with relapsed OS. The results of Study 15-096 are expected to be presented by the MSK sponsor/investigator team later this year at a scientific conference.

Our partner the Beat Childhood Cancer Research Consortium, or BCC, is leading a multi-center Phase 2 trial evaluating naxitamab in combination with standard induction therapy for patients with newly diagonalized HR NB. We have 17 active sites and treated 10 patients with recruitment is ongoing as of June 30, 2024. The amended protocol for the transition to a randomized trial is currently in process and being evaluated. We expect the trial to transition from a single-arm trial, to a randomized trial where we compare a control arm consisting of current standard of care for Induction therapy, versus an interventional arm consisting of naxitamab added to current standard of care with naxitamab. Our aim for the randomized trial is to demonstrate superiority in Complete Response at the end of induction therapy in the naxitamab arm versus the standard of care. The BCC expects to file an IND potentially initiate the new randomized study by the end of 2024

In triple negative breast cancer, we are partnering with the Ohio State University on a Phase 1b/2 trial investigating TGFβ NKs, gemcitabine plus naxitamab in patients with GD2-positive metastatic breast cancer. We expect the first patient to be treated with naxitamab in the second half of 2024. Upon the outcome of this trial, we would consider moving forward with a multi-center Phase 2 trial.

In patients with refractory Ewing sarcoma, the Institute of Mother and Child in Poland is leading a randomized Phase 2 trial evaluating the efficacy and safety of naxitamab. This trial was initiated during the fourth quarter of 2023. Three patients have been dosed in the naxitamab arm and recruitment is ongoing as of June 30, 2024. We expect a total of 16 patients in the naxitamab arm. We expect to complete the trial in 2028.

In addition, we are in discussions with the MD Andersen Cancer Center to initiate a multi-center Phase 1/2 study with a Phase 1 run-in, that seeks to test the hypothesis that the addition of naxitamab to current standard of care, will increase the objective response rate in patients with metastatic Triple Negative Breast Cancer who have received at least one prior line of systemic therapy for metastatic disease. The study, which is anticipated to start in mid- 2025, will further inform us on a future Phase 2 program in Triple Negative Breast Cancer.

We are using our proprietary SADA PRIT Technology 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. 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 as of June 30, 2024. Patients dosed with the GD2-SADA protein have not experienced dose limiting toxicities or related 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 have completed cohorts 1, 2, 3 and 4, 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, 1 mg/kg and 3 mg/kg of protein appears to match our pre-clinical models in terms of clearance data, and the blood PK profiles from patients are comparable and supportive of the current dose interval of two to five days.

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. 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 the first half of 2025.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 PRIT

Technology platform. We have determined to deprioritize our radiolabeled omburtamab development program for CNS-LM. In addition, we 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 then workforce.

As previously disclosed, earlier this year we further determined to deprioritize all development work on radiolabeled omburtamab for CNS-LM, and to deprioritize 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, should support our operations into 2027.

This estimate reflects our current business plan, including our development plans and business strategy following the restructuring, which 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, 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 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 the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q.

In May 2024, the Company entered into an exclusive named patient program license and distribution agreement with TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC, collectively TRPharm, for the distribution of DANYELZA in Turkey. There are no regulatory or sales-based milestone payments or royalties under this distribution agreement.

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 the Priority Review Voucher, or PRV, obtained upon FDA approval of DANYELZA.

As of June 30, 2024 and December 31, 2023, we had an accumulated deficit of $473.3 million and $457.5 million, respectively. We experienced net losses of $9.2 million and $15.9 million for the three and six months ended June 30, 2024, and our net loss was $6.3 million and $12.7 million for the three and six months ended June 30, 2023, respectively. We have incurred significant net operating losses in every year since our inception. We expect our net operating losses to decrease in the future as our DANYELZA product revenue grows to help fund our significant research and development expenses. Our net losses may fluctuate significantly from quarter to quarter and year to year as we:

- continue to advance DANYELZA through the various regulatory processes both in the United States and internationally;
- continue to advance our other product candidates through pre-clinical and clinical development;
- continue to identify additional research programs and additional product candidates, as well as additional indications for existing product candidates;

- initiate pre-clinical studies and clinical trials for any additional product candidates we identify;
- develop, maintain, expand and protect our intellectual property portfolio; 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 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 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.

In July 2024, we announced the appointment of our new Chief Financial Officer.

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. For a discussion of our material license agreements, refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the notes to the consolidated financial statements included in Item 8. Financial Statements in our Annual Report on Form 10-K for the year ended December 31, 2023.

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.

License royalties

License royalties include third-party royalty expenses related to license revenues that have been recognized.

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 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;
- the actual probability of success for our product candidates, including the safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- significant and changing government regulation and regulatory guidance;
- the performance of our existing and any future collaborators;
- the number of doses patients receive;
- the duration of patient follow-up;
- the results of our clinical trials and pre-clinical studies;
- the establishment of commercial manufacturing capabilities;

- adequate ongoing availability of raw materials and drug substance for clinical development and any commercial sales;
- the terms and timing of potential regulatory approvals, including the timing of any BLA and Marketing Authorization Application, or MAA, submissions and their acceptance;
- the potential receipt of marketing approvals, including a safety, tolerability and efficacy profile that is satisfactory to the FDA, the European Medicines Agency, or EMA, 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, and we have determined to deprioritize our radiolabeled omburtamab development program for CNS-LM. If we are required and we determine to conduct additional clinical trials of a product candidate, 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 PRIT Technology platform. In addition to deprioritizing development of omburtamab for CNS-LM, we have deprioritized further work related to the GD2-GD3 Vaccine and CD33 bispecific antibody constructs. Following the January 2023 restructuring, our research and development expenses have decreased from historic averages. Our Research and Development expenses have stayed consistent for the three and six months ended June 30, 2024 and 2023.

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 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 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, net

Other income, net primarily consists of interest income earned on our money market fund and foreign currency transaction gains and losses. Other income, 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 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.

A summary of significant changes in critical accounting policies and significant judgements and estimates for the six months ended June 30, 2024 are included in *NOTE 3— SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this 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-K for the fiscal year ended December 31, 2023.

Results of Operations

Comparison of the Three Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the three months ended June 30, 2024 and 2023:

	Three Months Ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
REVENUES				
Product revenue, net	$ 22,798	$ 20,751	$ 2,047	10 %
Total revenues	22,798	20,751	2,047	10
OPERATING COSTS AND EXPENSES				
Cost of goods sold	3,014	4,649	(1,635)	(35)
Research and development	12,341	12,055	286	2
Selling, general, and administrative	17,232	11,270	5,962	53
Total operating costs and expenses	32,587	27,974	4,613	16
Loss from operations	(9,789)	(7,223)	(2,566)	36
OTHER INCOME, NET				
Interest and other income	640	1,100	(460)	(42)
LOSS BEFORE INCOME TAXES	(9,149)	(6,123)	(3,026)	49
Provision for income taxes	100	179	(79)	(44)
NET LOSS	$ (9,249)	$ (6,302)	$ (2,947)	47 %

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 June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Product revenue, net by geographical location:				
United States	$ 15,226	$ 15,851	$ (625)	(4)%
International:				
Western Europe	2,076	—	—	N/A
Eastern Asia	3,415	4,553	(1,138)	(25)
Latin America	1,749	—	—	N/A
Other regions	332	347	(15)	(4)
Total international	7,572	4,900	2,672	55
Total product revenue, net	$ 22,798	$ 20,751	$ 2,047	10 %

The $2.0 million, or 10%, increase in product revenue, net was mainly due to increased product revenue, net from international markets, partially offset by decreased product revenue, net in the United States. Our international product revenue, net was $7.6 million for the three months ended June 30, 2024, an increase of 55% over $4.9 million in the three months ended June 30, 2023. The increase of product revenue, net in the three months ended June 30, 2024, compared to the three months ended June 30, 2023, was a result of recurring orders from Eastern Asia and Western Europe, as well as the commercial launches for Brazil and Mexico in the Latin America region. Product revenue, net from Eastern Asia in the three months ended June 30, 2023 included an initial commercial launch inventory stocking order from our distribution partner, SciClone, which launched commercial sales in China during the three months ended June 30, 2023. We did not have any shipments to the Western Europe or Latin America regions in the three months ended June 30, 2023. Product revenue, net from the United States was $15.2 million and $15.9 million for the three months ended June 30, 2024 and 2023, respectively, representing a 4% decline driven by a volume decrease in the United States. Our distribution partner in Western Europe operates our named patient program in the region.

We recognized royalty revenue from our distribution partners of $2.8 million and $2.6 million in the three months ended June 30, 2024 and 2023, respectively.

License revenue

There was no license revenue in the three months ended June 30, 2024 and 2023.

Cost of Goods Sold

Our cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, indirect labor costs, third-party royalties for approved products, and indirect overhead costs. Cost of goods sold was $3.0 million and $4.6 million for the three months ended June 30, 2024 and 2023, respectively. Cost of goods sold included lower vial volumes in the three months ended June 30, 2024 compared to the same period in 2023, and an inventory write-down of $0.5 million for an inventory batch that had to be scrapped in the production process in the three months ended June 30, 2023.

We define gross margin as net product revenues less cost of goods sold divided by net product revenues. Our gross margin was at 87% for the three months ended June 30, 2024, compared to 78% for the three months ended June 30, 2023. Our gross margins increased in the three months ended June 30, 2024 due to a favorable gross profit mix from revenues in our international regions in the three months ended June 30, 2024 and the above noted inventory write-down in the three months ended June 30, 2023.

License Royalties

License royalties include third-party royalty expenses related to license revenues that have been recognized. We did not record any license royalty expense for the three months ended June 30, 2024 and 2023.

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.

	Three Months Ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Outsourced manufacturing	$ 3,036	$ 4,665	$ (1,629)	(35)%
Clinical trials	2,290	1,781	509	29
Outsourced research and supplies	243	273	(30)	(11)
Personnel costs	3,797	2,346	1,451	62
Professional and consulting fees	238	424	(186)	(44)
Stock-based compensation	1,191	1,372	(181)	(13)
Information technology expenses	538	589	(51)	(9)
Other	1,008	605	403	67
Total research and development	$ 12,341	$ 12,055	$ 286	2 %

Research and development expenses were $12.3 million for the three months ended June 30, 2024, and were relatively flat compared to $12.1 million for the three months ended June 30, 2023. The decrease in outsourced manufacturing was driven by SADA PRIT programs, which had increased production in the three months ended June 30, 2023 in anticipation of the clinical trial activities in 2023 and 2024.

Selling, General, and Administrative

Selling, general, and administrative expenses were $17.2 million for the three months ended June 30, 2024, as compared to $11.3 million for the three months ended June 30, 2023. The $5.9 million increase in selling, general and administrative expenses was primarily attributable to a net impact of $3.6 million related to the settlement of a shareholder class-action lawsuit, which is the net impact of the $19.7 million accrued legal settlement, net of the corresponding insurance recovery receivable of $16.1 million, a $0.9 million increase in personnel cost, inclusive of stock-based compensation, and a $0.2 million legal settlement in the three months ended June 30, 2024. Both settlements are described in *NOTE 9— LICENSE AGREEMENT AND COMMITMENTS* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q.

Interest and Other Income

Interest and other income for the three months ended June 30, 2024 was $0.6 million as compared to interest and other income of $1.1 million for the three months ended June 30, 2023. Our interest and other income decreased by $0.5 million primarily due to a $0.2 million gain from repayment of secured promissory note in the three months ended June 30, 2023, and a $0.2 million increase in foreign currency transaction losses in the three months ended June 30, 2024. We did not have any repayment of secured promissory note in the three months ended June 30, 2024.

Provision for Income Taxes

Provision for income taxes was $0.1 million for the three months ended June 30, 2024 as compared to $0.2 million for the three months ended June 30, 2023. The decrease in provision for income taxes was primarily driven by an increase in loss before income taxes.

Comparison of the Six Months Ended June 30, 2024 and 2023

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
REVENUES				
Product revenue, net	$ 42,229	$ 41,002	$ 1,227	3 %
License revenue	500	—	500	N/A
Total revenues	42,729	41,002	1,727	4
OPERATING COSTS AND EXPENSES				
Cost of goods sold	5,111	6,732	(1,621)	(24)
License royalties	50	—	50	N/A
Research and development	25,608	25,473	135	1
Selling, general, and administrative	28,657	23,521	5,136	22
Total operating costs and expenses	59,426	55,726	3,700	7
Loss from operations	(16,697)	(14,724)	(1,973)	13
OTHER INCOME, NET				
Interest and other income	1,079	2,211	(1,132)	(51)
LOSS BEFORE INCOME TAXES	(15,618)	(12,513)	(3,105)	25
Provision for income taxes	260	179	81	45
NET LOSS	$ (15,878)	$ (12,692)	$ (3,186)	25 %

Revenues

Product revenue, net

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

	Six months ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Product revenue, net by geographical location:				
United States	$ 33,836	$ 32,685	$ 1,151	4 %
International:				
Western Europe	2,076	2,516	(440)	(17)
Eastern Asia	3,466	5,304	(1,838)	(35)
Latin America	2,257	—	2,257	N/A
Other regions	594	497	97	20
Total international	8,393	8,317	76	1
Total product revenue, net	$ 42,229	$ 41,002	$ 1,227	3 %

Our product revenue, net was $42.2 million for the six months ended June 30, 2024, as compared to $41.0 million in the three months ended June 30, 2023. The slight increase was primarily driven by a $1.2 million increase in the United States product revenue, net in the six months ended June 30, 2024, while international product revenue, net was relatively flat. Product revenue, net from Eastern Asia in the six months ended June 30, 2023 included an initial commercial launch inventory stocking order for the commercial launch in China during the six months ended June 30, 2023, as noted above. Our distribution partner in Western Europe operates our named patient program in the region.

We recognized royalty revenue from our distribution partners of $3.2 million and $3.4 million in the six months ended June 30, 2024 and 2023, respectively.

License revenue

In January 2024, we accepted the price for DANYELZA in Brazil from 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 six months ended June 30, 2024. There was no license revenue in the six months ended June 30, 2023.

Cost of Goods Sold

Our cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, indirect labor costs, third-party royalties for approved products, and indirect overhead costs. Cost of goods sold was $5.1 million and $6.7 million for the six months ended June 30, 2024 and 2023, respectively. Cost of goods sold included lower vial volume in the six months ended June 30, 2024, compared to the same period in 2023, and an inventory write-down of $0.5 million for an inventory batch that had to be scrapped in the production process in the six months ended June 30, 2023.

We define gross margin as net product revenues less cost of goods sold divided by net product revenues. Our gross margin was at 87% for the six months ended June 30, 2024, compared to 84% for the six months ended June 30, 2023. Our gross margins increased in the six months ended June 30, 2024 due to a favorable gross profit mix from revenue in our international regions in the six months ended June 30, 2024 and the above noted inventory write-down in the six months ended June 30,2023.

License Royalties

License royalties include third-party royalty expenses related to license revenues that have been recognized. During the six months ended June 30, 2024, license royalties were related to MSK’s share of licensing revenues. We incurred license royalty expense of $50,000 during the six months ended June 30, 2024 in connection with the price approval from CMED in January 2024. We did not record any license royalty expense for the six months ended June 30, 2023.

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.

	Six Months Ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Outsourced manufacturing	$ 5,672	$ 6,720	$ (1,048)	(16)%
Clinical trials	5,376	2,321	3,055	132
Outsourced research and supplies	331	637	(306)	(48)
Personnel costs	7,450	8,158	(708)	(9)
Professional and consulting fees	600	867	(267)	(31)
Stock-based compensation	3,009	3,678	(669)	(18)
Information technology expenses	1,250	1,261	(11)	(1)
Other	1,920	1,831	89	5
Total research and development	$ 25,608	$ 25,473	$ 135	1 %

Research and development expenses were $25.6 million for the six months ended June 30, 2024, and relatively flat compared to $25.5 million for the six months ended June 30, 2023. The increase in clinical trials is driven by our increased SADA PRIT program clinical trial activities in 2024, which is partially offset by a decrease in outsourced manufacturing for SADA PRIT programs, which had increased production in the six months ended June 30, 2023 in anticipation of the clinical trial activities in 2023 and 2024.

Selling, General, and Administrative

Selling, general, and administrative expenses were $28.7 million for the six months ended June 30, 2024, as compared to $23.5 million for the six months ended June 30, 2023. The $5.2 million increase in selling, general, and administrative expenses was primarily attributable to a net impact of $3.6 million in charges related to the settlement of a shareholder class-action lawsuit in the six months ended June 30, 2024, which is the net impact of the $19.7 million accrued legal settlement, net of the corresponding insurance recovery receivable of $16.1 million, and an additional legal settlement of $0.2 million in the six months ended June 30, 2024. Both settlements are described in *NOTE 9— LICENSE AGREEMENT AND COMMITMENTS* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q, and, to a lesser extent, a $0.4 million increase in professional and consulting fees.

Interest and Other Income

Interest and other income for the six months ended June 30, 2024 was $1.1 million compared to $2.2 million for the six months ended June 30, 2023. Our interest and other income decreased by $1.1 million primarily due to a $0.8 million increase in foreign currency transaction losses related to the remeasurement of foreign currency denominated assets and liabilities.

Provision for Income Taxes

Provision for income taxes was $0.3 million and $0.2 million for the six months ended June 30, 2024 and 2023, respectively. The increase in provision for income taxes was primarily driven by certain U.S. state jurisdictions, and, to a lesser extent, limitation on utilization of U.S. federal net operating losses.

Liquidity and Capital Resources

Overview

We have experienced significant use of cash to fund our net operating losses since inception. We expect our net operating losses to decrease in the future as revenues from our only approved product, DANYELZA, grow and contribute to funding our significant research expenses. Our net losses may fluctuate significantly from quarter to quarter and year to year.

As of June 30, 2024 and December 31, 2023, we had cash and cash equivalents of $77.8 million and $78.6 million, respectively. We estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, should support our operations 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 income from new partnerships or other new business development activities, and no further development of the omburtamab 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 financing, collaborations, licensing arrangements, or other sources.

For an analysis of the type of contractual 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 refer to *NOTE 9 —LICENSE AGREEMENTS AND COMMITMENTS* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Form 10-Q.

Cash Flows

The following table provides information regarding our cash flows for the six months ended June 30, 2024 and 2023:

	Six Months Ended June 30,		Change	
	2024	2023	Amount	Percent
	(in thousands)			
Net cash used in operating activities	$ (3,179)	$ (17,858)	$ 14,679	(82)%
Net cash from investing activities	—	—	—	NA
Net cash from financing activities	2,346	—	2,346	NA
Effect of exchange rates on cash and cash equivalents	2	5	(3)	(60)
Net decrease in cash and cash equivalents	$ (831)	$ (17,853)	$ 17,022	(95)%

Net Cash Used In Operating Activities

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

Net cash used in operating activities was $3.2 million for the six months ended June 30, 2024, as compared to net cash used in operating activities of $17.9 million for the six months ended June 30, 2023. The $14.7 million decrease in cash used in operating activities was primarily due to a decrease in cash used for working capital of $18.1 million, which was primarily driven by a $9.6 million decrease in cash payments against accounts payables, and $6.9 million of increased accounts receivable collections, during the six months ended June 30, 2024 compared to the corresponding period in 2023, partially offset by increased net loss of $3.2 million.

Net Cash From Investing Activities

We did not generate or use cash for investing activities during the six months ended June 30, 2024 and 2023.

Net Cash From Financing Activities

Net cash provided by financing activities was $2.3 million for the six months ended June 30, 2024, which resulted from proceeds from exercised stock options. We did not generate or use cash for financing activities during the six months ended June 30, 2023.

Funding Requirements

Our cash and cash equivalents were $77.8 million as of June 30, 2024. We estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, should support operations 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 development and no further development of the omburtamab program, the GD2-GD3 Vaccine and the CD33 bispecific antibody constructs.

We plan to advance the development of our pipeline programs, initiate new research and pre-clinical development efforts, seek marketing approval for any additional product candidates and indications that we successfully develop, and promote commercialization of approved products. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. We cannot provide any assurance that we will be able to obtain additional capital from any new equity or debt financing, collaborations, licensing arrangements, or other sources. 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 commercialization efforts. 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 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

- the costs of operating as a public company.

We may never generate the necessary data or results required to obtain additional marketing approval and achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. We expect to finance our cash needs through a combination of securities offerings, debt financing, collaborations, strategic alliances and licensing arrangements. Further, adequate additional financing may not be available to us on acceptable terms, or at all.

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* in the notes to the consolidated financial 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, 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 for the Eastern Europe region, SciClone for the Eastern Asia region, and Takeda for Israel in 2020, Adium for the Latin America region in 2021, WEP for the Western Europe region in 2022, TRPharm İlaç Sanayi Ticaret A.Ş. and TRPharm FZ-LLC for Turkey in 2024, 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. 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 subsequently to the attack. Although the long-term implication of the conflict between Ukraine and Russia remains uncertain at this time, it did not result in material impact on our financial results for the three and six months ended June 30, 2024 and 2023.

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 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 our exclusive licensing and distribution agreement with Takeda Israel, 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. Although the long-term implication of the conflict in Middle East remains uncertain at this time, it did not result in material impact on our financial results for the three and six months ended June 30, 2024 and 2023.

We face various worldwide health care changes that may continue to result in pricing pressures, including health care cost containment and government legislation. 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.

Recent Accounting Pronouncements

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

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.

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 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 June 30, 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 June 30, 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 was 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 named 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 sought 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 based on the record at the time. The parties have since completed documentary discovery and depositions. On February 1, 2024, both the Plaintiff and Mr. Gad filed their respective motions for summary judgment. On August 5, 2024 the Court granted the defendants motion to dismiss the case and issued a judgment order releasing all claims and terminating the case. As a result of this decision, the Company considers this case closed.

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 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 February 5, 2024, the Court granted in part and denied in part the defendants' motion to dismiss the amended complaint. 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. On June 26, 2024, without admitting any liability, the remaining defendants entered into a Stipulation and Agreement of Settlement ("Stipulation") that, if approved, is expected to resolve the lawsuit. Under the terms of the Stipulation, in exchange for the release and dismissal with prejudice of all claims against all defendants in the action, the Company has agreed to a settlement amount of $19,650,000, which must be paid into an escrow account by the Company and the Company's insurance carriers by August 13, 2024. Based upon the retention limits of the company's Directors & Officers Insurance Policy, the Company is limited to a maximum liability relating to this matter of $5,000,000, inclusive of legal defense fees, of which the Company has paid approximately $1,375,000. The Company has recorded the settlement amount of $19,650,000 within accrued legal settlement and a corresponding insurance recovery receivable of $16,025,000 within insurance recovery receivable related to legal settlement on the consolidated balance sheet as of June 30, 2024. The Company has recorded the settlement amount of $19,650,000 and the corresponding insurance recovery receivable of $16,025,000, with net impact of $3,625,000, within selling, general and administrative expense on the consolidated statements of net loss and comprehensive loss. The determination that the recorded insurance recovery receivable is probable of collection is based on the terms of the applicable insurance policies and communications with the insurers. The proposed settlement under the Stipulation does not constitute an admission of fault or wrongdoing by the Company or any of the individual defendants. On July 1, 2024, the Court entered an order that, among other things, granted preliminary approval of the proposed settlement, approved plaintiffs' proposed form of notice of the proposed settlement, and scheduled a settlement fairness hearing to be held on October 28, 2024. The proposed settlement remains subject to final approval by the Court and certain other conditions.

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. Defendants' motion to dismiss the amended complaint was fully briefed as of September 8, 2023. On April 3, 2024, the parties informed the Court that they had agreed to resolve the matter on mootness grounds and hoped to reach agreement on formal documentation. On July 22, 2024, the parties executed a settlement agreement. As part of the resolution reached on mootness grounds, the Company agreed to: (i) cancel 5,000 shares of stock options issued to each of the Company's non-employee directors as compensation for the years 2020 and 2021; (ii) amend the Company's Compensation Committee Charter to provide that the Compensation Committee shall meet at least quarterly, or more frequently as necessary, to undertake its duties; and (iii) disclose in the annual proxy statements the constituents of the Company's peer group and relevant financial and business metrics considered in establishing the peer group, including market capitalization, and a reasonably detailed description of the process for determining and approving such peer group. As part of the settlement executed on July 22, 2024, the Company agreed to pay $225,000 in attorney's fees and expenses in full satisfaction of any and all claims by the plaintiff and his counsel for fees and expenses in the action. On July 24, 2024, the parties submitted a stipulation and proposed order, which, if entered by the court, would result in the dismissal of the action following a court-approved form of notice of the

resolution reached on mootness grounds. The Company has recorded the fee and expenses to be paid to the plaintiffs' counsel of $225,000 within accrued liabilities on the consolidated balance sheet as of June 30, 2024, and within selling, general and administrative expense on the consolidated statements of net loss and comprehensive loss for the three and six months ended June 30, 2024.

Item 1A. Risk Factors.

Below we are providing, in supplemental form, changes to our risk factors from those previously disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 and Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024. Our risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 and Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024 provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in Part I, Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2023 and Part II, Item 1A of our Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, together with the below, for a more complete understanding of the risks and uncertainties material to our business.

We do not know whether any clinical trials we or our partners 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 late June 2024, we received a preliminary draft abstract of certain results from MSK's investigator-initiated Phase 2 study of naxitamab in second line relapsed osteosarcoma patients (Study 15-096; NCT02502786). For the 39 patients in the study with pulmonary-only recurrence, the summary stated that there were 14 event-free patients at 12 months, rather than MSK's primary endpoint of 16 event-free patients at 12 months. Analysis of the full study results is still under way. Once we obtain the full data set, we plan to undertake further analysis to evaluate tumor GD2 expression in the study subjects, efficacy, and the degree of correlation with clinical response in both primary and secondary endpoints. We intend to use the results of such further analysis to inform our determinations with respect to further development of naxitamab-based immunotherapy in patients with relapsed OS. The results of Study 15-096 are expected to be presented by the MSK sponsor/investigator team later this year at a scientific conference. There can be no assurance that the data from this trial will support further development of DANYELZA for osteosarcoma.

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, and we have determined to deprioritize our radiolabeled omburtamab development program for CNS-LM. If we are required and we determine to conduct additional clinical trials of a product candidate, 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 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.

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 any IND filings and our ability to conduct clinical development activities.

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 trials and pre-clinical research.

Currently, MSK is conducting a clinical trial (Study 15-096; NCT 02502786) to address relapsed osteosarcoma using DANYELZA. Under the terms of the MCTA, we are obligated to pay for costs associated with this clinical trial. In late June 2024, we received a preliminary draft abstract of certain results from MSK's investigator-initiated Phase 2 study of naxitamab in second line relapsed osteosarcoma patients (Study 15-096; NCT02502786). For the 39 patients in the study with pulmonary-only recurrence, the summary stated that there were 14 event-free patients at 12 months, rather than MSK's primary endpoint of 16 event-free patients at 12 months. Analysis of the full study results is still under way. Once we obtain the full data set, we plan to undertake further analysis to evaluate tumor GD2 expression in the study subjects, efficacy, and the degree of correlation with clinical response in both primary and secondary endpoints. We intend to use the results of such further analysis to inform our determinations with respect to further development of naxitamab-based immunotherapy in patients with relapsed OS. The results of Study 15-096 are expected to be presented by the MSK sponsor/investigator team later this year at a scientific conference. There can be no assurance that the data from this trial will support further development of DANYELZA for osteosarcoma.

The outside scientists who conduct the clinical testing of DANYELZA and our other current product candidates, and who conduct the research and development upon which our product candidate pipeline depends, are not our employees; rather they serve as either independent contractors or the primary investigators under research and other agreements that we have entered into with MSK. Such scientists and collaborators may have other commitments that limit their availability to us. Although our scientific advisors generally agree not to do competing work, if an actual or potential conflict of interest between their work for us and their work for MSK or another entity arises, we may lose their

services. These factors could adversely affect the timing of our IND filings and our ability to conduct future planned clinical trials. It is also possible that some of our valuable proprietary knowledge may become publicly known through these scientific advisors if they breach their confidentiality agreements with us, which would cause competitive harm to, and have a material adverse effect on, our business.

Our existing agreements with MSK may be subject to termination by MSK upon the occurrence of certain circumstances including in the event of our insolvency or bankruptcy, if we are convicted of a felony relating to the manufacture, use, or sale of products licensed from MSK or if we fail to pay amounts owed to MSK under the agreements or other types of breach by us of our obligations under the agreements that remain uncured. If MSK terminates the MSK License, the MSK CD33 License, the SADA License Agreement or its other agreements with us, commercialization of any approved product, such as DANYELZA, or the research and development of the relevant product candidates would be suspended, and we would not be able to research, develop, and license our existing and future product candidates as currently contemplated. We may be required to devote additional resources to the development of our product candidates or seek a new collaboration partner, and the terms of any additional collaborations or other arrangements that we establish may not be favorable to us. Switching or adding third parties to conduct our clinical trial would involve substantial costs and delays and require extensive management time and focus, which can materially impact our ability to meet our desired clinical development timelines.

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

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability, or the ability of our potential future collaborators, to profitably sell any drugs for which we, or they, obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we, or our potential future collaborators, may receive for any approved drugs. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained for DANYELZA, and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad.

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

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level

of reimbursement physicians receive for administering any approved product we might bring to market. 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 state governments will pay for healthcare products and services, which could result in reduced demand for our drug candidates or additional pricing pressures. The cost of prescription pharmaceuticals in the United States has also been the subject of considerable discussion in the United States, and members of Congress and the Administration have stated that they will address such costs through new legislative and administrative measures. The pricing of prescription pharmaceuticals is also subject to governmental control outside the United States. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost effectiveness of our product candidates to that of other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our ability to generate revenues and become profitable could be impaired.

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

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 and on April 10, 2024, the Parliament adopted its related position. 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.

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.

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 trials and pre-clinical research.

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.

In October 2023, we announced 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 March 2024, we announced the resignation of our Executive Vice President, Chief Financial Officer, Secretary and Treasurer, which resignation became effective in July 2024 when his successor commenced employment with us in July 2024. We cannot assure you that these management changes or any future management changes, or any other changes that we have or may make with respect to our workforce, will not have an adverse impact on our business operations. The loss of the services of members of our executive management and other functions and the failure to find appropriate replacements in a timely fashion could impede the achievement of our research, development and commercialization objectives.

It is important to our success that any key employees who have recently joined us or who will 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.

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 area, in a region that is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we will need to recruit talent from outside of our region, and doing so may be costly and difficult.

To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock option and/or restricted stock grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the fair market value of our capital stock that are beyond our control and may at any time be insufficient to counteract more

lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance for any of our executives or other employees.

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

We have been named, and may in the future be named, as defendants in lawsuits or other legal proceedings that 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, 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 shareholder derivative action. As described in "Part II, Item 1—Legal Proceedings" of this report, the parties in both of these actions have entered into settlement agreements, and the proposed settlement of the class-action lawsuit is subject to final approval by the court in that case and certain other conditions.

We are also from time to time subject to legal proceedings arising out of our business and/or operations. Such legal proceedings may involve product liability claims, and other claims by third parties, and employment claims made by our current or former employees. Such proceedings may result in substantial costs and may divert management's attention and resources, may negatively impact our reputation and may lead to additional legal proceedings, investigations or claims, among other things, which may harm our business.

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 litigation to which we are party. Moreover, any conclusion of a matter 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, litigation has caused and will continue to cause our management and board of directors to divert time and attention and could adversely impact our 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.

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

None.

Item 3. Defaults on Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

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

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 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†	Amended and Restated Non-Employee Director Compensation Policy, effective April 26, 2024 (incorporated by reference to Exhibit 10.4 to the Registrant's Form 10-Q filed, May 7, 2024)
10.2†	Employment Agreement, entered into on June 28, 2024, between Peter Pfreundschuh and the Company (incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed, July 1, 2024)
10.3†	Separation Agreement entered into on July 16, 2024, between Bo Kruse and Y-mAbs Therapeutics A/S (incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed, July 19, 2024)
10.4†	Consultancy Agreement, entered into on July 16, 2024, between Investeringsselskabet GH ApS and the Company (incorporated by reference to Exhibit 10.2 to Registrant's Form 8-K filed, July 19, 2024)
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1+	Certification of Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2+	Certification of Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document

104	Cover Page Interactive Data File – The cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

* Filed herewith.

\+ Furnished herewith.

† Indicates management contract or compensatory plan.

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.

SIGNATURES

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

Y-MABS THERAPEUTICS, INC.

Dated: August 12, 2024

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

Dated: August 12, 2024

By: /s/ Peter Pfreundschuh
Name: Peter Pfreundschuh
Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)

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: August 12, 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, Peter Pfreundschuh, certify that:

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

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

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

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

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

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

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

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

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

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

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

Dated: August 12, 2024

By: /s/ Peter Pfreundschuh
Name: Peter Pfreundschuh
Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended June 30, 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

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

Dated: August 12, 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 June 30, 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

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

Dated: August 12, 2024

By: /s/ Peter Pfreundschuh
Name: Peter Pfreundschuh
Title: Chief Financial Officer and Treasurer
(Principal Financial Officer)