UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022.

OR

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

For the transition period from to

Commission file number 001-38650

Y-mAbs Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-4619612**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
230 Park Avenue, Suite 3350 New York, NY	**10169**
(Address of Principal Executive Offices)	(Zip Code)

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

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	The Nasdaq Global Select Market

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

NONE
(Title of class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes ☐ No ☒

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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§299.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a 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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined by Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

As of June 30, 2022 the aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of a share of common stock as reported by the Nasdaq Global Select Market on such date, was approximately $551 million. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose. The number of outstanding shares of the registrant's common stock as of March 23, 2023 was 43,677,767.

Documents Incorporated by Reference:

Portions of the Registrant's Definitive Proxy Statement relating to the 2023 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission within 120 days after the end of the Registrant's fiscal year ended December 31, 2022 are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the 2023 Proxy Statement expressly incorporated into this Annual Report on Form 10-K by reference, such document shall not be deemed to constitute part of this Annual Report on Form 10-K.

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FORWARD LOOKING STATEMENTS.

This Annual Report on Form 10-K 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 Annual Report on Form 10-K, 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 largely on our current expectations and projections about future events and trends that we believe may affect our financial condition, results of operations, business strategy, short-term and long-term business operations and objectives, and financial needs. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in Part I, Item 1A, "Risk Factors" in this Annual Report on Form 10-K. 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 Annual Report on Form 10-K may not occur and actual results could differ materially and adversely 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 make. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the “Risk Factors” section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, licensing agreements, collaborations, joint ventures or investments that we may make.

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

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

SUMMARY OF RISK FACTORS

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

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

- We may not be able to successfully commercialize DANYELZA® (naxitamab-gqgk), referred to as DANYELZA, for the treatment of relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow, in the United States or in any other jurisdictions where we may receive marketing approval in the future;
- We may not be able to successfully implement our business model and our plans to obtain regulatory approval and develop and commercialize our other product candidates, including the potential clinical efficacy, safety and other benefits thereof;
- Our expectations with respect to the rate and degree of market acceptance and clinical utility for DANYELZA or any current or future product candidate for which we may receive marketing approval may not be realized;
- We may not be successful in obtaining approval of our product candidates and expectations with respect to the commercial value of any of our product candidates may not be realized;
- We may not be successful in implementing our business strategy, including our ability and plans in continuing to build out our commercial infrastructure and successfully launching, marketing, and selling DANYELZA and any current or future product candidate for which we may receive marketing approval, including our plans with respect to the focus and activities of our sales force, the nature of our marketing, market access and patient support activities of DANYELZA and related assumptions;
- Expectations with respect to the pricing, coverage and reimbursement of, and the extent to which patient assistance programs are utilized for DANYELZA or other product candidate for which we may receive marketing approval may not be realized;
- Expectations with respect to our ongoing and future clinical trials for DANYELZA and other product candidates, whether conducted by us or by any of our collaborators, may not be realized, including the timing of initiation of these trials, the pace of enrollment, the completion of enrollment, the availability of data from, and the outcome of, these trials, and expectations with respect to regulatory submissions and potential regulatory approvals may not be realized on the anticipated timing or at all;
- We may be unable to attract, integrate, manage and retain qualified personnel or key employees;
- We may not realize the expected benefits from our recent business restructuring and workforce reduction and we may incur additional costs implementing it or other difficulties;
- Expectations with respect to the timing of and our ability to obtain and maintain regulatory, marketing and reimbursement approvals for our product candidates may not be realized;
- We may be unable to successfully implement our commercialization, marketing and manufacturing capabilities and strategy;
- If we are unable to establish and maintain sufficient intellectual property position, strategy and scope of protection for the intellectual property rights covering our product candidates and technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours and our ability to successfully commercialize our products, product candidates and other proprietary technologies, if approved, may be adversely affected;
- We may be unable to identify and develop additional product candidates and technologies with significant commercial potential;
- We may be unable to enter into collaborations or strategic partnerships for the development and commercialization of our product candidates and future operations, and the potential benefits of any such collaboration or partnership may not be realized;
- We are dependent on our ability to continue to maintain and leverage our relationship with Memorial Sloan Kettering Cancer Center, or MSK, including our exclusive rights to the 2015 MSK License

Agreement (as amended), or MSK License, the 2020 SADA Technology License Agreement, or SADA License Agreement, and current and future technology and our relationship with MSK as a user of DANYELZA and any future products;

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

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

PART I

ITEM 1. BUSINESS.

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

Our only approved drug DANYELZA® (naxitamab-gqgk) received accelerated approval by the United States Food and Drug Administration, or the FDA, in November 2020 for the treatment, in combination with Granulocyte-Macrophage Colony-Stimulating Factor, or GM-CSF, of pediatric patients one year of age and older and adult patients with relapsed or refractory, or R/R, high-risk neuroblastoma, or NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. We are commercializing DANYELZA in the United States and began shipping in February 2021. In December 2022, we announced a distribution agreement with WEP Clinical Ltd., or WEP, in connection with an early access program for DANYELZA in Europe and

in January 2023, the European Medicines Agency, or EMA, agreed to our proposed Pediatric Investigation Plan, or PIP, for naxitamab.

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

We submitted a Biologics License Application, or BLA, to the FDA for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We held a number of Type B meetings with the agency, including a pre-BLA meeting in January 2022, before we resubmitted the BLA for omburtamab in March 2022. In October 2022 we met with the FDA's Oncologic Drugs Advisory Committee, or ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In November 2022, we received a complete response letter, or CRL, for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

We are using our proprietary SADA BiDE (2-step Self-Assembly and DisAssembly Bispecific DOTA Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA Technology, a concept we also refer to as Liquid Radiation™, to advance a series of antibody constructs, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach. We have designated GD2-SADA for potential use in GD2-positive solid tumors as our first SADA constructs and filed an Investigational New Drug Application, or IND, for GD2-SADA in December 2021. We obtained clearance for the IND in July 2022. We have secured clinical supplies for a medical radioisotope no-carrier-added, or n.c.a., lutetium-177 from ITM Isotope Technologies Munich SE, or ITM, who will provide its n.c.a. ^{177}Lu for phase 1-3 clinical development of GD2-SADA. We announced our first hematological target CD38-SADA in December 2022, and expect to submit an IND for this construct in 2023. We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.

In January 2023 we announced a strategic restructuring plan designed to extend our cash resources and prioritize resources on the commercialization and potential label extension of DANYELZA and development of the SADA technology platform. In addition to deprioritizing the omburtamab program for all indications and product candidates, we have deprioritized other pipeline programs, including activities relating to GD2-GD3 Vaccine and CD33 bispecific antibody constructs by delaying trial initiation and overall timelines as part of the restructuring plan. The restructuring plan includes a reduction of our workforce by approximately 35% and is expected to be completed by the end of May 2023.

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

DANYELZA

DANYELZA, our first FDA-approved product is a recombinant humanized immunoglobulin G, subtype 1k, or IgG1κ, monoclonal antibody or mAb that targets ganglioside GD2, which is highly expressed in various

neuroectoderm-derived tumors and sarcomas. DANYELZA received regulatory approval by the FDA in November 2020 for the treatment, in combination with GM-CSF, of pediatric patients 1 year of age and older and adult patients with R/R high-risk NB in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. We are commercializing DANYELZA in the United States and began shipping it in February 2021. Sales of DANYELZA for the years ended December 31, 2022 and 2021 were $49.3 million and $32.9 million. In July 2021, SciClone Pharmaceuticals International Ltd., or SciClone, submitted a BLA for DANYELZA for the treatment of patients with R/R high-NB to the National Medical Products Administration, or NMPA, of China and the BLA was approved in December 2022.

In addition, DANYELZA is currently being studied in several clinical trials, including a pivotal-stage multicenter trial (Study 201) which is also designed to satisfy the confirmatory study and post-marketing requirements by the FDA, and a Phase 2 clinical trial (Study 15-096) for relapsed osteosarcoma. DANYELZA was also studied in a Phase 2 clinical trial (Study 16-1643) in front-line NB and a pilot study (Study 17-251) of chemoimmunotherapy for high-risk NB.

We believe DANYELZA has multiple potential advantages over other GD2-targeting antibody-based therapies. In particular, its toxicity profile allows for doses two-and-a-half times greater than existing GD2-targeting antibody-based therapies. Unlike currently approved GD2-targeting therapies for NB, which require 10 to 20 hours of infusion and hospitalization for several days, DANYELZA is administered in approximately 30 to 60 minutes in an outpatient setting. We believe this significantly shorter administration time is an important advantage considering the overall pain associated with treatment.

Other than DANYELZA, there are no FDA-approved therapies for primary refractory or second-line pediatric NB patients. DANYELZA has also received orphan drug designation, or ODD, and rare pediatric disease designation, or RPDD, from the FDA for the treatment of NB. In addition, DANYELZA has received breakthrough therapy designation, or BTD, in combination with GM-CSF, for the treatment of high-risk NB refractory to initial therapy or with incomplete response to salvage therapy in patients greater than 12 months of age with persistent, refractory disease limited to bone marrow with or without evidence of concurrent bone involvement. In 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB, and in 2023 the EMA agreed to the Company's proposed PIP for naxitamab.

While our current clinical efforts for DANYELZA are focused on rare pediatric cancers, we believe that we can potentially expand its application to the treatment of adults with cancers that express GD2. We estimate that there were more than 200,000 new adult patients diagnosed with GD2-positive cancers in the United States in 2022.

Omburtamab

Omburtamab is a murine monoclonal antibody that targets B7-H3, an immune checkpoint molecule that is widely expressed in tumor cells of several cancer types, including pediatric CNS/LM from NB. ^{131}I-omburtamab, which is omburtamab radiolabeled with Iodine-131, has been studied in several clinical trials including development Study 101 and Study 03-133 for the treatment of pediatric patients who have CNS/LM from NB. An analysis of 107 patients with pediatric CNS/LM from NB who were treated with ^{131}I-omburtamab in Study 03-133 demonstrated a median overall survival, or OS, of 50.8 months, as compared to historical median OS of approximately six to nine months. ^{131}I-omburtamab has received ODD and RPDD from the FDA for the treatment of NB, and BTD for the treatment of pediatric patients who have CNS/LM from NB. We submitted a BLA to the FDA for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We held a number of Type B meetings with the agency, including a pre-BLA meeting in January 2022, before we resubmitted the BLA for omburtamab in March 2022. In October 2022 we met with the U.S. Food and Drug Administration, or FDA,

and the ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In November 2022, we received a CRL for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

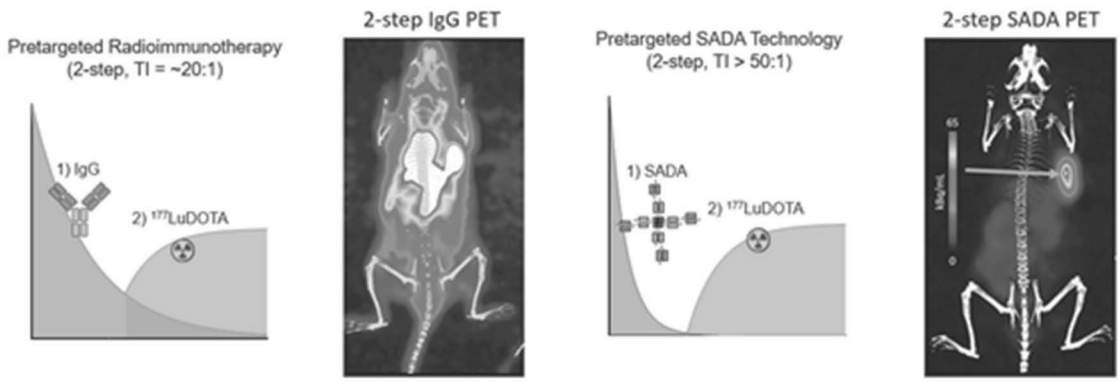
As part of the restructuring plan, we also deprioritized ^{124}I-omburtamab , which is omburtamab radiolabeled with Iodine-124, that was being studied for the treatment of Diffuse Intrinsic Pontine Glioma, or DIPG, and ^{131}I-omburtamab that was being studied for the treatment of Desmoplastic Small Round Cell Tumors, or DSRCT.

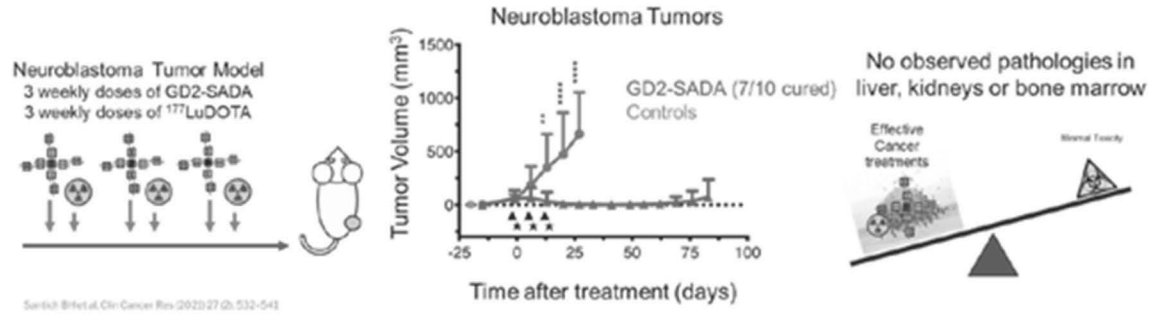
Our Phase 1 multicenter study for ^{177}Lu-omburtamab-DTPA, for the treatment of medulloblastoma, and our Phase 1 multicenter study with ^{177}Lu-omburtamab-DTPA targeting B7-H3 positive CNS/LM tumors in adults were also deprioritized in 2022.

The SADA Technology

On April 15, 2020, we entered into a license agreement, or the SADA License Agreement, with MSK and Massachusetts Institute of Technology, or MIT, that grants us an exclusive, worldwide, sublicensable license to certain patent and intellectual property rights developed by MSK and MIT to develop, make, and commercialize licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics and cancer treatments the SADA Technology. The patents and patent applications covered by the SADA License Agreement are directed, in part, to the SADA Technology, as well as a number of SADA constructs developed by MSK.

We are using the SADA Technology to advance a series of antibody constructs based on the SADA technology, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach. We have designated GD2-SADA for potential use in GD2-positive solid tumors as our first SADA construct and filed an IND for GD2-SADA in December 2021. We obtained clearance for the IND in July 2022. The first clinical sites were activated in November 2022, and MSK opened in March 2023. We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.





Overview of Active INDs

The table below sets forth our product candidates, date of the initial submission of the IND to the FDA, as well as the current sponsor, the subject matter and the current status of each such IND.

Product Candidate	Date of Initial Submission	Current Sponsor	Subject Matter of IND	Current Status
DANYELZA	June 14, 2011	MSK	NB and other GD2-positive tumors	Clinical trials completed
DANYELZA	September 5, 2017	Y-mAbs	Pediatric NB	Clinical trials ongoing
GD2-SADA	December 30, 2021	Y-mAbs	GD2-positive tumors solid	Clinical trial ongoing
Omburtamab* (^{131}I-omburtamab and ^{124}I-omburtamab).	September 22, 2000	Y-mAbs (MSK original sponsor)	CNS/LM from NB, DSRCT, DIPG and other B7-H3 positive tumors	Clinical trial follow-up ongoing for CNS/LM NB; clinical trials completed for DSRCT and DIPG
GD2-GD3 Vaccine . . .	July 29, 2008	MSK	Pediatric NB	Clinical trial ongoing

* We are currently considering the future for the omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

MSK License Agreements

We have exclusive rights to MSK's rights in all of our current product candidates under our 2015 license agreement, or the MSK License, with MSK. The MSK License also provides us with non-exclusive access to technology that involves the creation of a novel human protein tag that can potentially dimerize, or link together, bispecific T-cell engagers, or BiTEs. We refer to this technology as the MULTI-TAG technology. We believe that our strong relationship with MSK, one of the world's leading cancer treatment centers, and our access to certain of MSK's technologies and substantial research capabilities affords us several competitive advantages. In addition, under a separate 2020 SADA License Agreement with MSK and MIT we have exclusive, worldwide, sublicensable license to certain patent and intellectual property rights developed by MSK and MIT 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 Technology.

Material Funding Activities

Since our inception in April 2015, we have raised approximately $488.8 million through private placements of our securities, our initial public offering in September 2018 and our public offerings in November 2019 and February

2021. In our secondary public offering in February 2021, we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our secondary public offering in February 2021 of $115.0 million, when the transaction closed in February 2021. On December 28, 2020, we announced that we entered into a definitive agreement to sell our DANYELZA PRV to United Therapeutics Corporation for $105.0 million. The PRV was granted in conjunction with the approval by the FDA of DANYELZA, for the treatment of refractory/relapsed high-risk NB. Under the terms of the MSK License Agreement, we retained 60% of the net proceeds received from the sale, and the remaining 40% was paid to MSK. As a result, we received net proceeds from this sale of $62.0 million. As of December 31, 2022, we had cash and cash equivalents of $105.8 million.

Our Pipeline

The following table sets forth DANYELZA and our product candidates and their current development stages, estimated development timelines and anticipated milestones.

Product Candidate	Target	Study	Indication / Treatment	Preclinical	Phase 1	Phase 2	Phase 3 / Registration	Status/Next Anticipated Milestones
DANYELZA (naxitamab-gqgk)	GD2	201	Relapsed / Refractory High-Risk Neuroblastoma (Pediatric)	Ongoing Phase 2 trial (PMR)(1)				Approved in November 2020
		12-230	Relapsed / Refractory High-Risk Neuroblastoma (Pediatric)	Completed Phase 2 trial				
		BCC018	Chemo combination High-Risk Neuroblastoma (Pediatric)	Ongoing Phase 2 trial				
		15-096	Relapsed (Second-Line) Osteosarcoma(2)	Ongoing Phase 2 trial				IND Study 205 planned for 2023
GD2-SADA	GD2	1001	GD2 Positive Solid Tumors	Ongoing Phase 1 trial				IND open 2022
Omburtamab	B7-H3	101	CNS / Leptomeningeal Metastases from Neuroblastoma (Pediatric) (^{131}I)(3)	Completed pivotal Phase 2 trial				Q4 2022 CRL
		03-133	Intrathecal Immunotherapy for CNS/ Leptomeningeal Metastases (^{131}I)(3)	Ongoing Phase 1 trial				
huB7-H3	B7-H3		Systemic Solid Tumors (Adult) (Third-Line)					

(1) DANYELZA was approved by the FDA in November 2020. Pivotal registration studies supporting the BLA submission, comprised of Study 12-230 measuring pharmacokinetic, toxicity and efficacy and an additional pivotal multicenter Phase 2 study, Study 201, designed to prove comparability between study sites using a current good manufacturing practices, or cGMP, commercial manufacturer. Study 201 has also been designed to satisfy the confirmatory study and post-marketing requirements by the FDA.
(2) Initial study represents pediatric and young adult patients.
(3) Represents the radioactive isotope of iodine used to radiolabel omburtamab.

Our Business Strategy

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

Key elements of our strategy to achieve this goal are:

- **Independently commercialize DANYELZA in indications and territories where we believe we can maximize the value.** On November 25, 2020, DANYELZA received approval by the FDA following an expedited regulatory pathway and priority review under the BTD granted in 2018. We initiated commercialization of DANYELZA in the United States following the FDA approval. We plan to independently commercialize DANYELZA focusing on already-identified key treatment centers, as well as

educating doctors, patients and payors about DANYELZA and its current and future indication to drive acceptance and uptake. We believe that we will need to engage a small number of physician specialists for training regarding the appropriate administration and use of DANYELZA. The sales call points for DANYELZA in the United States are highly concentrated and generally addressable by a small commercial organization, which we believe will allow us to cost-effectively maintain our own commercial capability. Finally, we have already and we intend to form in the future commercial and development collaborations for indications and in territories that are better served by the resources of local specialists or larger biopharmaceutical companies.

- **Expand the indications and target patient populations for our existing product candidates.** Our goal is to maximize the potential of our existing product candidates in areas where there is a significant unmet medical need by exploring additional indications, as well as expanding the target population within existing indications. For example, we are developing DANYELZA for the treatment of front-line and third-line NB and relapsed osteosarcoma and we intend to discuss our BLA strategy in these indications with the FDA. We believe that we may qualify for a supplemental BLA, or sBLA, in each of these indications assuming positive pivotal data.

- **Advance our novel SADA constructs that we believe may offer potential substantial benefits over existing therapies.** We are also advancing a series of promising SADA constructs that we believe have the potential to allow for easy adaptation to different tumor targets and a variety of payloads. In 2022 we opened the IND for our GD2-SADA construct for the treatment of GD2-positive solid tumors, and in 2023 we expect to submit an IND for CD38-SADA for non-Hodgkin's Lymphoma.

- **Leverage our relationships with leading academic and clinical institutions to develop additional product candidates.** We intend to continue to partner with leading centers, such as MSK, for cancer treatments worldwide, to identify and develop additional product candidates. We believe that our relationship with MSK, our access to several of their technologies and MSK's significant expertise in pediatric cancer care provides us with significant competitive advantages. For example, our Investigator-Sponsored Master Clinical Trial Agreement, or the MCTA, with MSK provides us with ready access to patients for clinical trial enrollment, which is a significant advantage in rare disease drug development where patients are often hard to locate and recruit. Our Sponsored Research Agreement, or the SRA, with MSK, pursuant to which we agreed to provide research funding to MSK, grants us a first option to negotiate an exclusive license to MSK's rights in any new joint inventions discovered under the SRA. We plan to leverage our strong relationship with institutions such as MSK and their expertise and research capabilities to augment our own capabilities in order to identify new product candidates for the treatment of cancers where there is a significant unmet medical need and no effective therapy currently available.

Current Approaches to the Treatment of Cancer

Cancer Overview

Cancer is a broad group of diseases in which cells divide and grow in an uncontrolled fashion, forming malignancies that can invade other parts of the body. Cancers can subsequently spread throughout the body by processes known as invasion and metastases. Cancer cells that arise in the lymphatic system and bone marrow, or BM, are referred to as hematological malignancies. Cancer cells that arise in other tissues or organs are referred to as solid tumors.

Cancer is a major public health problem in the United States and worldwide. The National Cancer Institute, or NCI, estimated that approximately 40% of all men and women in the United States will be diagnosed with some form of cancer during their lifetime (based on 2017-2019 data). According to the U.S. Centers for Disease Control, or CDC, cancer is currently the second leading cause of death in the United States and is expected to surpass heart disease as the leading cause of death in the next several years. Although progress has been made in the diagnosis and treatment of cancer, the American Cancer Society, or ACS, estimates that an estimated 1.8 million new cancer cases will be diagnosed in the United States and over 600,000 people will have died from cancer in 2023 (Cancer statistics, 2023 -

Siegel - 2023 - CA: A Cancer Journal for Clinicians - Wiley Online Library). Thus, there remains a significant need for novel and improved treatment options for cancer patients.

Cancer treatment has traditionally included chemotherapy, radiotherapy, hormone therapy, surgery or a combination of these approaches. While small molecule chemotherapy agents and cytotoxic agents have demonstrated efficacy in treating certain types of cancers, they can also cause toxicities that may lead to life-threatening consequences, lower quality of life or untimely termination of treatment. Furthermore, these treatments are only partially effective in solid tumors, in part because the maximal achievable doses are limited by systemic toxicity, which consequently hinders the prospects of long-term remission in patients. Over a course of more than 20 years, cancer research and treatment has shifted to more targeted therapies, such as monoclonal antibodies, and immuno-oncology, a new field of cancer therapy focused on enhancing antitumor immune responses.

Advances in understanding the immune system's role in treating cancer have established immunotherapy, or the practice of harnessing immune system functions to combat malignant cell growth, as an important treatment approach. Cancer immunotherapy began with treatments that nonspecifically activated the immune system and had limited efficacy and/or significant toxicity. In contrast, new immunotherapy treatments can activate specific, key immune cells, leading to improved targeting of cancer cells, efficacy, and safety.

Cancer therapies are sometimes characterized as front-line, second-line, or third-line, and the FDA often approves new therapies initially only for third-line use. When cancer is detected early enough, front-line therapy is sometimes adequate to effectively treat the cancer or prolong life. Whenever front-line therapy, usually chemotherapy, radiation therapy, surgery, or a combination of these, proves unsuccessful, second-line therapy may be administered. Second-line therapies often consist of more chemotherapy, surgery, tumor-targeted therapies such as monoclonal antibodies and small molecules, or a combination of these. Third-line therapies can include bone marrow transplantation, antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies.

Immune System and Introduction to Antibodies

The immune system is often described as having two main branches—innate (non-specific) and adaptive (acquired) immunity. It defends against invading pathogens such as viruses, parasites, and bacteria, and provides surveillance against cancers. The innate immune system is the initial response to an infection, and the response is the same every time regardless of prior exposure to the infectious agent. The adaptive immune system includes B-cells, which secrete antibodies and T-cells, which can be either helper T-cells, suppressor T-cells or cytotoxic T-cells.

An antibody, also known as an IgG, is a large, Y-shaped protein produced mainly by plasma cells in response to foreign substances, such as viruses or cancer cells. Antibodies circulating in the bloodstream function by binding to the target or antigen they are generated to fight. The binding process involves a lock-and-key mechanism in which the paratope region of the antibody, analogous to a lock, binds to one particular epitope of a specific antigen, analogous to a key. This allows the antibody to bind to a specific antigen with precision, thereby attacking only its intended target.

Different types of antibodies include: (i) Monoclonal Antibodies—laboratory-made antibodies typically derived from immune cells of mammals that have been immunized with a desired antigen and are all clones of a unique parent; (ii) Humanized/Chimeric Antibodies—antibodies with both mouse and human antibody proteins that are humanized (i.e., engineered to replace mouse components with more human components) to reduce the immune system response against antibodies identified as foreign (i.e., from a different species) in nature; (iii) Naked Monoclonal Antibodies—antibodies without any drug or radioactive material attached and which are the most common type of antibodies in treating cancer; (iv) Antibody Drug Conjugates, or ADCs—monoclonal antibodies that are joined to a chemotherapy drug, a radioactive particle or cancer cell killing agent, in which the monoclonal antibody is used as a homing device to deliver these substances directly to the cancer cell; and (v) Bispecific antibodies comprised of two different monoclonal antibody constructs, which allows the antibody to bind to two specific therapeutic targets at the same time, typically one target on the tumor cell and one target on an immune system cell.

Antibodies may function through multiple mechanisms simultaneously, including binding to cancer cells and flagging for B-cells and T-cells to more easily detect the target, or delivering radiation treatment by acting as a vehicle to

transfer small radioactive particles directly to the cancer cells and to minimize the effect of radiation on normal cells. Other mechanisms include triggering cell-membrane destruction, preventing cell growth or blood vessel growth, blocking immune system inhibitors, directly attacking cancer cells and delivering chemotherapy or binding cancer cells and immune cells simultaneously.

Studies have shown that, as a drug class, antibodies have transformed oncology treatment and include some of the best-selling therapies on the biopharmaceutical market.

Our Product and Product Candidates

We have one FDA-approved product and a broad and advanced product pipeline including product candidates primarily targeting clinically validated tumors that express GD2 and CD38, respectively.

On November 25, 2020, DANYELZA, was approved by the FDA, in combination with granulocyte-macrophage Colony-Stimulating factor, or GM-CSF, for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. We began to commercialize DANYELZA in the United States upon receipt of FDA approval in November 2020. DANYELZA is also in mid-stage clinical development for additional cancers, and we have initiated clinical development in other indications.

Our product candidate ^{131}I-omburtamab, or omburtamab, is in development for pediatric CNS/LM from NB—a rare and life-threatening pediatric cancer for which no FDA-approved products currently exist. We submitted a BLA to the FDA for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We held a number of Type B meetings with the agency, including a pre-BLA meeting in January 2022, before we resubmitted the BLA for omburtamab in March 2022. In October 2022 we met with the FDA's ODAC who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In November 2022, we received a complete response letter, or CRL, for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

We are using our proprietary SADA BiDE (2-step Self-Assembly and DisAssembly Bispecific DOTA Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA Technology, a concept we also refer to as Liquid Radiation™, to advance a series of antibody constructs, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach. We have designated GD2-SADA for potential use in GD2-positive solid tumors as our first SADA constructs and filed an IND for GD2-SADA in December 2021. We obtained clearance for the IND in July. We announced our first hematological target CD38-SADA in December 2022, and expect to submit an IND for this construct in 2023. We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.

In January 2023 we announced a strategic restructuring plan designed to extend our cash resources and prioritize the commercialization and potential label extension of DANYELZA and development of the SADA technology platform. In addition to deprioritizing the omburtamab program for all indications and product candidates, we deprioritized other pipeline programs, including activities relating to GD2-GD3 Vaccine and CD33 bispecific antibody constructs, by delaying trial initiation and overall timelines as part of the restructuring plan. In addition,

nivatrotamab and ^{177}Lu-omburtamab were deprioritized during the first half of 2022. We have allocated de minimis resources to the deprioritized programs. In most cases, the INDs have been inactivated, which reduces our development costs while preserving our option to potentially revitalize programs at a later point.

We have exclusive worldwide commercial rights to all of our current product candidates and we have granted commercialization partners certain exclusive rights to develop and commercialize DANYELZA and omburtamab in select territories, including Greater China, Israel, Latin America, Russia and certain Eastern European countries.

DANYELZA Overview

DANYELZA is a humanized monoclonal antibody approved by the FDA in combination with Granulocyte-Macrophage Colony-Stimulating factor, or GM-CSF, for the treatment of pediatric patients 1 year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy, and being evaluated for the treatment of other GD2-positive tumors, including osteosarcoma. DANYELZA targets GD2, which, based on our research, is expressed on almost all NB cancer cells regardless of disease stage and in almost all osteosarcomas. DANYELZA was granted BTD for treatment of patients with pediatric R/R high-risk NB in 2018.

In November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB. In January 2023, the EMA agreed to our proposed PIP for naxitamab. DANYELZA also received ODD and RPDD from the FDA for the treatment of NB in 2013 and 2017, respectively. The RPDD qualified us for receipt of a PRV upon approval of DANYELZA for treatment of NB, and we did receive such PRV in November 2020. As of December 2022, DANYELZA has been administered to more than 900 patients in clinical trials, including patients treated under our expanded access and compassionate use programs. Sales of DANYELZA for the year ended December 31, 2022 were $49.3 million.

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

In pediatric R/R high-risk NB, we believe that DANYELZA has multiple potential advantages over other GD2-targeting antibody-based therapies. In particular, the modest toxicity it exhibits allows for doses 2.5 times greater than the other GD2-targeting antibody-based therapies. DANYELZA also has a significantly shorter infusion time (approximately 30 to 60 minutes compared to 10 to 20 hours for other GD2-targeting antibody-based therapies being used in front-line therapy), which we believe is important given the pain associated with the therapy and the ability to be administered in an outpatient setting.

In addition, DANYELZA has been evaluated in a Phase 2 clinical study (Study 16-1643) in front-line NB, a pilot study (Study 17-251) of chemoimmunotherapy for high-risk NB and is currently being evaluated in a Phase 2 clinical study (Study 15-096) in second-line relapsed osteosarcoma patients. Moreover, we are planning an international multicenter randomized pivotal clinical study with DANYELZA compared to Standard of Care in patients with relapsed osteosarcoma with Pulmonary Only Recurrence (Study 205).

GD2 Overview

We believe that monoclonal antibodies such as DANYELZA that target ganglioside GD2 are one of the most promising cancer immunotherapy approaches. Gangliosides, including GD2, GM2, GD3, NGcGM3 and OAcGD2, have been shown to be expressed at very high levels in tumor cells of several types of cancers.

As a potential target molecule for anti-tumor therapy, GD2 has certain advantages when compared to other tumor associated gangliosides because it is highly expressed in tumor cells of several types of cancers and is not

expressed at all, or expressed at very low levels, in normal cells. A National Cancer Institute pilot program for the prioritization of the most important cancer antigens ranks GD2 as number 12 out of 75 potential targets for cancer therapy based on therapeutic function, immunogenicity, role of the antigen in oncogenicity, specificity, expression level and percent of antigen-positive cells, stem cell expression, number of patients with antigen-positive cancers, number of antigenic epitopes, and cellular location of antigen expression. GD2 ranks as number six when compared to antigens that are directly targetable on the cell surface. Antibodies directed against GD2 have been shown to effectively induce cell death through a combination of both apoptosis and tumor cell necrosis in GD2-positive tumors.

GD2 Expression in Various Cancer Types

Studies have shown that GD2 is highly expressed on neuroectoderm-derived tumors and sarcomas, including NB, retinoblastoma, melanoma, small cell lung cancer, brain tumors, osteosarcoma, rhabdomyosarcoma, Ewing's sarcoma in children and adolescents, as well as liposarcoma, fibrosarcoma, leiomyosarcoma and other soft-tissue sarcomas in adults. These cancers have a high mortality rate ranging from 20-80% depending on the tumor type.

We believe there is a large market opportunity for the treatment of solid tumors that express GD2. Based on our own research and our review of published research, we believe GD2 expression occurs in approximately 60-100% of tumor samples from various cancer types, and in substantially all NB and osteosarcoma tumor samples. We estimate that there were more than 200,000 new patients diagnosed with GD2-positive cancer in the United States in 2017. While our clinical development efforts for DANYELZA are currently focused on rare pediatric cancers, we believe we have the potential to expand DANYELZA's application beyond pediatric cancers to the treatment of adults with cancers that express GD2.

DANYELZA—mechanism of action

Our pre-clinical studies have shown that DANYELZA binds to GD2 molecules on tumor cells with high affinity and a slow off-rate, which indicates DANYELZA's strong binding ability. In mice that have been transplanted with human NB tissue, DANYELZA demonstrated dose-dependent inhibition of tumor growth (i.e., the effect of DANYELZA varied with dosage) and generally increased survival. In vitro studies show that when DANYELZA binds to tumor cells, it induces tumor cell death through antibody dependent cell-mediated cytotoxicity and complement-dependent cytotoxicity. DANYELZA may also inhibit tumor cell migration through its inhibitory effect on GD2 molecules, which are involved in tumor cell adhesion and migration. In vitro studies also show that Granulocyte-Macrophage Colony-Stimulating Factor, or GM-CSF, enhances the activity of DANYELZA in a dose-dependent manner and is therefore generally combined with DANYELZA in our clinical trials.

DANYELZA for the treatment of pediatric relapsed or refractory high-risk neuroblastoma

On November 25, 2020 DANYELZA® received regulatory approval by the FDA in the United States for treatment in combination with GM-CSF of high-risk R/R NB. This approval was based primarily on interim data from the Study 201 and Study 12-230. In order to meet certain post-marketing commitments issued by the FDA, Study 201 with DANYELZA is currently still ongoing for pediatric R/R high-risk NB. DANYELZA was granted BTD in this indication in 2018. In November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB. DANYELZA has also received ODD and RPDD from the FDA for the treatment of NB in 2013 and 2017, respectively. The RPDD qualified us for receipt of a PRV upon approval of DANYELZA for treatment of NB by the FDA, which we received in November 2020. The FDA has issued a post-marketing commitment to provide data on PFS, supporting the efficacy of the product. As of January 1, 2023 we have enrolled 87 patients and we anticipate completing the study no later than March 31, 2027. We believe DANYELZA has multiple potential advantages over other GD2-targeting antibodies such as higher doses and administration on an outpatient basis.

In our studies to date, DANYELZA has demonstrated a manageable safety profile, which allows for 2.5 times greater dosing as compared to other GD2-targeting antibody-based therapies. This results in fewer doses per cycle and a significantly shorter infusion time (approximately 30 to 60 minutes versus 10 to 20 hours for dinutuximab). Notably, since severe pain is one of the most common side effects of treatment with GD2-targeting antibody-based therapies, we

believe that the ability to reduce infusion time to approximately 30 to 60 minutes is very important for patients and may result in a significant reduction in demand for pain medication such as morphine. These factors allow DANYELZA to be administered in an outpatient setting whereas other GD2-targeting antibody-based therapies require hospitalization which usually lasts for four days or more.

Overview of Neuroblastoma

NB is a rare and almost exclusively a pediatric cancer that develops in the sympathetic nervous system, a network of nerves that carries messages from the brain throughout the body. It is the third most common childhood cancer, after leukemia and brain tumors, and is the most common solid extracranial tumor in children. NB is a life-threatening disease associated with poor long-term survival. It accounts for approximately six percent of all childhood cancers and approximately 15% of pediatric cancer deaths. Nearly 90% of patients with NB are diagnosed by age five and NB is very rare in people over the age of 10 years. The average age of children when they are diagnosed with NB is one to two years.

The stage of NB, which describes how far the cancer has spread, is based on results of physical exams, imaging tests, and biopsies. The International Neuroblastoma Staging System stages the disease from Stage 1 to Stage 4. Other factors that also affect prognosis of NB include age and amplification of MYCN oncogene.

NB patients can also be placed into different risk groups from low, intermediate to high based on the stage and other prognostic factors. High-risk NB is defined as MYCN amplified Stage 2, 3, 4S and 4 in patients of any age and MYCN non amplified Stage 4 in patients over 18 months of age.

There are approximately 700 children diagnosed with high-risk NB in the United States each year. We believe the European market is at least one and a half times the size of the U.S. market and that there are approximately 1,050 patients diagnosed with high-risk NB in Europe each year. We believe the current addressable market for DANYELZA consists of approximately 960 new front-line high-risk NB patients each year and 675 primary or second-line eligible R/R NB pediatric patients each year, representing approximately 40% of all pediatric patients diagnosed with NB in the United States and Europe, combined. Moreover, based on the protocol we have developed with MSK, between treatment and maintenance therapy, we believe that typically patients will receive five to ten treatment cycles of DANYELZA, each cycle consisting of three doses.

DANYELZA for Pediatric Relapsed or Refractory High-Risk Neuroblastoma—Current Treatment Landscape and Associated Limitations

Currently, front-line treatment for pediatric NB patients usually occurs in three stages: induction, consolidation, and maintenance. During the induction phase, patients receive chemotherapy, radiotherapy and possibly surgery to eliminate as much tumor tissue and as many tumor cells as possible. Commonly used agents for induction treatment include cisplatin, etoposide, doxorubicin, cyclophosphamide, and vincristine. Following surgery and/or radiotherapy, most patients enter into consolidation therapy with the goal of eliminating any residual tumor usually with single dose myeloablative agents (e.g. carboplatin-etoposide-melphalan) with stem cell support or an autologous stem cell transplant or repeated transplants with thiotepa-cyclophosphamide followed by cyclophosphamide, etoposide, and ranimustine. Many treatment centers also use immunotherapy as part of the consolidation stage of treatment. Relapse is a frequent occurrence after consolidation.

Other than DANYELZA, there are no approved therapies in the United States for R/R NB patients. Other treatments typically include chemotherapy, radiotherapy and other experimental therapies.

In 2015, the FDA and the EMA, approved Unituxin (dinutuximab), a monoclonal GD2-targeting antibody developed by United Therapeutics Corporation, or United Therapeutics, and administered in combination with GM-CSF, interleukin-2, or IL-2, and isotretinoin, also known as 13-cis-retinoic acid, for the treatment of pediatric patients with high-risk NB who achieve at least a partial response, or PR, to prior front-line multiagent, multimodality therapy. The marketing authorization for Unituxin was voluntarily withdrawn by United Therapeutics in the European Union in 2017. In 2017 the EMA approved Dinutuximab beta Apeiron (also known as dinutuximab beta, ch14.18/CHO, Isqette and

currently being commercialized under the name Qarziba® in Europe), a monoclonal GD2-targeting antibody, for the treatment of high-risk NB in patients aged 12 months and older, who have had some improvement with previous treatments or patients whose NB has not improved with other cancer treatments or has relapsed.

DANYELZA for Pediatric Relapsed or Refractory High-Risk Neuroblastoma—Clinical Development Program

DANYELZA has been studied in several clinical trials for the treatment of pediatric R/R NB and other diseases, of which Study 201 and Study 15-096 are currently ongoing. The accelerated approval of DANYELZA by the FDA was based primarily on interim data from Study 201 and Study 12-230.

Study 12-230: Phase 1/2 Study of Combination Therapy of Antibody Naxitamab with Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) in Patients with Relapsed/Refractory High-Risk Neuroblastoma

Phase 1 Portion of Study 12-230

Primary Objective

- To establish the maximum tolerated dosage, or MTD, of naxitamab when combined with GM-CSF.

Secondary Objectives

- To study the pharmacokinetics of naxitamab when combined with GM-CSF.
- To assess activity of naxitamab plus GM-CSF against NB.
- To quantitate pain during naxitamab and GM-CSF treatment.
- To study markers of granulocyte mediated cytotoxicity and NK-mediated cytotoxicity, anti-naxitamab immunity, and anti-tumor immunity before and after treatment with naxitamab/GM-CSF.
- To quantitate the response of NB in BM by quantitative reverse-transcription-polymerase chain reaction, or RT-PCR.

Patient Population

In addition to satisfying certain other criteria, patients must be over one year of age and must have been diagnosed with NB as defined by a) histopathology, or b) BM metastases or Meta-iodobenzylguanidine, or MIBG, avid lesion(s) plus high urine catecholamine levels.

Patients must have R/R high-risk NB (including MYCN-amplified Stage 2, 3, 4, or 4S of any age and MYCN-non-amplified Stage 4 in patients over 18 months of age) resistant to standard therapy. Standard therapy for these types of patients includes intensive induction chemotherapy, followed by a variety of consolidation or salvage therapies, depending on response.

Patients are mainly children and adolescents.

Treatment Protocol

The Phase 1 portion of Study 12-230 assessed dose escalation of intravenous, or IV, naxitamab (days one, three, five) in the presence of subcutaneous GM-CSF (days minus four through five). These three doses of naxitamab and 10 days of GM-CSF constituted a single treatment cycle. Patients who completed 4 cycles without PD were eligible to continue treatment for up to 24 months. For the Phase 2 part of study, patient were eligible to continue treatment for up to 4 cycles after major clinical response was obtained again with a maximum treatment period of 24 months.

Phase 2 Portion of Study 12-230

The Study 12-230 protocol was amended in May 2016 to include an expansion Phase 2 portion. In October 2020, topline results from the first 71 patients (including 29 patients with no evidence of disease, or NED patients) in this Phase 2 study were presented, which continued to show response rates at the same levels as in the dose escalation part of the study with 13 of 15 evaluable, or 87% of, primary refractory patients responding and 7 of 23 evaluable, or 30% of, secondary refractory patients responding.

The expansion Phase 2 single-arm portion of Study 12-230 was designed to assess the anti NB activity of naxitamab and GM-CSF in patients who presented with lesions that could be objectively measured and/or monitored by ^{123}I-MIBG scans and who were deemed to have measurable disease and be eligible for response classification by the INRC classification incorporating ^{123}I-MIBG scans. These patients were classified as having evaluable disease and consisted of patients that were primary refractory patients or secondary refractory patients. Another group of patients included those with NED but with a high-risk of relapse.

Primary Objectives

- In Group 1: (NED patients) To assess the impact of naxitamab and GM-CSF on PFS in patients in greater than or equal to second CR/very good partial response, or VGPR, but at high-risk of another relapse.

- In Group 2: To assess the activity of naxitamab and GM-CSF in patients who have primary refractory disease in the bone and BM by measuring response and by calculating PFS.

- In Group 3: To assess the activity of naxitamab and GM-CSF in patients who have secondary refractory disease in the bone and BM by measuring response and by calculating PFS.

Secondary Objectives

- In patients with primary refractory or relapsed disease (groups 1 and 3):

    - To evaluate the PFS from the start of hu3F8+GM-CSF treatment.
    - To evaluate human anti-human antibody (HAHA).

    In patients in >2nd CR (Group 2):

    - To evaluate PFS from the start of hu3F8+GM-CSF treatment.
    - Evaluate event free survival (EFS) from the start of hu3F8+GM-CSF treatment.

- In all patients: To evaluate the safety of naxitamab

Patient Population

In addition to satisfying certain other criteria, patients must be over one year of age and will be mainly children and adolescents.

Study 12-230 is now completed.

Study 201: A Phase 2 Trial of Antibody Naxitamab and Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) in High-Risk Neuroblastoma Patients with Primary or Secondary Refractory Osteomedullary Disease

Study 201 is a single-arm multi-center pivotal study using current Good Manufacturing Practices, or cGMP, manufactured naxitamab, which commenced recruitment in the second quarter of 2018. We have completed the initial enrollment target of 37 patients and continue recruitment at sites outside the U.S.

Primary Objective

- To evaluate the efficacy of IV naxitamab and GM-CSF.

Secondary Objectives

- To evaluate the safety of IV naxitamab and GM-CSF.
- To evaluate the duration of response from the start of naxitamab and GM-CSF. Duration of response is defined as the length of time from patient response to PD.
- To evaluate PFS of naxitamab and GM-CSF.
- To evaluate median OS at two years following naxitamab and GM-CSF.
- To evaluate the pharmacokinetics of naxitamab and investigate the formation of HAHAs.

Patient Population

In addition to satisfying certain other criteria, patients must have high-risk NB with primary or secondary refractory osteomedullary disease. Primary refractory disease is defined as no prior relapse but incomplete response to treatment in BM as documented by histology and/or 123I-MIBG scan. Secondary refractory disease is defined as prior relapse and incomplete response to salvage therapy in BM as documented by histology and/or 123I-MIBG scan. Patients must be older than one year of age.

Treatment Protocol

Study 201 follows the same treatment protocol as described for Study 12-230 above.

We initiated Study 201 to form the primary basis for our BLA, to establish comparability of study population with Study 12-230 and to satisfy the post-marketing requirements by the FDA. The FDA granted approval under the accelerated approval regulation. The post-marketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which will enroll a minimum of 80 patients with evaluable disease with a minimal follow-up of 12 months from CR/PR onset and report ORR, DOR, PFS or OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint, PFS and OS are secondary endpoints in long-term follow up. As of January 1, 2023 we have enrolled 87 patients and we anticipate completing the study no later than March 31, 2027.

Study 16-1643: Naxitamab/GM-CSF Immunotherapy Plus Isotretinoin for Consolidation of First Remission of Patients with High-Risk Neuroblastoma: A Phase 2 Study

Study 16-1643 was a Phase 2 single-arm clinical trial where patients with high-risk NB in first CR/VGPR undergo consolidation with naxitamab and GM-CSF for five cycles and isotretinoin for six cycles. The primary objective of the study was to determine relapse-free survival following treatment with naxitamab combined with GM-CSF and isotretinoin.

A total of 59 patients have completed enrollment in the study which constituted full accrual. The data is currently being evaluated and prepared for publication.

Primary Objective

- To determine two years relapse-free survival.

Secondary Objective

- To determine MRD by using BM specimens.

Patient Population

In addition to satisfying certain other criteria, patients must have a diagnosis of NB as defined by a) histopathology, or b) BM metastases or MIBG-avid lesion(s) plus high urine catecholamine levels. Patients must have high-risk NB (MYCN amplified Stage 2, 3, 4, and 4S of any age and MYCN-nonamplified Stage 4 in patients above 18 months of age). Patients must be in first CR/VGPR.

Patients will mainly be children and adolescents.

Treatment Protocol

The dosing and regimen for naxitamab and GM-CSF is similar to the protocol in Study 12-230. Naxitamab and GM-CSF is given for five cycles and isotretinoin for six cycles. In addition to naxitamab and GM-CSF, isotretinoin, which has been shown to decrease the risk of relapse in patients treated in CR, is administered at 160mg/m2/d, divided into two doses, for 14 days. This treatment can be repeated after a minimum rest period of 14 days, for a total of six cycles starting after two cycles of naxitamab and GM-CSF unless HAHA develops and precludes timely administration of cycle 2 of naxitamab and GM-CSF. The interval between the end of a treatment cycle of naxitamab and GM-CSF and start of next treatment cycle is two to four weeks through cycle 4, then the interval is up to six to eight weeks until cycle 5.

Safety Results

One patient was reported with an unexpected neuropathic event. The patient suffered from short-term lower limb paralysis that resolved upon hospitalization treatment.

Study 17-251: Pilot Study of Naxitamab, Irinotecan/Temozolomide and Sargramostim (HITS) Chemoimmunotherapy for High-Risk Neuroblastoma

Study 17-251 was a single-arm pilot, Phase 2 study at MSK in high-risk R/R NB patients with soft-tissue disease. Patients were treated with naxitamab in combination with irinotecan, temozolomide and sargramostim, or HITS. A total of 48 patients completed enrollment in the study which constituted full accrual. The data is currently being evaluated and prepared for publication.

Primary Objective

- To evaluate the safety of HITS in patients with NB

Secondary Objective

- To evaluate tumor responses to HITS in patients with NB

Patient Population

In addition to satisfying certain other criteria, the patients must have a diagnosis of NB as defined by international criteria, including histopathology or bone marrow metastases plus high urine catecholamine levels.

High-risk NB is defined as any of the following:

- Stage 4 with MYCN amplification (any age)

- Stage 4 without MYCN amplification (greater than one and a half years of age)
- Stage 3 with MYCN amplification (unresectable; any age)
- Stage 4S with MYCN amplification (any age)

Patients must have a history of tumor progression or relapse or failure to achieve CR following standard therapy. Patients must also have evaluable disease documented after completion of prior systemic therapy.

Treatment Protocol

Each cycle consists of four doses of naxitamab, five doses each of irinotecan and temozolomide and five doses of sargramostim. Irinotecan 50mg/m2/day IV will be administered from day one through five concurrently with temozolomide 150mg/m2/day orally. Naxitamab 2.25mg/kg IV will be administered on days two, four, eight and 10. Sargramostim 250mg/m2/day subcutaneous will be administered from day six through 10. If patients do not experience significant toxicity they will commence a second cycle four to six weeks after the first cycle. If there is no progressive disease and patients do not experience significant toxicity they may receive combination therapy up to two years.

Safety Results

Safety and efficacy data for Study 17-251 were published as an abstract at the June 2022 meeting of the American Society of Clinical Oncology. Toxicities included myelosuppression and diarrhea as expected with irinotecan/temozolomide, pain and hypertension as expected with naxitamab, plus febrile neutropenia. No other >grade 2 unexpected toxicities occurred, and the treatment was outpatient. In this trial, human anti-human antibody did not develop in any of the 50 patients providing samples for testing.

DANYELZA for the Treatment of Relapsed Osteosarcoma

DANYELZA is currently being evaluated in an ongoing Phase 2 clinical study (Study 15-096) for the treatment of patients with relapsed osteosarcoma that have been rendered surgically free of evident disease.

Overview of Osteosarcoma

Osteosarcoma is the most commonly diagnosed primary malignancy of bone, particularly among children and adolescents. It is relatively rare and represents less than one percent of all cancers diagnosed in the United States. According to the ACS, most osteosarcomas occur in children and adolescents between the ages of 10 and 30. In young patients, it most often arises in the metaphyses of long bones, such as the distal femur, proximal tibia, and proximal humerus.

Each year, approximately 1,000 new patients are diagnosed with osteosarcoma in the United States. Assuming similar prevalence as in the United States, we estimate that approximately 1,500 patients diagnosed with osteosarcoma per year in Europe.

DANYELZA for Relapsed Osteosarcoma—Current Treatment Landscape and Associated Limitations

Current treatment options for front-line and relapsed osteosarcoma consist of surgery, chemotherapy, radiotherapy, or a combination of the three. Multimodality treatment is increasingly recognized as an important approach for increasing a patient's chance of prolonged survival. Approximately 50% to 70% of patients treated with aggressive surgical resection and systemic therapy (combination methotrexate, doxorubicin, and cisplatin chemotherapy) achieve long-term EFS if they have localized disease at diagnosis. However, as discussed below, the prognosis for patients with metastatic disease at diagnosis or those with relapsed disease is very poor. Over the past three decades, several attempts at improving the prognosis for these patients have achieved little success. Strategies that incorporated dose-intensification of existing agents or addition of other conventional chemotherapeutic agents as well as biological agents,

have not achieved long-term benefit in patients with relapsed osteosarcoma. We believe that at present, there are no novel compounds that have demonstrated activity in relapsed osteosarcoma and few therapeutic options exist for patients with relapsed disease.

The poor prognosis in relapsed osteosarcoma has been confirmed in several reports. A study from the Cooperative Osteosarcoma Study Group reported that while only one of 205 patients with recurrence survived past five years without surgical resection, the five-year OS and EFS rates were 32% and 18% for second recurrence, 26% and 0% for third recurrence, 28% and 13% for fourth recurrence, and 53% and 0% for fifth recurrence, respectively, in which a renewed surgical remission was achieved.

DANYELZA for Relapsed Osteosarcoma—Clinical Development Program

Currently, DANYELZA is being evaluated in an ongoing Phase 2 clinical trial (Study 15-096) for the treatment of relapsed osteosarcoma. This Phase 2 clinical trial is designed to assess the efficacy of DANYELZA when combined with GM-CSF in patients with relapsed osteosarcoma who have been rendered surgically free of evident disease. The study commenced in July 2015, and as of January 2023, 42 patients had been enrolled. This trial is designed to distinguish between a 12-month EFS of 30% versus 50%.

Study 15-096: A Phase 2 Study of Monoclonal Antibody Naxitamab with Granulocyte-Macrophage Colony-Stimulating Factor (GM-CSF) in the Treatment of Recurrent Osteosarcoma

Study 15-096 is a Phase 2 clinical trial to assess the efficacy naxitamab combined with GM-CSF, in patients with recurrent osteosarcoma who have been rendered surgically free of evident disease.

Primary Objective

- To evaluate EFS at 12 months

Secondary Objectives

- To evaluate time to recurrence, OS and toxicity associated with naxitamab and GM-CSF.

Patient Population

In addition to satisfying certain other criteria, patients must be older than one year and up to 40 years of age. To enroll, patients must have a diagnosis of relapsed osteosarcoma. Patients must also be in or beyond their second CR.

Treatment Protocol

Each cycle of therapy is 10 days. The treatment protocol defined one cycle of treatment with IV naxitamab at a dose of 2.4 mg/kg/dose for three days (days one, three, and five) in the presence of subcutaneous GM-CSF (administered on day minus four before dose one of naxitamab). These three doses of naxitamab with GM-CSF administered subcutaneously before dose one of naxitamab constitute a treatment cycle. Cycles can be repeated at two-to-four-week intervals between the first days of naxitamab, through five cycles. A maximum of five cycles were administered on protocol. No simultaneous anti-cancer therapy was permitted while on study.

Study 205: A Global Randomized Pivotal Trial of Naxitamab Compared to Standard of Care in Patients with Pulmonary Only Recurrent Osteosarcoma

Study 205 is a planned international multicenter randomized pivotal clinical study with naxitamab compared to Standard of Care in patients with Pulmonary Only Recurrent Osteosarcoma. We plan to submit an IND for this study in 2023.

Omburtamab Overview

Omburtamab is a novel murine monoclonal antibody designed for compartmental immunotherapy, for example in the CNS. Omburtamab targets B7-H3, an immune checkpoint molecule that is widely expressed in tumor cells of several types of cancers, including pediatric CNS/LM from NB. We have radiolabeled omburtamab with either Iodine-131 (^{131}I-omburtamab) or Iodine-124 (^{124}I-omburtamab). ^{131}I-omburtamab was granted BTD by the FDA based on investigator blinded reviewed radiographical imaging. In 2016, ^{131}I-omburtamab was granted ODD and RPDD, in each case, for the treatment of NB. The RPDD qualifies us for receipt of a PRV upon approval of omburtamab for treatment of NB, if such approval occurs. An analysis of 107 patients treated through June 2019 demonstrated median OS of 50.8 months (including a five-year median OS of approximately 44%), as compared to historical median OS of approximately six to nine months.

We submitted a BLA to the FDA for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We held a number of Type B meetings with the agency, including a pre-BLA meeting in January 2022, before we resubmitted the BLA for omburtamab in March 2022. In October 2022 we met with the FDA and ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In November 2022 the FDA issued a CRL for the BLA. In the CRL for omburtamab and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

B7-H3 Overview

B7-H3 is a member of the B7 family of immune regulatory ligands. The family includes B7-1, B7-2, PD-L1, PD-L2, B7-H3, B7-H4, B7-H6 and their ligands on T-cells PD-1, CD28, CTLA-4 and ICOS. B7-H3 is highly expressed on many solid cancers and displays high-tumor-versus normal tissue binding differential. In mice, studies have shown that members of the B7 family have the capability to regulate the immune system through both stimulatory and inhibitory signals. Inhibition of certain members of the B7 family has been shown to have significant anti-tumor effects in several solid tumor types. As such, we believe that B7-H3 is a promising target for designing targeted therapeutics with a range of modalities.

B7-H3 Expression in Various Cancer Types

Studies have shown that B7-H3 is highly expressed on a variety of solid cancer tumors, including prostate, ovarian, breast, colon, renal, non-small cell lung, pancreatic, head and neck cancers, as well as melanoma, glioblastoma, and NB and other small round blue cell tumors of childhood. In addition, a high degree of B7-H3 expression on solid tumors has been correlated with greater disease severity, poor outcomes and worse median OS in a number of these cancer types.

We believe there is a large market opportunity for the treatment of solid tumors that express B7-H3, with hundreds of thousands of new cases estimated in the United States each year. Based on our review of published research, we believe that B7-H3 expression occurs in a range of 70% to 100% of tumor samples for various cancer types, which makes B7-H3 a promising immunotherapy target. Our literature review also revealed that B7-H3 expression on the systemic tumor is replicated in the metastasized tumor. While our clinical development efforts for omburtamab has been focused on rare pediatric cancers, we believe we have the potential to expand omburtamab's application to both the treatment of CNS/LM from solid tumors that express B7-H3 and certain underlying solid systemic tumors. As part of

Study 03-133, we also treated a small number of adult patients with solid tumors that have metastasized to the CNS/LM compartment with ^{131}I-omburtamab.

^{131}I-omburtamab Mechanism of Action

^{131}I-omburtamab is a monoclonal antibody that is radiolabeled with Iodine-131, and targets B7-H3. Upon administration, radiolabeled omburtamab binds selectively to B7-H3 ligand that is expressed on the tumor cell surface. Iodine-131 emits beta radiation, resulting in deoxyribonucleic acid, or DNA, damage and tumor cell death. Beta radiation from iodine isotopes penetrates 1-3 mm, affecting not only the antibody bound cell but also the neighboring tumor cells. Iodine-131 has a half-life of eight days. Iodine-131 emits electrons. Radiolabeling of omburtamab with Iodine-131 takes place at qualified radio pharmacies according to a well-established procedure.

^{131}I-omburtamab for the Treatment of Pediatric Central Nervous System/Leptomeningeal Metastases from Neuroblastoma

^{131}I-omburtamab has been studied for the treatment of pediatric CNS/LM from NB, and was granted BTD in this indication in 2017. In 2016, ^{131}I-omburtamab was granted ODD and RPDD, in each case, for the treatment of NB. The RPDD qualifies us for receipt of a PRV upon approval of omburtamab for treatment of NB, if such approval occurs. As of June 2019, 107 patients with pediatric CNS/LM from NB had been treated with ^{131}I-omburtamab in Study 03-133. An analysis of these 107 patients demonstrated a median OS of 50.8 months (including an estimated five-year OS of approximately 44%), as compared to historical median OS of approximately six months. ^{131}I-omburtamab can be administered as a push injection in an outpatient setting.

Overview of Central Nervous System/Leptomeningeal Metastases from Neuroblastoma

CNS/LM is a rare and usually fatal complication of NB in which the disease spreads to the membranes, or meninges, surrounding the brain and spinal cord in the CNS. It is expected that the incidence of CNS/LM from NB disease will increase concurrently with better treatment options for systemic NB, as more patients achieve longer systemic remissions allowing for more CNS relapses. Relapsed metastatic NB is difficult to treat particularly in patients with R/R NB who have CNS/LM from NB. The median OS after detection of the CNS/LM from NB is approximately six months even with early detection and intervention.

Approximately 700 children are diagnosed with NB in the United States each year. Of these, approximately 50-60% are high-risk, and of those at high-risk who relapse, we believe approximately 20% will suffer from CNS/LM from NB. A published study analyzing frozen sections from tumors with histologically confirmed diagnosis of NB using immunohistochemistry showed 87 out of 90 sections (or approximately 97%) were B7-H3 positive. We believe the European market is at least one and a half times the size of the U.S. market and that there are approximately 1,050 patients diagnosed with NB in Europe each year.

^{131}I-omburtamab for Pediatric Central Nervous System/Leptomeningeal Metastases from Neuroblastoma—Current Treatment Landscape and Associated Limitations

There are currently no approved products for patients with R/R NB who have CNS/LM from NB. A variety of treatments are used alone and in combination with other treatments. It is widely accepted that no effective treatment regimens for CNS/LM from NB are available, and the goals of treatment are generally palliative. For recurrence in the CNS, the therapeutic approach consists primarily of surgery, radiation therapy and/or chemotherapy. These treatments have had very limited success, with median OS of approximately six months. The current standard of care treatment paradigm typically involves the following:

- Surgery—for debulking the tumor prior to irradiation and chemotherapy and to reduce edema and hemorrhage;

- Radiation—focal, craniospinal or whole brain irradiation used for symptom alleviation, cerebrospinal fluid, or CSF, flow correction or for debulking to facilitate chemotherapy; and/or

- Chemotherapy—standard combinations of chemotherapy such as irinotecan and temozolomide.

The uniformly poor outcomes associated with these different regimens highlight the significant unmet medical need for treatment of CNS/LM from NB:

1. Our review of published research representing 83 patients treated between 1979 and 2013 showed a median OS of 5.6 months (95% CI of three to eight months) for patients with R/R NB who have CNS/LM from NB. We also performed a restricted analysis after removing patients who died before receiving therapy for the CNS/LM from NB disease and only received palliative treatment, or who presented with rapidly progressing systemic disease. The restricted analysis comprised of 58 patients with a median OS of 8.7 months (95% CI of 5.8 to 11 months) after diagnosis of CNS/LM from NB. There were only three cases of survival beyond three years.

2. Data from 85 patients sourced from The Central German Childhood Cancer Registry, or CGCCR, showed a median OS of 4.7 months. The data was extracted from patients diagnosed between 1990 and 2010. It is estimated that more than 90% of all German childhood cancer patients are registered in this database.

3. Finally, our review of data from 19 patients treated at MSK prior to when ^{131}I-omburtamab was first introduced in 2004, demonstrated a median OS of 5.5 months.

^{131}I-omburtamab for Pediatric Central Nervous System/Leptomeningeal Metastases from Neuroblastoma—Clinical Development Program

^{131}I-omburtamab for the treatment of pediatric CNS/LM from NB is a potential monotherapy after patients have completed standard of care treatment. As of January 2021, 177 patients with pediatric CNS/LM from NB had been treated with ^{131}I-omburtamab in Study 03-133 which closed for recruitment in the third quarter of 2019. As of January 2023, we have treated a total of 52 patients in a multi-center pivotal Phase 2 trial (Study 101) the purposes of analyzing pharmacokinetic and dosimetry comparability between study sites using ^{131}I-omburtamab from our cGMP commercial manufacturer, versus drug product previously produced by and used in earlier studies at MSK. Both studies are closed for recruitment but several patients are still attending follow-up.

Study 03-133: Phase 1/2 Study of Intrathecal Radioimmunotherapy using ^{131}I-omburtamab for Central Nervous System/Leptomeningeal Neoplasms

The trial was originally designed as a Phase 1/2 clinical dose escalation study followed by cohort expansion at the recommended dose. To determine the MTD, patients received up to 70 millicurie, or mCi, ^{131}I-omburtamab in an outpatient setting. No DLTs were experienced in the dose escalation part. Based on treatment results the 50 mCi dose to treat NB with CNS/LM metastasis was chosen for the expansion cohort as implemented by a protocol amendment. Study 03-133 was closed for recruitment in the third quarter of 2019. As of January 2021, 177 patients had been treated with ^{131}I-omburtamab in the study. Of these, 107 patients were diagnosed with pediatric CNS/LM metastasis from NB. The study is closed for recruitment but several patients are still attending follow-up.

Patient Population

In addition to satisfying certain other criteria, patients must have a histologically confirmed diagnosis of a malignancy known to be reactive to omburtamab, a B7-H3 binding antibody. Furthermore, patients must have CNS/LM from NB disease which is refractory to conventional therapies or for which no conventional therapy exists, or a relapsed brain tumor with a predilection for LM dissemination (primitive neuroectodermal tumor, rhabdoid tumor, medulloblastoma).

Before enrollment in Study 03-133, most patients underwent biopsy or debulking surgery to remove brain metastases as much as possible, followed by radiation therapy and chemotherapy. A majority of the patients were also treated with an anti-GD2 immunotherapy such as naxitamab to control systemic disease after completing the

^{131}I-omburtamab treatment under Study 03-133. All patients had an intraventricular device implanted before enrollment in the study.

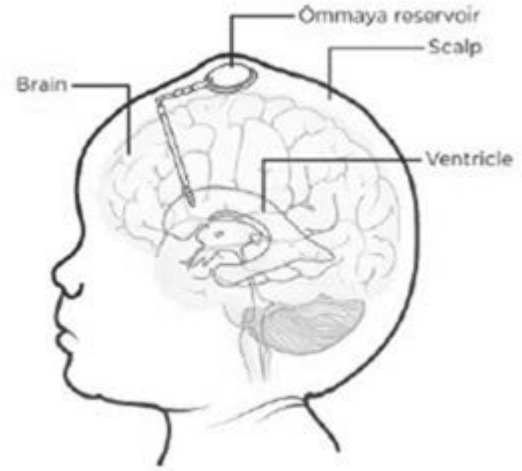
Approximately 80% of all CNS/LM from NB patients presenting at MSK since the initiation of the study were included in the study and the remaining patients were primarily excluded due to the fact that they had already received the maximum dose of previous radiotherapy to CNS, or had progressive systemic disease.

Treatment Protocol

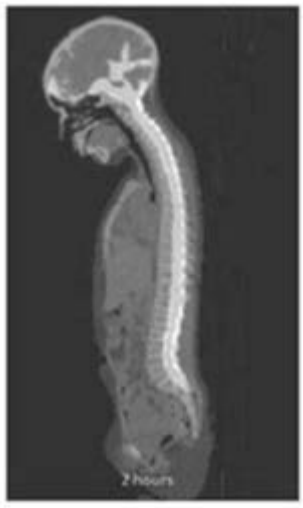
Patients are treated with up to two cycles (each consisting of a treatment dose and a dosimetry dose) of ^{131}I-omburtamab administered through intrathecal infusion via an Ommaya reservoir by which the drug is distributed at the intrathecal space to the entire CSF, (as shown in the figure on the left below). A treatment cycle with ^{131}I-omburtamab under Study 03-133 proceeds as follows:

- Week 1: ^{131}I-omburtamab (dosimetry dose: 2 mCi imaging test dose);
- Week 2: ^{131}I-omburtamab (treatment dose: 30-50 mCi depending on age);
- Weeks 3 and 4: observation period; and
- Week 5: post-treatment evaluation comprised of magnetic resonance imaging, or MRI, of the head and spine, CSF cytology.

Administration of our radiolabeled omburtamab via Ommaya reservoir



PET scan of distribution of our radiolabeled omburtamab two hours after administration



The diagram on the left depicts how our radiolabeled omburtamab can be administered via the Ommaya reservoir and catheter into the deep ventricles of the brain where the CSF is produced. From the ventricles, our radiolabeled omburtamab will flow with the CSF and spread throughout the entire CNS compartment potentially binding and killing B7-H3 positive cancer cells it may find on its way. The diagram on the right is a PET scan showing the distribution of our radiolabeled omburtamab two hours after administration where it has flowed from the central ventricles throughout the entire CNS compartment.

Primary Objective

- To define the clinical toxicities of intrathecal ^{131}I-omburtamab.

Secondary Objective

- To collect neurocognitive and long-term follow-up data.

Safety Results

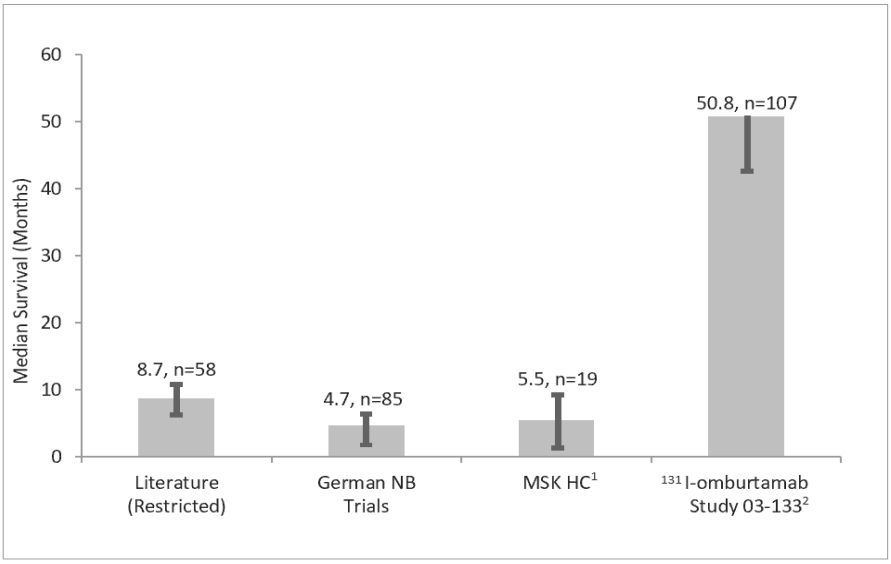
No MTD was reached in the dose escalation portion of the trial. Although not a DLT, myelosuppression was observed in patients who had received craniospinal radiation and ^{131}I-omburtamab at dose levels six and seven (60 and 70 mCi, respectively). As a result, a dose of 50 mCi was chosen for the expansion cohort. Among the 107 patients treated with ^{131}I-omburtamab and diagnosed with pediatric CNS/LM metastasis from NB, a total of 340 injections were administered and myelosuppression was observed in approximately 88 patients. No increased risk of radionecrosis was observed.

As of September 2018, 29% of the patients had an SAE that was considered related to treatment by the investigator. The SAEs considered related by investigator were mainly in the System organ Class: investigations reflecting ^{131}I mediated myelosuppression, which were considered related for the majority of the events. Related SAEs of vomiting were reported in five patients (3.4%), headache and meningitis chemical by four patients (2.7%) each.

Efficacy Results

Data reported as of June 2019 indicate that the median OS for the 107 patients diagnosed with pediatric CNS/LM metastasis from NB and treated under Study 03-133 was 50.8 months. Based on calculations per the Kaplan-Meier Plot, the estimated three-year OS of these 107 patients is 56% and the estimated five-year OS and ten-year OS is 44%, and 38%, respectively.

Comparison of Median Overall Survival (Months)



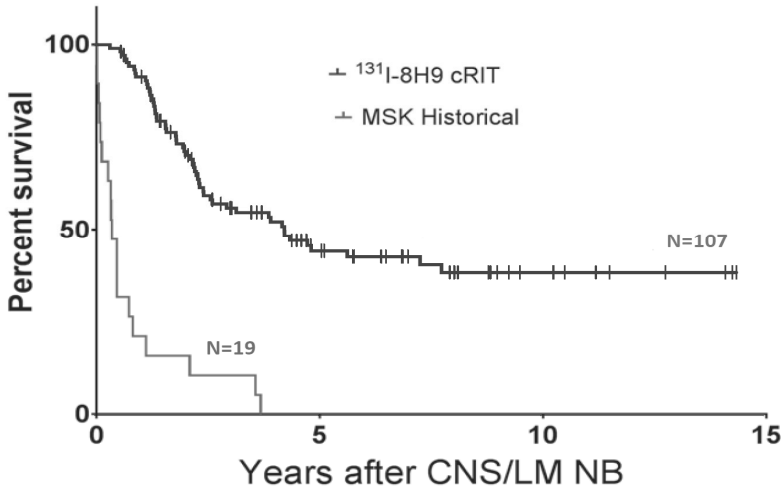
(1) MSK HC = NB patients with CNS / LM treated at MSK prior to 2003.

(2) ^{131}I-omburtamab = Patients diagnosed with pediatric CNS/LM metastasis from NB treated under Study 03-133.

The figure above compares median OS data from Study 03-133 with historical controls. Historical patient data extracted from three sources revealed median OS of 8.7 months in the literature, 4.7 months in the German NB Trials, and 5.5 months in the MSK historical cohort prior to the introduction of ^{131}I-omburtamab treatment. These results further

demonstrate the lack of an established, effective therapy for these patients that we believe can potentially be addressed by ^{131}I-omburtamab.

The chart below shows the historical comparable data and median OS following the introduction of ^{131}I-omburtamab treatment. This represents 107 treated patients from Study 03-133 diagnosed with pediatric CNS/LM metastasis from NB, as at June 2019. The estimated three-year median OS was 56% and the five-year median OS was 44%. Survivors have been followed for up to 14 years.



Study 101: A Multicenter Phase 2 Trial of the Efficacy and Safety of Intracerebroventricular Radioimmunotherapy using ^{131}I-omburtamab for Neuroblastoma Central Nervous System/Leptomeningeal Metastases

Study 101 is a pivotal Phase 2 single-arm, Open-Label, non-randomized, multi-center efficacy, safety, pharmacokinetics and dosimetry trial of intracerebroventricular ^{131}I-omburtamab in pediatric patients with R/R NB who have CNS/LM from NB. Patients will receive up to two cycles of ^{131}I-omburtamab. This study commenced in the second quarter of 2018, and as of January 2023, we have treated a total of 52 patients in a multi-center pivotal Phase 2 trial (Study 101) for an interim analysis for the purposes of pharmacokinetic and dosimetry comparability between study sites using ^{131}I-omburtamab from our cGMP commercial manufacturer, versus drug product previously produced by MSK. Study 101 has also been designed to satisfy potential confirmatory study and post-marketing requirement by the FDA, and, as a result, we will continue to follow the patients in the study. Study 101 is closed for recruitment but several patients are still in follow-up.

Safety and efficacy data will be investigated with short-term follow up at 26 weeks after treatment and with long-term follow up for up to three years following treatment. Final analysis will be performed when at least 50 treated patients have completed long-term follow up (three years or until death).

Median OS at three years and its 95% CI will be estimated using Kaplan-Meier methods. Efficacy will be achieved if the lower limit of the 95% CI of three-year median OS exceeds 10%. PFS will also be analyzed using Kaplan Meier methods.

Patient Population

In addition to satisfying certain other criteria, patients must be less than 18 years of age at the time of screening. Patients must have a histologically confirmed diagnosis of CNS/LM from NB with relapse.

Treatment Protocol

A single treatment cycle will last five weeks and will include premedication, intracerebroventricular ^{131}I-omburtamab administration (one dosimetry dose and one treatment dose), an observation period, and post-treatment evaluations (see figure below). The dosimetry dose will be used only for the first 24 patients.

One ^{131}I-omburtamab treatment cycle for Study 101

Patients without objective PD are eligible for a second dosing cycle.

Primary Objective

- To determine OS rate at three years.

Secondary Objectives

- To determine ORR up to three years.
- To assess PFS at six months after the first therapeutic dose of ^{131}I-omburtamab.
- To assess radiation doses delivered to the blood and CSF.
- To assess the frequency, type, of adverse events and human anti-mouse antibodies, or HAMA, response formation.
- To assess the effects on cognitive functions.

We originally initiated Study 101 to form the primary basis for our BLA, to establish comparability of study population and pharmacokinetics analysis with Study 03-133 and to satisfy potential confirmatory study and post-marketing requirements by the FDA. We submitted to a BLA for omburtamab in 2022. In November 2022, we received a CRL for the BLA. For additional details, see "Item 1. – Business – omburtamab."

Humanized Omburtamab Overview

We have an early stage development program for huB7-H3, a humanized version of omburtamab, for potential clinical testing in adult patients with B7-H3 positive solid tumors where systemic immunotherapy is needed. The program seeks to explore the use of huB7-H3 as a radio-conjugated antibody designed to overcome limitations of murine antibodies that may induce HAMA, which may lead to decreased efficacy and increased toxicity when used for systemic immunotherapy.

GD2-GD3 Vaccine Overview

Neuroectoderm-derived tumors, including NB and sarcomas, have high expression of tumor antigens GD2 and GD3. Our investigational bivalent GD2-GD3 Vaccine has been studied in a Phase 2 study (Study 05-075) conducted at MSK for the immunization of high-risk NB patients previously treated with DANYELZA. In addition, MSK has started

a new Phase 2 study (Study 21-206) of the GD2-GD3 Vaccine with the immunological adjuvant OPT-821 (QS-21), in combination with oral ß-glucan and randomization of GM-CSF, for the immunization of high-risk NB patients. The vaccine, in combination with adjuvants, is being studied to induce patients to produce their own anti-GD2 and anti-GD3 serum titers, with the goal of preventing subsequent relapse. Although MSK is pursuing clinical development of the GD2-GD3 Vaccine, and we are providing only limited support for Study 21-206, this program was deprioritized by us as part of the 2023 restructuring plan, and we are not devoting significant financial resources to this program.

SADA Technology - Liquid Radiation™

The SADA technology, also referred to as Liquid Radiation™, represents a 2-step pre-targeting radio immune therapy (pRIT). The radiation payload is encaged into a carrier molecule (DOTA) which in non-clinical setting has been demonstrated specifically to bind to the DOTA binding domain of the SADA molecule. Such payload deliveries have been achieved in non-clinical *in-vivo* settings, where xenograft tumors have been shown to shrink or completely disappear, with less exposure to other tissues. No clearing agent is needed, and no significant toxicity to bone marrow, kidneys or liver tissues has been observed in the non-clinical settings. Based on non-clinical data, we believe that the SADA technology may allow for rapid clearance of the unbound compound, while maintaining target uptake, and thereby causing optimal tumor to normal tissue ratio. As SADA reflects a humanized protein structure, less immunogenicity is expected. In addition, the SADA technology appears to be modular, embracing a tumor-binding domain, a DOTA binding domain and a tetramerization domain. Hence, DOTA-modified radioactive payloads combined with different tumor-binding domains seems possible.

We are using the SADA Technology to advance a series of antibody constructs based on the SADA technology, with the initial approach using ^{177}Lu-DOTA as the radioactive payload (b-emitter) We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.

GD2-SADA

Our first SADA molecule to enter clinical development is GD2-SADA for potential use in GD2 positive solid tumors. The IND for GD2-SADA is open and four clinical sites in the U.S are open for enrollment.

In the first in human clinical Phase 1 trial (Study 1001), GD2-SADA is administered at various timepoints before administration of ^{177}Lu-DOTA payload. The trial will be composed of three serial parts. The first part addresses optimization of protein doses and spacing between SADA protein administration and payload administration. The second part addresses optimal, safe levels of the payload delivery. In the third part, repeated exposures are investigated in order to monitor long-term safety signals.

Patient populations to be exposed in Study 1001 include those patients with small cell lung cancer, or SCLC, melanoma or one of several types of sarcomas, including osteosarcomas, soft tissue sarcomas, Ewing and angiosarcomas that can all be enrolled in the study. The target, disialoganglioside GD2, has limited expression in normal human tissues though it is expressed on peripheral neurons, central nervous system and skin melanocytes. It is highly expressed in the targeted indications.

Overview of SCLC

GD2 is highly expressed in SCLC. In addition, data for a radio-conjugated anti-GD2 monoclonal antibody (antibody 3F8, with similar scFv as GD2-SADA) demonstrated binding in 10 of 10 patients with SCLC. Lung cancer is the second most common cancer in both men and women, with an estimate of more than 200,000 new cases diagnosed annually in the United States. SCLC accounts for approximately 13% to 15% of all lung cancers. This high-grade neuroendocrine tumor is characterized by rapid growth and early development of metastases to both regional lymph nodes and distant sites, including the central nervous system. SCLC generally has a poor prognosis, and less than 5% of patients with extensive disease survive two years or more. Currently, the only approved first-line treatment approach for extensive disease, or ED, in SCLC is platinum-based chemotherapy with or without the addition of an immune checkpoint inhibitor. Second line therapies can include topotecan and lubinectidin. There is no approved therapeutic agent for patients with progressive SCLC following second-line treatment.

Overview of Sarcomas

Sarcomas are a group of cancers which arise in the bones and connective tissue. GD2 is highly expressed in several sarcomas including osteosarcomas, soft tissue sarcomas, angiosarcomas and Ewing sarcoma. Patients with any of these types of sarcomas are eligible to be enrolled into Study 1001.

Overview of osteosarcomas

Osteosarcoma is the most common type of cancer that arises in bone, accounting for two-thirds of all bone cancer cases. Most osteosarcomas occur in children, adolescents, and young adults. The treatment approach has not changed significantly over the past three decades. Conventional treatment regimens typically include neoadjuvant chemotherapy (e.g., high-dose methotrexate, doxorubicin, cisplatin) followed by surgical resection and reconstruction (with the goal of limb salvage) and adjuvant chemotherapy.

Overview of soft tissue sarcoma

The incidence of new soft tissue sarcomas is estimated to approximately 13,460 in the United States in 2023. GD2 is highly expressed in soft tissue sarcomas. Treatment options include surgery, radiotherapy, chemotherapy, and tyrosine kinase inhibitors. Different therapeutic approaches targeting GD2 in sarcoma are in early clinical development. For patients with localized disease at diagnosis the 5-year survival rate is approximately 80%. However, this survival rate declines to only 15% for patients with metastatic disease.

Overview of angiosarcoma

Angiosarcoma is an aggressive subtype of soft-tissue sarcoma. It is rare, representing <1% of soft-tissue sarcomas. The origin is the endothelial cell of blood or lymphatic vessels. It can affect any organ throughout the body, but the cutaneous form is the most common with the skin of the head and neck region, a frequent tumor location. Angiosarcoma can occur at any age, but the median age at diagnosis is 60-70 years. Treatment options include surgery, radiotherapy, chemotherapy, and tyrosine kinase inhibitors. The response to therapy is impacted location and size of the tumor, but generally the prognosis is poor with 5-year survival rates ranging from 12% to 35%.

Overview of Ewing sarcoma

Ewing sarcoma is a rare malignancy that occurs primarily in the bone or in the soft tissue around a bone. The tumor is most common in older children and adolescents, but it can occur at any age. Ewing sarcoma accounts for about 1% of all childhood cancers and approximately 200-250 children and adolescents in the United States are diagnosed with a tumor in the Ewing family of tumors each year. Treatment options include surgery, radiotherapy, chemotherapy, and tyrosine kinase inhibitors. The response to therapy is dependent on the stage of the tumor. The 5-year survival rates range from 81% for patients with localized disease to 38% for patients with metastatic disease.

Overview of malignant melanoma

GD2 is expressed in the majority of melanomas. Melanoma is an uncommon type of skin cancer that arises in the epidermis from melanocytes. It accounts for approximately 1% of all skin cancers but accounts for approximately 75% of deaths from skin cancers. In one estimate, in 2021, the incidence in the United States of newly diagnosed melanomas was approximately 106,000 and approximately 7,000 people were projected to die from melanoma in the United States.

Treatment is dependent on the extent of disease. Excision is the treatment for Stage 0 and Stage I melanomas. Sentinel lymph node biopsy, or SLNB, may be done for Stage I and Stage II disease. A positive SLNB may lead to adjuvant treatment with an immune checkpoint inhibitor or targeted drug therapy. Treatment for Stage III and Stage IV disease is based on the location and extent of disease. The primary tumor is usually excised, followed by adjuvant treatment with immune checkpoint inhibitors, high-dose interleukin-2 or targeted therapy drugs; and local treatments e.g. radiation. Immune checkpoint inhibitors include the anti-PD1 antibodies nivolumab, pembrolizumab, and the anti-CTLA-4 antibody, ipilimumab. Targeted therapies include treatments for melanoma with mutations in the BRAF gene, including vemurafenib, dabrafenib, and encorafenib. Chemotherapy may be used to treat refractory or recurrent Stage IV disease, most commonly temozolomide or Dacarbazine. Recurrent disease is treated in a similar manner to Stage IV disease.

Treatment Protocol

Clinical Trial 1001; Phase 1 trial with GD2-SADA:^{177}Lu-DOTA Complex in adult patients with recurrent or refractory metastatic solid tumors known to express GD2, including SLCA, sarcoma and malignant melanoma. An estimated 60 participants will participate in the trial and we expect that this trial will initially run in the United States. The IND is open and we began activating clinical trial sites in the fourth quarter of 2022.

The trial is planned as a Phase 1 trial with three parts, A, B and C. Escalation in this trial will be based on a classical 3+3 trial design. Part A is a GD2-SADA dose escalation phase, in which patients will receive one treatment cycle. Part B is a ^{177}Lu-DOTA dose escalation phase, in which patients will receive up to 2 treatment cycles. Part C is a repeated dosing phase where the doses determined in Part A and B will be administered. Patients will receive repeated treatment cycles with a maximum of 5 cycles.

Primary Objectives

- To determine the optimal, safe GD2-SADA protein dose and dosing interval between GD2-SADA and ^{177}Lu-DOTA administrations
- To determine maximum tolerable activity of ^{177}Lu-DOTA
- Occurrence of DLTs (Part A and B)
- To assess cumulative toxicity signals and safety profile following repeated dosing and determine the recommended phase 2 dose (RP2D)

CD38-SADA

We are preparing for a planned IND submission for our CD38-SADA as the second SADA construct and anticipate IND submission in 2023. This trial would be a first in human, dose-escalation, open-label, single-arm, multi-center trial (Study 1201) investigating the safety and tolerability of the CD38 SADA:^{177}Lu-DOTA Drug Complex in Relapsed or Refractory non-Hodgkin Lymphoma. We currently expect that the trial is will be conducted at sites in the United States assuming the IND is cleared.

MULTI-TAG Technology

We believe that our non-exclusive access to the MULTI-TAG technology will help us make further advances to our BsAb program by optimizing BiTEs. While there has been significant enthusiasm for BiTEs given their high potency and ability to penetrate more efficiently than conventional IgG-like BsAbs, their efficacy remains hampered by their size and binding characteristics. BiTEs are relatively small in size, approximately 55kD, resulting in a short serum half-life given rapid renal clearance. As a result, they require continuous infusion for several weeks in order to achieve a therapeutic response. They also bind monovalently, which often results in suboptimal tumor-binding. Further, therapeutic dosing of BiTEs is limited by the risk of excessive cytokine release in patients.

Using the MULTI-TAG technology, we have designed a novel protein tag of human origin that dimerizes, or links, BiTEs, in a unique conformation, which we believe may result in improved tumor-binding, a longer half-life, and greater T-cell mediated tumor cell killing. We are using the MULTI-TAG technology platform to dimerize our BsAbs into proteins of approximately 120kD in size, thereby increasing serum half-life without the need for continuous infusion. The unique dimerized conformation, while binding bivalently to tumors, also binds monovalently to T-cells, which we believe, leads to limiting excessive cytokine release.

Manufacturing

Currently, we contract with third-party cGMP vendors for the manufacturing of our product candidates for pre-clinical studies, clinical trials and commercial supply. We do not currently own or operate any manufacturing facilities to produce clinical or commercial quantities of our product candidates. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. To meet our projected needs for commercial manufacturing third parties with whom we currently work may need to increase their scale of production or we may need to secure alternate suppliers. Although we rely on our cGMP manufacturers, we have personnel with substantial manufacturing experience to oversee our relationships with such manufacturers.

Manufacturing clinical and commercial products is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. Our vendors are required to comply with cGMP regulations, which are regulatory requirements enforced by the FDA and other regulatory bodies like the EMA to assure proper design, monitoring and control of manufacturing processes and facilities for human pharmaceuticals. We have established an in-house quality assurance, or QA, function with a certified Qualified Person to perform final release of our product for both clinical and commercial supply.

Our current product candidates are mainly manufactured based on well-established technology known from mAb products. These manufacturing processes involve the genetic engineering of a parental host cell line to isolate a cell that produces the target product. Once a cell line is isolated, a cell bank is produced under prescribed and documented conditions. The cell bank, preserved frozen, is tested, as required by regulations, to demonstrate that the engineered cell line is free from potentially harmful impurities and contaminants, such as viruses.

The drug substance is an active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body. The manufacturing process for the drug substance begins with the thaw of vials from the cell bank and growth of these cells in established media until sufficient cells are cultured to inoculate a production bioreactor. The cells in the production bioreactor are grown in chemical defined media and under controlled and monitored conditions that stimulate the production of the antibody into the culture media. The production bioreactor is cultured for an established period of time and is then harvested by filtration to remove the cells from the culture media.

The solution containing the product is purified through several steps to remove known process and product derived impurities. The technologies employed include ultrafiltration and column and membrane chromatography. Additional steps are performed to inactivate or remove viruses. The final step of the drug substance process adjusts the antibody concentration and produces the final formulation to be used for drug product production. The drug substance is tested to meet pre-established product specific release criteria for purity, potency and safety, and is then periodically

tested to demonstrate stability upon storage as required by regulations. The drug substance is stored at prescribed temperatures, typically refrigerated or frozen.

The drug product is produced by sterilization filtration of the drug substance solution, followed by aseptic filling into glass vials and then stoppered. The drug product is subjected to product specific release testing for purity, potency and safety according to pre-established specifications. Drug product lots are periodically tested to demonstrate stability over the established storage expiry period. The drug product is stored and shipped under temperature-controlled conditions, typically refrigerated, to sites designated for clinical trial testing, or eventually to commercial pharmaceutical logistics providers.

DANYELZA is a recombinant humanized IgG1κ monoclonal antibody against GD2 expressed in Chinese Hamster Ovary, or CHO, cells. A one mL ampoule from the cell bank is used to establish material for seeding of 1,000 L fed batch bioreactor in chemical defined media with no animal derived component. After growth of the cells are completed the un-processed bulk from the bioreactor containing the DANYELZA drug substance undergoes clarification by filtration, and subsequent multi-step product purification. The DANYELZA drug substance is manufactured by Patheon Biologics B.V. in Groningen, The Netherlands and the DANYELZA drug product is manufactured at Patheon Manufacturing Services LLC in Greenville, North Carolina, (both part of the Thermo Fisher Scientific Inc., group of companies) collectively Patheon/Thermo Fisher. All manufacturing activities are performed in compliance with cGMP regulations and no excipients of human or animal origin have been used. The DANYELZA drug product is packaged in 10 mL ISO 10R glass vials and refrigerated.

While we believe that Patheon/Thermo Fisher is capable of producing sufficient quantities of drug product to support our clinical and commercial supply for DANYELZA, we also believe that there are a number of alternative third-party manufacturers that have similar capabilities that would be capable of providing sufficient quantities of drug product. However, should Patheon/Thermo Fisher not be able to provide sufficient quantities of drug product for our planned clinical trials or commercial sales, we would be required to seek and then qualify another contract manufacturer to provide this drug product, likely resulting in a delay in such trials and loss of, or delayed, commercial sales.

The GD2-SADA is manufactured at Rentschler Biopharma SE, Laupheim, Germany, using traditional manufacturing and control principles for monoclonal antibodies. The DOTA chemical is sourced as a GMP bulk product and is being filled into a sterile intermediate at Patheon/Thermo Fisher in Ferentino, Italy. Radiolabeling of the DOTA intermediate with Lu-177 is performed at ABX Advanced Biochemical Compounds – Biomedizinische Forschungsreagenzien GmbH, Radeberg, Germany, and final released product is delivered directly to clinical sites.

Commercialization Plan

The sales call points for DANYELZA in the United States are highly concentrated. This enables us to effectively service our customers and call points with a small commercial organization.

Our management team understands the complexity of rare oncological diseases and we believe we have the necessary expertise to be a true partner to patients, caregivers, and advocacy and healthcare teams leading to shared success. As we advance our product pipeline to address larger patient populations, we intend to expand our specialty sales force and continue the development of our organizational infrastructure to support the network of relevant hospitals, cancer centers, oncologists and other physicians as well as continue to provide support to patients, care givers and other healthcare providers. We plan to commercialize any potential future pediatric product candidates in the United States ourselves, and will continue to evaluate strategic collaborations in select territories in order to maximize the potential of our product and product candidates.

As additional product candidates advance through our pipeline, our commercial plans may change. The size of the development programs, size of the target market, size of a commercial infrastructure, and manufacturing needs may all influence our strategies in the United States, the European Union and other parts of the world.

Commercialization Partnerships

After the approval of DANYELZA by the FDA, we have entered a number of strategic collaborations in the form of partnerships with select companies to maximize the potential value for the Company. In November 2020, we entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, West Bank and Gaza Strip, and in September 2022, DANYELZA was approved for commercialization in Israel. In December 2020, we entered into a distribution agreement for DANYELZA and omburtamab with Swixx BioPharma AG for the Eastern European territories Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia and Slovenia. Finally, later in December 2020, we entered into a license agreement for DANYELZA and omburtamab with SciClone for Greater China, including Mainland China, Taiwan, Hong Kong and Macau. In July 2021, SciClone submitted a BLA for DANYELZA for the treatment of patients with R/R high-NB to the NMPA of China and the BLA was approved in December 2022. In May 2021, we entered into an exclusive distribution agreement with Adium Pharma S.A., or Adium, to be the exclusive distributor in Latin America of DANYELZA and omburtamab. Adium submitted regulatory filings for DANYELZA in Brazil, Mexico and Columbia in 2022. In December 2022, we announced a distribution agreement with WEP in connection with an early access program for DANYELZA in Europe.

Competition

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.

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, its efforts to develop a humanized version of Unituxin and plans to develop Unituxin within R/R NB, DANYELZA faces competition from Qarziba® (dinutuximab beta) a similar antibody product against GD2 developed by Apeiron Biologics AG, or Apeiron. EUSA Pharma (UK) Ltd., or EUSA, has acquired global commercialization rights to Qarziba® (dinutuximab beta), and it is currently being commercialized in Europe and was approved by the EMA to treat high-risk NB and R/R NB. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba® in mainland China and in August 2021 EUSA and BeiGene announced that the China 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 Industria Chimica E Farmaceutica S.pA., or Recordati, in March 2022.

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

Intellectual Property

Patent Portfolio

We strive to protect and enhance the proprietary technology, inventions, and improvements that we believe are commercially important to our business, including seeking, maintaining, and defending patent rights, whether developed internally or licensed from our collaborators or other third parties. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements, and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology and product candidates, continuing innovation, and in-licensing opportunities to develop, strengthen, and maintain our proprietary position in the field of immunotherapy. We additionally rely on data exclusivity, market exclusivity, and patent term extensions when available, and plan to seek and rely on regulatory protection afforded through orphan drug designations. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions, and improvements, whether developed internally or licensed from our collaborators or other third parties; to preserve the confidentiality of our trade secrets; to maintain our licenses to use intellectual property owned by third parties; to defend and enforce our proprietary rights, including our patents; and to operate without infringing on the valid and enforceable patents and other proprietary rights of third parties.

We have in-licensed numerous patents and patent applications and substantial know-how relating to the development and commercialization of our immunotherapy product candidates, including related manufacturing processes and technology. An international patent application has been filed claiming the inventions of investigators at MSK as well as our personnel. In addition, ten international patent applications have been filed solely in our name.

As of December 31, 2022, our patent portfolio included:

- For our DANYELZA patent portfolio, we have an exclusive license from MSK to MSK's rights in two patent families. The first family consists of patents and patent applications with composition of matter claims covering humanized or chimeric antibodies or fragments thereof comprising specific sequences and capable of binding to GD2, and includes three U.S. patents, one Australian patent, two New Zealand patents, one Chinese patent, one Japanese patent, one South Korean patent, one Hong Kong patent, one Indian patent, one Canadian Patent and one pending patent application in Europe. We expect that any patents that issue in this first family will expire in June 2031. A core U.S. patent in this family is expected to expire on June 20, 2031. An application for Patent Term Extension was filed in 2021 for this core U.S. patent, and if granted it is expected that it will extend the term of the core U.S. patent until February 4, 2034. The second family consists of applications with composition of matter claims covering high affinity anti-GD2 antibodies, and includes one US patent, one German patent, one French patent, one patent in United Kingdom, one Australian patent, one Japanese patent, one Russian patent, one Chinese patent, one Hong Kong patent, one Canadian patent, one South Korean patent and one pending patent application Brazil. We expect that any patents that issue in this second family will expire in March 2034.

- For our omburtamab patent portfolio, we have an exclusive license from MSK to MSK's rights in two patent families. The first family consists of patents and patent applications with composition of matter claims covering antibodies produced by a distinct hybridoma cell line, antibodies comprising specific sequences, polypeptides comprising specific sequences, and process claims covering a method of inhibiting the growth of tumor cells, a method for imaging a tumor in a subject and a method for treating a mammalian subject, and includes three U.S. patents, one German patent, one Spanish patent, one French patent, one patent in United Kingdom, one Italian patent and one Canadian patent. A core U.S. patent in this family is expected to expire on January 19, 2026 and core patents in Germany, Spain, France, United Kingdom and Italy in this family are expected to expire on March 6, 2023. The second family consists of

patents and patent applications with process claims covering a method of improving the prognosis or prolonging the survival of a subject bearing a tumor, and includes one Chinese patent, one Indian patent and one Canadian patent. Core patents in Canada, China, and India in this family are expected to expire on March 24, 2028.

- For our huB7-H3 patent portfolio, we have an exclusive license from MSK to MSK's rights in one patent family consisting of a patent and patent applications with composition of matter claims covering antibody agents that bind specifically to protein 2Ig-B7H3 or 4Ig-B7H3, and includes one patent in the United States, one patent in Germany, one patent in Spain, one patent in France, one patent in United Kingdom, one patent in Italy, one patent in Australia, one patent in China, one patent in Eurasia, one patent in Hong Kong and one patent in Japan and 5 pending patent applications in other jurisdictions, including Canada, New Zealand, South Korea, India and Brazil. We expect that any patents that issue in this family will expire in August 2035. In addition, an international patent application has been filed, with MSK and us as applicants, claiming a method for treating a central nerve system (CNS) cancer using huB7H3, as well as ^{177}Lu-DTPA-8H9 conjugates. Request for entry into the national phase has been filed in the United States, Canada, Europe, Australia, New Zealand, Japan, China, South Korea, India, Brazil, Eurasian, Russia and Hong Kong. We expect that any patent that issue in this family will expire in May 2038. Further, we have one patent family filed by Y-mAbs claiming B7H3 binding antibodies conjugated with chelators in specific chelator to antibody ratios. The family includes pending patent applications in the United States, Europe, China and Taiwan. Any patents issued in this family are expected to expire in 2041.

- For our huB7-H3 technology we further have one patent family, assigned to us, related to new humanized B7-H3 binding antibodies having high human germline content and exhibiting strong bonding to B7-H3 antigen. In this family we have pending patent applications in Taiwan, Australia, Brazil, Canada, China, Europe, Hong Kong, India, Japan, South Korea, New Zealand and the United States. We expect that any patents that issue in this family will expire in June 2041.

- For our B7-H3 technology we have one additional patent family assigned to us, relating to formulations containing radiolabeled B7-H3 antibodies, stabilized with ascorbic acid. One International patent application is pending in this family. We expect that any patents that may issue in this family will expire in February 2042.

- Our Multimerization Technology patent portfolio, which inter alia relates to nivatrotamab, includes one patent family under which we have a partly exclusive license to MSK's rights in the patent application. The license is exclusive for MSK's rights in the patents rights of this family that claim products, such as bispecific antibodies which are also claimed by other patent rights licensed from MSK, and non-exclusive for patents rights of this family that claim a product that is not claimed by another patent right licensed from MSK. This family consists of patents and patent applications with composition of matter claims covering bispecific binding agents comprised of two fusion proteins, and includes two U.S. patents, one Japanese patent, one Australian patent, one German patent, one French patent one South Korean patent, one Russian patent, one patent in United Kingdom, one patent in Canada, one Chinese patent and one patent in Hong Kong and two pending patent applications in Brazil. We expect that any patents that issue in this family will expire in March 2034. A core U.S. patent in this family is expected to expire on March 25, 2034.

- Our CD33 antibody patent portfolio, which includes one patent family under which we have an exclusive license from MSK to MSK's rights in the patent application. This family consists of one pending patent application in the United States, and five pending patent applications in other jurisdictions, including Europe, Canada, China, Hong Kong and Eurasia relating to anti Siglec-3 (CD33) antibodies generated from a specific principal investigator's laboratory at MSK. We expect that any patents that issue in this family will expire in April 2038.

- Our GD2-GD3 Vaccine patent portfolio, which inter alia relates to a vaccine for stimulation or enhancing production of an antibody which recognized a specific ganglioside, expired in 2022.

- For our DOTA-PRIT or SADA patent portfolio, we have an exclusive license from MSK and MIT to MSK's and MIT's rights in the field of Radioimmunotherapy for the diagnosis and treatment of cancer. The license gives access to seven patent families owned by MSK and one patent family owned by MIT. The first patent family covers bispecific antibodies capable of binding A33 and DOTA, and use thereof for the treatment of cancer. This first patent family consists of granted patents in the United States, the United Kingdom, France, Germany, Spain, Italy, the Netherlands Hong Kong and Australia and pending patent applications in the United States, China, Canada, Israel and Japan. We expect that any patents granted in this first family will expire in February 2036. A core U.S. patent in this family is expected to expire on July 15, 2037. The second family covers specific bispecific antibodies binding A33 and DOTA, and the use thereof for the treatment of cancer. This second family consists of a granted patent in the United stated and pending applications in Australia, Canada, China, Europe, Hong Kong, Israel, Japan, India, South Korea, New Zealand, Eurasia and the United States. We expect that any patents granted in this second family will expire in September 2038. A core U.S. patent in this family is expected to expire on January 27, 2039. The third family covers bispecific antibodies and the use therefore in a three-step PRIT procedure comprising the use of a clearing agent. In particular the family discloses Herceptin conjugated for Pre-targeted Radioimmunotherapy and application as a theranostic product. The license for this patent family has been limited to pending applications in Europe and the United States. We expect that any patents granted in this third family will expire in March 2039. The fourth patent family covers a multimeric antibody for two-step targeting (SADA). This fourth patent family consists of a granted patent in the United States, and pending patent applications in Australia, Canada, Europe, Hong Kong and the United States. We expect that any patents granted in this fourth family will expire in May 2038. A core U.S. patent in this family is expected to expire November 26, 2038. The fifth patent family covers the use of small molecule haptens for pre-targeted radioimmunotherapy (PRIT) using DOTA and bispecific antibodies. This fifth patent family consists of granted patents in Australia and the United States, and pending patent applications in Canada, China, Europe, Hong Kong, Japan and the United States. We expect that any patents granted in this fifth family will expire in July 2038. A core U.S. patent in this family is expected to expire on July 2, 2039. The sixth patent family covers new clearing agents for DOTA-PRIT. The license for this sixth patent family has been limited to pending patent applications in the United States and in Europe. We expect that any patents granted in this family will expire in July 2039. The seventh patent family covers PET-based methods for individualizing tumor targeting of antibodies. This seventh patent family consists of granted patents in the United Kingdom, France, Germany, Spain, Italy, the Netherlands and the United States, and pending applications in Australia and Canada. We expect that patents granted in this seventh family will expire in May 2036. The eighth patent family, owned by MIT, covers bispecific antibodies binding DOTA. This eighth patent family consists of granted patents in Belgium, France, Germany, Ireland, Italy, Spain, Switzerland, the United Kingdom and the United States. We expect that European patents in this eighth family expire in March 2030 and that the patent in the United States expires in July 2030.

- We further have one patent family, assigned to us, related to an humanized CD38-binding antibody and the use thereof for treatment of certain cancers. Pending patent applications exist in the United states, in Europe, in Australia, In Brazil, In Canada, in China, in Taiwan, in Hong Kong, in India, in Japan, in South Korea and in New Zealand. We expect that any patents that issue in this family will expire in June 2041.

The term of individual patents depends upon the legal term for patents in the countries in which they are granted. In most countries, including the United States, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. In the United States, a patent's term may, in certain cases, be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the United States Patent and Trademark Office, or USPTO, in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over a commonly owned patent or a patent naming a common inventor and having an earlier expiration date. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration date of a U.S. patent as partial compensation for the length of time the drug is under regulatory review while the patent is in force. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. We cannot provide any

assurance that any patent term extension with respect to any U.S. patent will be obtained and, even if obtained, what the duration of such extension may be.

Similar provisions are available in the European Union and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates receive approval by the FDA or non-U.S. regulatory authorities, we expect to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each drug and other factors. The expiration dates referred to above are, unless explicitly expressed, without regard to potential patent term extension or other market exclusivity that may be available to us. However, we cannot provide any assurance that any such patent term extension of a non-U.S. patent will be obtained and, even if obtained, the duration of such extension.

As for the immunotherapy products and processes we develop and commercialize, in the normal course of business, we intend to pursue, when possible, composition, method of use, dosing and formulation patent protection. We may also pursue patent protection with respect to manufacturing and drug development processes and technology.

Individual patents extend for varying periods of time, depending upon the date of filing of the patent application, the date of patent issuance, and the legal term of patents in the countries in which they are obtained. Generally, patents issued for applications filed in the United States are effective for 20 years from the earliest effective filing date. In addition, in certain instances, a patent term can be extended to recapture a portion of the term effectively lost as a result of the FDA regulatory review period. The restoration period cannot be longer than five years and the total patent term, including the restoration period, must not exceed 14 years following FDA approval. The duration of patents outside of the United States varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date. Generally, as noted above, our in-licensed issued patents in all jurisdictions will expire on dates ranging from 2021 to 2039. If patents are issued on our pending patent applications, the resulting patents are projected to expire on dates ranging from 2021 to 2041. However, the actual protection afforded by a patent varies on a product-by-product basis, from country-to-country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country, and the validity and enforceability of the patent.

Trademarks

We have obtained USPTO trademark registration of the "Y-mAbs" mark, USPTO and EU trademark registration as well as registration in other jurisdictions of DANYELZA and certain other trademarks that we intend to use to commercialize our product candidates. We currently rely on our registered and unregistered trademarks, trade names and service marks, as well as our domain names and logos, as appropriate, to market our brands and to build and maintain brand recognition. We are seeking to register and will continue to seek to register and renew, or secure by contract where appropriate, trademarks, trade names and service marks as they are developed and used, and reserve, register and renew domain names as appropriate.

Trade Secrets

We may also rely, in some circumstances, on trade secrets to protect our technology. However, trade secrets are difficult to protect. We seek to protect our technology and product candidates, in part, by entering into confidentiality agreements with those who have access to our confidential information, including our employees, contractors, consultants, collaborators, and advisors. We also seek to preserve the integrity and confidentiality of our proprietary technology and processes by maintaining physical security of our premises and physical and electronic security of our information technology systems. Although we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or may be independently discovered by competitors. To the extent that our employees, contractors, consultants, collaborators, and advisors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For this and more comprehensive risks related to our intellectual property and proprietary technology, inventions, improvements and products, please see the section on "Risk Factors—Risks Related to Our Intellectual Property."

MSK Agreements

On August 20, 2015, we entered into the MSK License, which grants us a worldwide, sub-licensable license to MSK's rights in certain patent rights and intellectual property rights related to certain know-how 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. The MSK License is exclusive with respect to MSK rights in such patent rights and tangible materials within such know-how, and nonexclusive with respect to MSK's rights in such know-how and related intellectual property rights. The patents and patent applications covered by the MSK License are directed, in part, to the DANYELZA and omburtamab antibody families, including humanized and chimeric antibodies, as well as MSK's rights in BsAbs, compositions, and their respective use for immunotherapy. Upon entering into the MSK License in 2015 and in exchange for the licenses thereunder, we paid to MSK an upfront payment of $500,000, issued 1,428,500 shares of our common stock to MSK and agreed to provide certain anti-dilution rights to MSK as further described below. In addition, we are required to pay to MSK certain royalty and milestone payments.

The MSK License requires us 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 us and our affiliates and sublicensees. We are 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. Total expensed minimum royalty payments under the MSK License were $1,200,000 in 2016 upon determination that the payment of such minimum royalties was probable and the amount was estimable. We are also obligated to pay to MSK certain clinical, regulatory and sales-based milestone payments under the MSK License, which payments become due upon achievement of the related clinical, regulatory or sales-based milestones. Certain of these clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License. Total clinical and regulatory milestones potentially due under the MSK License are $2,450,000 and $9,000,000, respectively. There are also sales-based milestones that become due should we achieve certain amounts of sales of licensed products resulting from the license arrangement with MSK, with total potential sales-based milestones potentially due of $20,000,000. As product candidates progress through clinical development, regulatory approval and commercialization, certain milestone payments will come due either as a result of the milestones having been met or the passage of time even if the milestones have not been met. In addition, to the extent we enter into sublicense arrangements, we are required to pay to MSK a percentage of certain payments that we receive from sublicensees of the rights licensed to us by MSK, which percentage will be based upon the date we receive such payments or the achievement of certain clinical milestones. We have entered into sublicenses and distribution agreements related to DANYELZA and omburtamab under the MSK License with Takeda Israel, Swixx BioPharma AG and SciClone in 2020, with Adium in 2021 and WEP in 2022.

The terms of the MSK License provide that MSK is entitled to receive 40% of the income generated from the sale of first PRV, and 33% of any income generated from the sale of any subsequent PRV or the sale of other comparable incentives provided by any non-U.S. jurisdiction. We sold the PRV received upon FDA approval of DANYELZA to United Therapeutics for $105 million. Pursuant to the agreement with MSK, we were entitled to retain 60% of the net proceeds from monetization of the PRV, and the remaining 40% was due to MSK. We received our portion of the net proceeds of from the sale of the PRV in the amount of approximately $62.0 million when the transaction was consummated in January 2021.

The MSK License will expire, on a country-by-country basis, and on a licensed-product-by-licensed-product or licensed-service-by-licensed-service basis, on the later of (i) the expiration of the last to expire of the patents and patent applications covering such licensed product or service in such country, (ii) the expiration of any market exclusivity period granted by a regulatory authority for such licensed product or service in such country, or (iii) 15 years from the first commercial sale of such licensed product or service in such country.

MSK may terminate the MSK License upon prior written notice in the event of our uncured material breach, or upon prior written notice if such breach is of a payment obligation. MSK may also terminate the MSK License upon written notice in the event of our bankruptcy or insolvency or our conviction of a felony relating to the licensed products, or if we challenge the validity or enforceability of any licensed patent right. In addition, we have the right to terminate the MSK License in its entirety at will upon prior written notice to MSK, but if we have commenced the

commercialization of licensed products and/or licensed services we can only terminate at will if we cease all development and commercialization of such licensed products and/or licensed services.

Our failure to meet certain conditions under the MSK License could cause the related license to such licensed product to be canceled and could result in termination of the MSK License by MSK.

On November 10, 2015, we entered into the Sponsored Research Agreement, or the SRA, with MSK pursuant to which we committed to provide aggregate research funding to MSK for a term of five years. The research will be conducted in accordance with a written plan and budget approved by the parties. MSK has granted us a non-exclusive, non-commercial, non-transferable, royalty-free license to use any inventions or discoveries developed by MSK within the scope of the information resulting from the project, for our internal, non-commercial research purposes. We have also been granted both a first option to negotiate an exclusive or non-exclusive commercial license to MSK's rights in inventions developed by MSK and a first option to negotiate an exclusive license to MSK's rights in inventions jointly developed by the parties. The SRA was amended on September 12, 2019, and will expire five years from the date of the amendment. The SRA may be terminated for convenience by either party upon prior written notice.

On September 20, 2016, we entered into a Master Data Services Agreement, or the MDSA, with MSK pursuant to which we committed to make certain payments to MSK annually in exchange for certain services, including transfer of clinical data and databases, regulatory files and other know-how to us by employees at MSK who are specifically assigned to assist with such services to us. The MDSA will expire upon the completion of activities set forth in each project description entered into thereunder; however we have the option to extend the term upon written notice to MSK. Either party may terminate the MDSA upon prior written notice in the event of an uncured material breach.

On June 21, 2017, we entered into the Investigator-Sponsored Master Clinical Trial Agreement, or the MCTA, as later amended on October 11, 2017, with MSK pursuant to which we committed to provide aggregate funding to MSK up to a certain amount for clinical studies to be conducted at MSK. Each such clinical study will be conducted in accordance with a written plan and budget and protocol approved by the parties. Under the MCTA, we and MSK have granted each other a non-exclusive, non-transferable, worldwide, royalty-free license, without right to sublicense, to use any inventions or discoveries developed by personnel of each such party, that is within the scope of the information resulting from the relevant study, for the other party's internal, non-commercial research purposes until such invention is commercially available. We have also been granted a first option to negotiate an exclusive or non-exclusive commercial license to MSK's rights in inventions or discoveries developed by MSK personnel under this MCTA and a first option to negotiate an exclusive license to MSK's rights in inventions or discoveries jointly developed by MSK and our personnel under this MCTA. The MCTA will continue in effect through completion of the studies, and may be terminated by either party upon prior written notice.

On June 27, 2017, we entered into two separate Core Facility Service Agreements, or CFSAs, with MSK pursuant to which we committed to make certain payments to MSK in exchange for certain laboratory services over the term of the CFSAs. Either party may terminate either of these CFSAs for any reason, or for no reason, upon prior written notice. In the event of termination of either of these CFSAs, we will make full payment to MSK for all work performed on, or expenses related to the project up to the date of termination including all non-cancelable obligations following receipt from MSK of any completed or in-process deliverables in connection with the project.

On November 13, 2017, we entered into the MSK CD33 License, with MSK, which grants us a worldwide, sub-licensable license to MSK's rights in certain patent rights and intellectual property rights related to certain know-how to develop, make and commercialize licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics in connection with certain CD33 antibodies generated in a specific principal investigator's laboratory at MSK and constructs thereof. The MSK CD33 License is exclusive with respect to such patent rights and tangible materials within such know-how, and nonexclusive with respect to MSK's rights in such know-how and related intellectual property rights. As product candidates progress through clinical development, regulatory approval and commercialization, certain milestone payments will come due either as a result of the milestones having been met or the passage of time even if the milestones have not been met. Also, we will owe MSK customary royalties on commercial sales of our approved products, if any. Total potential milestones due under the MSK CD33 License are $550,000, $500,000 and $7,500,000 for clinical, regulatory and sales based milestones, respectively. In

addition, the MSK CD33 License contains minimum royalty payments that become due beginning in year 10 of $40,000 per year over the royalty term, increasing to $60,000 once a patent within the licensed rights is issued, subject to increase and creditable against any royalty payments due based on sales in the future. We are required to pay mid to high single-digit royalties on sales of licensed products. Additionally, the terms of the MSK CD33 License provide that MSK is entitled to receive 25% of any income generated from the sale of any PRV or the sale of other comparable incentives provided by any non-U.S. jurisdiction.

The MSK CD33 License will expire, on a country-by-country basis, and on a licensed product-by-licensed-product or licensed-service-by-licensed-service basis, on the later of (i) the expiration of the last to expire of the patents and patent applications covering such licensed product or service in such country, (ii) the expiration of any market exclusivity period granted by a regulatory authority for such licensed product or service in such country, or (iii) 15 years from the first commercial sale of such licensed product or service in such country.

MSK may terminate the MSK CD33 License upon prior written notice in the event of our uncured material breach, or upon prior written notice if such breach is of a payment obligation. MSK may also terminate the MSK CD33 License upon written notice in the event of our bankruptcy or insolvency or our conviction of a felony relating to the licensed products, or if we challenge the validity or enforceability of any licensed patent right. In addition, we have the right to terminate the MSK CD33 License in its entirety at will upon prior written notice to MSK, but if we have commenced the commercialization of licensed products and/or licensed services we can only terminate at will if we cease all development and commercialization of such licensed products and/or licensed services.

On December 2, 2019, we entered into the Settlement and Assumption and Assignment, or SAAA, of MSK License and Y-mAbs Sublicense Agreement, or the MabVax/Y-mAbs Sublicense, between us and MabVax dated June 27, 2018, with MabVax Therapeutics Holdings, Inc. and MabVax Therapeutics, Inc., or together, MabVax, and MSK, which became effective on December 13, 2019. Pursuant to the MabVax/Y-mAbs Sublicense, MabVax sublicensed to us certain patent rights and know-how for development and commercialization of products for the prevention or treatment of NB by means of administering a bi-valent ganglioside vaccine granted to MabVax, pursuant to an exclusive license agreement dated June 20, 2008 between MabVax and MSK, as amended, or the MabVax/MSK License Agreement.

On March 21, 2019, MabVax filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code. The essence of the transaction created by the SAAA was for us, in light of the Chapter 11 bankruptcy proceedings affecting MabVax, to preserve the MabVax/MSK License Agreement and the rights granted to us under the MabVax/Y-mAbs Sublicense and for us to create a direct relationship with MSK with respect to the rights covered under the MabVax/Y-mAbs Sublicense. Pursuant to the SAAA, MabVax agreed to assume the MabVax/Y-mAbs Sublicense and the MabVax/Y-mAbs License Agreement pursuant to Section 365 of the Bankruptcy Code and concurrently to assign both of these agreements to MSK. We remain responsible for any potential downstream payment obligations to MSK related to the GD2-GD3 Vaccine that were specified in the MabVax/MSK License Agreement. This includes the obligation to pay development milestones totaling $1,400,000 and mid single-digit royalty payments to MSK. In addition, if we obtain FDA approval for the GD2-GD3 Vaccine, then we are obligated to file with the FDA for a PRV. The SAAA stipulates that, if we are granted a PRV from the FDA covering a licensed product under the MabVax/Y-mAbs Sublicense and the PRV is subsequently sold, we will pay directly to MabVax and to MSK, respectively, a total of twenty percent of the proceeds from the sale thereof. The MabVax/MSK License Agreement will expire with effect for us, on a country-by-country basis, on the later of the expiration of (i) 10 years from the first commercial sale of the licensed product in such country or (ii) the last-to-expire valid claim covering such licensed product rights at the time of and in the country of sale.

On April 15, 2020, we entered into a license agreement, or the SADA License Agreement, with MSK and Massachusetts Institute of Technology, or MIT, that grants us an exclusive, worldwide, sublicensable license to certain patent and intellectual property rights developed by MSK and MIT to develop, 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 SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA Technology, a concept we also refer to as Liquid Radiation™. The patents and patent applications covered by the SADA License Agreement are directed, in part, to the SADA

Technology, as well as a number of SADA constructs developed by MSK. Upon entering into the SADA License Agreement in April 2020 and in exchange for the licenses, we paid MSK and MIT a cash upfront payment and issued an aggregate of 42,900 shares of our common stock to them. During the year ended December 31, 2021, we made a cash payment in the amount of $1.0 million to MSK and MIT under the agreement. During the year ended December 31, 2022, we made another cash payment in the amount of $1.0 million to MSK and MIT under the agreement.

The SADA License Agreement requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License Agreement.

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

Under the SADA License Agreement, we also committed to funding scientific research at MSK for up to $1,500,000 over the next three years. Accordingly, in October 2020, we entered into a SADA sponsored research agreement with MSK pursuant to which we agreed to fund $1,500,000 in scientific research at MSK over the next three years to related to the intellectual property licensed under the SADA License Agreement. The scientific research took place over a period that commenced in September 2020 and ended in February 2022.

Government Regulation

The FDA and other regulatory authorities at federal, state, and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring, and post-approval reporting of biologics such as those we are developing. We, along with third-party contractors, will be required to navigate the various pre-clinical, clinical and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval or licensure of our product candidates. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

The process required by the FDA before biologic product candidates may be marketed in the United States generally involves the following:

- completion of pre-clinical laboratory tests and animal studies performed in accordance with the FDA's GLP regulation;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an independent Institutional Review Board, or IRB, or ethics committee at each clinical site before the trial is begun;

- performance of adequate and well-controlled human clinical trials to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;

- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;

- satisfactory completion of an FDA Advisory Committee review, if applicable;

- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;

- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with cGMP and to assure that the facilities, methods and controls are adequate to preserve the biological product's continued safety, purity and potency, and of selected clinical investigations to assess compliance with Good Clinical Practices, or GCPs; and

- FDA review and approval of our BLA to permit commercial marketing of the product for particular indications for use in the United States, which must be updated annually when significant changes are made.

Prior to beginning the first clinical trial with a product candidate, we must submit an IND to the FDA. An IND is a request for authorization from the FDA to administer an investigational new drug product to humans. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. An IND must become effective before human clinical trials may begin. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial. In such a case, the IND may be placed on clinical hold and the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin. Submission of an IND therefore may or may not result in FDA authorization to begin a clinical trial.

A clinical trial involves the administration of the investigational product to human patients under the supervision of qualified investigators in accordance with GCPs, which includes the requirement that all research patients provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the patients are being exposed to an unacceptable health risk or that the trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for patients or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap.

- Phase 1—The investigational product is initially introduced into healthy human patients with the target disease or condition. In oncology, clinical Phase 1 trials are normally conducted in patients, who have been

exposed to and failed/relapsed on available standard of care therapies. These studies are designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.

- Phase 2—The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3—The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval.

- In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved to gain more information about the product. These so-called Phase 4 studies may be made a condition to approval of our BLA.

Phase 1, Phase 2 and Phase 3 testing may not be completed successfully within a specified period, if at all, and there can be no assurance that the data collected will support FDA approval or licensure of the product. Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate, and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product, or for biologics, the safety, purity and potency. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, non-clinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. The BLA must include all relevant data available from pertinent pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data can come from company-sponsored clinical studies intended to test the safety and effectiveness of a use of the product, or from a number of alternative sources, including studies initiated by investigators. The submission of a BLA requires payment of a substantial User Fee to FDA, and the sponsor of an approved BLA is also subject to annual program fees. These fees are typically increased annually. A waiver of user fees may be obtained under certain limited circumstances.

Once a BLA has been submitted, the FDA's goal is to review the application within 10 months after it files the application, or, if the application relates to an unmet medical need in a serious or life-threatening indication, six months after the FDA files the application. The review process is often significantly extended by FDA requests for additional information or clarification. The FDA reviews a BLA to determine, among other things, whether a product is safe, pure and potent and the facility in which it is manufactured, processed, packed, or held meets standards designed to assure the product's continued safety, purity and potency. The FDA may convene an advisory committee to provide clinical insight on application review questions. Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request

additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all, and we may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the product will be produced, the FDA may issue an approval letter, or a Complete Response Letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter may request additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing regulatory standards is not maintained or if problems occur after the product reaches the marketplace. The FDA may require one or more Phase 4 post-market studies and surveillance to further assess and monitor the product's safety and effectiveness after commercialization, and may limit further marketing of the product based on the results of these post-marketing studies. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our products under development.

A sponsor may seek approval of its product candidate under programs designed to accelerate FDA's review and approval of new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for fast track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address an unmet medical need for the condition. For a fast-track product, the FDA may consider sections of the BLA for review on a rolling basis before the complete application is submitted if relevant criteria are met. A fast-track designated product candidate may also qualify for priority review, under which the FDA sets the target date for FDA action on the BLA at six months after the FDA files the application. Priority review is granted when there is evidence that the proposed product would be a significant improvement in the safety or effectiveness of the treatment, diagnosis, or prevention of a serious condition. If criteria are not met for priority review, the application is subject to the standard FDA review period of 10 months after FDA files the application. Priority review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

Under the accelerated approval program, the FDA may approve a BLA on the basis of either a surrogate objective that is reasonably likely to predict clinical benefit, or on a clinical objective that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. Post-marketing studies or completion of ongoing studies after marketing approval are generally required to verify the biologic's clinical benefit in relationship to the surrogate objective or ultimate outcome in relationship to the clinical benefit. In addition, a sponsor may seek FDA designation of its product candidate as a breakthrough therapy if the product candidate is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the therapy may demonstrate substantial improvement over existing therapies on one or more clinically significant objectives, such as substantial treatment effects observed early in clinical development. Sponsors may request the FDA to designate a breakthrough therapy at the time of or any time after the submission of an IND, but ideally before an end of Phase 2 meeting with FDA. If the FDA designates a breakthrough therapy, it may take actions appropriate to expedite the development and review of the application, which may include holding meetings with the sponsor and the review team throughout the development of the therapy; providing timely advice to, and interactive communication with, the

sponsor regarding the development of the drug to ensure that the development program to gather the non-clinical and clinical data necessary for approval is as efficient as practicable; involving senior managers and experienced review staff, as appropriate, in a collaborative, cross disciplinary review; assigning a cross disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor; and considering alternative clinical trial designs when scientifically appropriate, which may result in smaller trials or more efficient trials that require less time to complete and may minimize the number of patients exposed to a potentially less efficacious treatment. Breakthrough designation also allows the sponsor to file sections of the BLA for review on a rolling basis.

Fast Track designation, priority review and BTD do not change the standards for approval but may expedite the development or approval process.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. ODD must be requested before submitting a BLA. After the FDA grants ODD, the generic identify of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the BLA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

Breakthrough Therapy Designation

When a drug, alone or in combination with one or more other drugs, is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development, it can be granted breakthrough therapy designation. The standard for breakthrough therapy designation is not the same as the standard for drug approval, as the clinical evidence needed to support breakthrough designation is of preliminary nature.

Rare Pediatric Disease Designation

The Rare Pediatric Disease Priority Review Voucher Program, or the PRV Program, is intended to incentivize pharmaceutical companies to develop drugs for rare pediatric diseases. A company that obtains approval of an IND or a BLA for a designated rare pediatric disease may be eligible for a PRV from the FDA, which may be redeemed to obtain priority review for a subsequent new drug application or BLA by the owner of such PRV. A PRV is fully transferable and can be sold to any company, who in turn can redeem the PRV for priority review of a marketing application in six

months, compared to the standard timeframe of approximately ten months. A drug that receives a RPDD before September 30, 2024 continues to be eligible for a PRV if the drug is approved before September 30, 2026. Extension beyond these dates will require further Congressional action.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual program user fee requirements for any marketed products, as well as new application fees for supplemental applications with clinical data. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP, which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. We cannot be certain that we or our present or future suppliers will be able to comply with the cGMP regulations and other FDA regulatory requirements. If our present or future suppliers are not able to comply with these requirements, the FDA may, among other things, halt our clinical trials, require us to recall a product from distribution, or withdraw approval of the BLA.

We rely, and expect to continue to rely, on third parties for the production of clinical and commercial quantities of our product candidates. Future FDA and state inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of previously unknown problems with a product or the failure to comply with applicable requirements may result in restrictions on a product, manufacturer or holder of an approved BLA, including withdrawal or recall of the product from the market or other voluntary, FDA-initiated or judicial action that could delay or prohibit further marketing. The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising and promotion of biologics. A company can make only those claims relating to safety and efficacy, purity and potency that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among

other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties. Physicians may prescribe legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products.

Other Healthcare Laws and Compliance Requirements

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted regulatory approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Such restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration (including any kickback, bribe or rebate), directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, lease or order of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willingly executing, or attempting to execute, a scheme or making false statements in connection with the delivery of or payment for health care benefits, items, or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and its implementing regulations, which also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information on covered entities and their business associates and covered contractors that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;

- the federal transparency requirements known as the federal Physician Payments Sunshine Act, under the Patient Protection and Affordable Care Act, as amended by the Health Care Education Reconciliation Act, or collectively the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the U.S. Department of Health and Human Services, information related to payments and other transfers of value to certain physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors), other healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals and information regarding ownership and investment interests held by such physicians and their immediate family members; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payors, including private insurers.

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

Also, the U.S. Foreign Corrupt Practices Act and similar worldwide anti-bribery laws generally prohibit companies and their intermediaries from making improper payments to foreign officials for the purpose of obtaining or retaining business. No assurance can be given that our internal control policies and procedures will protect us from reckless or negligent acts committed by our employees, future distributors, partners, collaborators or agents. Violations of these laws, or allegations of such violations, could result in significant fines, penalties or prosecution and have a negative impact on our business, results of operations and reputation.

Coverage and Reimbursement

Sales of pharmaceutical products depend significantly on the availability of third-party coverage and reimbursement. Third-party payors include government health administrative authorities, managed care providers, private health insurers and other organizations. Third-party payors are increasingly challenging the price and examining the cost-effectiveness of medical products and services. In addition, significant uncertainty exists as to the reimbursement status of newly approved healthcare products. We may need to conduct expensive clinical studies to demonstrate the comparative cost-effectiveness of our products. The product candidates that we develop may not be considered cost-effective. It is time consuming and expensive for us to seek coverage and reimbursement from third-party payors. Moreover, a payor's decision to provide coverage for a drug product does not imply that an adequate reimbursement rate will be approved. Reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

Review and Approval of Medicinal Products in the European Union

In the European Union, medicinal products are subject to extensive regulatory requirements. As in the United States, medicinal products can be marketed only if a marketing authorization from the competent regulatory agencies has been obtained.

The various phases of preclinical and clinical research in the European Union are subject to significant regulatory controls. Although the EU Clinical Trials Directive 2001/20/EC has sought to harmonize the EU clinical trials regulatory framework, setting out common rules for the control and authorization of clinical trials in the European Union, the EU Member States have transposed and applied the provisions of the Directive differently into their national laws. This has led to significant variations in the member state regimes.

The Clinical Trials Regulation (EU) No 536/2014 entered into application on January 31, 2022. The Regulation harmonizes and streamlines clinical trial authorizations, simplifies adverse-event reporting procedures, improves the supervision of clinical trials and increases their transparency. Specifically, the new Regulation, which is directly applicable in all EU Member States, introduces a streamlined application procedure via a single-entry point, the "EU portal"; a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials is divided into two parts. Part I is assessed by the competent authorities of a reference member state selected by the trial sponsor largely of the type of clinical trial, risk-benefit analysis, and compliance with technical requirements. This assessment, which is valid for the entire EU, is then in Part II submitted to the competent authorities of all the concerned member states in which the trial is to be conducted.

In the European Economic Area, or EEA, which consists of the 27 Member States of the European Union, as well as Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after a related marketing authorization has been granted. A company may submit a marketing authorization application, or MAA, either on the basis of the centralized or decentralized procedure. Under the centralized procedure, MAAs are submitted to the EMA for scientific review by the EMA's Committee for Medicinal Products for Human Use, or CHMP. The CHMP issues an opinion concerning whether the quality, safety and efficacy of the product has been demonstrated. The opinion is considered by the EC which is responsible for granting a centralized marketing authorization in the form of a binding EC decision. If the application is approved, the EC grants a single marketing authorization that is valid throughout the EEA. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, advanced-therapy medicines such as gene-therapy, somatic cell-therapy or tissue-engineered medicines and medicinal products containing a new active substance indicated for the treatment of HIV, AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and other immune dysfunctions and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

National marketing authorizations, which are issued by the competent authorities of EEA countries and only cover their respective territory, are available for products not falling within the mandatory scope of the centralized procedure. Where a product has already been authorized for marketing in an EEA country, this national marketing authorization can be recognized in another EEA country through the mutual recognition procedure. The mutual recognition procedure provides for the EEA countries selected by the applicant to mutually recognize a national marketing authorization that has already been granted by the competent authority of another EEA country, referred to as the Reference Member State, or RMS. The decentralized procedure is used when the product in question has yet to be granted a marketing authorization in any EEA country. Under this procedure the applicant can select the EEA country that will act as the RMS. In both the mutual recognition and decentralized procedures, the RMS reviews the application and submits its assessment of the application to the EEA countries for which marketing authorizations are being sought, referred to as Concerned Member States. Within 90 days of receiving the application and assessment report, each Concerned Member State must decide whether to recognize the RMS assessment or reject it on the basis of potential serious risk to public health. If the disputed points cannot be resolved, the matter is first referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures for agreement. If the Group cannot reach an agreement, a referral is made to the EMA. The CHMP will provide an opinion that will form the basis of a decision to be issued by the EC that is binding on all EEA countries. If the application is successful during the decentralized or mutual recognition procedure, national marketing authorizations will be granted by the competent authorities in each of the EEA countries chosen by the applicant.

In principle, a marketing authorization has an initial validity of five years. The marketing authorization may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EEA country in which the original marketing authorization was granted. To support the application, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the Electronic Common Technical Document, or eCTD, providing up to date data concerning the quality, safety and efficacy of the product, including all variations introduced since the marketing authorization was granted, at least nine months before the marketing authorization ceases to be valid. The EC or the competent authorities of the EEA countries may decide, on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the marketing authorization. Once subsequently definitively renewed, the marketing authorization shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (in case of centralized procedure) or on the market of the authorizing EEA country within three years after authorization ceases to be valid (the so-called sunset clause).

In the EU, conditional marketing authorizations may be granted in the centralized procedure for a limited number of medicinal products for human use in cases where the related clinical dataset is not yet complete. A conditional marketing authorization may be granted for a medicinal product, if (1) the risk-benefit balance of the product is positive, (2) it is likely that the applicant will be in a position to provide the required comprehensive data after the authorization, (3) the medicinal product fulfills unmet medical needs and (4) the benefit to public health of the immediate availability on the market of the medicinal product outweighs the risk inherent in the fact that additional data are still required. The authorization is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional marketing authorization can be converted into a traditional marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Data and Market Exclusivity in the EU

In the EU, innovative medicinal products that are subject to marketing authorization on the basis of a full dossier and do not fall within the scope of the concept of global marketing authorization qualify for eight years of data exclusivity upon marketing authorization and an additional two years of market exclusivity. The concept of global marketing authorization prevents the same marketing authorization holder or members of the same group, or companies that have concluded tacit or explicit agreements concerning the marketing of the same medicinal product, from obtaining separate data and market exclusivity periods for medicinal products that contain the same active substance. Data exclusivity, if granted, prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application or biosimilar application for eight years from the date of authorization of the innovative product, after which a generic or biosimilar marketing authorization application can be submitted, and the innovator's data may be referenced. However, the generic product or biosimilar products cannot be marketed in the EU for a further two years thereafter. The overall ten-year period may be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a PIP agreed with the EMA's Pediatric Committee, or PDCO. The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which marketing authorization is being sought. The PDCO may grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Furthermore, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the marketing authorization is obtained in all EU Member States and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate or SPC if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Orphan Designation and Exclusivity in the EU

Regulation (EC) No. 141/2000, as implemented by Regulation (EC) No. 847/2000 provides that a medicinal product can be designated as an orphan medicinal product by the European Commission if its sponsor can establish that : (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) such conditions affect not more than 5 in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (3) there exists no satisfactory authorized method of diagnosis, prevention, or treatment of the condition that has been authorized in the EU, or even if such method exists, the product will be of significant benefit to those affected by that condition.

Orphan medicinal product designation entitles an applicant to incentives such fee reductions or fee waivers, protocol assistance, and access to the centralized marketing authorization procedure. Upon grant of a marketing authorization, orphan medicinal products are entitled to a ten-year period of market exclusivity for the approved therapeutic indication, which means that the EMA cannot accept another marketing authorization application, or grant a marketing authorization, or accept an application to extend a marketing authorization for a similar product for the same indication for a period of ten years. The period of market exclusivity is extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan, or PIP. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. Orphan medicinal product designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product destination, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold. Additionally, an MA may be granted to a similar medicinal product with the same orphan indication during the 10 year period if: (i) if the applicant consents to a second original orphan medicinal product application, (ii) if the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) if the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. A company may voluntarily remove a product from the register of orphan products.

Post-Approval Requirements in the EU

Where a marketing authorization is granted in relation to a medicinal product in the EU, the holder of the marketing authorization is required to comply with a range of regulatory requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products.

Healthcare Reform

A primary trend in the United States healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States.

In March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for drug products under government health care programs. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability; and

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

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 2031 unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester.

Since its enactment, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the ACA. We expect that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our ability to maintain or increase sales of our existing products that we successfully commercialize or to successfully commercialize our product candidates, if approved. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. In addition to the ACA, there will continue to be proposals by legislators at both the federal and state levels, regulators and third-party payors to keep healthcare costs down while expanding individual healthcare benefits.

Further, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry.

Human Capital

We believe the success of the company depends on our ability to continue to attract, retain and motivate qualified employees. We seek to meet this objective by offering competitive compensation and benefits packages in our expanding organization, with opportunities for our employees to thrive, grow and develop in their careers. We hold our employees to high ethical performance standards and our compensation plans include, as applicable, equity and cash compensation components designed to enable us to offer competitive base pay and attractive incentive schemes.

As of December 31, 2022, we had 147 full time employees. Of these employees, 105 were employed in research and development roles, 26 were employed in commercial roles and 16 were employed within general and administration. Women represented approximately 60% of our workforce and men represented approximately 40%. Following the execution of our 2023 restructuring plan, we had 95 full time employees by the end of February 2023.

The health and safety of our employees is of utmost importance to us. We offer comprehensive benefits to protect the health of our employees and their families.

The members of our management team are employed by both our company and Y-mAbs Therapeutics A/S, our wholly owned Danish subsidiary. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated in Delaware on April 30, 2015. Our principal executive offices are located at 230 Park Avenue, Suite 3350, New York, New York 10169, and our telephone number is (646) 885-8505. Our website address is www.ymabs.com.

We make available, free of charge on our website, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports filed or furnished with the SEC pursuant to

Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable. The information contained on, or accessible through, our website is not incorporated by reference into this Annual Report on Form 10-K, and you should not consider any information contained in, or that can be accessed through, our website as part of this Annual Report on Form 10-K or in deciding whether to purchase our common stock.

We use our website https://ymabs.com/ as a channel of distribution of material company information. For example, financial and other material information regarding our company is routinely posted on and accessible on our website. Accordingly, investors should monitor this channel, in addition to following our press releases, SEC filings and public conference calls and webcasts. The contents of our website are not, however, a part of this Annual Report on Form 10-K and are not incorporated by reference herein.

Our Code of Conduct applies to all of our employees, directors and officers, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and those of our subsidiaries. The Code of Conduct is available on our website at https://ir.ymabs.com/ under the section entitled "For Investors" under "Corporate Governance." We intend to satisfy the disclosure requirements under Item 5.05 of the SEC Form 8-K regarding an amendment to, or waiver from, a provision of our Code of Conduct by posting such information on our website at the website address and location specified above.

ITEM 1A.RISK FACTORS.

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

Risks Related to Our Financial Condition and Need for Additional Capital

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

We are a commercial-stage biopharmaceutical company with a limited operating history. Since our inception in 2015, we have incurred significant losses each year. As of December 31, 2022 our accumulated deficit was approximately $436.0 million. We have financed our operations principally through private placements, the initial public offering of our common stock in 2018 as well as subsequent public offerings of our common stock in November 2019 and February 2021, and the sale of the PRV granted to us upon FDA approval of DANYELZA.

To date, we have devoted substantially all our efforts to research and development, and more recently, commercialization of DANYELZA, which is our only approved product to date and omburtamab. On November 25, 2020, DANYELZA was approved by the FDA for the treatment, in combination with GM-CSF, of pediatric patients 1 year of age and older and adult patients with relapsed/refractory, or R/R, high-risk neuroblastoma, or NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. Although in May 2022 our biologic license application, or BLA, for omburtamab was accepted for priority review by the FDA, in November 2022 the FDA issued a complete response letter, or CRL, for the BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022.

In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a

favorable benefit-risk profile. We are currently considering the future for our omburtamab development program, and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

Our other product candidates are in the early stages of clinical development or pre-clinical research. As a result, we expect that it will be a number of years, if ever, before we have any of these other product candidates approved and ready for commercialization.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. Our only approved product for sale is DANYELZA, which received FDA accelerated approval on November 25, 2020. We began limited sales and shipments of DANYELZA in February 2021 and the revenue generated from product sales does not fully fund our operating expenses. We do not anticipate generating revenue that will fully fund our operating expenses for a period of time, if ever. No assurance can be given that we will ever receive regulatory approval for any of our product candidates other than DANYELZA. Our ability to generate revenue and achieve profitability depends significantly on our success in many factors, including:

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

We anticipate incurring research, development, clinical trial, manufacturing and marketing costs associated with commercializing even approved products such as DANYELZA. Our expenses could increase beyond expectations if we are required by the FDA or other regulatory agencies, domestic or foreign, to change our manufacturing processes or assays, or to perform clinical, non-clinical, or other types of studies in addition to those that we currently anticipate. If we are successful in obtaining regulatory approvals to market more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval, the accepted price for any such product, the ability to obtain reimbursement at any price, and whether we own the commercial rights

for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the reasonably expected populations for treatment are narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate sufficient revenue from the sale of DANYELZA or any other approved products, we may never become profitable.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We were incorporated and began our operations on April 30, 2015. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, commercializing DANYELZA, conducting clinical trials of DANYELZA and other products and conducting pre-clinical studies and clinical trials of our other product candidates, and identifying additional potential product candidates. Typically, it takes about six to 10 years to develop a new drug from the time it is in Phase 1 clinical trials to when it is approved for treating patients, but in many cases it may take longer. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products. In addition, as a business with a limited operating history, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors as we continue to develop and commercialize DANYELZA and our other product candidates.

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

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

However, the changes to our business strategy and the reduction in workforce may yield unintended consequences and costs, such as the loss of institutional knowledge and expertise, attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk that we may not achieve the anticipated benefits, all of which may have an adverse effect on our development activities, ability to progress our technology roadmap, and results of operations or financial condition. We expect to incur restructuring expenses of approximately $4.7 million, consisting predominantly of cash related notice and severance payments of approximately $3.0 million and acceleration of stock-based compensation of approximately $1.7 million in 2023. We may also incur other charges, costs, future cash expenditures or impairments not currently contemplated due to events that may occur as a result of, or in connection with, the revised business plan and reduction in workforce. For example, we recorded an impairment charge of $0.6 million to write-off the net book value of fixed assets that were related to the production of omburtamab in 2022. In addition, we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. In addition, our management may need to divert a disproportionate amount of its attention away from our day-to-day strategic and operational activities and devote a substantial amount of time to managing these organizational changes.

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

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

Under the MSK License, we have committed to funding scientific research as well as conducting certain clinical trial activities at MSK. As licensed product candidates progress through clinical development and commercialization, certain milestone payments will come due, and we will owe MSK customary royalties on commercial sales of our approved products, if any. Milestone payments become due upon achievement of the related clinical, regulatory or sales-based milestone set forth in the MSK license agreements and all milestones are accrued for when they are probable and estimable. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK license agreements, whether or not the milestone activity has been achieved. Total clinical and regulatory milestones potentially due under the MSK License are $2.5 million and $9.0 million, respectively. There are also sales-based milestones that become due should we achieve certain amounts of sales of licensed products with total sales-based milestones potentially due of $20.0 million.

Under the MSK CD33 License, we are obligated to make potential payments of $0.6 million, $0.5 million and $7.5 million for clinical, regulatory and sales-based milestones, respectively.

In April 2020, we entered into the SADA License Agreement which requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the SADA License. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License. We are also obligated to pay to MSK and MIT certain clinical, regulatory and sales-based milestone payments under the SADA License Agreement. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestone payments potentially due under the SADA License Agreement are $4.7 million and $18.1 million, respectively. Additionally, we are also obligated to make sales-based milestones payments totaling $23.8 million, that become due should we achieve certain amounts of sales of licensed products under the SADA License. In addition, for each of the SADA constructs generated by MSK and sold on our behalf by one of our sublicenses, we may pay sales-based milestone payments in the total amount of $60.0 million based on the achievement of various levels of cumulative net sales by the sublicensee. Under the SADA License Agreement, we also committed to fund scientific research at MSK under a Sponsored Research Agreement for $1.5 million. The scientific research took place over a period that commenced in September 2020 and ended in February 2022.

In addition, we have committed to acquire certain personnel and laboratory services at MSK under a Master Data Services Agreement, or MDSA, and two separate Core Facility Service Agreements, or CFSAs. We have also entered into an Investigator-Sponsored Master Clinical Trial Agreement, or the MCTA, with MSK under which we are providing drug product and funding for certain clinical trials at MSK under separate executed appendices. Additionally, we have entered into a Sponsored Research Agreement, or the SRA, with MSK pursuant to which we paid MSK to conduct certain research projects over a period of five years related to the intellectual property licensed under the MSK License. The SRA was amended on September 13, 2019, and will expire five years from the date of the amendment. We also remain responsible for any potential downstream payment obligations to MSK related to the GD2-GD3 Vaccine. This includes our obligation to make development and regulatory milestone payments, if achieved, totaling $1.4 million, annual minimum royalties of $10,000, increasing to $25,000 from approval of the first new drug application, or NDA, or BLA for a licensed product over the royalty term, and mid-single-digit royalty payments to MSK on sales.

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

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

Developing pharmaceutical products, including conducting pre-clinical studies and clinical trials and commercialization of any approved products, is a very time-consuming, expensive and uncertain process that takes years to complete. We expect our expenses to increase in connection with our ongoing activities, particularly as we grow our sales and marketing team to support sale of DANYELZA and conduct clinical trials of, and seek marketing approval for our other product candidates. We expect to incur commercialization expenses, which may be significant, related to product sales, marketing, manufacturing and distribution of DANYELZA. Accordingly, until at least such time as we can generate substantial additional revenues from sales of DANYELZA or our product candidates, if approved, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise sufficient amounts of additional capital when needed or on attractive terms, we may be forced to delay, reduce or eliminate our research and drug development programs or our future commercialization efforts.

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

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

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

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

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

or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

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

We have focused our efforts and managerial resources on specific products and product candidates and on specific indications such as DANYELZA for the treatment of R/R high-risk NB in bone and/or bone marrow and omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB. As a result, we may forgo or delay pursuit of opportunities with other products or product candidates or for other indications that may prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Failure to properly assess potential product candidates for indications could result in focusing on product candidates for indications with lower market potential, which could harm our business and financial condition. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through partnering, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or product. For example, in November 2022 the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. This was consistent with the outcome of the ODAC Meeting held in October 2022. In its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

Risks related to product development and commercialization

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

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must complete pre-clinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates. No assurance can be given that any clinical studies will be conducted as planned or completed on schedule, if at all. In addition, we cannot be sure that we will be able to submit investigational new drug applications, or INDs, for any of our product candidates in the future and we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin. Moreover, even if these clinical studies begin, issues may arise that could suspend or terminate such clinical trials. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to outcome. Failure of one or more clinical trials can occur at any stage of testing.

The outcome of pre-clinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial, such as the results of our ongoing clinical trials of our lead product candidates, do not necessarily predict final results. Moreover, pre-clinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in pre-clinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. The nature of the patient populations that we study in our clinical trials means that the treatment effect of our product candidates has to be demonstrated despite being the second or third-line of treatment, and in some cases, despite concomitant treatment with radiation or chemotherapy. Some of our target indications, including CNS/LM from NB, may also be difficult to assess via current imaging technology and other testing methods, which may lead to in conclusory or equivocal data regarding treatment effect. Furthermore, because our study populations are small, statistical

analyses may not fully adjust for these and other potential bias in the data. Such was the case for omburtamab, any or all of these factors may mean that we are unable to demonstrate substantial evidence of the effectiveness of or product candidates to the satisfaction of the FDA or comparable foreign regulatory authorities.

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

DANYELZA and our product candidates and related technologies represent novel approaches to cancer treatment generally. Developing and commercializing these products therefore subjects us to a number of challenges. Although the FDA accepted our BLA for omburtamab for priority review, in November 2022 the FDA issued a CRL for our BLA for omburtamab. The letter indicated that the FDA completed the review of the application and determined that it is unable to approve the BLA in its current form. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and there is no assurance that we will continue to develop omburtamab or receive approval of our BLA for omburtamab. We may never be able to develop a marketable product other than DANYELZA. Our ability to generate product revenue is highly dependent on our ability to successfully commercialize DANYELZA and to obtain additional regulatory approvals of and successfully commercialize additional product candidates. This will require additional clinical and non-clinical development, regulatory review and approval in each jurisdiction in which we intend to market them, substantial investment, access to sufficient commercial manufacturing capacity, and significant marketing efforts. We cannot be certain that any of our other product candidates will be successful in clinical studies and they may not receive regulatory approval even if they are successful in clinical studies.

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

- successful and timely completion of our ongoing clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- timely receipt of marketing and reimbursement approvals for our lead product candidates from applicable regulatory authorities;
- the performance of our future collaborators, if any;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- establishment of supply arrangements with third-party raw materials and drug product suppliers and manufacturers;
- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are appropriately packaged for sale;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protection of our rights in our intellectual property portfolio, including our licensed intellectual property;

- successful launch of commercial sales following any marketing approval including the hiring of a direct salesforce and creation of marketing campaigns;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by physicians and patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Further, competitors who are developing product candidates with technology similar to ours may experience problems with their product candidates that could identify problems in the technology that would potentially harm our business.

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

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

We are seeking to identify and develop a broad pipeline of product candidates using the SADA Technology. We have not commenced clinical trials for any product candidates developed using the SADA Technology. The scientific research that forms the basis of our efforts to develop product candidates with the SADA Technology is still ongoing. We are not aware of any FDA approved therapeutics utilizing a similar technology. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on the SADA Technology is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks, and it is difficult to predict the types of challenges and risks that we may encounter during development of our product candidates using the SADA Technology. For example, we have not tested any of the product candidates being developed using the SADA platform in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. Further, relevant animal models and assays may not accurately predict the safety and efficacy of our product candidates based on the SADA Technology in humans, and we may encounter significant challenges creating appropriate models and assays for demonstrating the safety and purity of our product candidates. In addition, the SADA Technology has potential safety risks related to, but not limited to, the radiation stemming from the delivery of radioactive payloads. As a result, it is possible that safety events or concerns could negatively affect the development of our product candidates developed using the SADA Technology, including adversely affecting patient enrollment among the patient populations that we intend to treat.

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

Additionally, an element of our strategy is to use and expand the SADA Technology to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different cancers. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at cancers, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building a pipeline of product candidates developed using the SADA Technology, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop, get approval for and begin to commercialize any product candidates developed using the SADA Technology, we will face difficulty in obtaining product revenue therefrom in future periods, which could result in significant harm to our financial position and adversely affect our share price.

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

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

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

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

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

- establish and maintain our relationships with healthcare providers who will be treating the patients who may receive our products and any future products;

- maintain adequate pricing and reimbursement for DANYELZA and any future products;

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

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

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

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

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

- the willingness of the target patient populations to try new therapies and enroll in ongoing clinical trials, and of physicians to prescribe these therapies;

- relative convenience and ease of administration;

- availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors; and

- the timing of competitive product introductions and other actions by competitors in the marketplace.

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

We have only recently established our sales and marketing organization and have only limited experience in marketing and sale of biopharmaceutical products. We began small shipments of DANYELZA in February 2021. Other than our commercialization partnerships for DANYELZA and omburtamab covering certain territories outside the United States with SciClone Pharmaceuticals International Ltd, Takeda Israel, Swixx Biopharma AG, Adium Pharma S.A. and WEP Clinical Ltd., we are not currently a party to any strategic collaboration that provides us with access to a collaborator's resources in selling or marketing drugs. To achieve commercial success for any future approved products we must successfully maintain and expand our sales and marketing organization or outsource these functions to strategic collaborators and other third parties. We have built our own focused, specialized sales and marketing organization in the United States. We continue to explore selectively establishing partnerships in markets outside the United States to support the commercialization of our product candidates for which we obtain marketing approval and that can be commercialized with such capabilities.

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

Factors that may inhibit our efforts to commercialize our drugs on our own after obtaining any marketing approval include:

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;

- our inability to raise financing necessary to maintain and grow our commercialization infrastructure;

- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe DANYELZA or any future approved products;

- the lack of complementary drugs to be offered by our sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive offerings;

- unforeseen costs and expenses associated with creating an independent sales and marketing organization; and

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

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

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

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

Specifically, MacroGenics, Inc. and Daiichi Sankyo Co. are developing antibodies against the B7-H3 molecule that is the target of omburtamab. With respect to DANYELZA, which targets GD2-positive tumors, United Therapeutics Corporation, or United Therapeutics, has commercialized Unituxin (dinutuximab), an antibody against GD2, in the United States, Canada and Japan. Although United Therapeutics has discontinued its efforts to investigate Unituxin's potential activity against adult cancerous tumors, its efforts to develop a humanized version of Unituxin and plans to develop Unituxin within R/R NB, DANYELZA faces competition from Qarziba® (dinutuximab beta) a similar antibody product against GD2 developed by Apeiron Biologics AG, or Apeiron. EUSA Pharma (UK) Ltd., or EUSA, has acquired global commercialization rights to Qarziba® (dinutuximab beta), and it is currently being commercialized in Europe and was approved by the EMA to treat high-risk NB and R/R NB. In January 2020, EUSA and BeiGene Ltd., or BeiGene, announced an exclusive collaboration to commercialize Qarziba® in mainland China and in August 2021 EUSA and BeiGene announced that the China National Medical Products Administration, 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 mainland China, DANYELZA is not the first approved antibody treatment for R/R NB. If approved in Europe, DANYELZA will not be the first approved antibody treatment for R/R NB in Europe. We may not be the first to market in other geographies, which may affect the price or demand for DANYELZA. Similarly, we may not be the first to market for any of our other future products, if approved. Additionally, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our DANYELZA or for any other future products, if approved. We may not be able to implement our business plan if the acceptance of DANYELZA or for any other future products, if approved, is inhibited by price competition or the reluctance of physicians to switch from

existing methods of treatment to our products, or if physicians switch to other new drug or biologic products or choose to reserve our products for use in limited circumstances. Additionally, a competitor could obtain orphan product exclusivity from the FDA with respect to such competitor's product. If such competitor product is determined to be the same product as one of our product candidates, that may prevent us from obtaining approval from the FDA for such product candidate for the same indication for seven years, except in limited circumstances.

The market opportunities for DANYELZA and our other product candidates, if approved, may be limited to those patients who are ineligible for or have failed prior treatments and may be small. Also, the market opportunity for DANYELZA and our product candidates, if approved, may be smaller than we expect.

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

Our current target patient populations are small as we have so far focused our clinical development efforts on rare pediatric cancers. By way of example, only approximately 700 children are diagnosed with high-risk NB in the United States each year. Even if we obtain significant market share for DANYELZA, or our other product candidates, if approved, because the initial target populations we are seeking to treat are small, we may never achieve profitability without obtaining regulatory approval for additional and broader indications, including use of DANYELZA or our product candidates, if approved, for front-line and third-line therapy.

DANYELZA is approved only as second-line treatment for patients with R/R high-risk NB in bone and/or bone marrow. Even if we would seek approval as front-line or third-line therapy for DANYELZA or another product candidate there is no guarantee that any will be approved. In addition, we may have to conduct additional clinical trials prior to gaining approval for front-line or third-line therapy.

The indications we seek to treat have low prevalence and it may be difficult to identify and enroll patients with these diseases. If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

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

- the size and nature of the patient populations;
- the patient eligibility criteria defined in the protocol;
- the size of the study population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;

- competing clinical trials for similar therapies or other new therapeutics not involving our product candidates and or related technologies;

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

- our ability to obtain and maintain patient consents; and

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

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead enroll in a trial being conducted by one of our competitors. We expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Moreover, because our product candidates represent a departure from more commonly used methods for cancer treatment, potential patients and their doctors may be inclined to use conventional therapies, such as chemotherapy and radiation, rather than enroll patients in any of our clinical trials.

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

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

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

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

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

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

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

- regulatory authorities may withdraw approvals of such product or seize the product;
- we, or any future collaborators, may be required to recall the product, change the way such product is administered to patients or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular product;
- regulatory authorities may narrow the indications for use or, as the FDA did in its approval of DANYELZA for the treatment of R/R high-risk NB rather than NB that was not R/R;
- we, or any future collaborators, may be required to create a Risk Evaluation and Mitigation Strategy, or REMS, which could include a medication guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers, and/or other elements to assure safe use;
- we, or any future collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive; and
- our reputation may suffer.

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

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

Success in pre-clinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety

and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through pre-clinical studies and early-stage clinical trials. Product candidates that have shown promising results in pre-clinical studies and early-stage clinical trials may still suffer significant setbacks in subsequent clinical trials. Additionally, the outcome of pre-clinical studies and early-stage clinical trials may not be predictive of the success of larger, later-stage clinical trials.

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

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

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. We have multiple clinical trials currently ongoing or planned. In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials of the same product candidate, such event could adversely affect our other clinical trials of our other product candidates. We have received clinical holds on our IND applications for certain of our product candidates in the past and there is no assurance that we will not be subject to additional clinical holds in the future, which may ultimately delay or otherwise adversely affect the clinical development of our product candidates. We submitted a BLA to the FDA for radiolabeled 131I-omburtamab for CNS LM from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC, Module and the Clinical Module of the BLA required further detail. We completed the resubmission of the BLA for omburtamab in March 2022. Survival and safety data from our pivotal Phase 2 clinical trial 03-133 formed the primary basis for our resubmission of the BLA for omburtamab, and we compared this data with data from an external cohort comprising data from the Central German Childhood Cancer Registry, or CGCCR, database. Furthermore, we believe interim efficacy, safety and pharmacokinetic data from our pivotal Phase 2 clinical trial 101 supported the BLA resubmission. In May 2022, the FDA indicated that our BLA had been accepted for priority review. The FDA convened an Advisory Committee, which met on October 28, 2022 and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. In November 2022, the FDA issued a CRL for our BLA for omburtamab indicating that the FDA determined that it was unable to approve the BLA in its current form since it did not provide substantial evidence of effectiveness of omburtamab for the proposed indication.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

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

consider our present or future clinical trials to be sufficient to serve as the basis for approval of omburtamab or any of our other product candidates for any indication. The FDA and non-U.S. regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective.

In the November 2022 CRL for our BLA for omburtamab, the FDA determined that it was unable to approve the BLA in its current form since it did not provide substantial evidence of effectiveness of omburtamab for the proposed indication. Further, the FDA stated that comparisons of overall survival between our Study 101 and the external control could not be used to estimate the treatment effect of omburtamab on survival and support claims of effectiveness. Additionally, the FDA held that response rate data from our study 101 were not reliable to verify the anti-tumor activity of omburtamab. This was consistent with the outcome of the ODAC Meeting held in October 2022.

In its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile.

If we are required and we determine to conduct additional clinical trials of a product candidate, including if we determine to resume development of omburtamab, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or other pivotal trials. The FDA or non-U.S. regulatory authorities may disagree with our trial design and our interpretation of data from pre-clinical studies and clinical trials or conclude that we do not have adequate manufacturing controls or quality systems. For example, as was the case for our BLA for omburtamab, analysis of the clinical data may rely on external control comparator populations to demonstrate efficacy, rather than blinded, placebo-controlled comparator populations. Data from our clinical trials may therefore be subject to heightened scrutiny regarding potential sources of bias such as treatment-center selection bias or differences in treatment patterns between countries and over time. Furthermore, because our clinical trials typically enroll a small number of patients, statistical analyses may only partially adjust to account for such potential bias. For example, FDA identified key review issues with our BLA for omburtamab, stating that the external control population for our omburtamab BLA is not fit-for-purpose as a comparator and limits the ability to reliably attribute survival differences to omburtamab treatment, that the BLA application does not include reliable response rate data to provide supportive evidence of the treatment effect of omburtamab, and that differences in survival cannot be reliably attributed to omburtamab and provide a large degree of uncertainty regarding whether the observed differences in overall survival between patients treated with omburtamab and external control populations are due to omburtamab or whether they are due to differences in other anticancer treatment, supportive care regimens, unknown differences between the two populations, or a combination of these factors.

In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or another regulatory authority. Any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials. The FDA or other non-U.S. regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

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

Other than DANYELZA, the product candidates and related technologies we have licensed have not yet led, and may never lead, to approved products. Our only approved product DANYELZA was only approved in late 2020 by the FDA and launched in the United States in early 2021. Further, DANYELZA was only approved by the Israeli Ministry of Health in Israel, in August 2022 and by the NMPA in China in December 2022. Hence its commercial

potential cannot be judged with accuracy at this point in time. Even if we are successful in continuing to build our pipeline, obtaining regulatory approvals and commercializing our other product candidates will require substantial additional funding and are prone to the risks of failure inherent in medical product development. Investment in biopharmaceutical product development involves significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and/or become commercially viable. We cannot provide any assurance that we will be able to successfully obtain marketing approval for omburtamab or advance any of our other product candidates through the development process. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development or commercialization for many reasons, including the following:

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

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, or we may not be able to identify, discover, develop, or commercialize additional product candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. As for DANYELZA, which has been approved by the FDA for the US market, the Israeli Ministry of Health in Israel for Israel and NMPA in China for China, no assurance can be given that it will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives.

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

We currently have in place several agreements with MSK, including the MSK License, the CD33 License, the MabVax Sublicense and the SADA License Agreement, which are important to us, and we may form or seek strategic alliances, create joint ventures or collaborations, or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. In addition, we anticipate that MSK, because it is a hospital where patients are treated, may become a major source for the distribution and administration of DANYELZA. Any disruption of our relationship with MSK could have a material adverse effect on our business, results of operations

and financial condition. In addition, any of these relationships may require us to incur other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation of strategic collaborations is time consuming and complex. We may not be successful in our efforts to establish a strategic partnership, other than the one we have with MSK, or other alternative arrangements for our product candidates because potential strategic partners may deem our product candidates to be at too early a stage of development for collaborative effort, because third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy or because the commercial potential of our product candidates is too difficult to predict.

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

- such third parties may have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- such third parties may not pursue development and commercialization of our products or product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- such third parties may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials, or require a new formulation of a product candidate for clinical testing;
- such third parties could independently develop, or develop with others, products that compete directly or indirectly with our products or product candidates;
- product candidates discovered through such arrangements or any potential future collaborations with us may be viewed by such third parties as competitive with their own product candidates or products, which may cause such third parties to cease to devote resources to the commercialization of our products or product candidates;
- such third-party with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- such third parties may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and such third-party or any current or potential future collaborator that cause the delay or termination of the research, development or commercialization of our products or product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- such third parties may infringe the intellectual property rights of others, which may expose us to litigation and potential liability;
- such arrangements or any current or potential future collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product or product candidate; and

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

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

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

Our research and development activities may involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us or third parties, such as CROs and CMOs. We have used Lutetium-177, Iodine-131 and Iodine-124 label and conjugated antibody treatments. Our uses involve the inherent risk of exposure from beta ray emissions, which can alter or harm healthy cells in the body. We, our CROs, our CMOs and other third parties are subject to federal, state, and local laws and regulations in the United States and Europe governing the use, manufacture, storage, handling, and disposal of medical and hazardous materials. Although we believe that our and such third-parties' procedures for using, handling, storing, and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous materials. As a result of any such contamination or injury, we may incur liability or local, city, state, or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition, or results of operations.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials. We do not have insurance coverage for pollution cleanup and removal. Currently the costs of complying with applicable federal, state, local and foreign environmental regulations are not significant, and consist primarily of waste disposal expenses. However, compliance could become expensive, and current or future environmental laws or regulations may impair our research, development, production and commercialization efforts. Furthermore, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Risks related to our dependence on third parties

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

We rely on third parties to conduct our clinical trials under agreements with MSK, universities, medical institutions, CROs, strategic partners, and others. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory, and scientific standards, and our reliance

on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators, and trial sites. If we or any of these third parties fail to comply with applicable GCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional non-clinical or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the GCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMP regulations and will require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed, or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. We may also rely on investigator-reported interim data in making business decisions. Independent review of the data could fail to confirm the investigator reported interim data, which may lead to revisions in disclosed clinical trial results in the future. Any such revisions that reveal more negative data than previously disclosed investigator-reported interim data could have an adverse impact on our business prospects and the trading price of our common stock. Such revisions could also reduce investor confidence in investigator-reported interim data that we disclose in the future.

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

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

We do not currently own any facility that may be used for commercial or clinical-scale manufacturing and processing, and we rely on outside vendors to manufacture DANYELZA for commercial supply and for supplies and processing of our product candidates, including our antibody constructs based on the SADA technology, for pre-clinical studies and clinical trials. Our other product candidates have only been manufactured or processed on a limited basis and we and our CMO may not be able to continue manufacturing any of our other product candidates. The manufacturing process that we have developed may be more difficult or expensive than other approaches currently in use. We may make changes as we work to optimize the manufacturing process, and we cannot be sure that even minor changes in the process will not result in significantly different substances that may not be as safe and effective as any substances deployed by our third-party research institution collaborators.

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

We rely also on CMOs and third-party collaborators for the manufacture of DANYELZA for commercial supply, and we expect that this will be the manufacturing arrangement for any of our other potential products, if approved. If we are unable to establish agreements with CMOs on acceptable terms, or at all, our business and results of operations may be materially adversely affected.

If we determine to resume development of omburtamab, we expect to continue to be highly dependent on our current CMO, EMD/Merck, for the production of omburtamab since this manufacturing process uses a hybridoma cell line in a relatively small scale (200 liters) cGMP manufacturing process. Many manufacturers refuse to allow hybridoma cell lines to be used in their facilities due to the risk of contamination. In addition, the relatively small scale of the cGMP system required for manufacture of omburtamab may increase the risk that we are unable to establish an alternative manufacturing arrangement on commercially reasonable terms because the small scale may lead to less commercially attractive terms for us.

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

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

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

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

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

- Any of our third-party manufacturers may not perform as agreed, according to our schedule or specifications, or at all. Any such third-party manufacturer may not devote sufficient resources to our product candidates, may give greater priority to the supply of other products over our product candidates, or may not remain in the contract manufacturing business for the time required to supply our clinical trials or commercial needs.

- We are exposed to the risk of cross-contamination from other drug substances if more than one product is manufactured at a third-party manufacturer's production facilities.

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

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

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

- The raw materials and components used to manufacture and process DANYELZA and our product candidates, particularly those for which we have no other source or supplier, may not be available or may not be suitable or acceptable for use due to material or component defects.

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

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

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

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

Each of these risks could delay or prevent the completion of our clinical trials, could delay any additional BLA submissions or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. Any shortage in the supply of such raw materials used in the manufacture of our product candidates could delay or prevent the completion of our clinical trials or the approval of any of our product candidates by the FDA, result in higher costs or adversely impact commercialization of our product candidates. For example, in the past, we experienced a shortage in the supply of Iodine-131, one of the components of 131I-omburtamab product candidate, from our single source supplier.

In addition, we have and will continue to rely on third parties to perform certain specification tests on our product candidates prior to delivery to patients. If these tests are not appropriately done and test data are not reliable, patients could be put at risk of serious harm and the FDA could place significant restrictions on us until deficiencies are remedied.

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

Any performance failure on the part of our existing or future manufacturers could adversely affect our commercialization of approved products, such as DANYELZA, and delay clinical development or marketing approval of other product candidates. We do not currently have arrangements in place for redundant supply of DANYELZA or other product candidates, and we currently use only a single third-party manufacturer for fill-and-finish services for DANYELZA and other product candidates. If any of our current CMOs cannot perform as agreed, we may be required to replace such manufacturer and we may incur added costs and delays in identifying and qualifying any such replacement.

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

We currently have limited internal research and development capabilities. We conduct independent clinical trials and perform pre-clinical research but we also rely on third-party research institutions for both clinical trial and pre-clinical research.

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

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

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

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

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

DANYELZA and our product candidates are biologics and the process of manufacturing them is complex, highly regulated and subject to multiple risks. As a result of the complexities, the cost to manufacture biologics is generally higher than traditional small molecule chemical compounds, and the manufacturing process for biologics is

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

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

In addition, the manufacturing process for any products that we may develop is subject to FDA, EMA and other foreign regulatory authority approval process, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and other foreign regulatory authority requirements on an ongoing basis. If we, or our CMOs, are unable to reliably produce products to specifications acceptable to the FDA, EMA or other foreign regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such products. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our CMOs will be able to manufacture the approved product to specifications acceptable to the FDA, EMA or other foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods, and have an adverse effect on our business, financial condition, results of operations and growth prospects. Although we are working to develop commercially viable processes, our manufacturing capabilities could be affected by cost overruns, unexpected delays, equipment failures, labor shortages, natural disasters, power failures and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business. We may ultimately be unable to, among other things, develop a manufacturing process and distribution network that will, reduce the cost of goods for our product candidates to levels that will allow for an attractive return on investment if and when those product candidates are commercialized.

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

In November 2020, we entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, West Bank and Gaza Strip. In December 2020, we entered into a distribution agreement for DANYELZA and omburtamab with Swixx BioPharma AG for the Eastern European territories Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia and Slovenia. Sanctions issued by the U.S. and other countries against Russia in response to its attack on Ukraine and related counter-sanctions issued by Russia have made it very difficult for us to operate in Russia and may have a material adverse impact

on our ability to sell our products and/or collect receivables from customers in Russia. In December 2020, we entered into a license agreement for DANYELZA and omburtamab with SciClone Pharmaceuticals International Ltd., or SciClone, for Greater China, including Mainland China, Taiwan, Hong Kong and Macau. In May 2021, we entered into an exclusive distribution agreement with Adium Pharma S.A., or Adium, for Latin America. Finally, in December 2022, we entered into a distribution agreement with WEP Clinical Ltd. in connection with an early access program for DANYELZA in Europe. We may enter into further strategic collaborations for the development, marketing and commercialization of all or some of our product candidates. Our current and future potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any further collaborations will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. We have and will for any future collaborations likely have limited control over the amount and timing of resources that our collaborators dedicate to the development, marketing and/or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our current and future potential collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, our current collaborators have and any future collaborators may have, the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms.

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

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development, marketing and/or commercialization of our product candidates or may elect not to continue or renew development, marketing or commercialization programs based on clinical trial results, changes in the collaborator's strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, drugs that compete directly or indirectly with our drugs or product candidates;
- a collaborator with marketing and distribution rights to one or more drugs may not commit sufficient resources to the marketing and distribution of such drug or drugs;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

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

- we may lose certain valuable rights under circumstances identified in any collaboration arrangement that we enter into, such as if we undergo a change of control;

- we may be restricted under then-existing collaboration agreements from entering into future agreements on certain terms with potential collaborators;

- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development, marketing and/or commercialization of the applicable product candidates;

- collaborators may learn about our discoveries, data, proprietary information, trade secrets, or compounds and use this knowledge to compete with us in the future; and

- the number and type of our collaborations could adversely affect our attractiveness to potential future collaborators or acquirers.

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

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all, if and when we seek to enter into collaborations. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue from sales of drugs.

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

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

The research, testing, manufacturing, labeling, approval, selling, import, export, marketing, and distribution of drug products, including biologics, are subject to extensive regulation by the FDA and other regulatory authorities in the United States. Even if we complete the necessary pre-clinical studies and clinical trials, we will not be permitted to market any biological drug product in the United States until we receive a Biologics License from the FDA. Although we have received a Biologics License for DANYELZA for R/R high-risk NB in bone and/or bone marrow, we intend to discuss with the FDA submission of additional BLAs for approval of DANYELZA to treat additional indications that currently lack an FDA-approved treatment option.

The FDA standard for regular approval of a BLA generally requires two well-controlled Phase 3 studies or one large and robust, well-controlled Phase 3 study in the patient population being studied that provides substantial evidence that a biologic is safe, pure and potent. Phase 3 clinical studies typically involve hundreds of patients, have significant costs and take years to complete. However, product candidates studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may be

eligible for accelerated approval and may be approved on the basis of adequate and well-controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of accelerated approval, the FDA may require a sponsor to perform post-marketing studies to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the drug or biologic may be subject to withdrawal procedures by the FDA that are more accelerated than those available for regular approvals. The FDA may ultimately require one or multiple Phase 3 clinical trials prior to approval of any product candidates for which we seek accelerated approval.

We have some, but only limited, experience in completing a submission of a BLA to the FDA, or similar approval submissions to comparable foreign authorities. Our BLA for DANYELZA was approved, but we received a CRL for our BLA for omburtamab. A BLA must include extensive pre-clinical and clinical data and supporting information to establish that the product candidate is safe, pure, and potent for each desired indication. The BLA must also include significant information regarding the chemistry, manufacturing, and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection. We expect the novel nature of our product candidates and the small size of our target patient populations, to create further challenges in obtaining regulatory approval from the FDA and other regulatory authorities. For example, for product candidates targeting ultra-rare diseases, such as CNS/LM from NB, where the very small patient population makes it difficult or impossible to conduct two traditional, adequate and well-controlled studies, the FDA or comparable foreign regulatory authorities may need to exercise flexibility in approving therapies for such diseases. Even flexibility from the FDA may not be sufficient to obtain approval. For instance, in its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of adequate and well-controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data, and the use of control groups to support licensure. For example, in connection with our BLA for omburtamab, the FDA convened an Advisory Committee that met on October 28, 2022, which voted 16 to 0 that the BLA did not provide sufficient evidence to conclude that omburtamab improves overall survival among the target patient population. The opinion of this and any other Advisory Committee, although not binding, may have a significant impact on our ability to obtain licensure our product candidates based on the completed clinical trials, such as was the case for omburtamab. Accordingly, the regulatory approval pathway for our product candidates may be uncertain, complex, expensive, and lengthy, and approval may not be obtained.

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

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

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

- obtaining regulatory approval to begin a trial, if applicable;

- the availability of financial resources to begin and complete the planned trials;
- reaching agreement on acceptable terms with prospective CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval at each clinical trial site by an Institutional Review Board or IRB;
- recruiting suitable patients to participate in a trial in a timely manner;
- having patients complete a trial or return for post-treatment follow-up;
- clinical trial sites deviating from trial protocol, not complying with GCPs, or dropping out of a trial;
- addressing any patient safety concerns that arise during the course of a trial;
- addressing any conflicts with new or existing laws or regulations;
- adding new clinical trial sites;
- manufacturing qualified materials under cGMPs for use in clinical trials;
- impact of the COVID-19 pandemic or other health epidemic or macroeconomic conditions;
- impact of the Russian invasion of Ukraine; or
- inspection of clinical trial sites and manufacturing facilities by regulatory authorities.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors. See the risk factor above "—If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected." for additional information on risks related to patient enrollment. Further, a clinical trial may be suspended or terminated by us, the IRBs for the institutions in which such trials are being conducted, the Data Monitoring Committee for such trial, or the FDA or other regulatory authorities due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product candidate, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. If we experience termination of, or delays in the completion of, any clinical trial of our product candidates, the commercial prospects for our product candidates will be harmed, and our ability to generate potential future product revenue will be delayed. In addition, any delays in completing our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue.

Our third-party research institution collaborators may also experience similar difficulties in completing ongoing clinical trials and conducting future clinical trials of product candidates. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates.

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

- the FDA, EMA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;

- we may be unable to demonstrate to the satisfaction of the FDA, EMA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;

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

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

- the FDA, EMA or comparable foreign regulatory authorities may disagree with our interpretation of data from pre-clinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a BLA or other submission or to obtain marketing approval in the United States, the EU or elsewhere;

- the FDA, EMA or comparable foreign regulatory authorities may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;

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

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

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

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

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

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

On April 27, 2021 we submitted a MAA, to the EMA for omburtamab for the treatment of pediatric patients with CNS/LM from NB. In December 2022, the European Committee for Medicinal Products for Human Use, or CHMP, adopted a negative opinion recommending a refusal of the MAA. CHMP determined that it was not possible to conclude on the effectiveness of omburtamab as the main study did not have a randomized comparator. We are assessing the implications of the negative opinion and our plans for the omburtamab program.

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

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

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

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

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

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

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

Our clinical trial results may also not support approval, whether accelerated approval, conditional marketing authorizations, or regular approval. The results of pre-clinical and clinical studies may not be predictive of the results of

later-stage clinical trials, and product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through pre-clinical studies and initial clinical trials.

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

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

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

In June 2017, ^{131}I-omburtamab received BTD for the treatment of pediatric patients with R/R NB who have CNS/LM from NB. We may seek BTD for some or all of our other product candidates, but we may never receive another BTD, or, if received, such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to drugs considered for approval under conventional FDA procedures. BTD does not change the standards for product approval nor assure ultimate approval by the FDA.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product candidate no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as an indication with a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In November 2018, the European Commission granted orphan medicinal product designation, or OMPD, for naxitamab for the treatment of NB. In February 2017, the European Commission granted OMPD to omburtamab for the treatment of NB. In August 2016, the FDA granted ODD to ^{131}I-omburtamab for the treatment of NB. In 2013, the FDA granted ODD to DANYELZA for the treatment of NB.

In the United States, ODD entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has ODD subsequently receives the first FDA approval for the disease for which it has such designation, the product may be entitled to orphan drug exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full BLA, to market the same drug for the same indication for seven years, except in limited circumstances. The corresponding exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for ODD or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

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

A drug that receives RPDD before September 30, 2024, will continue to be eligible for a PRV if the drug is approved by the FDA before September 30, 2026. If development of omburtamab continues and the BLA for omburtamab is not approved prior to September 30, 2026, regardless of whether it meets the criteria for a rare pediatric disease PRV, it will not be eligible for a PRV.

Even if we obtain ODD or RPDD for any of our product candidates in the future, we may not be able to maintain such status or enjoy the anticipated associated benefits. We may not be the first to obtain marketing approval of any product candidate that has ODD for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we, or any future collaborators, obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. ODD neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

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

Once marketing approval has been granted, as it was for DANYELZA in the United States, an approved drug and its manufacturer and marketer are subject to ongoing review and extensive regulation. The accelerated approval of DANYELZA is subject to certain post-marketing requirements and commitments, including a confirmatory post-marketing trial of clinical benefit, that must be completed in order to convert the BLA to full approval and prevent withdrawal of the license by FDA. The confirmatory post-marketing clinical trial required by the FDA to verify and to further characterize the clinical benefit is our ongoing Study 201, which will enroll a minimum of 80 evaluable patients and report overall rate of response, or ORR, duration of response, or DOR, progression free survival, or PFS, and overall survival, or OS. The ORR is the primary endpoint for the study, DOR is the secondary endpoint and PFS and OS are secondary endpoints in long-term follow up. As of March 1, 2023 we have enrolled 87 patients and we anticipate completing the study no later than by March 31, 2027. Other post-marketing requirements associated with the approval of DANYELZA include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. We, and any collaborators we may have in the future, must also comply with requirements concerning advertising and promotion for any of our product candidates for which we or they obtain marketing approval. Promotional communications with respect to prescription drugs are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the drug's approved labeling. Thus, we, and any collaborators we may have in the future, may not be able to promote any drugs we develop for indications or uses for which they are not approved.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a drug. For example, the approval may be subject to limitations on the indicated uses for which the drug may be marketed or to the conditions of approval, including the requirement to implement a Risk

Evaluation and Mitigation Strategy, which could include requirements for a restricted distribution system. Manufacturers of approved drugs and those manufacturers' facilities are also required to comply with extensive FDA requirements, including ensuring that quality control and manufacturing procedures conform to cGMPs, which include requirements relating to quality control and quality assurance as well as the corresponding maintenance of records and documentation and reporting requirements. We, our contract manufacturers, our future collaborators and their contract manufacturers could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs. Accordingly, assuming we, or our potential future collaborators, receive marketing approval for one or more of our product candidates, we, and our potential future collaborators, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control.

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

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

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

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

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

- litigation involving patients taking our drug;
- restrictions on such drugs, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a drug;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the drugs from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;

- recall of drugs;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- damage to relationships with any potential collaborators;
- restrictions on coverage by third-party payors;
- unfavorable press coverage and damage to our reputation;
- refusal to permit the import or export of drugs;
- drug seizure; or
- injunctions or the imposition of civil or criminal penalties.

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

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

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

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

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment

methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. For example, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and creating a new manufacturer discount program. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

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

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

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

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

We expect that coverage and reimbursement of pharmaceutical products may be increasingly restricted both in the U.S. and internationally. The escalating cost of health care has led to increased pressure on the health care industry to reduce costs. In particular, drug pricing by pharmaceutical companies has come under increased scrutiny and continues to be subject to intense political and public debate in the U.S. and abroad. Government and private third-party payors have proposed health care reforms and cost reductions. A number of federal and state proposals to control the cost of health care, including the cost of drug treatments, have been made in the U.S. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs and reform government program reimbursement methodologies for drugs. For example, the IRA, among other things, (i) directs the U.S. Department of Health and Human Services, or HHS, to negotiate the price of certain high-expenditure, single-source drugs and biologics covered under Medicare, and subject drug manufacturers to civil monetary penalties and a potential excise tax

by offering a price that is not equal to or less than the negotiated "maximum fair price" for such drugs and biologics under the law, and (ii) imposes rebates with respect to certain drugs and biologics covered under Medicare Part B or Medicare Part D to penalize price increases that outpace inflation. The IRA permits HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. These provisions will take effect progressively starting in fiscal year 2023, although they may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. In some international markets, the government controls the pricing, which can affect the profitability of drugs.

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

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

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

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

- Anti-Kickback Statute—the federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation or arranging of, any good or service, for which payment may be made under federal and state healthcare programs, such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- False Claims Act—the federal False Claims Act imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment by a federal healthcare program or making a false statement or record material to payment of a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per-claim penalties;

- HIPAA—the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, also imposes obligations on certain covered entity healthcare providers, health plans, and

healthcare clearinghouse as well as their business associates and covered contractors that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms and technical safeguards, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

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

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

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

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

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information.

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

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

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

States are also constantly amending existing laws, requiring attention to frequently changing regulatory requirements. For example, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020, collectively the CCPA, imposes obligations on covered businesses. These obligations include, without limitation, providing specific disclosures in privacy notices and affording California residents certain rights related to their personal data. The CCPA allows for statutory fines for noncompliance (up to $7,500 per violation) and a private right of action for certain data breaches. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA may increase compliance costs and potential liability with respect to other personal data we may maintain about California residents. In addition, in 2020 the CCPA expanded to add a new right for individuals to correct their personal data and establish a new regulatory agency to implement and enforce the law. Other states have also enacted data privacy laws, including Virginia, Colorado, Utah, and Connecticut, all of which differ from the CPRA and become effective in 2023. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation, or EU GDPR, the United Kingdom's GDPR, or UK GDPR, Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or LGPD) (Law No. 13,709/2018), and China's Personal Information Protection Law, or PIPL, impose strict requirements for processing personal data. In particular, the EU GDPR applies to any company established in the European Economic Area, or EEA, and to companies established outside the EEA that process personal data in connection with the offering of goods or services to data subjects in the EEA or the monitoring of the behavior of data subjects in the EEA. The obligations from the EU and UK GDPR, together referred to as GDPR, may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; complying with specific requirements to process health-related data; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals; and mandating the appointment of representatives in the UK and/or the EU in certain circumstances. Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros (17.5 million British Pounds under the UK GDPR) or 4% of annual global revenue, whichever is greater; or private litigation related to

processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and UK have significantly restricted the transfer of personal data to the United States and other countries whose data privacy and security laws they believe are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the EU GDPR's cross-border data transfer limitations. In addition to data privacy and security laws, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR and the CCPA, require our customers to impose specific contractual restrictions on their service providers.

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

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

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims); additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials.

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

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

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

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive information and information technology systems, and those of the third parties upon which we rely, including our current and future CROs, CMOs, other contractors and consultants. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we, the third parties upon which we rely, and our customers may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services.

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

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

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

We rely on third-party service providers and technologies to operate critical business systems to process sensitive information in a variety of contexts, including, without limitation, communication systems, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award.

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

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

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

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

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

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

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

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

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

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

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

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. To date, although a number of third-party providers have established coverage policies and provided reimbursement for DANYELZA, there is no guarantee that third-party providers will establish coverage policies or provided reimbursement for any of our other product candidates, if approved. The reimbursement payment rates for DANYELZA or any other product we commercialize might not be adequate for us to achieve or sustain profitability or may require co-payments that patients find unacceptably high. Additionally, third-party payors may not cover, or provide adequate reimbursement for, long-term follow-up evaluations required following the use of our products, if approved. Patients are unlikely to use our product unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Because our products and product candidates have a higher cost of goods than conventional therapies, and may require long-term follow up evaluations, the risk that coverage and reimbursement rates may be inadequate for us to achieve profitability may be greater. Further, coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future. In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics.

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

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

Physicians have the discretion to prescribe drug products for uses that are not described in the product's labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician's choice of treatments, the FDA and other regulatory agencies regulate a manufacturer's communications regarding off-label use and prohibit off-label promotion, as well as the dissemination of false or misleading labeling or promotional

materials. Manufacturers may not promote drugs for off-label uses. Accordingly, we may not promote DANYELZA in the United States for use in any indications other than relapsed/refractory high-risk neuroblastoma in bone and/or bone marrow. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained. A company that is found to have improperly promoted off-label uses may be subject to significant liability, which may include civil and administrative remedies as well as criminal sanctions.

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

Due to the nature of radioactive isotopes in radioimmunotherapy product candidates, the product shelf life is limited and susceptible to spoilage and/or loss, which could adversely affect our business, financial condition and operating results.

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

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

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

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

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

We currently have operations in the United States and Denmark and we maintain relationships with CMOs in other parts of Europe as well as in the United States for the manufacture of our product candidates. If we further expand our operations outside of the United States, we must comply with numerous laws and regulations in each new

jurisdiction in which we plan to operate. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. No assurance can be given that our compliance policies and procedures are or will be sufficient or that our directors, officers, employees, representatives, consultants and agents have not engaged and will not engage in conduct for which we may be held responsible, nor can we assure you that our business partners have not engaged and will not engage in conduct that could materially affect their ability to perform their contractual obligations to us or even result in our being held liable for such conduct.

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

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

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

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

Risks related to our intellectual property

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

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

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

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

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

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

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

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates, products and related proprietary technologies. More established companies may have a competitive

advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

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

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

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which many legal principles remain unresolved. In recent years patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights and in-licensed patent rights are highly uncertain. Our pending and future patent applications and in-licensed patent applications may not result in patents being issued in the United States or in other jurisdictions which protect our products or product candidates or related technologies or which effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our and in-licensed patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the U.S. Patent and Trademark Office, or USPTO, might require that the term of a patent issuing from a pending patent application be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. As a result, the issuance, scope, validity, enforceability and commercial value of our as well as in-licensed patent rights are highly uncertain.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our and in-licensed patent applications and the enforcement or defense of the issued patents. In March 2013, under the Leahy-Smith America Invents Act, or America Invents Act, the United States moved from a “first to invent” to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a new post-grant review system. The effects of these changes are currently unclear as the USPTO only recently developed new regulations and procedures in connection with the America Invents Act and many of the substantive changes to patent law, including the “first-to-file” provisions, only became effective in March 2013. In addition, the courts have yet to address many of these provisions and the applicability of the act and new regulations on specific patents discussed herein have not been determined and would need to be reviewed. However, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition. During examination of our own as well as our in-licensed patent applications third parties may present observations or submit patents, published patent applications or other prior art which may affect the patentability of the claimed inventions. The costs for obtaining patent protection may be increased significantly by the need for appeal proceedings or oral proceedings, which may also result in a patent not being issued. We may become involved in opposition, interference, derivation, post grant review, inter partes review, ex-parte re-examination or other proceedings

challenging our patent rights or the patent rights of others, and the outcome of any proceedings are highly uncertain. An adverse determination in any such proceeding could reduce the scope of, or invalidate, our and in-licensed patent rights, allow third parties to commercialize our products, product candidates and related technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights.

Intellectual property rights do not necessarily address all potential threats.

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

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

- others may be able to make or use compounds that are similar to the pharmaceutical compounds used in our products or product candidates but that are not covered by the claims of our patents;
- the APIs in our current products or product candidates may eventually become commercially available in generic drug products, and no patent protection may be available with regard to formulation, method of manufacture or method of use;
- we may not be able to prevent parallel importation of products into the U.S., EU member states and/or other jurisdictions, which may reduce our profit margin;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regard to any in-licensed patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;
- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our products or product candidates and proprietary technologies;
- it is possible that our owned or in-licensed pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- we may not be able to obtain patent term extensions or supplementary protection certificates covering our products;

- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our product candidates, products or technologies similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or products;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- we have engaged in scientific relationships in the past, such as with MSK, and expect to continue to do so with MSK and/or other third parties in the future. Such third parties may develop adjacent or competing products to ours that are outside the scope of our licensed patents and/or the respective research collaboration/agreement with such third-party;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that products, product candidates or diagnostic tests we develop may be covered by third parties' patents or other proprietary rights; or
- the patents of others may have an adverse effect on our business.

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

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

If any of our owned or in-licensed patents are found to be invalid or unenforceable, or if we are otherwise unable to adequately protect our rights, it could have a material adverse impact on our business and our ability to commercialize or license our technology products and product candidates. Likewise, our current owned patents and patents in-licensed from MSK relating to our proprietary technologies and our product candidates comprise patents that are expected to expire on various dates from 2022 through 2039, without taking into account any possible patent term adjustments, extensions or supplementary protection. Upon the expiration of our current patents, we may lose the right to exclude others from practicing the relevant inventions. The expiration of these patents could also have a similar material adverse effect on our business, results of operations, financial condition and prospects. We own or in-license pending patent applications from MSK and others covering our proprietary technologies or our product candidates that if issued

as patents are expected to expire from 2031 through 2041, without taking into account any possible patent term adjustments, extensions or supplementary protections. However, no assurance can be given that the USPTO or relevant foreign patent offices will grant any of these patent applications. Even if granted, we may fail to obtain patent term extensions or supplementary protection certificates covering our products.

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

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

There is also a risk that, even if the validity of these patents is upheld, the court will refuse to stop the third-party on the ground that such third-party's activities do not infringe our owned or in-licensed patents. In addition, the U.S. Supreme Court has changed some legal principles that affect patent applications, granted patents and assessment of the eligibility or validity of these patents. As a consequence, issued patents may be found to contain invalid claims according to the newly revised eligibility and validity standards. Some of our owned or in-licensed patents may be subject to challenge and subsequent invalidation or significant narrowing of claim scope in proceedings before the USPTO, or during litigation, under the revised criteria which could also make it more difficult to obtain patents. Similar considerations pertain to patents granted outside of the United States, for which the validity, enforceability and/or scope of protection may be influenced by changing national and/or international legal principles.

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

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

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

former employees or current employees. In addition, adequate remedies may not be available in the event of an unauthorized access, use, or disclosure of our trade secrets or know-how.

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

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

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

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

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

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

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

- infringement and other intellectual property claims, which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds that

the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates or products, or from using our proprietary technologies, unless the third-party licenses its product rights to us, which it is not required to do;

- if a license is available from a third-party, it may not be offered on reasonable terms and may require that we pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and

- redesigning our products or product candidates or processes so they do not infringe, which may not be possible or may require substantial monetary expenditures and time.

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

We may choose to challenge the patentability of claims in a third-party's U.S. patent by requesting that the USPTO review the patent claims in an ex-parte re-exam, inter partes review or post-grant review proceedings. These proceedings are expensive and may consume our time or other resources. We may choose to challenge a third-party's patent in patent opposition proceedings in the EPO, or other foreign patent office. The costs of these opposition proceedings could be substantial, and such proceedings may consume our time or other resources. If we fail to obtain a favorable result at the USPTO, EPO or other patent office then we may be exposed to litigation by a third-party alleging that the patent may be infringed by our product candidates or products or proprietary technologies.

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

Filing, prosecuting and defending patents on all of our products or product candidates throughout the world would be prohibitively expensive. Competitors may use our technology in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as in the United States. These products may compete with our products or product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. Our failure to comply with such requirements could result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event,

competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force, which would have a material adverse effect on our business.

Failure to secure trademark registrations could adversely affect our business.

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

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

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest, which may have a material adverse effect on our business.

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

Risks related to employee matters and managing growth

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

We are highly dependent on the members of our executive management as well as the other principal members of our management and scientific teams. Our agreements with any of them do not prevent them from terminating their employment with us at any time.

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

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

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

To induce valuable employees to join and remain at our company, in addition to salary and cash incentives, we have provided, and intend to continue to provide, stock option and/or restricted stock grants that vest over time. The value to employees of these equity grants that vest over time may be significantly affected by movements in the fair market value of our capital stock that are beyond our control, and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We do not maintain "key person" insurance for any of our executives or other employees.

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

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

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

Risks related to our common stock

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

As of December 31, 2022, our executive officers, directors and our stockholders, which own more than 5% of our outstanding common stock beneficially own shares representing approximately 21.20% of our common stock. As a result, if these stockholders were to choose to act together, they would be able to exert significant influence over all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would have significant influence over the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of voting power could delay or prevent an acquisition of our company on terms that other stockholders may desire.

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

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

- establish a classified board of directors such that not all members of the board are elected at one time;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from the board;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws.

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

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

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point cumulative change (by value) in the equity ownership of certain stockholders over a rolling three-year period), an annual limitation is imposed on the corporation's use of its pre change net operating loss carryforwards and certain other pre change tax attributes to offset its post change taxable income or taxes. Based on our analysis of our Section 382 ownership changes through December 31, 2022, we believe that it is more likely than not that none of our net operating loss carryforwards will expire because of existing limitations under Section 382 of the Code, due to the large size of such limitations. We may experience Section 382 ownership changes in the future as a result of subsequent shifts in our equity ownership, many of which are outside our control. State net operating loss carryforwards may be similarly limited, and there may be periods during which the use of such net operating loss carryforwards is suspended or otherwise limited, which could accelerate or permanently increase our state taxes owed.

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

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

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

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

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Sales of our common stock may be made by holders of our public float or by holders of restricted securities in compliance with the provisions of Rule 144 of the Securities Act of 1933, or the Securities Act. There were 43,677,767 shares of common stock outstanding as of March 23, 2023. Of these shares of our common stock, 6,900,000 shares sold in our initial public offering in 2018, 5,134,750 shares sold in our public offering in 2019 and 2,804,878 shares sold in our public offering in February 2021 are freely tradable, without restriction, in the public market. As of March 23, 2023 holders of approximately 2,005,347 shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. We have also registered 6,200,000 shares of our common stock that we may issue under our equity compensation plans and we plan to increase that number further.

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

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

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

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

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

The price of our common stock has been and is likely to be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock. Also, the volatility of our stock price may adversely affect our ability to attract equity funding in the future on reasonable terms or at all.

Our stock price has been and is likely to be volatile. The stock market in general and the market for pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. Since our common stock began trading on The Nasdaq Global Select Market on September 22, 2018, our stock has traded at prices as low as $2.77 per share and as high as $55.22 per share through March 23, 2023. As a result of this volatility, investors in our common stock may not be able to sell their shares at or above the prices they paid. Further, as a result of this volatility it may be difficult for us to attract new equity investments, including additional public offerings of our common stock, on terms we consider reasonable, or at all.

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

- our ability to successfully launch and commercialize DANYELZA and any other product candidates, if approved;
- the timing and results of clinical trials of any of our product candidates;
- regulatory actions with respect to our products or product candidates or our competitors' products and product candidates;
- the success of existing or new competitive products or technologies;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, collaborations or capital commitments;
- establishment or termination of collaborations for our products and product candidates or development programs;
- failure or discontinuation of any of our development programs;
- results of clinical trials of product candidates of our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of revenues and expenses related to any of our products, product candidates or development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates or products;
- our ability to accurately forecast demand for our products, actual or anticipated changes in forecasts of financial performance, or changes in development timelines;
- announcement or expectation of additional financing efforts;

- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in estimates or recommendations by securities analysts, if any, that cover our stock;
- changes in the structure of healthcare payment systems;
- market conditions and investor sentiment in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, such as an increased rate of inflation, increased cost of goods, supply chain disruptions and uncertain global financial markets, and geopolitical events, such as the conflict between Ukraine and Russia and related sanctions; and
- the other factors described in this "Risk Factors" section.

In the past, securities class action litigation has often been instituted against companies following periods of volatility in the price of their common stock. For example, following volatility in the price of our common stock following the ODAC meeting in October, the CRL in November 2022 and our January 2023 announcement of our restructuring plan, one of our stockholders filed suit in the Delaware Chancery Court for alleged breaches of fiduciary duties, unjust enrichment, and waste of corporate assets. Litigation could result in substantial costs and divert our management's attention and resources, which could have a material and adverse effect on our financial condition, business, and the per share trading price of our common stock.

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

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

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

General risk factors

Our business, financial condition and results of operations have been and may in the future be adversely affected by the COVID-19 pandemic or similar health crises, macroeconomic conditions and by geopolitical events, including the recent global conflict resulting from the invasion of Ukraine by Russia, and sanctions related thereto, which resulted in the suspension of our clinical trial and regulatory activities in Russia.

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

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

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

There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including weakened demand for any product candidates we may develop and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in

supply disruption. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could impair our ability to achieve our growth strategy, could harm our financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that our current or future service providers, manufacturers or other collaborators may not survive such difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget. We cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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

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

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

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

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

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

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

- We have obtained and plan to continue to seek regulatory approval of our product candidates outside of the United States. We also have existing commercialization collaborations in certain territories outside the United States such as with SciClone, Takeda Israel, Swixx Biopharma AG, Adium, and WEP Clinical Ltd. Takeda Israel obtained regulatory approval for DANYELZA in Israel in August 2022 and we obtained regulatory approval for DANYELZA in China in December 2022. Accordingly, we and our existing and potential collaborators in jurisdictions outside the US, are subject to additional risks related to operating in foreign countries, including:

- differing regulatory requirements in foreign countries;

- unexpected changes in tariffs, trade barriers, price and exchange controls, and other regulatory requirements;

- economic weakness, including inflation, or political instability in particular foreign economies and markets;

- compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad;

- foreign taxes, including local transfer pricing regulations and withholding of payroll taxes;

- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;

- difficulties staffing and managing foreign operations;

- workforce uncertainty in countries where labor unrest is more common than in the United States;

- potential liability under the FCPA, or OFAC, Anti-Money Laundering Program as required by the Bank Secrecy Act and its implementing regulations, or comparable foreign laws;

- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

- business interruptions resulting from geo-political actions, including war and terrorism.

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

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

Our operations, and those of our third-party research institution collaborators, CROs, CMOs, suppliers, other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, droughts, floods, hurricanes, typhoons, fires, extreme weather conditions, climate change events, medical epidemics, terrorist activities, wars or other armed conflicts, geopolitical tensions, such as the ongoing conflict between Russia and Ukraine and related sanctions, cyber security attacks and other natural or man-made disasters or business interruptions, for which we are predominantly self-insured, and other severe hazards or global health crises, such as an

outbreak of Ebola or the ongoing global COVID-19 pandemic, or other actual or threatened epidemic, pandemic, outbreak and spread of a communicable disease or virus, in the countries where we operate or plan to sell our products, if approved, could adversely affect our operations and financial performance. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process DANYELZA, and our other product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man made or natural disaster or other business interruption. Damage or extended periods of interruption to our third-party collaborators', including MSK's, corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we intend to maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption. The ultimate extent of the impact of any epidemic, pandemic or other global health crisis, such as COVID-19, on our business, financial condition and results of operations will depend on future developments which are highly uncertain and cannot be predicted, including new information that may emerge concerning the duration and severity of such epidemic, pandemic or other global health crisis, actions taken to contain or prevent their further spread and the pace of global economic recovery following containment of the spread.

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

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

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

- loss of any potential future revenue; and
- a decline in our share price.

Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of DANYELZA or any product candidates we develop, alone or with collaborators. The amount of clinical trial and product liability insurance coverage that we may obtain, may not be adequate, we may be unable to maintain such insurance, or we may not be able to obtain additional or replacement insurance at a reasonable cost, if at all. Our insurance policies may also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

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

We are exposed to the risk of fraud, misconduct or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and negligent conduct that fails to: comply with the regulations of the FDA, the EMA and other similar foreign regulatory bodies; provide true, complete and accurate information to the FDA, the EMA and other similar foreign regulatory bodies; comply with manufacturing standards we have established; comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or report financial information or data accurately or to disclose unauthorized activities to us. As we have obtained FDA approval of DANYELZA and have begun commercializing DANYELZA in the United States, our exposure under such laws has increased significantly, and our costs associated with compliance with such laws have increased significantly and are likely to continue to increase. These laws impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

As is common in the biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and, if securities analysts or investors perceive these results to be negative, it could have a

substantial adverse effect on the price of our common stock. This type of litigation or proceeding could substantially increase our operating losses and reduce our resources available for development activities. We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other intellectual property related proceedings could adversely affect our ability to compete in the marketplace.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate headquarters are located in New York, New York, where we currently lease 4,312 square feet pursuant to a lease agreement dated as of January 10, 2018. The term of the lease is six years from the date the Company began to occupy the premises and the lease expires in April 2024. In addition, we lease 4,783 square feet of combined office and laboratory space located in Nutley, New Jersey pursuant to a lease agreement dated as of February 11, 2019, as amended, which expires on January 31, 2024.

Our wholly owned Danish subsidiary, Y-mAbs Therapeutics A/S, leases approximately 29,288 square feet of office space in Hørsholm, Denmark pursuant to a lease agreement dated September 26, 2021, which commenced on November 1, 2021. The lease is expected to last for 48 months, and after June 1, 2022, we have the option, at our discretion, to terminate a portion of the lease.

We believe that suitable additional or alternative space for both our U.S. and Danish locations would be available as required in the future on commercially reasonable terms.

ITEM 3. LEGAL PROCEEDINGS.

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

The Company has been named a nominal defendant in a lawsuit filed in the U.S. District Court, Southern District of New York, on August 25, 2021, by one of the Company's stockholders, Deborah Donoghue (Case No. 1:21-cv-07182). The suit names the Company's President, Interim Chief Executive Officer and Head of Business Development and Strategy, and member of the Company's board of directors, Mr. Thomas Gad as an additional defendant, and it seeks to compel Mr. Gad to disgorge alleged short swing profits stemming from a certain transaction involving the Company's common stock undertaken by Mr. Gad on March 10, 2021 together with appropriate interest and costs of the lawsuit. On December 17, 2021, Mr. Gad filed a Motion to Dismiss the lawsuit. On August 8, 2022, the Court denied Mr. Gad's Motion to Dismiss the lawsuit and the lawsuit has entered the discovery phase. The Company is of the opinion that the claim is without merit and intends to maintain this position in the proceedings. In addition, the Company has been informed by Mr. Gad that he also believes the claim is without merit, that he has strong defenses against such claim and that he intends to vigorously defend the action. The Company has assessed the proceedings and do not believe that it is probable that a gain or a liability will be realized by the Company. As a result, the Company did not record any loss or gain contingencies for this matter.

Corwin v. Y-mabs Therapeutics, Inc., et al.

On January 18, 2023, Robert Corwin, a purported Y-mAbs stockholder, filed a putative class action lawsuit against the Company and certain of the Company's current and former officers for alleged violations of the U.S. federal securities laws in the United States District Court, Southern District of New York (Case No.: 1:23-cv-00431). The complaint asserts claims under Section 10(b) and 20(a) of the Securities Exchange Act of 1934 on behalf of a proposed class consisting of those who acquired the Company's common stock between October 6, 2020 and October 28, 2022. The complaint alleges that there were material misrepresentations and/or omissions regarding the FDA's consideration of the Company's BLA for omburtamab and seeks an unspecified amount of damages, interest thereon, and the proposed class's costs and expenses, including attorneys' fees. On March 20, 2023, four motions for appointment as lead plaintiff of the proposed class were filed. Oppositions to these motions are due on April 3, 2023. The Company is in the early stages of evaluating the complaint, but based on current knowledge believes the claims are without merit.

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

On February 8, 2023, Jeffrey Hazelton, a purported Y-mAbs stockholder, filed a putative stockholder derivative action in the Court of Chancery of the State of Delaware (*Hazelton vs. Y-mAbs Therapeutics Inc., et al*, Case No.: 2023-0147). The complaint purports to asserts claims on behalf of the Company against certain current and former officers and directors for alleged breaches of fiduciary duties, unjust enrichment, and waste of corporate assets in connection with certain compensation awards to named executive officers and non-employee directors. The complaint seeks an unspecified amount of damages, changes to corporate governance and internal procedures, disgorgement of the individual defendants' compensation, and the plaintiff's costs and expenses, including attorneys' fees. The Company is in the early stages of evaluating the complaint, but based on current knowledge believes the claims are without merit.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Certain Information Regarding the Trading of Our Common Stock

Our common stock trades under the symbol "YMAB" on The Nasdaq Global Select Market and has been publicly traded since September 21, 2018. Prior to this time, there was no public market for our common stock.

On March 23, 2023, the last reported sale price for our common stock on The Nasdaq Global Select Market was $2.85 per share.

Holders of Our Common Stock

As of March 23, 2023 there were 7 holders of record of shares of our common stock. This number does not include stockholders for whom shares are held in "nominee" or "street" name.

Dividends

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities authorized for issuance under equity compensation plans

Information about our equity compensation plans will be included in our definitive proxy statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders and is incorporated herein by reference.

Unregistered Sales of Equity Securities and Use of Proceeds

Recent Sales of Unregistered Equity Securities

During the period covered by this Annual Report on Form 10-K, we have issued the following securities that were not registered under the Securities Act:

In April 2022, 42,800 shares of our common stock vested pursuant to a stock grant agreement entered into in connection with the entry into the SADA License Agreement in April 2020. The issuance did not result in proceeds to the Company.

We deemed the issuance in the paragraph above to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2) of the Securities Act, as transactions by an issuer not involving a public offering. Each of the recipients of securities either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities.

Use of Proceeds

On February 22, 2021, we completed a secondary public offering of our common stock pursuant to which we issued and sold 2,804,878 shares of our common stock at a price to the public of $41.00 per share which included the exercise in full of the underwriters' option to purchase additional shares. We received aggregate gross proceeds from our secondary public offering of $115.0 million, or aggregate net proceeds of approximately $107.7 million after deducting underwriting discounts and commissions and offering expenses J.P. Morgan, Morgan Stanley and BofA Securities acted as joint book-running managers for the secondary public offering. Kempen & Co. U.S.A. and H.C. Wainwright & Co. acted as co-managers for the secondary public offering.

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

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

As of December 31, 2022, we had cash and cash equivalents of $105.8 million.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not purchase any of our registered equity securities during the period covered by this Annual Report on Form 10-K.

ITEM 6. Reserved

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

You should read the following discussion and analysis of our financial condition and results of operations together with our accompanying financial statements and related notes thereto included elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. For a detailed discussion of these risks and uncertainties, see Item 1A "Risk Factors" in this Annual Report on Form 10-K. See also "Cautionary Note Regarding Forward-Looking Statements." We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K. We undertake no obligation to update forward-looking statements, which reflect events or circumstances occurring after the date of this Annual Report, except as required by law. For convenience of presentation some of the numbers have been rounded in the text below.

Overview

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

Our only approved drug DANYELZA® (naxitamab-gqgk) received accelerated approval by the United States Food and Drug Administration, or the FDA, in November 2020 for the treatment, in combination with Granulocyte-Macrophage Colony-Stimulating Factor, or GM-CSF, of pediatric patients one year of age and older and adult patients with relapsed or refractory, or R/R, high-risk neuroblastoma, or NB, in the bone or bone marrow who have demonstrated a partial response, minor response, or stable disease to prior therapy. We are commercializing DANYELZA in the United States and began shipping it in February 2021.

DANYELZA has been evaluated in a Phase 2 clinical study in front-line NB, a pilot study of chemoimmunotherapy for high-risk NB, and is currently being evaluated in a Phase 2 clinical study in second-line relapsed osteosarcoma patients.

We submitted a Biologics License Application, or BLA, to the FDA for radiolabeled ^{131}I-omburtamab for central nervous system, or CNS, leptomeningeal metastases, or LM, from NB in August 2020, and received a Refusal to File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. Among other things, the FDA requested that detailed validation data be included in the CMC Module, that clinical study data and external control data be reanalyzed using a propensity score adjusted analysis for important baseline characteristics, such as prior receipt of irradiation, and that further supportive evidence in the form of direct anti-tumor effect be included in the Clinical Module. We held a number of Type B meetings with the agency, including a pre-BLA meeting in January 2022, before we resubmitted the BLA for omburtamab in March 2022. In October 2022, we met with the FDA's Oncologic Drugs Advisory Committee, or ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In December 2022, we received a complete response letter, or CRL, for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of adequate and well-controlled trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

We are using our proprietary SADA BiDE (2-step Self-Assembly and DisAssembly Bispecific DOTA Engaging antibody system) Pre-targeted Radioimmunotherapy Platform, or the SADA Technology, a concept we also refer to as Liquid Radiation™, to advance a series of antibody constructs, where bispecific antibody fragments bind to the tumor before a radioactive payload is injected in a two-step approach. We have designated GD2-SADA for potential use in GD2 positive solid tumors as our first SADA constructs and filed an IND for GD2-SADA in December 2021. We obtained clearance for the IND in July 2022 and clinical sites have been activated. We obtained clearance for the IND in July 2022. We have secured clinical supplies for a medical radioisotope no-carrier-added, or n.c.a., lutetium-177 from ITM Isotope Technologies Munich SE, or ITM, who will provide its n.c.a. ^{177}Lu for phase 1-3 clinical development of GD2-SADA. We announced our first hematological CD38-SADA in December 2022, and expect to submit an IND for this construct in 2023. We believe the SADA technology could potentially improve the efficacy of radiolabeled therapeutics in tumors that have not historically demonstrated meaningful responses to radiolabeled agents.

In January 2023, we announced a strategic restructuring plan designed to extend our cash resources and prioritize the commercialization and potential label extension of DANYELZA and development of the SADA technology platform. In addition to deprioritizing the omburtamab program, for all indications and product candidates, we have deprioritized other pipeline programs, including activities relating to our GD2-GD3 Vaccine and CD33 bispecific antibody constructs, by delaying trial initiation and overall timelines as part of the restructuring plan. We have also deprioritized activities relating to nivatrotamab and ^{177}Lu-omburtamab. As a result of the estimated decrease in

operating expenses, we estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, will support operations into the first quarter of 2026.

This estimate reflects our current business plan, including the restructuring, that is supported by assumptions that may prove to be inaccurate, such that we could use our available capital resources sooner than we currently expect. This estimate assumes no income from new partnerships or other new business development activities, and no further development of the omburtamab program. 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.

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

Since our inception on April 30, 2015, we have devoted substantially all of our resources to organizing and staffing our company, business planning, identifying potential product candidates, conducting pre-clinical studies of our product candidates and clinical trials of our lead product candidates, commercializing our approved product, raising capital, and acquiring and developing our technology platform.

To date, we have financed our operations primarily through private placements of our securities, proceeds from our IPO and proceeds from our two subsequent public offerings, revenues generated from DANYELZA, license revenues, and the proceeds from the sale of our Priority Review Voucher, or PRV, granted upon FDA approval of DANYELZA.

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

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a PRV which we subsequently sold to United Therapeutics Corporation for a purchase price of $105 million. We paid 40% of the net proceeds from the sale of the PRV to MSK as required under the terms of the MSK License. The transaction closed in January 2021 upon the resolution of the substantive closing conditions, and the gain was recognized within "Other Income, Net" on the Consolidated Statements of Net Loss and Comprehensive Loss for the year ended December 31, 2021.

As of December 31, 2022 and December 31, 2021, we had an accumulated deficit of $436.0 million and $340.5 million, respectively. For the years ended December 31, 2022 and 2021, our net loss was $95.6 million and $55.3 million, respectively. We have incurred significant net operating losses in every year since our inception and expect to continue to incur net operating losses and significant expenses for the foreseeable future. Our net losses may fluctuate significantly from quarter to quarter and year to year as we:

- continue to advance our lead product candidates through the regulatory approval process both in the U.S. and internationally;
- continue to advance our other product candidates through pre-clinical and clinical development;
- continue to identify additional research programs and additional product candidates, as well as additional indications for existing product candidates;
- initiate pre-clinical studies and clinical trials for any additional product candidates we identify;

- develop, maintain, expand and protect our intellectual property portfolio; and

- hire additional research, sales force, commercialization, clinical and scientific personnel.

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

On April 15, 2020, we entered into the SADA Technology License Agreement, or the SADA License Agreement, with MSK and Massachusetts Institute of Technology, or MIT, that grants us an exclusive, worldwide, sublicensable license to certain patent and intellectual property rights developed by MSK and MIT to develop, manufacture, and commercialize licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics and cancer treatments using the SADA Technology, a concept we also refer to as Liquid Radiation™. The patents and patent applications covered by the SADA License Agreement are directed, in part, to the SADA Technology, as well as a number of SADA constructs developed by MSK. Upon entering into the SADA License Agreement in April 2020 and in exchange for the licenses, we paid MSK and MIT a cash upfront payment and issued an aggregate of 42,900 shares of our common stock to them. During the year ended December 31, 2021, we made a cash payment in the amount of $1.0 million to MSK and MIT under the agreement. During the year ended December 31, 2022 we made another cash payment in the amount of $1.0 million to MSK and MIT under the agreement.

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

Further, the SADA License Agreement requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay minimum annual royalties of $40,000, which shall increase to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License Agreement. As of December 31, 2022, we have determined that payment of the minimum royalties is not probable, and accordingly have not accrued for such royalties at December 31, 2022.

Under the SADA License Agreement, we are also obligated to pay MSK and MIT certain clinical, regulatory and sales-based milestone payments. Certain of the clinical and regulatory milestone payments become due at the earlier of either the completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestones potentially due under the SADA License Agreement are approximately $4.7 million and $18.1 million, respectively. Sales based milestone payments, totaling approximately $23.8 million, become due should the Company achieve certain amounts of sales. In addition, for each of the SADA constructs generated by MSK and sold on behalf of the Company by a sublicensee, the Company is obligated to make sales-based milestone payments in the total amount up to $60.0 million based on the achievement of various cumulative net sales made by the sub-licensee. Finally, under the terms of the SADA License, MSK is entitled to receive 25% of any income generated from the sale of any PRV or the sale of other comparable incentives provided by any non-U.S. jurisdiction. As of December 31, 2022, we have accrued $0.6 million of the clinical based milestones under the SADA License Agreement which we considered to be estimable and probable and we expect to pay this amount within one year.

These MSK agreements are important to our business. For a more detailed discussion of the terms and conditions of certain of these agreements, see *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS.*

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

Recent Developments

Omburtamab BLA and Advisory Committee Meeting

In August 2016, the FDA granted Orphan Drug Designation, or ODD, to omburtamab for NB, and in June 2017, the compound received breakthrough designation for the treatment of pediatric patients with R/R NB who have central nervous system, or CNS, leptomeningeal metastases, or LM, from NB. We submitted a BLA to the FDA for omburtamab for CNS /LM from NB in August 2020, and received a Refusal-to-File letter from the FDA in October 2020. The reason for the FDA's decision to issue the Refusal to File letter was that upon preliminary review, the FDA determined that certain parts of the Chemistry, Manufacturing and Control, or CMC Module and the Clinical Module of the BLA required further detail. We completed the resubmission of the BLA for omburtamab in March 2022 following a series of meetings with the FDA, and in May 2022, the agency accepted our BLA for priority review. In October 2022, we met with the FDA's Oncologic Drugs Advisory Committee, or ODAC, who reviewed ^{131}I-omburtamab and voted 16 to 0 that we had not provided sufficient evidence to conclude that omburtamab improves overall survival. In December 2022, we received a complete response letter, or CRL, for the BLA. In the CRL, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. We are currently considering the future for our omburtamab development program and we can provide no assurance that the development of omburtamab will continue or that omburtamab will ultimately receive FDA approval.

DANYELZA Regulatory Developments

On August 30, 2022, we announced that the Israeli Ministry of Health approved DANYELZA for marketing in Israel. We expect that our partner Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited (TSE:4502/NSY:TAK), will commercialize DANYELZA in Israel, under the 2020 exclusive license and distribution agreement with Takeda Israel.

On September 26, 2022, we announced that our partner Adium Pharma S.A. submitted a regulatory filing for DANYELZA for the treatment of patients with R/R high-risk NB to the Brazilian Health Regulatory Agency.

The Company entered into a license agreement for DANYELZA and omburtamab with SciClone Pharmaceuticals International Ltd., or SciClone, for Greater China, including Mainland China, Taiwan, Hong Kong and Macau in December 2022. In December 2022, the Company received a regulatory-based milestone payment of $15.0 million in connection with the conditional marketing approval of DANYELZA in China.

Known Trends, Geopolitical Events and Uncertainties

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

We continue to closely monitor the ongoing COVID-19 pandemic. The extent to which the COVID-19 pandemic impacts our operations or those of our third-party partners, including our pre-clinical studies, clinical trials, manufacturing operations and commercialization efforts, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the COVID-19 pandemic, the emergence of new variants of the virus and the actions to contain the coronavirus or treat its impact, among others. The COVID-19 pandemic was limiting certain commercialization efforts for DANYELZA and also led to slower initiation of new clinical trials and a fluctuating rate of recruitment for ongoing clinical trials, which has delayed our clinical development activities and thereby postponed certain accompanying costs.

Given the continued evolution of the COVID-19 pandemic and the related complexities and uncertainties associated with the additional variants, the future effects of COVID-19 are unknown and our financial results may be negatively affected in the future. The COVID-19 pandemic may also have long-term effects on the nature of the office environment and remote working, which may present strategy, operational, talent recruiting and retention and workplace culture challenges that may adversely affect our business.

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

The full economic and social impact of the sanctions imposed on Russia and possible future punitive measures that may be implemented, as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, supply chain continuity and reduced access to liquidity on acceptable terms, in both Europe and globally, and has introduced significant uncertainty into global markets.

The recent trends towards rising inflation may also materially affect our business and corresponding financial position and cash flows. Inflationary factors, such as increases in the cost of our clinical trial materials and supplies, interest rates and overhead costs may adversely affect our operating results. Rising interest rates also present a recent challenge impacting the U.S. economy and could make it more difficult for us to obtain traditional financing on acceptable terms, if at all, in the future. Additionally, the general consensus among economists suggests that we should expect a higher recession risk to continue over the next year, which, together with the foregoing, could result in further economic uncertainty and volatility in the capital markets in the near term, and could negatively affect demand for our product and our operations. Furthermore, such economic conditions have produced downward pressure on share prices. We may experience increases on our operating costs, including our labor costs and research and development costs, due to supply chain constraints, consequences associated with COVID-19 and the ongoing conflict between Russia and

Ukraine, and employee availability and wage increases, which may result in additional stress on the Company's working capital resources (especially if inflation rates continue to rise).

Components of Our Results of Operations

Product Revenue

Product revenue consists of sales of DANYELZA.

License Revenue

License revenue consists of payments received for the licensing rights to DANYELZA. Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* for additional details.

Operating Costs and Expenses

Cost of goods sold

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

Licensing royalties

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

Research and Development Expenses

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

- sponsored research, laboratory facility services, clinical trial and data service at MSK under the Sponsored Research Agreements, or the SRAs, the two CFSAs, the MCTA, and the MDSA, with MSK;
- expenses incurred under agreements with CROs, as well as investigative sites and consultants that conduct our non-clinical and pre-clinical studies and clinical trials;
- expenses incurred under agreements with CMOs, including manufacturing scale-up expenses and the cost of acquiring and manufacturing pre-clinical 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 EMA or any other non-U.S. regulatory authority;
- any requirement by the FDA, the EMA or any other non-US regulatory authority to conduct post market surveillance or safety studies;
- the expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- the success of commercialization of approved products.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, in its CRL for omburtamab, and in our Type A meeting held subsequent to receipt of the CRL, the FDA made recommendations for us to consider in terms of a potential trial design to demonstrate substantial evidence of effectiveness and a favorable benefit-risk profile. If we are required and we determine to conduct additional clinical trials of a product candidate, including if we determine to resume development of omburtamab, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

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

Selling, General, and Administrative Expenses

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

We anticipate that our selling, general, and administrative, or SG&A, expenses will decrease based our January 2023 restructuring. SG&A expenses include administrative costs to support continued research and development activities, potential commercialization of additional product candidates and additional indications and costs associated with operating as a public company, including expenses related to services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

Other Loss, Net

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

Critical Accounting Policies and Significant Judgments and Estimates

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

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

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, net product revenues, the accrual for research and development expenses, the accrual of milestone and royalty payments, the valuation of stock options and asset impairments. Estimates are periodically reviewed in light of changes in

circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

The full extent to which the COVID-19 pandemic and macroeconomic conditions will directly or indirectly impact our business, results of operations and financial condition, including revenues, expenses, manufacturing, clinical trials, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of the economic impact on local, regional, national and international markets.

Product revenue

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

The vast majority of our product sales were in the United States with additional sales outside the United States in China and Israel through sublicenses and distribution agreements. We had product sales to certain customers that accounted for more than 10% of total gross product revenue for the years ended December 31, 2022 and 2021. McKesson, AmerisourceBergen, and Cardinal Health accounted for 70.8%, 17.4%, and 10.1%, respectively, of our gross product revenue for the year ended December 31, 2022. McKesson and AmerisourceBergen accounted for 73.2% and 17.6%, respectively, of our gross product revenue for the year ended December 31, 2021.

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

License Revenue

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

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

Research and Development Expenses

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of compensation cost for our employees and consultants that perform our research activities, the costs to obtain and maintain our licenses, the payments to third parties for CMOs

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

Fair Value Measurements

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

- Level 1 — Unadjusted quoted prices for identical assets or liabilities in active markets;
- Level 2 — Inputs other than quoted prices in active markets for identical assets and liabilities that are observable either directly or indirectly for substantially the full term of the asset or liability; and
- Level 3 — Unobservable inputs for the asset or liability, which include management's own assumption about the assumptions market participants would use in pricing the asset or liability, including assumptions about risk.

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

Income Taxes

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

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

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

Stock-Based Compensation

We measure stock options granted to employees, directors, and consultants based on the fair value on the date of the grant and recognize compensation expense of those awards, over the requisite service period, which is the vesting

period of the respective award for employees and directors. Forfeitures are accounted for as they occur. We issue stock options to employees and directors with only service-based vesting conditions and record the expense for these awards using the straight-line method over the requisite service period.

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

Fair Value of Stock Options

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

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

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

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

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

Results of Operations

Comparison of the Years Ended December 31, 2022 and 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and 2021:

	Years Ended December 31,		Amount Change 2022 vs. 2021	Percentage Change 2022 vs. 2021
	2022	2021		
	(in thousands)		(in thousands)	
REVENUES				
Product revenue, net	$ 49,267	$ 32,897	$ 16,370	% 50
License revenue	16,000	2,000	14,000	700
Total revenues	65,267	34,897	30,370	87
OPERATING COSTS AND EXPENSES				
Cost of goods sold	7,467	2,304	5,163	224
License royalties	100	210	(110)	(52)
Research and development	91,572	93,245	(1,673)	(2)
Selling, general, and administrative	60,939	54,571	6,368	12
Total operating costs and expenses	160,078	150,330	9,748	6
Loss from operations	(94,811)	(115,433)	20,622	(18)
OTHER INCOME / (LOSS), NET				
Gain from sale of priority review voucher, net	—	62,010	(62,010)	(100)
Interest and other loss, net	(757)	(1,852)	1,095	(59)
NET LOSS	$ (95,568)	$ (55,275)	$ (40,293)	% 73

Revenues

We recorded $65.3 million and $34.9 million in net revenues for the years ended December 31, 2022 and 2021, respectively. Our total revenues consist of product revenue, net and license revenue.

We recorded product revenue, net of $49.3 million and $32.9 million in the years ended December 31, 2022 and 2021, respectively. The increase was primarily driven by an increase in new US patients in the second half of 2022 and also included a $1.8 million benefit related to a change in estimate as discussed further in NOTE 4—PRODUCT REVENUE in the consolidated financial statements included within this annual report on Form 10-K. The geographic breakout for the $49.3 million of product revenue, net between in the United States and other countries were $46.3 million and $3.0 million, respectively.

In addition, we recorded $16.0 million and $2.0 million in license revenue for the years ended December 31, 2022 and 2021, respectively. During the year ended December 31, 2022, we recognized license revenue for a regulatory-based milestone payment received of $15.0 million from SciClone Pharmaceuticals International Ltd., or SciClone, we received in connection with the conditional marketing approval of DANYELZA in China and we recognized $1.0 million license revenue upon the delivery of the updated FDA BLA Dossier under our sublicense with Adium. The license revenue of $2.0 million for the year ended December 31, 2021 was attributable to the revenues earned from the entering into of the sublicense agreement with Adium to out-license DANYELZA and omburtamab in Latin America. As part of this agreement, we received a non-refundable up-front fee of $2.0 million for the transfer of the license and know-how related to the constructs that we concluded was distinct from other promises within the arrangement. Please refer to NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES in the consolidated financial statements included within this annual report on Form 10-K for further information related to our license revenue.

Cost Of Goods Sold

We began capitalizing inventory costs once DANYELZA received accelerated approval by the FDA in November 2020. Cost of goods sold was $7.5 million and $2.3 million for the years ended December 31, 2022 and 2021, respectively. The increase in cost of goods sold was primarily driven by our increased net product revenue and also included a $1.2 million charge in 2022 related to a DANYELZA production batch that did not meet our quality specifications and the below noted impact associated with minimum royalties which began to impact cost of goods sold in 2022. Our cost of goods sold includes amounts related to materials, third-party contract manufacturing, third-party packaging services, freight, labor costs for personnel involved in the manufacturing process, third-party royalties for approved products, and indirect overhead costs. In periods prior to receiving FDA approval for DANYELZA, we recognized inventory and related manufacturing costs of DANYELZA as research and development expenses.

In addition, in 2016, we expensed $1.2 million of minimum royalties related to DANYELZA prior to commercial launch which were fully creditable against earned royalties in future periods. As a result, there was no royalty expense recorded for the year ended December 31, 2021. If we had not sold previously expensed inventory and if we had not utilized the minimum royalty credit, our cost of goods sold would have been approximately $3.9 million for the year ended December 31, 2021.

Licensing Royalties

We incurred license royalty expenses of $0.1 million and $0.2 million during the years ended December 31, 2022 and 2021, respectively related to licensing revenues which is included in Licensing Revenue on the Consolidated Statements of Net Loss and Comprehensive Loss.

We recognized an intangible asset of $1.5 million for the royalty payable to MSK for their share of the regulatory-based milestone payment of $15.0 million by SciClone for the conditional approval of DANYELZA in China, as discussed further in NOTE 7—INTANGIBLE ASSETS in the consolidated financial statements included within this annual report on Form 10-K.

Research and Development Expenses

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

	Years Ended December 31,		Change
	2022	2021	2022 vs. 2021
	(in thousands)		(in thousands)
Outsourced manufacturing	$ 34,750	$ 35,599	$ (849)
Clinical trials	8,904	10,096	(1,192)
Outsourced research and supplies	9,945	12,248	(2,303)
Milestones and license acquisition costs	300	10	290
Personnel costs	18,532	17,599	933
Professional and consulting fees	3,077	2,663	414
Stock-based compensation	7,830	7,402	428
Other	8,234	7,628	606
Total research and development expense	$ 91,572	$ 93,245	$ (1,673)

Research and development expenses were $91.6 million for the year ended December 31, 2022, as compared to $93.2 million for the year ended December 31, 2021. The $1.6 million decrease mainly reflects decreased clinical trial activities in 2022.

Selling, general, and Administrative Expenses

SG&A expenses were $60.9 million for the year ended December 31, 2022, as compared to $54.6 million for the year ended December 31, 2021. The $6.3 million increase in SG&A expenses was primarily attributable to a $7.8 million increase in severance and share-based compensation expense related to our former Chief Executive Officer as discussed further in NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS in the consolidated financial statements included within this annual report on Form 10-K.

Other Loss, Net

On December 28, 2020, we announced that we had entered into a definitive agreement to sell our DANYELZA PRV to United Therapeutics Corporation for $105.0 million. The PRV was granted in conjunction with the approval by the FDA of DANYELZA for the treatment of refractory/relapsed high-risk NB. Under the terms of the MSK License, we retained 60% of the net proceeds received from the sale of the PRV, and the remaining 40% was paid to MSK. The transaction closed on January 21, 2021 and we recognized a net gain of $62.0 million during the year ended December 31, 2021 related to the sale of the PRV. There were no PRV sales during the year ended December 31, 2022.

Interest and other loss, net for the years ended December 31, 2022 and December 31, 2021 were $0.7 million and $1.9 million, respectively. The $1.2 million change in our interest and other loss, net reflects increased interest income for the year ended December 31, 2022 driven by increased interest rates, partially offset by impairment charges totaling $1.4 million related to the write down of the book value to fair value for two Secured Promissory Notes.

Liquidity and Capital Resources

Overview

Each year we have experienced a significant use of cash to fund our net operating losses since inception and expect to continue to have to fund net operating losses. We expect our use of cash to fund our net operating losses to decrease as a result of our restructuring plan announced in January 2023. Our net losses may fluctuate significantly from quarter to quarter and year to year. We currently have one approved product, DANYELZA, which launched in the first quarter of 2021. We have financed our operations through December 31, 2022 primarily through gross proceeds from the sale of our common stock of $493.8 million in the years 2015 through 2021, as well as additional funding from the proceeds from the sales of DANYELZA and from proceeds from the sale of the DANYELZA PRV. As of December 31, 2022 and 2021, we had cash and cash equivalents of $105.8 million and $181.6 million, respectively. As a result of the estimated decrease in operating expenses, we estimate that our cash and cash equivalents, when combined with anticipated DANYELZA revenues, will support operations into the first quarter of 2026. This estimate is based on our current business plan, including our restructuring, and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. This estimate assumes no income from new partnerships or other new business development activities, and no further development of the omburtamab program. 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.

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a PRV, which we subsequently sold to United Therapeutics Corporation in a transaction that closed in January 2021 based on an agreed valuation of $105.0 million. We were obligated to pay 40% of the net proceeds to MSK. We have used the remaining proceeds to fund further research and development and other operational programs.

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.

Cash Flows

The following table provides information regarding our cash flows for the years ended December 31, 2022 and 2021:

	Years Ended December 31,		Amount Change	Percentage Change
	2022	2021	2022 vs. 2021	2022 vs. 2021
	(in thousands)		(in thousands)	
Net cash used in operating activities	$ (75,921)	$ (102,556)	$ 26,635	(26)%
Cash provided by investing activities	—	61,043	(61,043)	(100)
Net cash provided by financing activities	84	108,314	(108,230)	(100)
Effect of exchange rates on cash and cash equivalents	35	129	(94)	(73)
Net increase / (decrease) in cash and cash equivalents	$ (75,802)	$ 66,930	$ (142,732)	(213)%

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 $75.9 million for the year ended December 31, 2022, as compared to net cash used in operating activities of $102.6 million for the year ended December 31, 2021. The $26.6 million decrease in cash used in operating activities during the year ended December 31, 2022, compared to 2021, was primarily due to a $29.7 million decreased use of cash to fund the net loss, net of non-cash adjustments.

Net Cash Used in Investing Activities

We did not generate or use cash for investing activities during the year ended December 31, 2022. Net cash provided by investing activities was $61.0 million for the year ended December 31, 2021. The net change of $61.0 million was primarily the result of the $62.0 million payment related to our share of the gross proceeds received from the sale of our PRV to United Therapeutics Corporation in the year ended December 31, 2021. For additional information on the PRV sale, please refer to the section entitled “Other Loss, Net”.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.1 million for the year ended December 31, 2022, as compared to $108.3 million for the year ended December 31, 2021. The decrease of $108.2 million was primarily due to the net proceeds of $107.7 million received from the public offering in February 2021.

Future Funding Requirements

We plan to advance the development of other pipeline programs, initiate new research and pre-clinical development efforts and seek marketing approval for any additional product candidates and indications that we successfully develop. If we obtain approval for any additional product candidates and indications, we expect to incur commercialization expenses, which may be significant, related to establishing sales, marketing, manufacturing capabilities, distribution and other commercial infrastructure to commercialize such products. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations. However, global economic conditions have been worsening, with disruptions to, and volatility in, the credit and financial markets in the U.S. If these conditions persist and deepen, we could experience an inability to access additional capital or our liquidity could otherwise be impacted. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts.

In conjunction with the approval by the FDA of DANYELZA in November 2020 we received a PRV, which we subsequently sold to United Therapeutics Corporation for $105.0 million. We were obligated to pay 40% of the net proceeds to MSK. We have used the remaining net proceeds of $62.0 million to fund further research and development and other operational programs.

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

As a result of the estimated decrease in operating expenses, we estimate that our cash and cash equivalents of $105.8 million as of December 31, 2022, when combined with anticipated DANYELZA revenues, will support operations as currently planned into the first quarter of 2026. This estimate is based on our current business plan and on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. This estimate assumes no new partnerships or other new business development and no further development of the omburtamab program. 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. As a result of the reduction in workforce and revised business plan, we expect to incur restructuring expenses of approximately $4.7 million, consisting predominantly of cash related to notice and severance payments of approximately $3.0 million and acceleration of stock-based compensation of approximately $1.7 million. The restructuring expenses were recognized in the first quarter of 2023, and the majority of the payments were made in the first quarter of 2023. The charges that we expect to incur are subject to a number of assumptions, and actual expenses may differ materially from the estimates disclosed above.

Because of the numerous risks and uncertainties associated with the development and commercialization of DANYELZA, and the research, development and commercialization of other potential product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials for developing DANYELZA, and conducting pre-clinical studies and clinical trials for our SADA constructs;
- research and pre-clinical development efforts for any future product candidates that we may develop;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements, distribution agreements or other arrangements;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration or other agreements;
- the number of future product candidates that we may pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that may receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- the amount and timing of future revenue, if any, received from commercial sales of our current and future product candidates upon any marketing approvals;
- proceeds received, if any, from monetization of any future PRVs;
- our headcount and associated costs as we focus our research and development efforts on additional indications for DANYELZA and our SADA technology 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.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, existing ownership interest in our company may be materially diluted, and the terms of these securities may include liquidation or other preferences that adversely affect common stockholders' rights. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual Obligations and Commitments

A summary of our minimum contractual obligations related to our material outstanding contractual commitments is included in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* of our enclosed consolidated financial statements.

Contractual obligations as of December 31, 2022 are related to payments of operating leases for our office spaces at our corporate headquarters in New York, New York, a laboratory space located in Nutley, New Jersey, and office space in Hørsholm, Denmark. Our obligations and commitments are disclosed in the contractual obligations table below:

	Payments Due By Period (in thousands)		
	Total	Less Than 1 Year	1 to 3 Years
Operating Lease Commitments	$ 1,906	$ 997	$ 909
Total	$ 1,906	$ 997	$ 909

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

As further described below, under various licensing and related agreements with third parties, we have agreed to make milestone and royalty payments to third parties.

We have entered into three license agreements and certain other agreements with MSK. The license agreements are further described below as the MSK License, the CD33 License, and the SADA License. Additionally, through the Settlement and Assumption and Assignment agreement, or SAAA, we have established a direct license with MSK relating to the GD2-GD3 Vaccine, which was originally licensed by the Company from MabVax in 2018.

Under the MSK License and the CD33 License we are obligated to (i) make certain payments to MSK, which become due based upon the achievement of the related milestone activities or the passage of time in the event such milestone activities are not achieved, as well as certain sales-related milestones, (ii) pay mid to high single-digit royalties to MSK, on a product-by-product and country-by-country basis, based on net sales of products licensed under the applicable agreement and (iii) pay to MSK a percentage of any sublicense fees received by us. Under the CD33 License, we are obligated to pay annual minimum royalties of $40,000 over the royalty term beginning in 2027, increasing to $60,000 once a patent within the licensed rights is issued. These amounts are non-refundable but are creditable against royalty payments otherwise due under the respective agreements. We are also obligated to pay MSK certain clinical, regulatory and sales-based milestone payments under the MSK License and the CD33 License. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License. Total clinical, regulatory and sales-based milestones potentially due under the MSK License are $2.5 million, $9.0 million and $20.0 million, respectively. In addition, under the CD33 License, we are obligated to make potential payments of $0.6 million, $0.5 million and $7.5 million for clinical, regulatory and sales-based milestones, respectively. We record milestones in the period in which the contingent liability is probable and the amount is reasonably estimable.

On April 15, 2020, we entered the SADA License Agreement, which requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License Agreement. Under the SADA License Agreement, we are also obligated to pay MSK and MIT certain clinical, regulatory and sales-based milestone payments. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement. Total clinical and regulatory milestones potentially due under the SADA License Agreement are $4.7 million and $18.1 million, respectively. There are also sales-based milestones, totaling $23.8 million, that become due should we achieve certain amounts of sales of licensed products. In addition, for each SADA construct generated by MSK and out-licensed by the Company to a sublicensee, we are obligated to pay sales milestones up to $60.0 million in total, based on the achievement of various levels of cumulative net sales by the sublicensee.

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

licensed product in such country or (ii) the last to expire valid claim covering such licensed product rights at the time of and in the country of sale.

Research and development is inherently uncertain and, should such research and development fail, the MSK License, the CD33 License, and SADA License are cancelable at our option. We have also considered the development risk and each party's termination rights under the three license agreements when considering whether any contingent payments, certain of which also contain time-based payment requirements, were probable. In addition, to the extent we enter into sublicense arrangements, we are obligated to pay to MSK a percentage of certain payments that we receive from sublicensees of the rights licensed to us by MSK, for which the percentage varies based upon the nature of the clinical or development milestone. To date, we have not entered into any sublicenses related to the CD33 License, the SADA License or the MabVax License. We have entered sublicenses with SciClone and Takeda in 2020, Adium in 2021 and WEP Clinical Ltd. in 2022 as allowed under the MSK License. Our failure to meet certain conditions under such arrangements could cause the related license to such licensed product to be canceled and could result in termination of the entire respective arrangement with MSK. In addition, we may terminate the MSK License, the CD33 License, or the SADA License with prior written notice to MSK.

Recent Accounting Pronouncements

Refer to *NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES* in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

ITEM 7A. 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 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Y-MABS THERAPEUTICS, INC.

Index to Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Y-mAbs Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Y-mAbs Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of net loss and comprehensive loss, of changes in stockholders' equity, and of cash flows for the years then ended, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Revenue Recognition – United States (U.S.) Product Revenue

As described in Notes 3 and 4 to the consolidated financial statements, product revenue is generated from sales of DANYELZA, which are recognized as revenue at the point in time when the customer is deemed to have obtained control of the product, which occurs upon receipt at the end-user hospital. Product sales are primarily recognized through the Company's arrangements with three national U.S. specialty distributors. The Company's consolidated net product revenue was $49.3 million for the year ended December 31, 2022, of which $46.3 million is generated from the U.S.

The principal consideration for our determination that performing procedures relating to revenue recognition for U.S. product revenue is a critical audit matter is a high degree of auditor effort in performing procedures related to the Company's revenue recognition.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing the effectiveness of controls relating to U.S. revenue recognition. These procedures also included, among others, (i) testing management's reconciliation of gross revenue recognized from product sales to third-party information; (ii) evaluating the gross revenue recognized on a sample basis by obtaining and inspecting source documents, including the customer arrangements, purchase orders, invoices, proof of delivery, and cash receipts from customers; (iii) confirming sales terms with all of the Company's U.S. customers; and (iv) confirming a sample of outstanding customer invoice balances as of December 31, 2022 and, for confirmations not returned, obtaining cash receipts from customers.

/s/ PricewaterhouseCoopers LLP

Florham Park, New Jersey
March 30, 2023

We have served as the Company's auditor since 2017.

Y-MABS THERAPEUTICS, INC.

Consolidated Balance Sheets

(in thousands, except share data)

	December 31, 2022	December 31, 2021
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 105,762	$ 181,564
Accounts receivable, net	12,531	7,712
Inventories	6,702	5,512
Other current assets	5,452	7,473
Total current assets	130,447	202,261
Property and equipment, net	604	1,847
Operating lease right-of-use assets	1,739	3,842
Intangible assets, net	2,986	1,663
Other assets	5,680	3,170
TOTAL ASSETS	$ 141,456	$ 212,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
LIABILITIES		
Accounts payable	$ 14,175	$ 13,552
Accrued liabilities	13,241	12,540
Operating lease liabilities, current portion	868	1,783
Total current liabilities	28,284	27,875
Accrued milestones	2,250	2,100
Operating lease liabilities, long-term portion	899	1,851
Other liabilities	802	851
TOTAL LIABILITIES	32,235	32,677
Commitments and contingencies (Note 9)		
STOCKHOLDERS' EQUITY		
Preferred stock, $0.0001 par value, 5,500,000 shares authorized and none issued at December 31, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value, 100,000,000 shares authorized at December 31, 2022 and December 31, 2021; 43,670,109 and 43,694,716 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	4	4
Additional paid in capital	543,929	519,206
Accumulated other comprehensive income	1,331	1,371
Accumulated deficit	(436,043)	(340,475)
TOTAL STOCKHOLDERS' EQUITY	109,221	180,106
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 141,456	$ 212,783

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Net Loss and Comprehensive Loss

(In thousands, except share and per share data)

	For the years ended December 31,	
	2022	2021
REVENUES		
Product revenue, net	$ 49,267	$ 32,897
License revenue	16,000	2,000
Total revenues	65,267	34,897
OPERATING COSTS AND EXPENSES		
Cost of goods sold	7,467	2,304
License royalties	100	210
Research and development	91,572	93,245
Selling, general, and administrative	60,939	54,571
Total operating costs and expenses	160,078	150,330
Loss from operations	(94,811)	(115,433)
OTHER LOSS, NET		
Gain from sale of priority review voucher, net	—	62,010
Interest and other loss, net	(757)	(1,852)
NET LOSS	$ (95,568)	$ (55,275)
Other comprehensive income		
Foreign currency translation	(40)	1,897
COMPREHENSIVE LOSS	$ (95,608)	$ (53,378)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.19)	$ (1.28)
Weighted average common shares outstanding, basic and diluted	43,703,663	43,181,808

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Changes in Stockholders' Equity

(In thousands, except share data)

	Common Stock		Additional	Accumulated Other Comprehensive	Accumulated	Stockholders'
	Shares	Amount	Paid-in Capital	Income / (Loss)	Deficit	Equity
Balance December 31, 2020	40,688,447	$ 4	$ 391,558	$ (526)	$ (285,200)	$ 105,836
Issuance of common stock to investors, net of issuance costs	2,804,878	—	107,725	—	—	107,725
Exercise of stock options	190,492	—	589	—	—	589
Stock-based compensation expense	10,899	—	19,334	—	—	19,334
Foreign currency translation	—	—	—	1,897	—	1,897
Net loss	—	—	—	—	(55,275)	(55,275)
Balance December 31, 2021	43,694,716	$ 4	$ 519,206	$ 1,371	$ (340,475)	$ 180,106
Exercise of stock options	20,000	—	84	—	—	84
Retirement of treasury shares – refer to Note 10	(57,887)	—	(963)	—	—	(963)
Stock-based compensation expense	13,280	—	25,602	—	—	25,602
Foreign currency translation	—	—	—	(40)	—	(40)
Net loss	—	—	—	—	(95,568)	(95,568)
Balance December 31, 2022	43,670,109	$ 4	$ 543,929	$ 1,331	$ (436,043)	$ 109,221

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

Y-MABS THERAPEUTICS, INC.

Consolidated Statements of Cash Flows

(In thousands)

	For the years ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (95,568)	$ (55,275)
Adjustments to reconcile net loss to net cash used in operating activities:		
Gain from sale of priority review voucher, net	—	(62,010)
Depreciation and amortization	839	782
Stock-based compensation	25,602	19,334
Foreign currency and other transactions	3,577	1,897
Changes in assets and liabilities:		
Accounts receivable, net	(4,819)	(7,712)
Inventories	(1,190)	(5,512)
Other current assets	(360)	256
Other assets	(2,510)	120
Accounts payable	(919)	4,180
Accrued liabilities and other	(573)	1,384
NET CASH USED IN OPERATING ACTIVITIES	(75,921)	(102,556)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchase of property and equipment	—	(667)
Acquisition of intangible assets	—	(300)
Net proceeds from sale of priority review voucher	—	62,010
NET CASH PROVIDED BY INVESTING ACTIVITIES	—	61,043
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuance of common stock, net of issuance costs	—	107,725
Proceeds from exercised stock options	84	589
NET CASH PROVIDED BY FINANCING ACTIVITIES	84	108,314
Effect of exchange rates on cash and cash equivalents	35	129
NET INCREASE / (DECREASE) IN CASH AND CASH EQUIVALENTS	(75,802)	66,930
Cash and cash equivalents at the beginning of period	181,564	114,634
Cash and cash equivalents at the end of period	$ 105,762	$ 181,564
SUPPLEMENTAL DISCLOSURE OF NON-CASH ACTIVITIES		
Intangible assets acquisition in accrued liabilities	$ 1,500	$ 1,500
Right-of-use assets obtained in exchange for lease obligations	$ 347	$ 1,754
Acquisition of treasury shares upon repayment of secured promissory note – refer to Note 10	$ 963	$ —

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

NOTE 1—ORGANIZATION AND DESCRIPTION OF BUSINESS

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

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

NOTE 2—BASIS OF PRESENTATION

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

The Company's drug candidates are in various stages of development. DANYELZA (naxitamab-gqgk) received accelerated approval by the FDA in November 2020, but there can be no assurance that the Company's other research and development efforts will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development and commercialization efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. 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 $436,043,000 as of December 31, 2022 and $340,475,000 as of December 31, 2021. Through December 31, 2022, the Company has funded its operations primarily through proceeds from sales of shares of its common stock, including its initial public offering in September 2018 and its subsequent public offerings in November 2019 and February 2021, as well as additional funding from the sales of DANYELZA and from the sale of the DANYELZA PRV.

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

As of December 31, 2022, the Company had cash and cash equivalents of $105,762,000, and as of December 31, 2021 the Company had cash and cash equivalents of $181,564,000. As of the issuance date of the financial statements for the year ended December 31, 2022, the Company expects that its cash and cash equivalents at

December 31, 2022 will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next twelve months, irrespective of whether any additional product approvals are obtained.

The Company may raise additional capital to fund future operations through the sale of its securities, incurring debt, entering into licensing or collaboration agreements with partners, grants or other sources of financing. These financing sources are in addition to successful commercialization of DANYELZA and our product candidates which we may obtain regulatory approval and marketing authorization. The Company's commercialization strategy may be either directly or with a collaborator or distributor. Sufficient funds may not be available to the Company on attractive terms or at all when needed from any such financing. If the Company is unable to obtain additional financing from these or other sources when needed, it will likely be necessary to take other actions to enhance the Company's liquidity position which may include significantly reducing the current rate of spending through delaying or scaling back current operations, or suspending certain research and development programs and other operational programs.

The accompanying consolidated financial statements reflect the accounts of the Company and its wholly-owned subsidiary and have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All intercompany balances and transactions have been eliminated.

NOTE 3—SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Use of Estimates

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

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

Cash and Cash Equivalents

The Company considers all highly liquid instruments with original maturities of three months or less from date of purchase to be cash equivalents. All cash and cash equivalents are held in highly rated securities including a treasury money market fund, which is unrestricted as to withdrawal or use. Our cash and cash equivalents are primarily held at a large U.S. based global financial institution. To date, the Company has not experienced any losses on its cash and cash equivalents. The carrying amount of cash and cash equivalents approximates its fair value due to its short-term and liquid nature. The Company maintains cash balances in excess of insured limits. The Company monitors the financial performance, credit ratings and liquidity of the money market fund to timely assess and respond to any changes in the asset values of the fund. The Company does not anticipate any losses with respect to such cash balances.

Trade Accounts Receivables

The Company's trade accounts receivable balance consists of amounts due from sales of its approved product, DANYELZA. Receivables from product sales are recorded net of allowances which generally include chargebacks, doubtful accounts, rebates, returns, and discounts. The allowance is based primarily on assessment of specific identifiable customer accounts considered at risk or uncollectible, as well as an analysis of current receivables aging and

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

The Company has not experienced any write-offs related to our customers and has not recognized any allowance for doubtful accounts nor reversed any allowances during the years ended December 31, 2022 and 2021.

Concentration of Credit Risk

The Company product sales are made through arrangements primarily with three national specialty distributors in the United States of America. As of December 31, 2022, the receivables balances from such distributors totaled 94% of our outstanding accounts receivable. The Company has contractual payment terms with each of its customers and the Company monitors their financial performance, historical payment terms and credit worthiness to timely assess and respond to any changes in their credit profile.

Inventory

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

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

The Company performs an assessment of the recoverability of capitalized inventory during each reporting period, and writes down any excess and obsolete inventories to their estimated realizable value in the period in which the impairment is first identified. Such impairment charges, should they occur, are recorded within cost of goods sold. The determination of whether inventory costs will be realizable requires estimates by management. Other than the $1,200,000 recorded in the year ended December 31, 2022, as discussed further in NOTE 6 —INVENTORIES, there were no other material inventory write-downs and no reserves were reversed in the years ended December 31, 2022 and 2021.

Fair Value Measurements

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

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

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

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

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

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

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

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

During the years ended December 31, 2022 and 2021, there were no transfers between Level 1, Level 2 and Level 3.

Operating Leases

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

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

The Company currently elects the short-term lease recognition exemption for all leases that qualify. This means, for those leases that qualify, the Company will not recognize right-of-use assets or liabilities, and this includes not recognizing right-of-use assets or liabilities for existing short-term leases of those assets in transition. The Company also elects the practical expedient to not separate lease and non-lease components for all of its leases. The Company has made an accounting policy election to account for each separate lease component of a contract and its associated non-lease components as a single lease component. See the Lease Agreements section in NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS for the related disclosures.

Revenue Recognition

Product revenue

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

Under the practical expedient permitted under Topic 606, the Company expenses incremental costs of obtaining a contract as and when incurred if the expected amortization period of the assets is one year or less. If there are multiple distinct performance obligations, we allocate the transaction price to each distinct performance obligation based on its relative standalone selling price. The Company also considers the intended benefit of the contract in assessing whether a promised good or service is separately identifiable from other promises in the contract. If a promised good or service is not distinct, the Company combines that good or service with other promised goods or services until it identifies a bundle of goods or services that is distinct. The standalone selling price is generally determined based on the prices charged to customers.

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

The amount of revenue the Company recognizes from sales of DANYELZA varies due to rebates, chargebacks and discounts provided under governmental and other programs, distribution related fees and other sales-related deductions. In order to determine those deductions, the Company estimates, utilizing the expected value method, the amount of revenue that it will ultimately be entitled to. This estimate is based upon contracts with customers and government agencies, statutorily-defined discounts applicable to government-funded programs, estimated payor mix, and other relevant factors. Calculating these amounts involves estimates and judgments, and the Company reviews these estimates quarterly. If actual results vary from its original estimates, the Company will adjust these estimates quarterly, which would affect net product revenue and earnings in the period such variances occur.

- Rebates and chargebacks

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

- Discounts and distribution-related fees

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

- Returns

  The Company offers its customers limited product return rights for damaged, defective, or expiring products. The Company estimates returns on sales of DANYELZA mainly based on information provided to the Company from the hospitals and distributors. The return reserves are recorded in the same period the related revenue is recognized, resulting in a reduction of product revenue and an establishment of an accrued liability.

License revenue

In December 2020, the Company entered into a development and commercialization arrangement with SciClone International Pharmaceuticals Ltd., or SciClone, for certain indications of DANYELZA and omburtamab for Greater China, including Mainland China, Taiwan, Hong Kong and Macau. Based on the terms of the agreement, the Company may receive regulatory-based milestone payments up to $40,000,000 and sales-based milestone payments up to $60,000,000 and is entitled to royalties based upon the net sales generated by SciClone related to the product indications in the territory. Upon entering into the agreement, we received a nonrefundable up-front payment of $20,000,000 for the transfer of the license and know-how related to the product indications. We considered the license to be distinct from other promises within the arrangement based on the rights and know-how transferred, late-stage development of the underlying indications and anticipated lack of significant involvement required from the joint steering committee associated with the indications. Accordingly, the full up-front payment of $20,000,000 was recognized upon transferring of the license and know-how to SciClone. In December 2022, the Company received a regulatory-based milestone payment of $15,000,000 for the conditional approval of DANYELZA in China. We determined that the achievement of the remaining regulatory-based milestones within the agreement are constrained as they are contingent upon regulatory approvals which are not within our control and therefore not deemed probable. We expect that the sales-based milestones and royalty payments will be recognized when the milestone is achieved or the related sales occur. We reevaluate the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur, we assess whether this resolves the constraint and it is appropriate to recognize revenue.

In November 2020, we entered into an exclusive license and distribution agreement for DANYELZA and omburtamab with Takeda Israel, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited covering the State of Israel, West Bank and Gaza Strip. We received a nonrefundable upfront payment of $0.5 million which has been recognized in revenue in the fourth quarter of 2020. Based on the terms of the arrangement, the Company may receive regulatory-based milestone payments up to $750,000 and sales-based milestone payments up to $500,000 and is entitled to royalties based upon the net sales generated by Takeda related to the product in the territory. The Company recognized a regulatory-based milestone of $250,000 in the fourth quarter of 2020 when a regulatory milestone was achieved. We expect that the remaining regulatory-based and sales-based milestones will be recognized when the milestone is achieved, or the related sales occur.

In December 2020, we entered into a distribution agreement for DANYELZA and omburtamab with Swixx BioPharma AG for the Eastern European territories Bosnia & Herzegovina, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Romania, Russia, Serbia, Slovakia and Slovenia. There are no regulatory-based, sales-based milestone payments or royalty arrangements under this distribution agreement.

In May 2021, the Company entered into an exclusive distribution agreement with Adium Pharma S.A. ("Adium") for Adium to be the exclusive distributor in Latin America of the Company's antibodies omburtamab, if approved, and DANYELZA. As part of this agreement, the Company received and recognized a non-refundable up-front payment of $2,000,000 for the transfer of the license and know-how related to the product indications during the year ended December 31, 2021. The Company considered the license to be distinct from other promises within the arrangement based on the rights and know-how transferred, late-stage development of the underlying indications and anticipated lack of significant involvement required from the joint steering committee associated with the indications. Under the terms of the agreement, the Company may also receive regulatory-based milestone payments up to an aggregate of $3,000,000. The Company received the first of these milestone payments totaling $1,000,000 in April 2022 upon the submission of the updated FDA BLA dossier for DANYELZA. In addition, the Company is entitled to royalties based upon DANYELZA net sales generated by Adium in Latin America. We determined that the achievement of the remaining regulatory-based milestones within the agreement are constrained as they are contingent upon regulatory approvals which are not within the Company's control and therefore not deemed probable. The Company expects that the sales-based milestones and royalty payments will be recognized when the milestones are achieved or the related sales occur. The Company reevaluates the transaction price each quarter and as uncertain events are resolved or other changes in circumstances occur, the Company assesses whether this resolves the constraint and it is appropriate to recognize revenue.

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

Segment Information

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

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation. Depreciation expense is recognized using the straight-line method over the estimated useful life of each asset as follows:

	Estimated Useful Life
Furniture and fixtures	5 years
Machinery and equipment	5 years
Leasehold improvements	Shorter of life of lease or 15 years

Depreciation expense on property and equipment was $662,000 and $645,000 for the years ended December 31, 2022 and 2021.

Upon retirement or sale, the cost of assets disposed of and the related accumulated depreciation are removed from the accounts and any resulting gain or loss is included in loss from operations. Expenditures for repairs and maintenance are expensed as incurred.

Impairment of Long-Lived Assets

ASC 360, Property, Plant and Equipment, addresses the financial accounting and reporting for impairment or disposal of long-lived assets. The Company reviews the recorded values of long-lived assets for impairment whenever events or changes in business circumstance indicate that the carrying amount of an asset or group of assets may not be fully recoverable. During the year ended December 31, 2022, the Company recorded an impairment charge of $617,000 to write-off the net book value of fixed assets that were related to the production of omburtamab, which did not receive FDA regulatory approval, as the equipment has no alternative use. The impairment charge was recorded within research

and development expense within the Company's Consolidated Statements of Net Loss and Comprehensive Loss and foreign currency and other transactions within the Company's Consolidated Statements of Cash Flows.

Income Taxes

The Company accounts for income taxes under the asset and liability approach for the financial accounting and reporting of income taxes. Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to net operating loss carry forwards and temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases. These assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which the temporary differences are expected to reverse. We maintain a full valuation allowance on our deferred tax assets based on cumulative historical and expected losses. If we achieve profitability, we will consider the continued need for such valuation allowance.

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

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

In accordance with guidance issued by Financial Accounting Standards Board ("FASB"), companies should make and disclose a policy election as to whether they will recognize deferred taxes for basis differences expected to reverse as Global Intangible Low-Taxed Income ("GILTI") or whether they will account for GILTI as period costs if and when incurred. The Company has elected to recognize the resulting tax with respect to the GILTI provision as a period cost. No costs were incurred by the Company through December 31, 2022 as a result of GILTI.

Research and Development Costs

Research and development costs are charged to operations when incurred and are included in operating expenses. Research and development costs consist principally of compensation cost for our employees and consultants that perform our research activities, the fees paid to maintain our licenses, services performed by third parties for manufacturing of products in development, services performed by clinical research organizations for products in development, and consumables and other materials used in research and development. The Company records accruals for estimated ongoing research and development costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or clinical trials, including the phase or completion of events, invoices received and contracted costs. Actual results could differ from the Company's estimates. The Company is obligated to make certain milestone and royalty payments in accordance with the contractual terms of its license agreement with MSK based upon the resolution of certain contingencies. The Company records the milestone and royalty payments when the achievement of the milestone or payment of the milestone or royalty is probable and the amount of the payment is reasonably estimable. Research and development costs were $91,572,000 and $93,245,000 for the years ended December 31, 2022 and 2021.

Additionally, the Company is obligated to make certain royalty and clinical, regulatory and sales-based milestone payments in accordance with the contractual terms of the MSK License, CD33 License, MabVax Sublicense, and SADA License based upon the resolution of certain contingencies. We record the clinical and regulatory milestone payments when the achievement of the milestones or payment of the milestones is deemed probable, and the amount of the payment is reasonably estimable. As it relates to clinical and regulatory milestone payments under the licensing arrangements, those may become due and payable with the passage of time whether or not the milestones have actually

been met. When evaluating whether milestones should be recognized under the licensing arrangements, the Company uses its collective clinical experience to determine the likelihood of achievement, as well as the current stage of the compounds under development, estimates of the progress of its preclinical studies and clinical trials, completion of milestone events per underlying agreements, the time expected to complete certain development activities, each party's termination right under the license agreements, invoices received and contracted costs when evaluating whether the clinical milestones should be recognized in each reporting period. We review our assessment each period and make revisions to such estimates as necessary.

Patent Costs

The Company expenses the costs of obtaining and maintaining patents as selling, general, and administrative expenses.

Advertising and Promotion Costs

Advertising and promotion costs are included in selling, general, and administrative expenses and were immaterial in the years ended December 31, 2022 and 2021. Advertising and product promotion costs are expensed as incurred.

Stock-Based Compensation

The Company measures stock options granted to employees, directors and consultants 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 or immediate vesting conditions 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 date of grant using the Black-Scholes option pricing model. The Company's public trading commenced in September 2018, and, as a result, there is only limited available historical volatility experience. Therefore, we estimate our expected share price volatility based on the weighting of our own volatility in the estimation with the historical volatility of a group of publicly traded peer companies, and we expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards as the Company has limited historical data to support the expected term assumption. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that the Company has never paid cash dividends on common shares and does not expect to pay any cash dividends in the foreseeable future.

Stock-based compensation costs were $25,602,000 and $19,334,000 for the years ended December 31, 2022 and 2021.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with shareholders. The difference between net loss and comprehensive loss for the period presented in the accompanying financial statements was due to foreign currency translation.

Foreign Currency

The financial statements of our international subsidiaries with a functional currency other than the U.S. dollar are translated into U.S. dollars using period-end exchange rates for assets and liabilities, historical exchange rates for stockholders' equity and weighted average exchange rates during the period for operating results. Translation gains and

losses are included in accumulated other comprehensive income / (loss), net of tax, in stockholders' equity. Foreign currency translation gains and losses are included in the consolidated statements of net loss and comprehensive loss and totaled a loss of $40,000 and a loss of $1,897,000 for the years ended December 31, 2022 and 2021.

Recently Issued Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, ("FASB"), and are adopted by the Company as of the specific effective date. The Company adopted ASU 2020-10, ASU 2021-04 and ASU 2020-06 effective January 1, 2022, and adopted ASU 2020-04, ASU 2019-12, ASU 2018-13 and ASU 2018-15 effective January 1, 2021. The Company believes these adopted ASUs do not apply or have a material impact on our consolidated financial statements or disclosures.

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

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

NOTE 4—PRODUCT REVENUE

The Company's net product revenues were generated from sales of DANYELZA and totaled $49,267,000 and $32,897,000 for the years ended December 31, 2022 and 2021. The geographic breakout for the $49,267,000 of product revenue, net between the United States and other countries were $46,259,000 and $3,008,000, respectively.

Revenue from product sales is recorded net of applicable provisions for rebates, chargebacks, discounts, distribution-related fees and other sales-related deductions. Accruals for chargebacks, discounts and distribution-related fees with contractual right of offset are recorded as a direct reduction to accounts receivable. Accruals for rebates, distribution-related fees without contractual right of offset and other sales-related deductions are recorded within accrued liabilities. As of December 31, 2022, the company had recorded accounts receivable allowances of approximately $508,000 and accrued liabilities of $2,474,000 related to product sales.

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

	Discounts	Contractual Allowances and Government Rebates	Returns	Total
		(in thousands)		
Balance, December 31, 2021	$ 13	$ 3,027	$ 61	$ 3,101
Current provisions relating to sales in current year	102	5,660	381	6,143
Payments/credits relating to sales in current year	(82)	(3,996)	(398)	(4,476)
Change in estimate	—	(1,786)	—	(1,786)
Balance, December 31, 2022	$ 33	$ 2,905	$ 44	$ 2,982

The vast majority of the Company's product sales were in the United States with additional sales outside the United States in China and Israel through sublicenses and distribution agreements. The Company had product sales to certain customers that accounted for more than 10% of total gross product revenue for the years ended December 31, 2022 and 2021. McKesson, AmerisourceBergen, and Cardinal Health accounted for 70.8%, 17.4%, and 10.1%, respectively, of the Company's gross product revenue for the year ended December 31, 2022. McKesson and AmerisourceBergen accounted for 73.2% and 17.6%, respectively, of the Company's gross product revenue for the year ended December 31, 2021.

During the year ended December 31, 2022 the Company recorded a change in estimate resulting in a benefit of $1,786,000 as the Company assessed claims data and reserves for historical earned periods associated with government program related rebates.

NOTE 5—NET LOSS PER SHARE

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

	For the years ended December 31,	
	2022	2021
	(in thousands, except per share amounts)	
Net loss (numerator)	$ (95,568)	$ (55,275)
Weighted-average shares (denominator), basic and diluted	43,703,663	43,181,808
Basic and diluted net loss per share	$ (2.19)	$ (1.28)

Potentially dilutive securities excluded from the computation of diluted earnings per share relate to stock options and unvested restricted share units ("RSUs") outstanding totaled 7,113,122 shares as of December 31, 2022 and 6,716,035 shares as of December 31, 2021.

NOTE 6—INVENTORY

Inventories consist of the following (in thousands):

	December 31, 2022	December 31, 2021
Work In Progress	$ 11,317	$ 4,741
Finished Goods	666	771
Total Inventories	$ 11,983	$ 5,512

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

	December 31, 2022	December 31, 2021
CURRENT ASSETS		
Inventories	$ 6,702	$ 5,512
Total recorded in Current Assets	6,702	5,512
NONCURRENT ASSETS		
Other assets	5,281	—
Total recorded in Noncurrent Assets	5,281	—
Total Inventories	$ 11,983	$ 5,512

As of December 31, 2022, the Company has classified $5,281,000 of work in progress inventories as noncurrent assets based on its current demand schedule and expectation that such inventory will be utilized in excess of one year from the balance sheet date. Changes in noncurrent assets are reflected on the consolidated statements of cash flows within the caption of other assets.

During the year ended December 31, 2022, the Company recorded a $1,200,000 charge in cost of goods sold related to a batch of DANYELZA planned for commercial use that did not meet our quality specifications.

NOTE 7— INTANGIBLE ASSETS

The Company's intangible assets, net as of December 31, 2022 totaled $2,986,000, net of $314,000 of accumulated amortization, and related to capitalized milestone payments accrued following FDA approval and commercialization of DANYELZA. The Company recognized an intangible asset of $1,500,000 for the royalty payable to MSK for their share of the regulatory-based milestone payment of $15,000,000 by SciClone for the conditional approval of DANYELZA in China. The Company's intangible assets, net as of December 31, 2021 totaled $1,663,000, net of $137,000 of accumulated amortization.

Intangible assets are amortized on a straight-line basis based on a 10-year useful life of the assets. Annual amortization expense is expected to be $354,700 each year for the five-year period from 2023 to 2027, and $1,212,500 thereafter.

NOTE 8—ACCRUED LIABILITIES

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

	December 31, 2022	December 31, 2021
Accrued licensing milestone and royalty payments	$ 4,002	$ 3,090
Accrued clinical costs	932	915
Accrued compensation and board fees	2,445	1,877
Accrued manufacturing costs	2,977	2,622
Accrued sales reserves	2,474	2,615
Other	411	1,421
Total	$ 13,241	$ 12,540

NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS

The Company has entered into two license agreements and certain other agreements with Memorial Sloan Kettering Cancer Center ("MSK"). The license agreements are the MSK License Agreement and the CD33 License Agreement. Through a 2019 Settlement and Assumption and Assignment of the MSK License and Y-mAbs Sublicense Agreement, or SAAA, with MabVax Therapeutics Holdings, Inc. and MabVax Therapeutics, Inc., or together, MabVax, and MSK, the Company has established a direct license with MSK relating to the GD2-GD3 Vaccine, which was originally sublicensed by the Company in 2018 from MabVax. In addition, the Company entered the SADA License Agreement with MSK and Massachusetts Institute of Technology ("MIT") in 2020. These license agreements with MSK and MIT grant the Company certain patent rights and intellectual property rights, and in consideration thereof, the Company agreed to make certain payments and issue shares of the Company's common stock to MSK and MIT. Certain of the payments are contingent milestone and royalty payments, as disclosed in the table below. Amounts disclosed in NOTE 8—ACCRUED LIABILITIES for accrued milestone and royalty payments are inclusive of obligations under the MSK License Agreement, CD33 License Agreement, MabVax Agreement and SADA License Agreement, collectively.

MSK License

The MSK License requires us 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 upon achievement of the related clinical, regulatory or sales-based milestones. Certain of these clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the MSK License. Total clinical and regulatory milestones potentially due under the MSK License are $2,450,000 and $9,000,000, respectively. There are also sales based milestones that become due should the Company achieve certain amounts of sales of licensed products resulting from the license arrangement with MSK, with total

potential sales based milestones potentially due of $20,000,000. As product candidates progress through clinical development, regulatory approval and commercialization, certain milestone payments will come due either as a result of the milestones having been met or the passage of time even if the milestones have not been met. The Company will also owe MSK mid to high single digit royalties on commercial sales of the Company's approved products. In addition, to the extent the Company enters into sublicense arrangements, the Company is required to pay to MSK a percentage of certain payments that the Company receives from sublicensees of the rights licensed to the Company by MSK, which percentage will be based upon the date the Company receives such payments or the achievement of certain clinical milestones. The Company has entered into sublicenses and distribution agreements related to DANYELZA and omburtamab under the MSK License with Takeda Israel, Swixx BioPharma AG and SciClone in 2020, with Adium in 2021 and WEP Clinical Ltd. In 2022.

The terms of the MSK License provide that MSK is entitled to receive 40% of the income generated from the sale of first PRV, and 33% of any income generated from the sale of any subsequent PRV or the sale of other comparable incentives provided by any non U.S. jurisdiction. The Company sold the PRV received upon FDA approval of DANYELZA to United Therapeutics for $105,000,000. Pursuant to the agreement with MSK, the Company was entitled to retain 60% of the net proceeds from monetization of the PRV, and the remaining 40% was due to MSK. The Company received their portion of the net proceeds of from the sale of the PRV in the amount of approximately $62,000,000 when the transaction was consummated in January 2021.

The MSK License will expire, on a country by country basis, and on a licensed product by licensed product or licensed service by licensed service basis, on the later of (i) the expiration of the last to expire of the patents and patent applications covering such licensed product or service in such country, (ii) the expiration of any market exclusivity period granted by a regulatory authority for such licensed product or service in such country, or (iii) 15 years from the first commercial sale of such licensed product or service in such country.

MSK may terminate the MSK License upon prior written notice in the event of our uncured material breach, or upon prior written notice if such breach is of a payment obligation. MSK may also terminate the MSK License upon written notice in the event of our bankruptcy or insolvency or our conviction of a felony relating to the licensed products, or if the Company challenges the validity or enforceability of any licensed patent right. In addition, the Company has the right to terminate the MSK License in its entirety at will upon prior written notice to MSK, but if the Company has commenced the commercialization of licensed products and/or licensed services the Company can only terminate at will if the Company ceases all development and commercialization of such licensed products and/or licensed services.

The Company's failure to meet certain conditions under the MSK License could cause the related license to such licensed product to be canceled and could result in termination of the MSK License by MSK.

CD33 License

On November 13, 2017, the Company entered into the MSK CD33 License, with MSK, which grants the Company a worldwide, sub-licensable license to MSK's rights in certain patent rights and intellectual property rights related to certain know-how to develop, make and commercialize licensed products and to perform services for all therapeutic and diagnostic uses in the field of cancer diagnostics in connection with certain CD33 antibodies generated in a specific principal investigator's laboratory at MSK and constructs thereof. The CD33 License is exclusive with respect to such patent rights and tangible materials within such know-how, and nonexclusive with respect to MSK's rights in such know-how and related intellectual property rights. As product candidates progress through clinical development, regulatory approval and commercialization, certain milestone payments will come due either as a result of the milestones having been met or the passage of time even if the milestones have not been met. Also, the Company will owe MSK customary royalties on commercial sales of the Company's approved products, if any. Total potential milestones due under the CD33 License are $550,000, $500,000 and $7,500,000 for clinical, regulatory and sales based milestones, respectively. In addition, the CD33 License contains minimum royalty payments that become due beginning in year 10 of $40,000 per year over the royalty term, increasing to $60,000 once a patent within the licensed rights is issued, subject to increase and creditable against any royalty payments due based on sales in the future. The Company is required to pay mid to high single-digit royalties on sales of licensed products. Additionally, the terms of the CD33

License provide that MSK is entitled to receive 25% of any income generated from the sale of any PRV or the sale of other comparable incentives provided by any non-U.S. jurisdiction.

The MSK CD33 License will expire, on a country-by-country basis, and on a licensed product-by-licensed-product or licensed-service-by-licensed-service basis, on the later of (I) the expiration of the last to expire of the patents and patent applications covering such licensed product or service in such country, (ii) the expiration of any market exclusivity period granted by a regulatory authority for such licensed product or service in such country, or (iii) 15 years from the first commercial sale of such licensed product or service in such country.

MSK may terminate the CD33 License upon prior written notice in the event of our uncured material breach, or upon prior written notice if such breach is of a payment obligation. MSK may also terminate the CD33 License upon written notice in the event of the Company's bankruptcy or insolvency or the Company's conviction of a felony relating to the licensed products, or if the Company challenges the validity or enforceability of any licensed patent right. In addition, the Company has the right to terminate the CD33 License in its entirety at will upon prior written notice to MSK, but if the Company has commenced the commercialization of licensed products and/or licensed services the Company can only terminate at will if the Company ceases all development and commercialization of such licensed products and/or licensed services.

MabVax/MSK License

On December 2, 2019, the Company entered into the SAAA, of MSK License and Y mAbs Sublicense Agreement, or the MabVax/Y mAbs Sublicense, between the Company and MabVax dated June 27, 2018, with MabVax and MSK, which became effective on December 13, 2019. Pursuant to the MabVax/Y mAbs Sublicense, MabVax sublicensed to the Company certain patent rights and know-how for development and commercialization of products for the prevention or treatment of NB by means of administering a bi-valent ganglioside vaccine granted to MabVax, pursuant to an exclusive license agreement dated June 20, 2008 between MabVax and MSK, as amended, or the MabVax/MSK License Agreement.

On March 21, 2019, MabVax filed a voluntary petition for relief under Chapter 11 of the Bankruptcy Code. The essence of the transaction created by the SAAA was for the Company, in light of the Chapter 11 bankruptcy proceedings affecting MabVax, to preserve the MabVax/MSK License Agreement and the rights granted to the Company under the MabVax/Y mAbs Sublicense and for the Company to create a direct relationship with MSK with respect to the rights covered under the MabVax/Y mAbs Sublicense. Pursuant to the SAAA, MabVax agreed to assume the MabVax/Y mAbs Sublicense and the MabVax/Y mAbs License Agreement pursuant to Section 365 of the Bankruptcy Code and concurrently to assign both of these agreements to MSK. The Company remains responsible for any potential downstream payment obligations to MSK related to the GD2 GD3 Vaccine that were specified in the MabVax/MSK License Agreement. This includes the obligation to pay development milestones totaling $1,400,000 and mid-single digit royalty payments to MSK. In addition, if the Company obtains FDA approval for the GD2 GD3 Vaccine, then the Company is obligated to file with the FDA for a PRV. The SAAA stipulates that, if the Company is granted a PRV from the FDA covering a licensed product under the MabVax/Y mAbs Sublicense and the PRV is subsequently sold, the Company will pay directly to MabVax and to MSK, respectively, a total of twenty percent of the proceeds from the sale thereof. The MabVax/MSK License Agreement will expire with effect for the Company, on a country by country basis, on the later of the expiration of (i) 10 years from the first commercial sale of the licensed product in such country or (ii) the last to expire valid claim covering such licensed product rights at the time of and in the country of sale.

SADA License

On April 15, 2020, we entered into a license agreement (the "SADA License Agreement") with MSK and Massachusetts Institute of Technology ("MIT") that grants us 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 BiDE Pre-targeted Radioimmunotherapy Platform ("SADA technology"). At the time of entering into the arrangement, we assessed the licensing and other rights acquired and given the lack of outputs upon acquisition and that

no employees were acquired, among other factors, we have concluded that the licensing rights represented an asset acquisition.

Further, we concluded that the technology acquired under the licensing arrangement had no alternative future use. This conclusion was based on consideration of the rights conveyed under the agreement, extent of further development necessary and presence of uncertainty prior to obtaining regulatory approval for any product.

The SADA License Agreement requires us to pay to MSK and MIT mid to high single-digit royalties based on annual net sales of licensed products or the performance of licensed services by us and our affiliates and sublicensees. We are obligated to pay annual minimum royalties of $40,000, increasing to $60,000 once a patent has been issued, over the royalty term, commencing on the tenth anniversary of the license agreement. These amounts are non-refundable but are creditable against royalty payments otherwise due under the SADA License Agreement.

The Company is also obligated to pay MSK and MIT certain clinical, regulatory and sales-based milestone payments under the SADA License Agreement. Certain of the clinical and regulatory milestone payments become due at the earlier of completion of the related milestone activity or the date indicated in the SADA License Agreement.

In addition, to the extent we enter into sublicense arrangements, we are obligated to pay to MSK and MIT a percentage of certain payments received from sublicensees of the rights licensed to us by MSK and MIT, which percentage will be based upon the achievement of certain clinical milestones. The Company has not entered into any sublicenses related to the SADA License Agreement. For each of the constructs previously generated by MSK using the SADA technology and sold for the Company by a sublicensee, the Company may pay sales milestones up to $60,000,000, in total, based on the achievement of various levels of cumulative net sales made by the sublicensee.

Failure by the Company to meet certain conditions under the arrangement could cause the related license to such licensed products to be canceled and could result in termination of the entire arrangement with MSK and MIT. In addition, the Company may terminate the SADA License Agreement with prior written notice.

Summary of Significant License Agreements and Related Commitments

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

Agreements	Cash paid Twelve months ended December 31 2022	Cash paid Twelve months ended December 31 2021	Expense Twelve months ended December 31 2022	Expense Twelve months ended December 31 2021	Accrued liabilities Current as of December 31 2022	Accrued liabilities Non-current as of December 31 2022	Accrued liabilities Current as of December 31 2021	Accrued liabilities Non-current as of December 31 2021
MSK	$ 2,871	$ 1,480	$ 3,582	$ 1,170	$ 3,397	$ 1,950	$ 1,486	$ 1,650
CD33	150	100	—	—	—	300	—	450
MabVax	10	10	10	10	—	—	—	—
SADA	1,000	1,000	—	—	605	—	1,605	—

Minimum royalties and certain clinical milestones that become due based upon the passage of time under the CD33 License Agreement, the MabVax Agreement, and SADA Agreement are not recorded as a liability as the Company does not consider such obligations to be probable as of December 31, 2022 and December 31, 2021.

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

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

Research and development is inherently uncertain and should such research and development fail the MSK License Agreement, the CD33 License Agreement, the SADA License Agreement and the MabVax Agreement are cancelable at the Company's option. The Company will also consider the development risk and each party's termination rights under the respective agreement when considering whether any clinical or regulatory based milestone payments, certain of which also contain time-based payment requirements, are probable. The Company records milestones in the period in which the contingent liability is probable and the amount is reasonably estimable. With respect to the SADA License Agreement, all time-based milestones coming due within 36 months of the effective date of the agreement, totaling $605,000, have been accrued since the year ended December 31, 2020, as this continues to represent the time period the Company expects will be required to gather necessary clinical data to determine which patent rights to further pursue, if any, under the SADA License Agreement. The remaining total clinical milestones of $4,125,000 were determined to not be probable as of December 31, 2022.

Other agreements

The Company has also entered into various other support agreements with MSK including a sponsored research agreement to provide research services related to the intellectual property licensed under the MSK License Agreement; a master data services agreement, for services provided by approximately five full-time employees at MSK, who are engaged in transferring clinical data, databases, regulatory files and other know-how included in the MSK License Agreement to the Company; a master clinical trial agreement pursuant to which the Company committed to fund certain clinical trials at MSK; two separate core facility service agreements pursuant to which the Company committed to obtaining certain laboratory services from MSK; and in October 2020 the Company entered into a SADA sponsored research agreement pursuant to which the Company agreed to pay MSK to provide research services over a period of three years related to the intellectual property licensed under the SADA License Agreement. The scientific research took place over a period that commenced in September 2020 and ended in February 2022.

For the years ended December 31, 2022 and 2021, the Company incurred research and development expenses of $1,746,000 and $4,086,000, respectively, under these agreements.

Lease Agreements

In July 2019, the Company entered a development, manufacturing and supply agreement with SpectronRx in South Bend, Indiana, to secure access to clinical and commercial scale radiolabeling capacity for omburtamab. Under the terms of the agreement, SpectronRx has established a manufacturing unit designated for the Company within its existing facilities, at which both clinical and commercial supply of radiolabeled omburtamab can be produced. Since the Company possesses the right to substantially all the economic benefits and directs the use of the production area, the Company accounts for the payments related to the access to the manufacturing space under ASC 842 as an operating lease. The original term of the lease was two years from the commencement date of August 31, 2020, which was subsequently extended to December 2022. The extension resulted in an immaterial impact to the underlying right of use asset and lease liability. Upon the lease commencement date, the Company recorded $3,617,000 as right of use asset and $2,679,000 as lease liability with the difference of $938,000 resulting from certain prepayments and other costs incurred. The Company paid equal monthly installments of approximately $117,000 in additional access fees through December

2022. The Company entered into an additional one-month extension that terminated in January 2023 for a de minimis cost.

In February 2019, the Company entered into a lease agreement in connection with its 4,548 square feet laboratory in New Jersey. In December 2019, the Company expanded the space with an additional 235 square feet. The original term of the lease was three years from the date the Company occupied the premises, with an option to extend for an additional two years which expires in January 2024, which the Company exercised and has included in the determination of the related lease liability. Fixed rent payable under the lease is approximately $144,000 per annum and is payable in equal monthly installments of approximately $12,000.

In January 2018, the Company entered into a lease agreement in connection with its corporate headquarters in New York. The term of the lease is six years from the date the Company began to occupy the premises and the lease expires in April 2024. Fixed rent payable under the lease is approximately $384,000 per annum and is payable in equal monthly installments of approximately $32,000, which are recognized on a straight-line basis.

In February 2018, the Company entered into a lease agreement for certain office space in Denmark, which has been amended several times. The lease was renewed on November 1, 2021 with a four-year term that expires in November 2025. The lease is payable in monthly installments of approximately $41,000, which are recognized on a straight-line basis. In January 2023, the Company notified the landlord of their intention to reduce the leased premise as a result of the Company's strategic restructuring plan, which was approved by the Company's Board of Directors on January 4, 2023.

Total operating lease costs were $2,646,000 and $2,608,000 for the years ended December 31, 2022 and 2021, respectively. For the year ended December 31, 2022, the operating lease expenses were recorded as $2,404,000 in research and development expense and $242,000 in general and administrative expense. For the year ended December 31, 2021, the expenses were recorded as $2,367,000 in research and development expense and $241,000 in general and administrative expense. Cash paid for amounts included in the measurement of lease liabilities was $2,286,000 and $2,216,000 for the years ended December 31, 2022 and 2021, and was included in net cash used in operating activities in the Company's Consolidated Statements of Cash Flows.

Maturities of operating lease liabilities at December 31, 2022 and 2021 were as follows (in thousands):

	Operating Leases at December 31, 2022
Years ending December 31,	
2023	$ 997
2024	490
2025	419
Total lease payments	1,906
Less: Imputed interest	(139)
Total operating lease liabilities as of December 31, 2022	$ 1,767

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

Operating lease liabilities are based on the net present value of the remaining lease payments over the remaining lease term. In determining the present value of lease payments, the Company uses its estimate of its incremental borrowing rate based on the information available at the lease commencement date. As of December 31, 2022, the weighted average remaining lease term was 2.36 years and the weighted average discount rate used to determine the operating lease liability was 8.3%. As of December 31, 2021, the weighted average remaining lease term was 2.62 years and the weighted average discount rate used to determine the operating lease liability was 6.5%.

Former Chief Executive Officer Contractual Severance Related Benefits

On April 27, 2022, the Company announced certain executive management changes. Effective April 22, 2022, Dr. Claus Juan Møller San Pedro stepped down from his positions as Chief Executive Officer and as a member of the Company's Board of Directors. There were no disagreements with the Company expressed by Dr. Møller on any matters relating the Company's operations, policies or practices. Dr. Møller's contractual severance related benefits provided for cash compensation of $1,589,000, which includes salary and certain benefits continuation. Also, under terms of the equity award agreement, Dr. Møller's outstanding stock option awards will continue to vest as scheduled and become exercisable when vested. This resulted in a non-cash share-based compensation expense charge of $9,286,000 that the Company recognized in the year ended December 31, 2022 as there is no longer a service condition related to such awards. The total charge of $10,875,000 related to executive management change was recorded in selling, general and administrative expenses during the year ended December 31, 2022. The Company entered into a separation agreement with Dr. Møller in September 2022.

Legal Matters

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

The Company has been named a nominal defendant in a lawsuit filed in the U.S. District Court, Southern District of New York, on August 25, 2021, by one of the Company's stockholders, Deborah Donoghue (Case No. 1:21-cv-07182). The suit names the Company's President, Interim Chief Executive Officer and Head of Business Development and Strategy, and member of the Company's board of directors, Mr. Thomas Gad as an additional defendant, and it seeks to compel Mr. Gad to disgorge alleged short swing profits stemming from a certain transaction involving the Company's common stock undertaken by Mr. Gad on March 10, 2021 together with appropriate interest and costs of the lawsuit. On December 17, 2021, Mr. Gad filed a Motion to Dismiss the lawsuit. On August 8, 2022, the Court denied Mr. Gad's Motion to Dismiss the lawsuit and the lawsuit has entered the discovery phase. The Company is of the opinion that the claim is without merit and intend to maintain this position in the proceedings. In addition, the Company has been informed by Mr. Gad that he also believes the claim is without merit, that he has strong defenses against such claim and that he intends to vigorously defend the action. The Company has assessed the proceedings and does not believe that it is probable that a gain or a liability will be realized by the Company. As a result, the Company did not record any loss or gain contingencies for this matter.

Corwin v. Y-mAbs Therapeutics, Inc., et al.

On January 18, 2023, Robert Corwin, a purported Y-mAbs stockholder, filed a putative class action lawsuit against the Company and certain of the Company's current and former officers for alleged violations of the U.S. federal securities laws in the United States District Court, Southern District of New York (Case No.: 1:23-cv-00431). The complaint asserts claims on behalf of a proposed class consisting of those who acquired the Company's common stock between October 6, 2020 and October 28, 2022. The complaint alleges that the Company and the individuals named in the lawsuit violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder. The complaint alleges that there were material misrepresentations and/or omissions regarding the FDA's consideration of the Company's BLA for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma firstly submitted in 2020 and resubmitted in 2022. The complaint seeks unspecified damages, and reasonable costs and expenses, including attorneys' fees. The Company believes that these claims are without merit and intends to vigorously defend against these claims. The Company has not established a liability for this claim as of December 31, 2022 as the Company does not consider the loss on the claim to be probable.

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

On February 8, 2023, Jeffrey Hazelton, one of the Company's stockholders, filed a lawsuit against the Company and current and former members or the Company's board of directors in the Court of Chancery of the State of Delaware (Case No.: 2023-0147-). The complaint alleges that the Company's members of the Company's board of directors have awarded themselves excessive compensation since the Company's Initial Public Offering in 2018. The complaint seeks to recover alleged excessive and unfair compensation awarded to the Company's board members in what is alleged to be in breach of their fiduciary duties. Further, the complaint seeks to direct the Company to take certain actions to reform and improve the Company's corporate governance and internal procedures. The Company is of the opinion that the claims are without merit and intends to maintain this position in the proceedings. The Company has not established a liability for this claim as of December 31, 2022 as the Company does not consider the loss on the claim to be probable.

NOTE 10—STOCKHOLDERS' EQUITY

Authorized Stock

As of December 31, 2022 and 2021, the Company has authorized a total of 105,500,000 shares, 100,000,000 of which are common stock, par value $0.0001 per share, and 5,500,000 of which are preferred stock, par value $0.0001 per share.

Common Stock

Each share of common stock is entitled to one vote. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to preferential dividend rights of the preferred stock, none of which have been issued. The Company has issued 43,670,109 shares of its common stock as of December 31, 2022, and 43,694,716 shares of its common stock as of December 31, 2021.

Preferred Stock

Preferred stock may be issued from time to time in one or more series with such designations, preferences and relative participating, optional or other special rights and qualifications, limitations or restrictions as approved by the Company's Board of Directors. No preferred stock has been issued as of December 31, 2022 and 2021.

Stock grant agreements with non-employees

In April 2020, in connection with the SADA License Agreement, the Company entered into certain stock grant agreements pursuant to which it agreed to issue a total of 213,996 shares to two non-employee researchers who were involved in the development of the SADA-BiDE (2-step Self-Assembly and DisAssembly-Bispecific DOTA-Engaging

antibody system) Pre-targeted Radioimmunotherapy Platform (the "SADA Technology") licensed from MSK and MIT in consideration for their prior service. All 213,996 shares were issued in April 2020 into escrow with 40% of the shares immediately vesting at the time of issuance and the remaining 60% of the shares subject to vesting ratably over the next three years on the anniversary date of the agreement. In accordance with the terms of the agreement, during the year ended December 31, 2022, the non-employee researchers vested in an additional 20% of the awards. Therefore, as of December 31, 2022, the two non-employee researchers have vested in 80% of the total grant with the remaining 20% vesting on the anniversary date of the agreement in April 2023. The unvested shares are subject to forfeiture to the extent the SADA License Agreement is terminated prior to the vesting of the shares. There is no cash settlement feature, and no future service is required for the non-employee researchers to vest and receive the shares. In April 2020, the Company recognized a research and development expense of $7,376,000, which reflected the fair value of the issued shares on the grant date. There is no future expense related to these awards.

In July 2020, pursuant to the stock grant agreements, the Company also loaned the two researchers a total of $2,610,000 related to their individual tax payments due in conjunction with the stock grants. Each of the loans are evidenced by a three-year Secured Promissory Note, which matures in April 2023. The outstanding principal amounts of the loans, together with all accrued interest thereon at the rate of 1% per annum, is due and payable on the maturity date of the loans. The loans are secured by Pledge and Security Agreements, pursuant to which the researchers have pledged the shares as security for repayment of the loans with interest rates that are at market. In July 2022, one of the researchers repaid their Secured Promissory Note and accrued interest, which resulted in a de minimis loss compared to the amortized cost of the loan, in exchange for 57,887 shares that were pledged as part of their security. Upon receipt, the Company recorded treasury shares at an acquisition cost of $963,000, based on the share price on the settlement date. The Company subsequently cancelled the acquired treasury shares resulting in a reduction of outstanding common stock and a reduction of additional paid-in-capital totaling $963,000. During the fourth quarter of 2022, the Company concluded that the other loan receivable was impaired resulting in a $1,051,000 charge for the year-ended December 31, 2022. The remaining loan receivable balance is included in other current assets on the Company's Consolidated Balance Sheets as of December 31, 2022 and both loans are included in other assets on the Company's Consolidated Balance Sheets as of December 31, 2021. The impairment charges are recorded within interest and other loss, net within the Company's Consolidated Statements of Net Loss and Comprehensive Loss, and foreign currency and other transactions within the Company's Consolidated Statements of Cash Flows.

There were no shares issued to non-employee researchers in 2022 and 2021.

Issuance of common stock

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

NOTE 11—SHARE-BASED COMPENSATION

2015 Equity Incentive Plan

The Company's board of directors and stockholders have approved and adopted the 2015 Plan, which provided for the grant of incentive stock options, within the meaning of Section 422 of the Code (the Internal Revenue Code), to the Company's employees and any parent and subsidiary corporations' employees, and for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock and restricted stock units to the Company's employees, directors and consultants and its parent and subsidiary corporations' employees and consultants. A total of 4,500,000 shares of the Company's common stock were reserved for issuance pursuant to the 2015 Plan. Options granted under the 2015 Plan vest according to the schedule specified in the grant agreements, which is generally a four-year period and generally become immediately exercisable upon the occurrence of a change in control, as defined.

Upon the 2018 Equity Incentive Plan (the "2018 Plan") becoming effective in September 2018, no further grants are allowed under the 2015 Plan.

2018 Equity Incentive Plan

The Company's board of directors and stockholders approved and adopted the 2018 Plan. However, options outstanding under the 2015 Plan continue to be governed by the 2015 Plan. The 2018 Plan which became effective upon the Company's initial public offering in September 2018 and which provides for the grant of incentive stock options, within the meaning of Section 422 of the Code (the Internal Revenue Code), to the Company's employees and any parent and subsidiary corporations' employees, and for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock and restricted stock units to the Company's employees, directors and consultants and the Company's parent and subsidiary corporations' employees and consultants. A total of 5,500,000 shares of the Company's common stock, inclusive of the awards previously granted under the 2015 Equity Incentive Plan were initially reserved for issuance pursuant to the 2018 Plan. In addition, the number of shares available for issuance under the 2018 Plan will also include an annual increase on the first day of each fiscal year beginning in 2019 through 2029, equal to 4% of the outstanding shares of common stock as of the last day of the Company's immediately preceding fiscal year or by a lesser amount determined by the board of directors. The exercise price of options granted under the plans must at least be equal to the fair market value of the Company's common stock on the date of grant. The term of an incentive stock option may not exceed 10 years, except that with respect to any participant who owns more than 10% of the voting power of all classes of the Company's outstanding stock, the term must not exceed five years and the exercise price must equal at least 110% of the fair market value on the grant date. The administrator will determine the methods of payment of the exercise price of an option, which may include cash, shares or other property acceptable to the administrator, as well as other types of consideration permitted by applicable law. Options granted under the 2018 Plan vest according to the schedule specified in the grant agreements, which is generally between one and four years and generally become immediately exercisable upon the occurrence of a change in control, as defined.

Stock Options

For the years ended December 31, 2022 and 2021, stock-based compensation for stock option grants were $25,274,000 and $19,032,000, respectively, for options granted to employees and directors. Stock-based compensation during the year ended December 31, 2022 includes $9,286,000 related to the departure of the former Chief Executive Officer, which was recorded upon his separation in the second quarter of 2022 based on the terms of his service agreement and is further described in *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS*. For the year ended December 31, 2022, the expenses were recorded as $7,540,000 in research and development expense and $17,734,000 in selling, general, and administrative expense. For the year ended December 31, 2021, the expenses were recorded as $7,133,000 in research and development expense and $11,899,000 in selling, general, and administrative expense.

The assumptions that the Company used to determine the fair value of the stock options granted to employees, directors and consultants were as follows, presented on a weighted average basis:

	Year Ended December 31, 2022	Year Ended December 31, 2021
Risk-free interest rate	3.12 %	1.31 %
Expected term (in years)	5.9	6.3
Expected volatility	73.6 %	72.6 %
Expected dividend yield	— %	— %

The Company recognizes compensation expense for only the portion of awards that vest.

The following table summarizes common stock options issued and outstanding:

	Options	Weighted average exercise price	Aggregate intrinsic value (in thousands)	Weighted average remaining contractual life (years)
Outstanding and expected to vest at December 31, 2021	6,687,128	$ 22.43	$ 26,412	7.21
Granted	653,000	11.53		
Exercised	(20,000)	4.22		
Forfeited	(240,361)	28.32		
Outstanding and expected to vest at December 31, 2022	7,079,767	$ 21.27	$ 3,112	6.45
Exercisable at December 31, 2022	4,948,467	$ 19.47	$ 3,112	5.53

The weighted average grant-date fair value of stock options granted during the years ended December 31, 2022 and 2021 was $7.64 and $13.03, respectively.

Options granted in the year ended December 31, 2022, have a contractual term of ten years.

During the second quarter of 2022, 255,000 options were granted to senior executives and certain other employees under a retention program for their continued service to the Company over the next two years from the grant date. The options granted under the retention program have a vesting schedule in which 50% vest on the first anniversary of the grant date and the remainder vest on the second anniversary of the grant date, provided in each case that the recipient remains an employee of the Company through each vesting date. The remaining 398,000 options granted during the year end December 31, 2022, have a vesting schedule in which 25% vest on the first anniversary of the grant date and the remainder vest ratably on a monthly basis over the next 36 months, provided in each case that the recipient remain an employee of the Company through each vesting date.

The above noted retention program also included a cash bonus payable of $1,091,000 to the same senior executives and other employees that is payable on the anniversary of the grant date provided that the respective recipient remains an employee of the Company through such date and subject further to the achievement by such date of the Company's product candidate omburtamab having received marketing approval by the FDA. On November 30, 2022, the FDA issued a complete response letter which indicated that FDA was unable to approve the BLA of omburtamab in its current form. As a result, the Company determined that the bonus payment was not probable and therefore the Company did not record compensation expense related to the cash retention program in the year ended December 31, 2022.

The aggregate intrinsic value of stock options is calculated as the difference between the exercise price of the stock options and the fair value of the Company's common stock for those stock options that had exercise prices lower than the fair value of the Company's common stock. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model. The Company's public trading commenced in September 2018, and, as a result, there is only limited available historical volatility experience. Therefore, the Company estimates its expected share price volatility based on a combination of the historical volatility of a group of publicly traded peer companies and the historical volatility of the Y-mAbs share price, and the Company expects to continue to do so until such time as the Company has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards as the Company has limited historical data to support the expected term assumption. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The expected dividend yield is based on the fact that the Company has never paid cash dividends on shares of its common stock and does not expect to pay any cash dividends in the foreseeable future. Except for the risk-free interest rate, there were no significant changes to the inputs included in the Black-Scholes option pricing model during the year ended December 31, 2022.

As of December 31, 2022, we had $21,910,000 of unrecognized stock-based compensation expense related to employee stock options that are expected to vest over a period of 2.27 years.

Restricted Stock Units

For the years ended December 31, 2022 and 2021, stock-based compensation for restricted stock unit grants was $328,000 and $303,000, respectively. For the year ended December 31, 2022, the expenses were recorded as $289,000 in research and development expense and $39,000 in selling, general, and administrative expense. For the year ended December 31, 2021, the expenses were recorded as $270,000 in research and development expense and $33,000 in selling, general, and administrative expense.

The following table summarizes restricted stock units issued and outstanding:

	Restricted Stock Units	Weighted average grant price	Weighted average remaining vesting life (years)
Outstanding and expected to vest at December 31, 2021	28,907	$ 28.04	1.82
Granted	19,054	9.92	
Vested	(13,280)	26.47	
Forfeited	(1,326)	27.97	
Outstanding and expected to vest at December 31, 2022	33,355	$ 17.77	1.77

As of December 31, 2022, we had $418,000 of unrecognized compensation related to employee restricted stock units that are expected to vest over a period of 1.77 years.

NOTE 12—RELATED PARTY TRANSACTIONS

MSK is a shareholder of the Company. Under the MSK License Agreement, the SADA License Agreement, the CD33 License Agreement, the MabVax Agreement and various other supporting agreements with MSK, the Company has expensed costs in the total amount of $5,338,000 and capitalized an intangible asset of $1,500,000 during the year ended December 31, 2022 and expensed costs in the total amount of $5,266,000 in the year ended December 31, 2021, for milestones, minimum royalties, and research and development costs. Please refer to *NOTE 9—LICENSE AGREEMENTS AND COMMITMENTS* for additional details on the Company's agreements with MSK. As of December 31, 2022, the Company had a total of $240,000 recorded as accounts payable and $6,904,000 as accrued liabilities, thereby totaling $7,144,000 due to MSK. As of December 31, 2021, the Company had a total of $748,000 recorded as accounts payable, $5,443,000 as accrued liabilities, thereby totaling $6,191,000 due to MSK.

NOTE 13—INCOME TAXES

Domestic and foreign loss before income taxes are as follows (thousands):

	For The Years Ended December 31,	
	2022	2021
United States	$ (87,827)	$ (47,275)
Foreign	(7,741)	(8,000)
Total	$ (95,568)	$ (55,275)

The Company provided no income tax benefits on net losses of $95,568,000 and $55,275,000 for years ended December 31, 2022 and 2021, respectively, and maintains a full valuation allowance against its net deferred tax assets.

Current and deferred income taxes (tax benefits) are as follows (thousands):

	For The Years Ended December 31,	
	2022	2021
Current income tax		
Domestic	$ —	$ —
Foreign	18	304
Total current income taxes (tax benefits)	18	304
Deferred income tax		
Domestic	—	—
Foreign	(18)	(304)
Total deferred income taxes (tax benefits)	(18)	(304)
Total income taxes (tax benefits)	$ —	$ —

The difference between income taxes expected at the U.S. federal statutory income tax rate of 21% for tax years ended December 31, 2022 and 2021, respectively, and income taxes provided are set forth below (thousands):

	For The Years Ended December 31,	
	2022	2021
Taxes on income at U.S. federal statutory rate	$ (20,069)	$ (11,607)
State and local taxes, net of federal tax effects	(5,661)	(5,523)
Effect of rate change	861	(1,734)
Foreign tax rate differential	(95)	(80)
Valuation allowance	25,116	20,978
Tax credits	(1,749)	(1,904)
Uncertain tax position	18	304
Deferred adjustments	969	—
Other	610	(434)
Total	$ —	$ —

Significant components of the Company's net deferred tax assets/(liabilities) are as follows (thousands):

	December 31, 2022	December 31, 2021
Deferred tax assets/(liabilities):		
Acquired intangibles	$ 2,657	$ 4,316
Accrued bonus	—	—
Unrealized foreign exchange loss	263	38
Accrued royalty	914	377
Stock based compensation	13,353	9,222
Net operating loss carryforwards	86,072	88,968
Tax credit carryforwards	16,799	15,050
Right of use asset	(413)	(1,015)
Lease liability	435	960
Capitalized research and experimentation	21,902	—
Other	572	(479)
Total deferred tax assets/(liabilities)	142,554	117,437
Valuation allowance	(142,554)	(117,437)
Net deferred tax assets/(liabilities)	$ —	$ —

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.

As of December 31, 2022, the Company had U.S. federal and various state net operating loss ("NOL") carryforwards of approximately $279,038,000 and $203,159,000, respectively. The Company also had U.S. federal tax credit carryforwards of $16,799,000 as of December 31, 2022. The federal NOL carryforwards of approximately $18,606,000 will begin to expire from 2036 through 2037. The federal NOL of approximately $260,433,000 can be carried forward indefinitely but limited to offset 80% of taxable income. The State and City NOL and tax credit carryforwards will begin to expire in 2030. The NOL and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50%, as defined under Sections 382 and 383 of the Internal Revenue Code of 1986 ("IRC"). The Company has performed an analysis of its Section 382 ownership changes through December 31, 2021. Due to the large annual limitation, the Company believes that it is more likely than not that none of the net operating loss carryforwards will expire as a result of the limitation from the ownership change under Section 382. The Company also has Danish NOL carryforwards of $58,000 which have an indefinite carryforward period.

The Company recognizes income tax benefits for tax positions determined more likely than not to be sustained upon examination, based on the technical merits of the positions.

Changes in the Company's unrecognized tax benefits, excluding the related accrual of interest and penalties, from January 1 through December 31 are set forth below (thousands):

	Years Ended December 31,	
	2022	2021
Beginning balance	$ 304	$ —
Additions for prior year tax positions	18	304
Settlements	(322)	—
Ending balance	$ —	$ 304

The Company's tax returns for the years 2021, 2020, 2019, 2018, and 2017 are open for tax examination by U.S. federal and state, and the Danish tax authorities. During 2022, the review of the Company's transfer pricing policies by the Danish Tax Authorities for tax years 2016 through 2020 was completed resulting in the release of the corresponding reserve. The release did not have a material impact on the Company's income tax accounts.

The Company classifies interest and penalty expense related to income tax expense as components of the tax provision for income taxes. As of December 31, 2022, the Company does not have any interest or penalties accrued related to the total amount of unrecognized tax benefits.

NOTE 14—OTHER BENEFITS

The Company has adopted a defined contribution 401(k) savings plan ("401(k) plan") covering all U.S. employees of the Company. Participants may elect to defer a percentage of their pretax or after-tax compensation to the 401(k) plan, subject to defined limitations. The plan allows for a discretionary match by the Company. The Company made no matching contributions to the plan for the years ended December 31, 2022 and 2021.

The Company has established a retirement program for employees of the Company's Danish subsidiary pursuant to which all such employees can contribute an amount at their election from their base compensation and may receive contributions from the Company's Danish subsidiary. No contributions from the Danish subsidiary were made for the years ended December 31, 2022 and 2021. In addition, health insurance benefits for the Company's Danish employees are fully paid for by such employees. The Company's Danish subsidiary does not incur any costs for these health insurance benefits.

NOTE 15 —GAIN FROM SALE OF PRIORITY REVIEW VOUCHER

On December 28, 2020, the Company announced that it entered into a definitive agreement to sell its DANYELZA Priority Review Voucher, or PRV, to United Therapeutics Corporation for $105,000,000. The PRV was granted in conjunction with the approval by the FDA of DANYELZA, for the treatment of refractory/relapsed high-risk neuroblastoma. Under the terms of the Company's license agreement with MSK, the Company retained 60% of the net proceeds received from the sale, and the remaining 40% was paid to MSK. The transaction closed on January 21, 2021 and once the substantive closing conditions included within the agreement were resolved the Company recognized a net gain of $62,010,000 during the year ended December 31, 2021 related to the sale.

The Company did not recognize a corresponding gain during the year ended December 31, 2022.

NOTE 16 — SUBSEQUENT EVENTS

On January 4, 2023, the Company announced a strategic restructuring plan designed to extend its cash resources and prioritize resources on the commercialization and potential label extension of DANYELZA and development of the SADA technology platform. The Company expects a reduction in its current workforce by approximately 35%, with such reduction anticipated to be completed by the end of May 2023. Affected employees have been offered separation benefits, including severance and outplacement services along with temporary healthcare coverage assistance. The Company expects to record charges for these separation benefits in the first quarter of 2023. As a result of the reduction in workforce and revised business plan that was approved by the Board of Directors in January 2023, the Company expects to incur restructuring expenses of approximately $4,700,000, consisting predominantly of cash related to notice and severance payments of approximately $3,000,000 and acceleration of stock-based compensation of approximately $1,700,000. The restructuring expenses were recognized in the first quarter of 2023, and the majority of the payments were made in the first quarter of 2023.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. 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 Annual Report, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

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

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). Under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2022, using the criteria described in *Internal Control – Integrated Framework* (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that as of December 31, 2022, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting, (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of the year ended December 31, 2022 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item 10 is incorporated by reference to the information set forth in the sections titled "Proposal 1 – Election of Directors," "Executive Officers of the Company," and "Information Regarding the Board and Corporate Governance" and "Section 16(a) Beneficial Ownership Reporting Compliance" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION

The information required by this Item 11 is incorporated by reference to the information set forth in the section titled "Executive Compensation" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item 12 is incorporated by reference to the information set forth in the sections titled "Security Ownership of Certain Beneficial Owners and Management" and "Executive Compensation" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this Item 13 is incorporated by reference to the information set forth in the sections titled "Transactions with Related Persons" and "Information regarding the Board of Directors and Corporate Governance" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this Item 14 is incorporated by reference to the information set forth in the section titled "Principal Accountant Fees and Services" in our Definitive Proxy Statement to be filed with the SEC with respect to our 2023 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a)1. Financial Statements:
The financial statements listed in the Index to Financial Statements beginning on page 142 are filed as part of this Annual Report on Form 10-K.

(a)2. Financial Statement Schedules:
There are no Financial Statement Schedules included with this filing for the reason that they are not applicable or are not required or the required information is included in the Financial Statements or Notes listed in the Index to Financial Statements beginning on page 142.

(a)3. Exhibits

EXHIBIT INDEX

Exhibit No.	
3.3	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.3 to the Form S-1 filed August 24, 2018).
3.4	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.4 to the Form S-1 filed August 24, 2018).
4.1	Specimen stock certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to the Form S-1/A filed September 7, 2018).
4.2	Registration Rights Agreement, dated as of October 13, 2017, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.2 to the Form S-1 filed August 24, 2018).
4.3(a)	Registration Rights Agreement, dated as of November 17, 2017, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.3(a) to the Form S-1 filed August 24, 2018).
4.3(b)	Registration Rights Agreement, dated as of November 17, 2017, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.3(b) to the Form S-1 filed August 24, 2018).
4.3(c)	Registration Rights Agreement, dated as of November 17, 2017, among the Registrant and the other parties thereto (incorporated by reference to Exhibit 4.3(c) to the Form S-1 filed August 24, 2018).
4.4	Description of the registrant's securities registered pursuant to section 12 of the Securities Exchange Act of 1934.
10.1+	License Agreement, dated as of August 20, 2015, by and between the Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.1 to the Form S-1 filed August 24, 2018).

10.2+	License Agreement, dated as of November 13, 2017, by and between the Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.2 to the Form S-1 filed August 24, 2018).
10.3+	Sponsored Research Agreement, effective as of November 10, 2015, by and between the Registrant and Memorial Sloan Kettering Cancer Center Registrant (incorporated by reference to Exhibit 10.3 to the Form S-1 filed August 24, 2018).
10.4+	Sponsored Research Agreement, dated November 13, 2017, by and between the Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.4 to the Form S-1 filed August 24, 2018).
10.5+	Investigator-Sponsored Master Clinical Trial Agreement, dated as of June 21, 2017, as amended on October 11, 2017, by and between the Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.5 to the Form S-1 filed August 24, 2018).
10.6+	Master Data Services Agreement, dated as of September 23, 2016, as amended on October 11, 2017, by and between the Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.6 to the Form S-1 filed August 24, 2018).
10.7†	Amended and Restated 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.7 to the Form S-1 filed August 24, 2018).
10.8†	Form of Notice of Grant and Stock Option Agreement under the Amended and Restated 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.8 to the Form S-1 filed August 24, 2018).
10.9†	2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.9 to the Form S-1 filed August 24, 2018).
10.10†	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to the Form S-1 filed August 24, 2018).
10.11†	Form of Officers and Directors Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Form S-1 filed August 24, 2018).
10.12†	Service Agreement, effective as of April 1, 2016 between the Registrant and Thomas Gad (incorporated by reference to Exhibit 10.12 to the Form S-1 filed August 24, 2018).
10. 13†	Service Agreement, effective as of October 1, 2016 between Y-mAbs Therapeutics A/S and Bo Kruse (incorporated by reference to Exhibit 10.14 to the Form S-1 filed August 24, 2018).
10.14	Lease Agreement dated January 10, 2018, by and between the Registrant and RXR HB Owner LLC (incorporated by reference to Exhibit 10.15 to the Form S-1 filed August 24, 2018).
10.15†	Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.16 to the Form S-1 filed August 24, 2018).
10.16†	Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.17 to the Form S-1 filed August 24, 2018).
10.17†	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.18 to the Form S-1 filed August 24, 2018).

10.18†	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.19 to the Form S-1 filed August 24, 2018).
10.19+	Amended and Restated Sponsored Research Agreement by and between the Registrant and Memorial Sloan Kettering Cancer Center effective September 13, 2019 (incorporated by reference to Exhibit 10.1 to Form 8-K filed September 19, 2019).
10.20+	Sublicense Agreement by and between the Registrant and MabVax Therapeutics Holdings, Inc. effective June 28, 2018 (incorporated by reference to Exhibit 10.1 to Form 8-K filed December 19, 2019).
10.21+	Settlement and Assumption and Assignment Agreement of MSK License Agreement and Y-mAbs Sublicense Agreement by and among the Registrant, MabVax Therapeutics Holdings, Inc. MabVax Therapeutics, Inc. and Sloan Kettering Institute for Cancer Research effective December 2, 2019 (incorporated by reference to Exhibit 10.2 to Form 8-K filed December 19, 2019).
10.22++	License Agreement effective as of April 15, 2020, by and among the Registrant, Memorial Sloan Kettering Cancer Center and Massachusetts Institute of Technology (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed April 21, 2020).
10.23++	Master Sponsored Research Agreement by and between the Registrant and Memorial Sloan Kettering Cancer Center, effective October 7, 2020 (incorporated by reference to Exhibit 10.1 to the Registrant's Form 8-K filed October 8, 2020).
10.24	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (as amended, employees, consultants and service providers other than directors) (incorporated by reference to Exhibit 10.8 to Registrant's Form 10-Q filed November 5, 2020).
10.25†	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (as amended, directors) (incorporated by reference to Exhibit 10.9 to Registrant's Form 10-Q filed November 5, 2020).
10.26 ++	License Agreement dated December 17, 2020 by and between the Registrant and SciClone Pharmaceuticals International Ltd. (incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed December 22, 2020).
10.27	Asset Purchase Agreement by and between the Registrant and United Therapeutics Corporation, dated December 24, 2020 (incorporated by reference to Exhibit 10.1 to Registrant's Form 8-K filed February 19, 2021).
10.28++	Amendment No. 1, dated March 18, 2021 to License Agreement, dated as of August 20, 2015 between Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.7 to Registrant's Form 10-Q filed May 6, 2021).
10.29++	Amendment No. 2, dated March 18, 2021 to License Agreement, dated as of August 20, 2015 between Registrant and Memorial Sloan Kettering Cancer Center (incorporated by reference to Exhibit 10.7 to Registrant's Form 10-Q filed, May 6, 2022).
10.30†	Employment Agreement for Dr. Steen Lisby, effective as of August 1, 2017 (incorporated by reference to Exhibit 10.8 to Registrant's Form 10-Q filed, May 9, 2022).
10.31†	Amendment to Employment Agreement for Dr. Steen Lisby, effective as of June 1, 2020 (incorporated by reference to Exhibit 10.9 to Registrant's Form 10-Q filed, May 9, 2022).

10.32†	Employment Agreement for Dr. Vignesh Rajah, effective as of June 2, 2020 (incorporated by reference to Exhibit 10.10 to Registrant's Form 10-Q filed, May 9, 2022).
10.33†	Amendment to Employment Agreement for Dr. Vignesh Rajah, effective as of March 1, 2021 (incorporated by reference to Exhibit 10.11 to Registrant's Form 10-Q filed, May 9, 2022).
10.34†	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Registrant's Form 10-Q filed August 8, 2022).
10.35†	Retention Bonus Agreement, dated May 30, 2022 by and between EVP and Chief Financial Officer, Bo Kruse and Y-mAbs Therapeutics A/S (incorporated by reference to Exhibit 10.2 to Registrant's Form 10-Q filed August 8, 2022).
10.36†	Form of Retention Bonus Agreement of Y-mAbs Therapeutics A/S (incorporated by reference to Exhibit 10.3 to Registrant's Form 10-Q filed August 8, 2022).
10.37†	Form of Retention Bonus Agreement of Y-mAbs Therapeutics, Inc. (incorporated by reference to Exhibit 10.4 to Registrant's Form 10-Q filed August 8, 2022).
10.38†	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Registrant's Form 10-Q filed November 7, 2022).
10.39†	Form of Stock Option Grant Notice and Stock Option Agreement under the 2018 Equity Incentive Plan for directors (incorporated by reference to Exhibit 10.2 to Registrant's Form 10-Q filed November 7, 2022).
10.40†	Separation Agreement and General Release, effective as of September 22, 2022, between Y-mAbs Therapeutics, Inc. and Claus Juan Møller San Pedro (incorporated by reference to Exhibit 10.3 to Registrant's Form 10-Q filed November 7, 2022).
10.41*†	Non-Employee Director Compensation Policy, adopted on January 17, 2023 (filed herewith).
10.42*†	Employment Agreement for Ms. Susan Smith, effective as of January 1, 2022 (filed herewith).
21.1*	Subsidiaries of the Registrant.
23*	Consent of Pricewaterhouse Coopers LLP, Independent Registered Public Accounting Firm.
31.1*#	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
31.2*#	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act.
32.1*	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
32.2*	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act.
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 (formatted as Inline XBRL and contained in Exhibit 101).

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* Filed herewith.

\# The certifications attached as Exhibits 32.1 and 32.2 that accompany this Annual Report on Form 10-K are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of the Registrant under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Annual Report on Form 10-K, irrespective of any general incorporation language contained in such filing.

† Indicates management contract or compensatory plan.

\+ Portions of the exhibit have been omitted pursuant to an order granted by the Securities and Exchange Commission for confidential treatment.

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

ITEM 16. FORM 10-K SUMMARY.

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities indicated on March 30, 2023.

Y-MABS THERAPEUTICS, INC.

Dated: March 30, 2023

/s/ THOMAS GAD

Thomas Gad
Founder, Chairman, President, Interim Chief Executive Officer and Head of Business Development and Strategy
(Principal Executive Officer)

POWER OF ATTORNEY

Each person whose signature appears below constitutes and appoints Thomas Gad, acting individually, as his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities indicated on the 30th of March 2023.

/s/ THOMAS GAD Thomas Gad	Founder, President, Interim Chief Executive Officer and Head of Business Development and Strategy (Principal Executive Officer)
/s/ BO KRUSE Bo Kruse	Executive Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial Accounting Officer)
/s/ JOHAN WEDELL-WEDELLSBORG Johan Wedell-Wedellsborg	Director
/s/ LAURA J. HAMILL Laura J. Hamill	Director
/s/ GÉRARD BER Gérard Ber	Director
/s/ ASHUTOSH TYAGI Ashutosh Tyagi	Director
/s/ JAMES I. HEALY James I. Healy	Director
/s/ DAVID N. GILL David N. Gill	Director

EXHIBIT 31.1

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

I, Thomas Gad certify that:

1. I have reviewed this Annual Report on Form 10-K 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.

Date: March 30, 2023

/s/ Thomas Gad

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

EXHIBIT 31.2

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

I, Bo Kruse, certify that:

1. I have reviewed this Annual Report on Form 10-K 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.

Date: March 30, 2023

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

EXHIBIT 32.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

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

(i) the accompanying Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: March 30, 2023

/s/ Thomas Gad

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

EXHIBIT 32.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

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

(i) the accompanying Annual Report on Form 10-K of the Company for the fiscal year ended December 31, 2022 (the "Report") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Dated: March 30, 2023

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