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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 March 31, 2025
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.)

202 Carnegie Center
Suite 301
Princeton, NJ 08540
(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 45,283,677 shares of Common Stock ($0.0001 par value) outstanding as of May 6, 2025.

FORWARD-LOOKING STATEMENTS

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

We have based these forward-looking statements on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part II, Item 1A, "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2024, or Annual Report, and as supplemented in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q for the quarter ended March 31, 2025. 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 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, 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 strategy, 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 based on our Self-Assembly DisAssembly Pretargeted Radio-immuno Therapy, or SADA PRIT, technology platform;

- 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 marketing, expanding the indications for, or selling DANYELZA and any current or future product candidates for which we may receive marketing approval;

- 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, including as a result of government price controls or other changes in pricing regulation that could restrict the amount that we are able to charge for DANYELZA or any of our other product candidates that may be approved in the future;

- We currently depend on a small number of third-party contract manufacturing organizations, or CMOs, and expect it would be difficult to find suitable replacements 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. The anticipated transition of DANYELZA manufacturing to a new facility by our contract manufacturer may not be successful or completed in a timely manner to avoid production delays;

- The SADA PRIT technology that we use has not been approved for commercial use by the U.S. Food and Drug Administration, or 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 and collaboration with clinical and academic institutions, in particular on our exclusive rights with Memorial Sloan Kettering Cancer Center, or MSK, and Massachusetts Institute of Technology, or MIT, under the 2015 MSK License Agreement (as amended), and under the 2020 SADA License Agreement;

- 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;

- Our expectations with respect to the commercial value of any of our product candidates, including antibody constructs based on the SADA PRIT technology platform, may not be realized;

- Our expectations with respect to our ongoing and future clinical trials whether conducted by us or by any of our collaborators, including the 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, or may not delivered in accordance with our expected timelines;

- The outcome of pre-clinical studies and early clinical trials related to radioimmunotherapy, or RIT 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 of our clinical trials, such event could adversely affect clinical trials of our other product candidates;

- 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 establish and maintain sufficiently broad protection of the intellectual property rights covering our product candidates and technology;

- 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;

- We may be unable to identify and develop additional product candidates and technologies with significant commercial potential;
- We may be unable to attract, integrate, manage and retain qualified personnel or key employees;
- 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;
- We will require 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;
- Our common stock price and other factors that are beyond our control may impact our ability to raise additional capital on favorable terms or at all;
- We face significant competition in an environment of other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively;
- Our business, financial condition and results of operations have been and may in the future be adversely affected by pandemics or by similar health crises, macroeconomic conditions, including tariffs and escalating trade tensions, and by geopolitical events;
- Our expectations with respect to our business realignment strategy may not be realized, we may incur additional costs implementing it or other difficulties, and we may be unable to successfully run and manage the business effectively and efficiently
- Our expectations with respect to our financial performance, including our estimates regarding revenues, expenses, cash flow and capital expenditure requirements, may not be realized, and our estimates regarding how long our cash resources are expected to last, may be inaccurate;
- A variety of risks associated with operating our business internationally including through collaboration partners, could materially adversely affect our business;
- 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; and
- Any litigation to which we are a party could result in substantial damage 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 are made as of the date of this Quarterly Report, 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 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)

	March 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 60,310	$ 67,234
Accounts receivable, net	17,740	19,688
Inventories	7,995	7,214
Other current assets	4,403	4,373
Total current assets	90,448	98,509
Property and equipment, net	161	42
Operating lease right-of-use assets	601	817
Intangible assets, net	2,213	2,276
Inventories, long-term	18,472	17,772
Other assets	718	488
TOTAL ASSETS	$ 112,613	$ 119,904
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 4,627	$ 6,662
Accrued liabilities	13,875	16,406
Operating lease liabilities, current portion	455	630
Total current liabilities	18,957	23,698
Accrued milestones	3,200	3,200
Operating lease liabilities, long-term portion	148	190
Other liabilities	851	812
TOTAL LIABILITIES	23,156	27,900
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at March 31, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2025 and December 31, 2024; 45,250,794 and 44,988,313 shares issued and outstanding at March 31, 2025 and December 31, 2024, respectively	5	4
Additional paid-in capital	580,383	576,872
Accumulated other comprehensive income	1,401	2,264
Accumulated deficit	(492,332)	(487,136)
TOTAL STOCKHOLDERS' EQUITY	89,457	92,004
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 112,613	$ 119,904

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 March 31,	
	2025	2024
REVENUES		
Net product revenue	$ 20,904	$ 19,431
License revenue	—	500
Total revenues	20,904	19,931
COST OF GOODS SOLD	3,001	2,097
GROSS PROFIT	17,903	17,834
OPERATING COSTS AND EXPENSES		
License royalties	—	50
Research and development	11,359	13,267
Selling, general, and administrative	13,087	11,425
Total operating costs and expenses	24,446	24,742
Loss from operations	(6,543)	(6,908)
OTHER INCOME, NET		
Interest and other income	1,352	439
LOSS BEFORE INCOME TAXES	(5,191)	(6,469)
Provision for income taxes	5	160
NET LOSS	$ (5,196)	$ (6,629)
Other comprehensive income/(loss)		
Foreign currency translation	(863)	399
COMPREHENSIVE LOSS	$ (6,059)	$ (6,230)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.12)	$ (0.15)
Weighted average common shares outstanding, basic and diluted	45,104,476	43,779,456

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, 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

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2024	44,988,313	$ 4	$ 576,872	$ 2,264	$ (487,136)	$ 92,004
Exercise of stock options	57,000	—	114	—	—	114
Stock-based compensation expense	205,481	1	3,397	—	—	3,398
Foreign currency translation	—	—	—	(863)	—	(863)
Net loss	—	—	—	—	(5,196)	(5,196)
Balance March 31, 2025	45,250,794	$ 5	$ 580,383	$ 1,401	$ (492,332)	$ 89,457

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(unaudited)

(In thousands)

	Three months ended March 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (5,196)	$ (6,629)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	71	159
Stock-based compensation	3,341	3,846
Foreign currency transactions	(812)	492
Changes in assets and liabilities:		
Accounts receivable, net	1,948	1,866
Inventories	(724)	(3,383)
Other current assets	(30)	1,473
Inventories, long-term	(700)	1,207
Other assets	(230)	111
Accounts payable	(1,223)	176
Accrued liabilities and other	(3,356)	(2,795)
NET CASH USED IN OPERATING ACTIVITIES	(6,911)	(3,477)
NET CASH USED IN INVESTING ACTIVITIES		
Purchase of property and equipment	(127)	—
NET CASH USED IN INVESTING ACTIVITIES	(127)	—
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercised stock options	114	588
NET CASH PROVIDED BY FINANCING ACTIVITIES	114	588
Effect of exchange rates on cash and cash equivalents	—	1
NET DECREASE IN CASH AND CASH EQUIVALENTS	(6,924)	(2,888)
Cash and cash equivalents at the beginning of period	67,234	78,637
Cash and cash equivalents at the end of period	$ 60,310	$ 75,749

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 radioimmunotherapy, and antibody-based therapeutic products for the treatment of cancer. Y-mAbs is leveraging the Company's proprietary radioimmunotherapy and the antibody platforms, and the Company's deep expertise in the field of radioimmunotherapy and antibodies to develop a broad portfolio of innovative medicines largely in the space of pretargeted radio-isotope labeled therapeutics. Y-mAbs operates as two business units – DANYELZA and Radioimmunotherapy ("RIT").

The Company is headquartered in New Jersey 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 $492,332,000 as of March 31, 2025 and $487,136,000 as of December 31, 2024. Through March 31, 2025, 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 $60,310,000 and $67,234,000 as of March 31, 2025 and December 31, 2024, respectively. As of the issuance date of the consolidated financial statements for the quarter ended March 31, 2025, the Company expects that the cash and cash equivalents as of March 31, 2025 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 date of these financial statements are issued.

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 includes working with distributors and may include working with a collaborator. 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 months ended March 31, 2025, are not necessarily indicative of the results that may be expected for the year ending December 31, 2025, any other interim periods, or any future year or period. The consolidated balance sheet data as of December 31, 2024 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, 2024.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

The Company's significant accounting policies are detailed in our Annual Report on Form 10-K for the year ended December 31, 2024.

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 three months ended March 31, 2025. 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 March 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 56,255	$ —	$ 56,255
Total	$ —	$ 56,255	$ —	$ 56,255

	Fair Value Measurements as of December 31, 2024			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ —	$ 64,120	$ —	$ 64,120
Total	$ —	$ 64,120	$ —	$ 64,120

During the quarter ended March 31, 2025 and 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 based on the Company's public trading historical volatility experience. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards as the Company does not have enough exercise data to evaluate an exercise pattern. 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") issued in 2024 was determined using a Monte-Carlo simulation model. In February 2025, the Company modified the performance period for this grant, resulting in a change of expected term from 3 years to 2 years. 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 during a 2-year period determined by the board of directors. 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 cost of equity is determined based on risk-free interest, which is determined using the zero-coupon risk-free interest rate derived from the Treasury Constant Maturities yield curve on the modification date, the market risk and size premium, which is determined based on the Company's market capitalization. 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 the PRSUs issued in 2025 is determined at the grant-date price of the Company's common stock. Please refer to *Note 11— Stock-Based Compensation* for details of the vesting provisions for each PRSU grant.

Segment Information

Following the business realignment strategy announced in January 2025, the Company is now organized into two reportable segments: DANYELZA and RIT. Refer to *Note 14 – Segment Information* for details.

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.

In November 2024, the FASB issued ASU 2024-03, Disaggregation of Income Statement Expenses (Subtopic 220-40). ASU 2024-03 requires disclosures about specific types of expenses included in the expense captions presented on the face of the income statement and disclosures about selling expenses. In January 2025, the FASB issued ASU 2025-01 to provide clarification on adoption dates. ASU 2024-03 is required to be adopted by the Company for annual reporting periods beginning after December 15, 2026 and interim reporting periods beginning after December 15, 2027. The requirements will be applied prospectively with the option for retrospective application. Early adoption is permitted. The Company is evaluating the impact of this update on the Company's future 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 future 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 net product revenue was generated from sales of DANYELZA and consists of the following (in thousands):

	Three months ended March 31,	
	2025	2024
Net product revenue by geographical location:		
United States	$ 13,381	$ 18,610
Ex-U.S.:		
Eastern Asia	1,507	51
Latin America	2,013	508
Western Asia	3,838	—
Other regions	165	262
Total Ex-U.S.	7,523	821
Total net product revenue	$ 20,904	$ 19,431

The Company recognized royalty revenue from distribution partners of $1,918,000 and $462,000 in the three months ended March 31, 2025 and 2024, respectively.

Product sales to certain distribution partners that accounted for more than 10% of total net product revenue for the three months ended March 31, 2025 and 2024 consists of the following:

	Three months ended March 31,	
	2025	2024
McKesson	30 %	51 %
Cardinal Health	19	22
INPHARMUS	18	—
Cencora	15	25

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 March 31, 2025, the Company had recorded accounts receivable allowances of approximately $585,000 and accrued liabilities of approximately $1,569,000 related to product sales. As of December 31, 2024, the Company had recorded accounts receivable allowances of approximately $626,000 and accrued liabilities of $1,759,000 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, 2024	$ 88	$ 2,200	$ 97	$ 2,385
Current provisions relating to sales in current year	95	2,763	—	2,858
Payments/credits received in current year	—	(3,079)	—	(3,079)
Change in estimate related to sales in the prior year	(102)	92	—	(10)
Balance March 31, 2025	$ 81	$ 1,976	$ 97	$ 2,154

The Company had allowance for credit loss of $541,000 and $520,000 as of March 31, 2025 and December 31, 2024, respectively.

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 March 31,	
	2025	2024
Net loss (numerator)	$ (5,196)	$ (6,629)
Weighted-average shares (denominator), basic and diluted	45,104	43,779
Basic and diluted net loss per share	$ (0.12)	$ (0.15)

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options and unvested restricted share units outstanding totaled 12,037,319 shares and 11,226,739 shares as of March 31, 2025 and 2024, respectively.

NOTE 6—INVENTORIES

Inventories consist of the following (in thousands):

	March 31, 2025	December 31, 2024
Raw Material	$ 109	$ 150
Work In Progress	23,484	22,560
Finished Goods	2,874	2,276
Total Inventories	$ 26,467	$ 24,986

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

	March 31, 2025	December 31, 2024
CURRENT ASSETS		
Inventories	$ 7,995	$ 7,214
Total recorded in Current Assets	7,995	7,214
NON-CURRENT ASSETS		
Inventories, long-term	18,472	17,772
Total recorded in Non-current Assets	18,472	17,772
Total Inventories	$ 26,467	$ 24,986

As of March 31, 2025 and December 31, 2024, the Company has classified $18,472,000 and $17,772,000, respectively, of raw materials and work-in-progress inventories as non-current assets based on the Company's current demand schedule and expectation that such inventories will be utilized after one year from the balance sheet date. Changes in non-current assets are reflected on the Consolidated Statements of Cash Flows within the caption of inventories, long-term.

During the three months ended March 31, 2025 and 2024, the Company did not record any material charges to write off inventories.

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 March 31, 2025 and December 31, 2024 are as follows (in thousands):

	March 31, 2025			December 31, 2024		
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount
DANYELZA	$ 3,300	$ 1,087	$ 2,213	$ 3,300	$ 1,024	$ 2,276

In October 2024, following the approval of a patent term extension, the patent for DANYELZA was extended to February 2034. Intangible assets are amortized on a straight-line based over a remaining useful life of approximately 8.9 years. Annual amortization expense is expected to be $248,000 each year for the five-year period from 2025 to 2029, and $972,000 thereafter.

NOTE 8—ACCRUED LIABILITIES

Accrued liabilities as of March 31, 2025 and December 31, 2024 are as follows (in thousands):

	March 31, 2025	December 31, 2024
Accrued licensing, milestone and royalty payments	$ 3,368	$ 5,016
Accrued clinical costs	2,036	1,386
Accrued compensation and board fees	3,288	4,444
Accrued manufacturing costs	1,280	1,528
Accrued sales reserves	1,569	1,759
Accrued business realignment expenses	1,411	1,447
Other	923	826
Total	$ 13,875	$ 16,406

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"), the CD33 License Agreement, dated November 13, 2017, between the Company and MSK (the "CD33 License"), and the amendment to the MSK License, dated November 8, 2024, between the Company and MSK (the "Amended MSK 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 milestone and royalty payments are inclusive of obligations under the MSK License, Amended MSK License and SADA License Agreement, collectively. As part of a restructuring plan announced in January 2023, activities relating to the GD2-GD3 Vaccine and CD33 antibody constructs were deprioritized. The Company has incurred immaterial expenses and liabilities for the two programs as of and for the three months ended March 31, 2025 and 2024.

The Company's material license agreements are detailed in *NOTE 9— LICENSE AGREEMENTS AND COMMITMENTS* to the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024.

MSK License

The MSK License 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 even if the related milestone activity is not achieved.

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 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, 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* in the Company's audited consolidated financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2024 for sublicense agreements related to MSK License 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, net of which have been paid as of March 31, 2025 (in thousands):

Agreements	Maximum Clinical Milestones	Maximum Regulatory Milestones	Maximum Sales-based Milestones
MSK	$ 700	$ 7,800	$ 20,000
SADA	3,300	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 months ended March 31, 2025 and 2024, and as of March 31, 2025 and December 31, 2024 (in thousands):

Agreements	Cash paid three months ended March 31, 2025	Cash paid three months ended March 31, 2024	Expense three months ended March 31, 2025	Expense three months ended March 31, 2024	Accrued liabilities current as of March 31, 2025	Accrued liabilities non-current as of March 31, 2025	Accrued liabilities current as of December 31, 2024	Accrued liabilities non-current as of December 31, 2024
MSK	$ 3,141	$ 2,377	$ 1,494	$ 1,348	$ 1,644	$ 1,500	$ 3,291	$ 1,500
SADA	—	—	—	—	1,425	1,700	1,425	1,700

Minimum royalties and certain clinical, regulatory and sales milestones that become due based upon the passage of time under the MSK License, and the SADA License Agreement are excluded from the above table as the Company does not consider such obligations to be probable as of March 31, 2025 and December 31, 2024.

Research and development is inherently uncertain and should such research and development fail, the MSK License and the SADA License Agreement are cancelable at the Company's option. The Company will also consider the development risk and each party's termination rights under the respective agreement when considering whether any clinical or regulatory-based milestone payments, certain of which also contain time-based payment requirements, are probable. The Company records milestones in the period in which the contingent liability is probable and the amount is reasonably estimable.

Lease Agreements

In September 2024, the Company entered into a lease agreement for office space in Princeton, New Jersey to which the Company plans to transition the Company's headquarters location in the first half of 2025. The term of the lease is for ten years and nine months from the date the Company begins to occupy the premises, whereby the first nine months are rent free. Fixed rent payable under the lease ranges from approximately $362,000 in the first year after the free rent period concludes to $411,000 in the last year of the lease, with annual escalation. Rent is payable in equal monthly installments ranging from approximately $30,000 to $34,000 for each respective year. Pursuant to the lease agreement, the Company has two options to extend the lease for an additional five-year period per each option. At lease inception, the Company concluded the renewal option was not reasonably certain of being exercised. The Company has the option to terminate the lease before its expiration under limited circumstances. The lease agreement did not result in any financial impact for the three months ended March 31, 2025 as the leased space has not been made available for use; therefore, the commencement date had not occurred as of March 31, 2025. As part of the lease agreement, the Company was offered temporary office space for free before the lease commences.

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 was approximately $177,000 per annum and was payable in equal monthly installments of approximately $15,000 per month until February 2025. The fixed rent payable increased 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 former 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 will revert to a month-to-month lease after November 2025. 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 March 2025, the Company notified the landlord of the intention to reduce the leased premise effective April 1, 2026. The lease modification resulted in an immaterial charge in the three months ended March 31, 2025. The monthly payment will be approximately $12,000 after April 1, 2026.

Operating lease expenses for the three months ended March 31, 2025 and 2024, respectively, were as follows (in thousands).

	Three months ended March 31,	
	2025	2024
Operating lease expenses by type of expense		
Research and development	$ 170	$ 168
Selling, general and administrative	73	78
Total operating lease expenses	$ 243	$ 246

Cash paid for amounts included in the measurement of lease liabilities for the three months ended March 31, 2025 and 2024 was $244,000 and $251,000, respectively, and was included in net cash used in operating activities in the Company's Consolidated Statements of Cash Flows.

Maturities of operating lease liabilities as of March 31, 2025 and December 31, 2024 were as follows (in thousands):

	March 31, 2025	December 31, 2024
Remainder of 2025	$ 438	$ —
Years ending December 31,		
2025	—	670
2026	187	187
2027	16	16
Total lease payments	641	873
Less: Imputed interest	(38)	(53)
Total operating lease liabilities as of period end	$ 603	$ 820

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 March 31, 2025, the weighted average remaining lease term is 1.28 years, and the weighted average discount rate used to determine the operating lease liability was 8.4%. As of December 31, 2024, the weighted average remaining lease term is 1.39 years and the weighted average discount rate used to determine the operating lease liability was 8.5%.

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 lawsuit asserted claims against Mr. Thomas Gad, the Company's Chief Business Officer, and Vice Chairman of the Company's board of directors, and 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 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 denied Plaintiff's motion for summary judgement, granted Mr. Gad's motion for summary judgement and terminated the case. On August 26, 2024, Plaintiff filed a notice of appeal. The Company shall participate in the remaining appeal as a nominal party only, as it did in the

underlying action and mediation. Plaintiff/Appellant's appeal brief was filed on December 9, 2024. Mr. Gad's brief was filed in March 2025 and Plaintiff's reply brief was filed on April 2, 2025. The Court has scheduled oral argument on the appeal on May 22, 2025.

NOTE 10—STOCKHOLDERS' EQUITY

Authorized Stock

As of March 31, 2025 and December 31, 2024, 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 45,250,794 shares and 44,988,313 shares of common stock as of March 31, 2025 and December 31, 2024.

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 March 31, 2025 or December 31, 2024.

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 March 31, 2025, the Company had 2,696,825 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 months ended March 31, 2025 and 2024, the Company recognized the following stock-based compensation expense (in thousands):

	Three months ended March 31,	
	2025	2024
Stock-based compensation by type of award		
Restricted stock units (excluding PRSUs)	$ 640	$ 421
PRSUs	206	53
Stock options	2,494	3,372
Total stock-based compensation expense	$ 3,340	$ 3,846
Stock-based compensation by type of expense		
Research and development expenses	$ 1,069	$ 1,872
Selling, general and administrative expenses	2,271	1,974
Total stock-based compensation expense	$ 3,340	$ 3,846

The expense for the three months ended March 31, 2025 was inclusive of an acceleration of stock-based compensation of $405,000 related to the business realignment strategy announced in January 2025. Refer to *NOTE 15—BUSINESS REALIGNMENT* for further details.

Unrecognized Stock-Based Compensation Expense

The following table sets forth the Company's unrecognized stock-based compensation expense as of March 31, 2025, by type of award and the weighted-average period over which the Company expects to recognize the expense (in thousands):

	March 31, 2025	
	Unrecognized compensation expense	Weighted average recognition period (years)
Type of award		
Restricted stock units (excluding PRSUs)	$ 5,370	2.3
PRSUs	1,235	1.3
Stock options	21,821	2.9
Total unrecognized stock-based compensation expense	$ 28,426	

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 as of December 31, 2024	597,635	$ 9.20	1.71
Granted	490,396	6.15	
Vested	(205,481)	8.21	
Forfeited	(32,643)	8.79	
Outstanding as of March 31, 2025	849,907	$ 7.71	2.28

The 490,396 shares of RSUs granted in the three months ended March 31, 2025 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. The weighted average fair value of RSUs granted for the three months ended March 31, 2025 and 2024 was $6.15 and $10.96, respectively. The total fair value of RSUs vested during the three months ended March 31, 2025 and 2024 is $1,262,000 and $525,000, respectively. All unvested outstanding RSUs are expected to vest as of March 31, 2025.

Performance-based Restricted Stock Unit (PRSUs) Activity

The following table summarizes restricted stock units issued and outstanding:

	Performance Restricted Stock Units	Weighted average grant price	Weighted average remaining vesting life (years)
Outstanding as of December 31, 2024	54,000	$ 12.19	1.12
Granted	169,100	6.16	
Vested	—	—	
Forfeited	—	—	
Outstanding as of March 31, 2025	223,100	$ 5.66	1.31

The PRSUs of 169,100 shares issued to certain executive officers in the three months ended March 31, 2025 will vest in two equal tranches provided that in each case that the recipient remains an employee of the Company through each vesting date. The first tranche will vest on the date the Compensation Committee certifies in its discretion the Company's achievement of the addition of $50,000,000 or more in capital to the balance sheet of the Company during the period from January 17, 2025 through January 16, 2028 (the "Performance Period") through a combination of corporate financings or and/or business development initiatives, provided that the recipient remains an employee of the Company through the vesting date. The second tranche will vest on the date the Compensation Committee certifies in its discretion the Company's achievement of the successful filing of one new Investigational New Drug ("IND") application with the United Stated Food and Drug Administration for a radiopharmaceutical diagnostic or therapeutic target during the Performance Period, provided that the recipient remains an employee of the Company through the vesting date. If the performance goal for either tranche is not achieved during the Performance Period, the corresponding PRSUs will be forfeited upon expiration of the Performance Period. As of March 31, 2025, the Company deemed the vesting conditions for both tranches to be probable.

On February 11, 2025, the Company modified the performance period to be February 12, 2025 to February 12, 2027 for the PRSUs issued in February 2024 with all other vesting conditions remaining the same. The modification resulted in an immaterial impact on the Company's financial statements for the three months ended March 31, 2025. The assumptions that the Company used to determine the fair value of the PRSUs after modification in the three months ended March 31, 2025 using a Monte-Carlo simulation model were as follows:

	Three months ended March 31,	
	2025	2024
Risk-free interest rate	4.2 %	4.2 %
Expected term (in years)	2.0	3.0
Expected volatility	77.6 %	101.0 %
Expected dividend yield	— %	— %

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 as of December 31, 2024	9,924,026	$ 17.75	$ 8,086	6.54
Granted	1,255,699	6.10		
Exercised	(57,000)	2.00		
Forfeited	(158,413)	7.60		
Outstanding as of March 31, 2025	10,964,312	$ 16.65	$ 428	6.64
Exercisable as of March 31, 2025	6,857,737	$ 21.51	$ 428	5.26

All of the options granted in the three months ended March 31, 2025, have a maximum contractual term of ten years. Outstanding options consist of vested and expected to vest options. All unvested outstanding options are expected to vest as of March 31, 2025. During the three months ended March 31, 2025, 1,255,699 options were granted and have a vesting schedule in which 25% vest on the first anniversary of the grant date and the remainder vest ratably on a monthly basis over the next 36 months, provided in each case that the recipient remains an employee of the Company through each vesting date.

The weighted average fair value of stock options granted for the three months ended March 31, 2025 and 2024 was $6.10 and $8.24, respectively. The total intrinsic value of stock options exercised during the three months ended March 31, 2025 and 2024 was $199,000 and $924,000, respectively. The assumptions that the Company used to determine the fair value of the stock options granted to employees and directors in the three months ended March 31, 2025 and 2024 are set forth in the table below and presented on a weighted average basis:

	Three months ended March 31,	
	2025	2024
Risk-free interest rate	4.5 %	4.1 %
Expected term (in years)	6.3	6.3
Expected volatility	84.4 %	84.0 %
Expected dividend yield	— %	— %

NOTE 12—INCOME TAXES

During the three months ended March 31, 2025 and 2024, the Company experienced pre-tax net losses of $5,191,000 and $6,469,000. The Company's current income tax provision was $5,000 and $160,000 during the three months ended March 31, 2025 and 2024, respectively. There were no deferred income tax provisions during the three months ended March 31, 2025 and 2024.

The Company's tax returns for the years 2018 to 2023 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 months ended March 31, 2025 and 2024.

The Company has established a retirement program for employees of our Danish subsidiary pursuant to which all such employees can contribute an amount at their election from their base compensation and may receive contributions from our Danish subsidiary. The Danish subsidiary made no contributions during the three months ended March 31, 2025 and 2024. 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—SEGMENT INFORMATION

Following the business realignment strategy announced in January 2025, the Company is now organized into two reportable segments: DANYELZA and RIT. The segment results have been re-casted for all periods to reflect this realignment. The DANYELZA segment includes revenues, cost of goods sold, license royalties, research and development, and selling, general and administrative activities for DANYELZA, the Company's only FDA approved drug product. The RIT segment includes research and development, and selling, general and administrative activities for SADA PRIT platform. The Company's reportable segments are strategic business units that focus on different products and platforms. They are managed separately as each business unit requires different research and development, marketing and other operational investments. The accounting policies for the two segments are the same as those described in *Note 3 – Summary of Significant Accounting Policies*.

The Company's chief operating decision maker (the "CODM") is the Chief Executive Officer (Principal Executive Officer). For the DANYELZA and RIT reportable segments, the CODM measures and evaluates the Company's reportable segments based on segment revenues and segment profit/(loss) from operations. The CODM uses this information to evaluate the Company's business operations and allocate resources. The CODM considers budget-to-actual variances of segment net sales and segment profit /(loss) to assess performance and make decisions about allocating resources to the segments.

For the purpose of our CODM reviews, we do not consider any asset information by operating segment and, accordingly, the Company does not report asset information by operating segment.

Revenues for the three months ended March 31, 2025 and 2024 are generated by DANYELZA segment. Refer to *Note 4 – Net Product Revenue* for net product revenues by geographic and customers with over 10% net product revenues.

The Company incurred immaterial depreciation and amortization expenses for the three months ended March 31, 2025 and 2024.

Selected information by reportable segment was as follows (in thousands):

	Three Months Ended March 31,					
	2025			2024		
	DANYELZA	RIT	Total	DANYELZA	RIT	Total
REVENUES						
Net product revenue	$ 20,904	$ —	$ 20,904	$ 19,431	$ —	$ 19,431
License revenue	—	—	—	500	—	500
Total revenues	20,904	—	20,904	19,931	—	19,931
COST OF GOODS SOLD	3,001	—	3,001	2,097	—	2,097
OPERATING COSTS AND EXPENSES						
License royalties	—	—	—	50	—	50
Research and development	4,926	5,696	10,622	5,409	6,041	11,450
Selling, general, and administrative	4,156	411	4,567	3,699	—	3,699
Segment profit/(loss) from operations	$ 8,821	$ (6,107)	$ 2,714	$ 8,676	$ (6,041)	$ 2,635
Corporate and unallocated expenses - Research and development			737			1,817
Corporate and unallocated expenses - Selling, general, and administrative			8,520			7,726
Consolidated Loss from Operations			(6,543)			(6,908)
OTHER INCOME, NET						
Corporate and unallocated expenses - Interest and other income			1,352			439
CONSOLIDATED LOSS BEFORE INCOME TAXES			$ (5,191)			$ (6,469)

In addition to the significant segment expenses noted above, see below for disaggregated amounts that compromise research and development expense (in thousands):

	Three Months Ended March 31,			
	2025		2024	
	DANYELZA	RIT	DANYELZA	RIT
Outsourced manufacturing	$ 948	$ 2,286	$ 516	$ 2,240
Clinical trials	1,091	1,202	1,200	1,894
Personnel costs	1,658	1,610	1,888	1,090
Professional and consulting fees	59	33	358	18
Stock-based compensation	571	442	992	546
Information technology expenses	287	22	174	56
Other	312	101	281	197
Total segment research and development expenses	$ 4,926	5,696	$ 5,409	$ 6,041

NOTE 15—BUSINESS REALIGNMENT

On January 9, 2025, following Board approval, the Company announced a business realignment plan designed to optimize the Company's operations by realigning dedicated internal resources to two business units, with the goal of increasing operational flexibility and speed, and accelerating clinical development programs within the Company's radioimmunotherapy platform. The Company is expecting the cash payments related to the business realignment to continue into the first half year of 2026. In connection with this business realignment, the Company expects a reduction in the current workforce by up to approximately 13%, depending on whether a number of the impacted employees accept newly created positions. Severance benefits were primarily related to written arrangements in place with certain employees. In addition, affected employees were offered separation benefits in exchange for their execution of a severance agreement and general release.

Activities in accrued liabilities in connection with the business realignment were as follows (in thousands):

	Accrued Liabilities Related to Business Realignment
Balance December 31, 2024	$ 1,447
Accrued liabilities in current year	528
Payments in current year	(564)
Balance March 31, 2025	$ 1,411

The Company estimated restructuring expense of approximately $2,447,000 and $2,585,000 as of March 31, 2025 and December 31, 2024, respectively, with immaterial changes due to business needs. As of March 31, 2025, the Company has recorded $1,356,000 and $1,091,000, respectively, within research and development and selling, general and administrative, on the Consolidated Statements of Net Loss and Comprehensive Loss since the initiation of the business realignment. Expenses incurred in current year and cumulative expenses by reportable segment were as follows (in thousands):

	DANYELZA	RIT	Total
Cumulative expense incurred as of December 31, 2024	$ 1,257	$ 266	$ 1,523
Expense incurred in current year:			
Research and development expenses	347	50	397
Selling, general and administrative expenses	527	—	527
Cumulative expense incurred as of March 31, 2025	$ 2,131	$ 316	$ 2,447

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 and in our audited consolidated financial statements and related notes thereto included in our Annual Report 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, 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, and as supplemented by this Quarterly Report, 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. 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 radioimmunotherapy, and antibody-based therapeutic products for the treatment of cancer. We are leveraging our proprietary radioimmunotherapy and antibody platforms, and our deep expertise in the field of radioimmunotherapy and antibodies to develop a broad portfolio of innovative medicines largely in the space of pretargeted radio-isotope labeled therapeutics.

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

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. Our DANYELZA U.S. patent expires in February 2034.

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. The confirmatory post-marketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which is required to enroll a minimum of 80 evaluable patients with evaluable disease, with a minimal follow-up of 12 months from the onset of Complete Response/Partial Response, which is equivalent to at least a total 122 patients in Study 201. The study will report ORR, DOR, PFS and OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint, and PFS and OS are secondary endpoints in long-term follow-up. We have enrolled 110 patients, and we anticipate completing the study in 2028.

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. On November 24, 2024 MSK published an abstract at Connective Tissue Oncology Society using DANYELZA Anti-Gd2

Antibody in an ISS multi-center osteosarcoma trial (Study 15-096). Per the results of this trial, the data missed the established end point of 12-month event free survival, or EFS, of 40%. The underlying EFS response rates were as follows:

- Overall population 14 out of 39 patients – 12-month EFS: 36%
- 2nd CR: 37%
- 3rd CR: 33%

Looking into further association between 12-month EFS and GD2 expression

- 5 of 16 GD2 positive patients (31%) were event free at 12 months
- 4 of 8 GD2 positive patients (50%) with 4+ staining intensity were event free at 12 months

We believe that this data shows DANYELZA's potential to serve a high unmet need within osteosarcoma where survival rates have shown little or no improvement in decades. With the current standard of care, 12-months EFS is typically approximately 20% (as reported in various published reports). We also believe that the data supporting the use of DANYELZA for targeting GD2 is very compelling and worth further development. We are considering the advancement of a diagnostic tool for GD2, which could prove to be a valuable tool for a potential pivotal trial in this or other GD2 related indications.

In advanced breast cancer, we are partnering with the Ohio State University on a Phase 1b/2 trial investigating TGFβ natural killer, or NK cells, gemcitabine plus naxitamab in patients with GD2-positive, HER2-negative metastatic breast cancer. The recruiting for patients was initiated in the third quarter of 2024. Evaluation of dose-limiting toxicities with the combination of gemcitabine and NK cells, and the persistence of NK cells in the blood, will be followed by the addition of naxitamab. Upon the outcome of this trial, we may consider moving forward with a multi-center Phase 2 trial.

In patients with GD2-positive 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. Four patients have been treated in the naxitamab arm and recruitment is ongoing as of March 31, 2025. A total of 16 patients are expected in the naxitamab arm. The trial is expected to complete in 2028.

In addition, we are in discussions with the MD Anderson 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 the second half year of 2025, is anticipated to further inform us on a future Phase 2 program in Triple Negative Breast Cancer.

Our GD2-SADA, a first-in-class investigational therapy targeting GD2 in solid tumors, is being evaluated in an ongoing Phase 1 clinical trial.

The first patient was dosed in April 2023 as part of an ongoing dose-escalation study across multiple cancer types, including small cell lung cancer, sarcoma, and malignant melanoma. Recently, the trial expanded to include adolescent patients (16 years and older) with high-risk neuroblastoma (NB). The sixth patient cohort commenced treatment in the fourth quarter of 2024 and has recently been closed.

The study uses a radioactive payload up to 200 mCi and a two to five days interval between the GD2-SADA protein and the radioactive payload. The initial blood pharmacokinetic ("PK") profile of the construct in these patients dosed with 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.

To date, GD2-SADA has been well-tolerated across multiple dose cohorts, with no dose-limiting toxicities or treatment-related serious adverse events reported.

Our second investigational therapy in Phase I clinical trials targets CD38-SADA in hematological tumors for patients with Relapsed or Refractory Non-Hodgkin Lymphoma. The first patient was dosed in April 2025.

We believe 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 2025, we announced a business realignment plan designed to optimize our operations by aligning dedicated internal resources to two business units, with the goal of increasing operational flexibility and speed, and accelerating clinical development within our radiopharmaceutical platform. Please refer to *NOTE 15— BUSINESS REALIGNMENT* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Quarterly Report.

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 8. Financial Statements and Supplementary Data in our Annual Report.

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 March 31, 2025 and December 31, 2024, we had an accumulated deficit of $492.3 million and $487.1 million, respectively. We experienced net losses of $5.2 million and $6.6 million for the three months ended March 31, 2025 and 2024, respectively. We have incurred significant net operating losses in every year since our inception. We expect our net operating losses to continue in the future until, if ever, our DANYELZA product revenue provides sufficient funds 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 our lead product candidates through the regulatory process both in the U.S. and internationally;
- continue to advance our other product candidates through pre-clinical and clinical development;
- 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.

We expect that the manufacturer of the DANYELZA drug substance will transition the manufacturing from its facility in Greenville, North Carolina, to a facility in Monza, Italy and that no DANYELZA drug product will be manufactured from the date manufacturing ceases in Greenville, North Carolina, which is estimated to be in the second half of 2026, until the new facility becomes FDA approved to produce and begin production of the DANYELZA drug product. We expect to experience higher production costs and inventory levels, including as a result of tariffs, with respect to drug product produced after the planned transition.

Components of Our Results of Operations

Net Product Revenue

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. Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the notes to the consolidated financial statements included in Item 8. Financial Statements and Supplementary Data in our Annual Report.

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.

Operating Costs and Expenses

License royalties

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

Research and development

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

- sponsored research, laboratory facility services, clinical trial and data service at MSK under the Sponsored Research Agreements, or the SRAs, the two CFSAs, the MCTA, and the MDSA, with MSK;
- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our non-clinical and pre-clinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical study and clinical trial materials, including manufacturing of validation batches;
- upfront, milestone and other non-revenue related payments due under our third-party 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 the 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 or we could determine to cease development of that product candidate altogether.

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, inclusive of 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. Our research and development expenses is expected to stay consistent in 2025 as compared to 2024.

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 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 accounting policies is included in *NOTE 3— SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the notes to the Item 8. Financial Statements and Supplementary Data in our Annual Report, supplemented by *NOTE 3— SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in this Quarterly Report for the three months ended March 31, 2025.

For a discussion of critical accounting policies, see the section titled "*Critical Accounting Policies and Significant Judgments and Estimates*" in Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations in our Annual Report.

Results of Operations

Comparison of the Three Months Ended March 31, 2025 and 2024

The following table summarizes our results of operations for the three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
REVENUES				
Net product revenue	$ 20,904	$ 19,431	$ 1,473	8 %
License revenue	—	500	(500)	N/A
Total revenues	20,904	19,931	973	5 %
COST OF GOODS SOLD	3,001	2,097	904	43 %
GROSS PROFIT	17,903	17,834	69	0 %
OPERATING COSTS AND EXPENSES				
License royalties	—	50	(50)	N/A
Research and development	11,359	13,267	(1,908)	(14)%
Selling, general, and administrative	13,087	11,425	1,662	15 %
Total operating costs and expenses	24,446	24,742	(296)	(1)%
Loss from operations	(6,543)	(6,908)	365	(5)%
OTHER INCOME, NET				
Interest and other income	1,352	439	913	208 %
LOSS BEFORE INCOME TAXES	(5,191)	(6,469)	1,278	(20)%
Provision for income taxes	5	160	(155)	(97)%
NET LOSS	$ (5,196)	$ (6,629)	$ 1,433	(22)%

Revenues

Net product revenue

Our net product revenue was generated from sales of DANYELZA and consists of the following:

	Three months ended March 31,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
Net product revenue by geographical location:				
United States	$ 13,381	$ 18,610	$ (5,229)	(28)%
Ex-U.S.:				
Eastern Asia	1,507	51	1,456	2,855 %
Latin America	2,013	508	1,505	296 %
Western Asia	3,838	—	3,838	N/A
Other regions	165	262	(97)	(37)%
Total Ex-U.S.	7,523	821	6,702	816 %
Total net product revenue	$ 20,904	$ 19,431	$ 1,473	8 %

Our net product revenue increased from $19.4 million to $20.9 million for the three months ended March 31, 2025 when compared to the same period in 2024. Our Ex-U.S. DANYELZA net product revenues for the three months ended March 31, 2025 were $7.5 million, representing an increase of $6.7 million from the same period in 2024. The increase in the Ex-U.S. DANYELZA net product revenues was driven by a $3.8 million increase in net product revenues in Western Asia, where the named patient program launched in late 2024, and increased net product revenues in Eastern Asia, where a new marketing initiative program was introduced in late 2024, and Latin America regions.

Our U.S. DANYELZA net product revenues for the three months ended March 31, 2025 were $13.4 million, representing a decrease of 28% from the same period in 2024. The decline in the U.S. DANYELZA net product revenues was driven by enrollments in clinical studies and market dynamics.

We recognized royalty revenue from our distribution partners of $1.9 million and $0.5 million for the three months ended March 31, 2025 and 2024, respectively. The increase in royalty revenue was primarily due to increased sales in Ex-U.S. regions.

License revenue

There is no license revenue for the three months ended March 31, 2025. 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 first quarter of 2024.

Cost of Goods Sold

Our cost of goods sold includes direct and indirect costs related to the manufacturing and distribution of DANYELZA, including amounts related to materials, third-party manufacturing costs, packaging services, freight, labor costs for personnel involved in the manufacturing process, third-party royalties payable on our net product revenues, charges for excess and obsolete inventory reserves and inventory write-off.

Cost of goods sold was $3.0 million and $2.1 million for the three months ended March 31, 2025 and 2024, respectively. The increase in cost of goods sold in the three months ended March 31, 2025 compared to the same period in 2024, was driven by increased volume in Ex-U.S. regions which carry a lower gross margin.

Gross Profit

Gross profit was $17.9 million and $17.8 million for the three months ended March 31, 2025 and 2024, respectively.

Gross margins are 86% and 89% for the three months ended March 31, 2025 and 2024, respectively. Gross margin from total revenues decreased in the three months ended March 31, 2025, which was mainly attributable to the decreased U.S. net product revenue, which are at higher margins compared to our Ex-U.S. regions.

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 March 31, 2025. We incurred license royalty expense of $0.1 million during the three months ended March 31, 2024 in connection with the price approval from CMED in January 2024.

Research and Development

Research and development expenses consist of the following:

	Three Months Ended March 31,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
Outsourced manufacturing	$ 3,261	$ 2,636	$ 625	24 %
Clinical trials	2,291	3,086	(795)	(26)%
Personnel costs	3,461	3,653	(192)	(5)%
Professional and consulting fees	135	362	(227)	(63)%
Stock-based compensation	1,069	1,818	(749)	(41)%
Information technology expenses	528	712	(184)	(26)%
Other	614	1,000	(386)	(39)%
Total research and development	$ 11,359	$ 13,267	$ (1,908)	(14)%

Research and development expenses were $11.4 million and $13.3 million for the three months ended March 31, 2025 and 2024, respectively. The $1.9 million decrease in research and development expenses was primarily attributable to a decrease of $0.7 million in clinical trials due to the timing of completion in our GD2-SADA program and investment in our ongoing SADA PRIT programs, and a $0.9 million decrease in personnel costs and stock-based compensation costs, partially offset by a $0.6 million increase in outsourced manufacturing for investment in our naxitamab programs.

Selling, General, and Administrative

Selling, general, and administrative expenses were $13.1 million for the three months ended March 31, 2025, as compared to $11.4 million for the three months ended March 31, 2024. The $1.7 million increase in selling, general, and administrative expenses was primarily attributable to a $0.8 million increase in personnel costs and stock-based compensation costs, a $0.5 million charge related to our business realignment expense recorded in the three months ended March 31, 2025, as detailed in *NOTE 15— BUSINESS REALIGNMENT* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Quarterly Report, and a $0.4 million increase in legal expenses.

Interest and Other Income

Interest and other income for the three months ended March 31, 2025 was $1.4 million compared to $0.4 million for the three months ended March 31, 2024. Our interest and other income increased by $1.0 million primarily due to a $1.3 million increase in foreign currency transaction gains, partially offset by $0.3 million decrease in interest from money market fund investments.

Provision for Income Taxes

Provision for income taxes was $5,000 for the three months ended March 31, 2025 compared to $0.2 million for the three months ended March 31, 2024. The decrease in provision for income taxes was primarily driven lower estimated pre-tax loss in U.S. after business realignment announced in January 2025.

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 March 31, 2025 and December 31, 2024, we had cash and cash equivalents of $60.3 million and $67.2 million, respectively. On March 4, 2025, we entered into an Equity Distribution Agreement with Oppenheimer & Co. Inc. (the "Sales Agent"), under which we may issue and sell up to $35.0 million of our common stock through or to the Sales Agent (the "Sales Agreement") in at-the-market transactions. There were no sales of our shares under this agreement for the three months ended March 31, 2025.

We estimate that our cash and cash equivalents will be sufficient to fund operations as currently planned into 2027. This estimate is based on our current business plan, and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. This estimate assumes no income from new partnerships or other new business development activities or sale of our common stock under the Sales Agreement. We cannot provide any assurance that we will be able to obtain additional capital from additional equity or debt financings, 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 three months ended March 31, 2025 and 2024:

	Three Months Ended March 31,		Change	
	2025	2024	Amount	Percent
	(in thousands)			
Net cash used in operating activities	$ (6,911)	$ (3,477)	$ (3,434)	99 %
Net cash used in investing activities	(127)	—	(127)	N/A
Net cash from financing activities	114	588	(474)	(81)%
Effect of exchange rates on cash and cash equivalents	—	1	(1)	N/A
Net decrease in cash and cash equivalents	$ (6,924)	$ (2,888)	$ (4,036)	140 %

Net Cash Used In Operating Activities

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

Net cash used in operating activities was $6.9 million for the three months ended March 31, 2025, as compared to net cash used in operating activities of $3.5 million for the three months ended March 31, 2024. The $3.4 million increase in cash used in operating activities was primarily driven by an increase in cash used for working capital, including increased inventories, and payments of outstanding accounts payable and accrued liabilities during the three months ended March 31, 2025 compared to the corresponding period in 2024.

Net Cash Used In Investing Activities

Net cash used in investing activities was $0.1 million for the three months ended March 31, 2025. We did not generate or use cash for investing activities during the three months ended March 31, 2024.

Net Cash From Financing Activities

Net cash from financing activities was $0.1 million and $0.6 million for the three months ended March 31, 2025 and 2024, respectively, and consisted of proceeds from the exercise of stock options in both periods.

Funding Requirements

Our cash and cash equivalents were $60.3 million as of March 31, 2025. We estimate that our cash and cash equivalents will be sufficient to fund operations as currently planned into 2027. This estimate is based on our current business plan and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

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 further developing DANYELZA, and conducting pre-clinical studies and clinical trials for our SADA 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 potentially through a combination of securities offerings, debt financing, collaborations, strategic alliances and licensing or other arrangements, or a combination thereof. Further, adequate additional financing may not be available to us on acceptable terms, required timing, 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 Quarterly Report.

For a discussion of our material license agreements, see the *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* in the notes to the consolidated financial statements included in Item 8. Financial Statements and Supplementary Data in our Annual Report.

Research and development is inherently uncertain and, should such research and development fail, the MSK License 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 or the SADA License. We have entered into sublicenses and distribution agreements with Swixx for the Eastern Europe region in 2020, SciClone for the Eastern Asia region in 2020, Takeda for Israel in 2020, Adium for the Latin America region in 2021, WEP for the Western Europe region in 2022, INPHARMUS for Turkey in 2024 and Nobelpharma for Japan 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

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. We may also experience potential cost increases, supply delays or issues with collaborators or clinical trials in other countries due to current and potential sanctions imposed by the U.S. and other governments. Recently, the U.S. government has imposed, and is expected to impose additional, restrictions on international trade, such as tariffs on goods generally, and pharmaceutical and biological products in particular, imported into the U.S. In response, certain foreign governments, including China, have announced or implemented retaliatory tariffs, trade restrictions, trade barriers and/or other protectionist measures.

We conduct our business globally and have third-party suppliers located outside of the U.S., including countries in Eastern Asia, Western Europe, Latin America, Western Asia and other regions. In addition, as discussed above, we anticipate that the manufacturer of DANYELZA drug substance will transition manufacturing from its facility in Greenville, North Carolina, to a facility in Monza, Italy in the second half of 2026. We have obtained and plan to continue to seek regulatory approval of our product candidates outside of the United States, and we have commercialization arrangements in territories outside the United States. We cannot at this time predict the ultimate impact of such trade restrictions and tariffs, and we may experience increased costs as a result. Given the volatility and uncertainty regarding the scope and duration of such tariffs and other aspects of United States and foreign government trade policies, the ultimate impact on our operations and financial results remains uncertain and could be significant. See "Our business, financial condition and results of operations have been and may in the future be adversely affected by pandemics or similar health crises, macroeconomic conditions, including tariffs and escalating trade tensions, and by geopolitical events." and "A variety of risks associated with operating our business internationally, including through collaboration partners, could materially adversely affect our business." in Part II, Item 1A of this Quarterly Report.

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 March 31, 2025.

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 March 31, 2025, 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.

The information called for by this item is incorporated herein by reference to *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* in the notes to the consolidated financial statements included in Item 1. Financial Statements in this Quarterly Report.

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. Our risk factors disclosed in Part I, Item 1A of our Annual Report provide additional discussion regarding these supplemental risks and we encourage you to read and carefully consider all of the risk factors disclosed in those sections, together with the below, for a more complete understanding of the risks and uncertainties material to our business.

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

The biotechnology and pharmaceutical industries generally, and the cancer drug sector specifically, are characterized by rapidly advancing technologies, evolving understanding of disease etiology, intense competition and a strong emphasis on intellectual property. While we believe that our product candidates and our knowledge and experience provide us with competitive advantages, we face substantial potential competition from many different sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced manufacturing organizations as well as established marketing and sales forces. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized, or less costly than DANYELZA, or our other product candidates, or may develop proprietary technologies or secure patent protection that we may need for the commercialization of DANYELZA and the development of our product candidates and related technologies.

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

With respect to DANYELZA, which targets GD2-positive tumors, United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin® (dinutuximab), an antibody against GD2, in the United States, Canada and Japan. Although United Therapeutics has discontinued its efforts to investigate Unituxin®'s potential activity against

adult cancerous tumors, it has maintained its efforts to develop a humanized version of Unituxin® and plans to develop Unituxin® within R/R NB. DANYELZA also faces competition from Qarziba® (dinutuximab beta) a similar antibody product against GD2 developed by Apeiron Biologics AG. EUSA Pharma (UK) Ltd., or EUSA, has acquired global commercialization rights to Qarziba® (dinutuximab beta), and it is currently being commercialized in the European Union and was approved by the European Commission to treat high-risk NB and R/R NB. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba® in mainland China and in August 2021 EUSA and BeiGene announced that the China National Medical Products Administration, or NMPA, had granted Qarziba® (dinutuximab beta) conditional marketing approval for the treatment of high-risk NB and R/R NB. EUSA has previously announced plans to file for registration of dinutuximab beta in the United States for the treatment of R/R NB. EUSA was acquired by Recordati in March 2022. In addition, Renaissance Pharma Ltd in the United Kingdom announced in August 2023 a development program focused on Hu14.18, a humanized anti-GD2 monoclonal antibody, licensed from St. Jude Children's Research Hospital for the treatment of newly diagnosed high-risk neuroblastoma. US WorldMeds has also received FDA approval of eflornithine hydrochloride, to reduce the risk of relapse in pediatric patients with high-risk neuroblastoma who have completed multiagent, multimodality therapy.

The SADA PRIT technology, which utilizes bispecific fusion proteins that bind to tumor cells before a radioactive payload is injected in a two-step approach, faces competition from a range of companies investigating antibody or antibody-fragment based development paradigms for comparable one-two-or-three step approaches. We believe our major competitors include Roche Sequencing Solutions, Clarity Pharmaceuticals, OncoOne Research & Development GmbH, Perspective Therapeutics, Curium SAS, Cellectar Biosciences, ITM Isotope Technologies Munich SE, Actinium Pharmaceuticals, Inc Lantheus , Blue Earth Therapeutics and Tagworks Pharmaceuticals which may change in the future.

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, the Inflation Reduction Act of 2022, or IRA, was signed 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. In the U.S., reductions in staffing and funding at the FDA and other governmental agencies may adversely impact agency review times. 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 contemplates a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as CROs, may impact our development plans.

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 European Commission proposals to revise the existing EU laws governing authorization of medicinal products may result in a decrease in data and market exclusivity opportunities for our product candidates in the EU and make them open to generic or biosimilar competition earlier than is currently the case with a related reduction in reimbursement status.

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

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

We expect that coverage and reimbursement of pharmaceutical products may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. In particular, drug pricing by pharmaceutical companies has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source biologics that have been on the market for at least 11 years and covered under Medicare, and subject manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such biologics under the law (the "Medicare Drug Price Negotiation Program"), and (ii) imposes rebates with respect to certain products covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the Medicare drug price negotiation program is currently subject to legal challenges. These provisions began to take effect progressively starting in fiscal year 2023. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiation, which take effect in January 2026. On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework.

The current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the Centers for Medicare & Medicaid Services, or CMS, and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions include, for example, directives to reduce agency workforce, program cuts, rescinding a Biden administration executive order tasking the Center for Medicare and Medicaid Innovation to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration's executive order that directed HHS to establish an AI task force and develop a strategic plan, directing HHS and other agencies to lower prescription drug costs for Medicare through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program, and directing certain federal agencies to enforce existing law regarding hospital and price plan transparency and by standardizing prices across hospitals and health plans. Additionally, in its June 2024 decision in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under the IRA. The foregoing may effectively reduce the price at which DANYELZA, or our other product candidates, if approved, is sold, which would have a negative adverse effect on our revenues.

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

We have obtained and plan to continue to seek regulatory approval of our product candidates outside of the United States. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone, Takeda Israel, Swixx Biopharma AG, Adium and WEP. In addition, we have entered into distribution agreements with INPHARMUS and Nobelpharma in 2024. Moreover, we currently have operations in the United States and Denmark, we maintain relationships with CMOs in the United States as well as other parts of Europe for the manufacture of SADA PRIT product candidates, and the manufacturer of the DANYELZA drug substance currently plans to move the manufacture of the DANYELZA drug substance from the U.S. to Italy in the second half of 2026. Accordingly, we and our existing and potential collaborators in jurisdictions outside the U.S., are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;
- tariffs, potential new or additional tariffs and escalating trade tensions, trade barriers, price and exchange controls, and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;
- foreign taxes, including local transfer pricing regulations and withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the FCPA, or OFAC, Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

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

Our business, financial condition and results of operations have been and may in the future be adversely affected by pandemics or similar health crises, macroeconomic conditions, including tariffs and escalating trade tensions, and by geopolitical events.

Our financial condition, results of operations, business and cash flow may be negatively affected by general conditions in the global economy and in the global financial markets and uncertainty about economic stability. The global economy has experienced extreme volatility and disruptions, including as a result of inflationary conditions and escalating trade tensions, as well as from international conflicts, terrorism and other geopolitical events.

The current international trade and regulatory environment is subject to significant ongoing uncertainty. The U.S. government has recently announced substantial new tariffs affecting a wide range of products and jurisdictions and has indicated an intention to continue developing new trade policies, including with respect to the pharmaceutical industry. In response, certain foreign governments have announced or implemented retaliatory tariffs and other protectionist measures. These developments have created a dynamic and unpredictable trade landscape, which may adversely impact our business, results of operations, financial condition and prospects.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of DANYELZA and our product candidates for commercialization and clinical testing. Currently, several of our suppliers are located outside of the U.S., and our principal suppliers of critical raw materials are located in the Netherlands. The active pharmaceutical ingredients (APIs) for DANYELZA is manufactured in the United States and will be transitioned to Italy in 2026, and our SADA PRIT product candidate is manufactured in Italy and Germany. We also rely on specialized laboratory equipment, supplies, materials, and precursor compounds, all or part of which we believe may be ultimately sourced from multiple countries outside the U.S., to advance our research and development efforts. While we cannot at this time predict the ultimate impact of tariffs and other trade restrictions, our margins may be adversely affected, depending on the ultimate scope and duration of tariffs imposed. While we may seek to increase prices for DANYELZA as a result of such tariffs, such price adjustments could reduce the competitiveness of DANYELZA and our ability to secure and maintain reimbursement coverage for DANYELZA, which could act to limit the prices that we charge, limit the commercial opportunities for DANYELZA, and/or negatively impact revenues from sales of DANYELZA. Additionally, it is expected that such tariffs and other trade restrictions will result in additional costs to our business, including costs with respect to APIs and other raw materials and will generally increase our manufacturing and research and development costs.

Such tariffs and trade restrictions will also increase our supply chain complexity and could also potentially disrupt our existing supply chain. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased costs and extended commercialization and development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. Given the volatility and uncertainty regarding the scope and duration of such tariffs and

other aspects of U.S. and foreign government trade policies, the ultimate impact on our operations and financial results is uncertain and could be significant. In any event, further trade restrictions and export regulations, or new or increased tariffs, including further retaliatory measures, could increase our supply chain complexity and our manufacturing costs, decrease our margins, reduce the competitiveness of DANYELZA, or restrict our ability to sell DANYELZA, or purchase necessary supplies. Any of these factors could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In addition, the complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the United States or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the U.S. and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and may impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and prospects. In addition, trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Quarterly Report and in our Annual Report.

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

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

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, droughts, floods, hurricanes, typhoons, fires, extreme weather conditions, climate change events, medical epidemics, terrorist activities, wars or other armed conflicts, geopolitical tensions and related sanctions, and the potential resumption of the conflict between Hamas and Israel and a potential larger conflict, cyber security attacks and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured, and other severe hazards or global health crises, such as an outbreak of Ebola or COVID-19, or other actual or threatened epidemic, pandemic, outbreak and spread of a communicable disease or virus, and/or increased tariff imposed on certain U.S. imports and trade restrictions, in the countries where we operate or plan to sell our products, if approved, could

adversely affect our operations and financial performance. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process DANYELZA, and our product candidates. We currently have operations in the United States and Denmark. Additionally, we maintain relationships with CMOs in the United States as well as other parts of Europe for the manufacture of SADA PRIT product candidates and we expect the manufacturer of the DANYELZA drug substance to move the manufacture of the DANYELZA drug substance from the U.S. to Italy in the second half of 2026. Our ability to obtain commercial supplies of DANYELZA and clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or other business interruption, and we anticipate that our ability to obtain commercial and clinical supplies of DANYELZA will be interrupted in connection with the transition of production of DANYELZA drug product from our supplier Patheon/Thermo Fisher's manufacturing facility in Greenville, North Carolina to its manufacturing facility in Monza, Italy . See the risk factor titled "We rely on third parties to manufacture DANYELZA for commercial and clinical supply and our product candidates, including our antibody constructs based on the SADA PRIT Technology, for our ongoing and planned pre-clinical studies and clinical studies. Our business could be harmed if third parties fail to provide us with enough DANYELZA or our other product candidates, including our antibody constructs based on the SADA PRIT Technology, or fail to do so at acceptable quantities, quality levels or prices or fail to maintain adequate compliance with CMC guidelines of the FDA and comparable foreign regulatory authorities. Our third-party manufacturers have in the past and may in the future experience manufacturing difficulties, and any such difficulties could harm our business." in our Annual Report for further information. Damage or extended periods of interruption to our third-party collaborators', including MSK's, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we intend to maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. The ultimate extent of the impact of any epidemic, pandemic or other global health crisis, such as COVID-19, on our business, financial condition and results of operations will depend on future developments which are highly uncertain and cannot be predicted, including new information that may emerge concerning the duration and severity of such epidemic, pandemic or other global health crisis, actions taken to contain or prevent their further spread and the pace of global economic recovery following containment of the spread.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits

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

3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities and Exchange Commission on September 26, 2018)
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Registrant's Current Report on Form 8-K (File No. 001-38650) filed with the Securities and Exchange Commission on September 26, 2018)
10.1	Equity Distribution Agreement, dated March 4, 2025, by and between the Registrant and Oppenheimer & Co. Inc. (incorporated by reference to Exhibit 1.1 to the Registrant's Form 8-K filed, March 4, 2025)
10.2	Amended and Restated Non-Employee Director Compensation Policy, effective March 18, 2025 (incorporated by reference to Exhibit 10.44 to the Registrant's Amendment No. 1 on Form 10-K/A filed, April 29, 2025)
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.

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: May 13, 2025

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

Dated: May 13, 2025

By: /s/ Peter Pfreundschuh
Name: Peter Pfreundschuh
Title: Chief Financial Officer and Treasurer
(Principal Financial and Accounting 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: May 13, 2025

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: May 13, 2025

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 March 31, 2025 (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: May 13, 2025

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

Exhibit 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

(i) the accompanying Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2025 (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: May 13, 2025

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