

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): January 8, 2024

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-38650
(Commission
File Number)

47-4619612
(I.R.S. Employer
Identification No.)

230 Park Avenue
Suite 3350
New York, New York 10169
(Address of principal executive offices) (Zip Code)

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

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.0001 par value	YMAB	Nasdaq Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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.

Item 2.02 Results of Operations and Financial Condition.

On January 8, 2024, Y-mAbs Therapeutics, Inc. (the "Company") made available in the investor relations portion of its website, <https://ir.ymabs.com>, a corporate overview presentation that the Company plans to use in investor meetings and in its podium presentation at the J.P. Morgan Healthcare Conference. The presentation includes the Company's statement that it is maintaining its previously announced financial guidance for the year ended December 31, 2023. The presentation also includes the Company's expectations with respect to its financial runway and presents corporate updates, including updates with respect to the Company's business, clinical trials and development pipeline. A copy of the presentation is attached hereto as Exhibit 99.1.

The information furnished pursuant to Item 2.02 on this Form 8-K, including Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Presentation dated January 2024
104	Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Exchange Act, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Y-MABS THERAPEUTICS, INC.

Date: January 9, 2024

By: /s/ Michael Rossi
Michael Rossi
President and Chief Executive Officer



Oncology Leadership in Pretargeted Radioimmunotherapy Platform and Antibody-based Therapies

January 2024



Disclaimer

Statements in this presentation about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, constitute "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934. Such statements include, but are not limited to: the Company's growth prospects and expectations related thereto; expectations with respect to the Company's financial expectations, including the Company's 2023 operating performance, DANYELZA net product revenue guidance, and the Company's estimated cash runway and sufficiency of cash resources and related assumptions; the Company's ability to commercialize DANYELZA with respect to the achievement of milestones and the timing thereof; implied and express statements regarding the future of the Company's business, including with respect to the Company's plans and strategies, development, commercialization and product distribution plans, including potential partnerships; expectations with respect to the Company's product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the Company's technology and potential benefits and applications and the timing thereof; SADA's potential to be an industry game-changer; expectations with respect to current and future studies and the Company's and its partners' research and development programs, including with respect to timing and results; expectations related to the timing of the Company's regulatory submissions; additional product candidates and technologies; expectations regarding collaborations or strategic partnerships and the potential benefits thereof; the use of cash and cash equivalents, and the need for, timing and amount of any future financing transaction; expectations with respect to the Company's future financial statements that are not historical facts. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "hope," "intend," "may," "might," "plan," "project," "should," "target," "will," "would", "guidance," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain identifying words. The Company's product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with the Company's financial condition and near-term risks that actual results of the Company's restructuring plan and revised business plan will not be as expected; risks associated with the Company's development work, including the Company's product development activities and clinical trials; the risks of delay in the timing of the Company's regulatory submissions or failure to receive approval of its product candidates related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of product candidates; development of sales and marketing associated with failure to obtain sufficient reimbursement for products; the risks related to the Company's dependence on third parties including for conduct of clinical testing and the Company's ability to enter into new partnerships and to maintain existing partnerships; the risks related to government regulation; risks related to market size and application of the Company's intellectual property rights; risks related to employee matters and managing growth; risks related to the Company's common stock; risks associated with conditions, including the conflict between Russia and Ukraine and sanctions related thereto, the state of war between Israel and Hamas and the related risk of a larger conflict; increased interest rates, uncertain global credit and capital markets and disruptions in banking systems; the completion of financial closing procedures, final audit adjustments and other risks that may arise that would cause the Company's expectations with respect to the Company's 2023 guidance to differ, perhaps materially, from the financial results that will be reported in the audited consolidated financial statements for the fiscal year ended December 31, 2023; and other risks and uncertainties affecting the Company including those described in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended December 31, 2022, and future filings and reports by the Company. Any forward-looking statements contained in this press release speak only as of the date hereof, and the Company undertakes no obligation to update or revise any forward-looking statement, whether as a result of new information, future events or otherwise.

This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third-party publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. All of the market data used in this presentation involves a number of assumptions and limitations, and you are cautioned not to rely on such estimates. While we believe these industry publications and third-party research, surveys and studies are reliable, we have not independently verified such data. The industry is subject to a high degree of uncertainty, change and risk due to a variety of factors, which could cause results to differ materially from those expressed in the estimates made and by us.

Strongly Positioned to Drive Future Value

Novel Platforms in Development



**Self-Assembly
DisAssembly (“SADA”)
Pretargeted
Radioimmunotherapy
Platform (“PRIT”)
Monoclonal Antibodies**

Commercial Leverage



**DANYELZA
(naxitamab-gqgk)
Anti-GD2 Antibody
Marketed for
R/R High-Risk
Neuroblastoma**

Anticipated 2024 Milestones



**GD2-SADA Phase I
Part A Data Readout
CD38-SADA Phase I
Study Initiation
MSK Data Readout of
Phase II Osteosarcoma
Trial Anticipated**

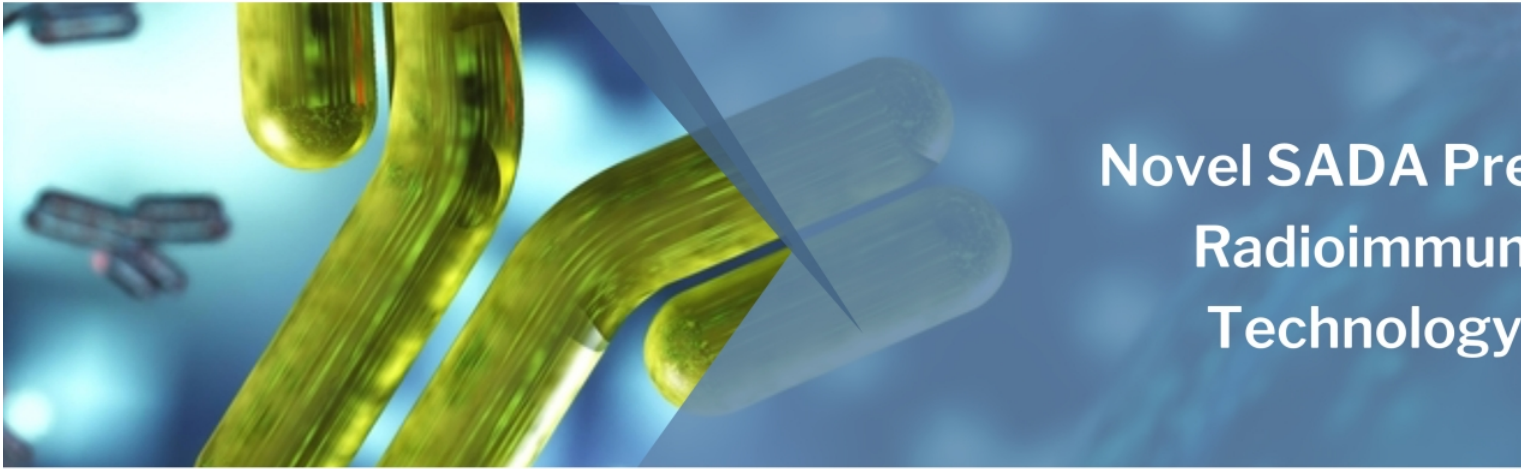
Cap Effic

**Indep
Commer
Biotech Co
Cash of ~\$
Financia
into
Maintai
Guid**

* As of September 30, 2023

Advancing Focused Pipeline with Multiple Value-Added Catalysts

	Study	Therapeutic Area	Preclinical	Phase I	Phase II/Pivotal	Approved	Trial Sponsor	
Lead Programs								
Naxitamab-gqgk (Anti-GD2)	201	Relapsed/Refractory High-Risk Neuroblastoma (Pediatric)	DANYELZA (naxitamab-gqgk) Confirmatory Trial				✓	
	12-230	Relapsed/Refractory High-Risk Neuroblastoma (Pediatric)	DANYELZA (naxitamab-gqgk)				✓	Memorial Sloan K Cancer Center
	BCC018	Front-Line Induction in High-Risk Neuroblastoma (Pediatric)						Beat Childhood C RESEARCH CONSOR
	15-096	Relapsed Second-Line Osteosarcoma						Memorial Sloan K Cancer Center
	17-251	Chemoimmunotherapy for Relapsed/ Refractory High-Risk Neuroblastoma						Memorial Sloan K Cancer Center
SADA (Radioimmunotherapy)	1001	GD2-SADA: Solid Tumors (SCLC, Malignant Melanoma, Sarcoma)						
	1201	CD38-SADA: Non-Hodgkin Lymphoma						
Early Programs								
SADA (Radioimmunotherapy)		GD2-SADA: Neuroblastoma						
		HER2-SADA						
		B7H3-SADA						



**Novel SADA Pre
Radioimmun
Technology**



Current Radiopharma Challenges Negatively Impact Patient Care



Simpler, more user-friendly solutions greatly needed for physicians and patients

SADA's Novel Pretargeted 2-Step Approach a Potential Industry Game

Traditional Radioimmunotherapy



Risk of systemic high toxicity



Prone to drug shortages / supply issues with single-isotope only capabilities



Limited administration sites with licensed nuclear medicine radiologists



High investment needed for specific infrastructure and manufacturing



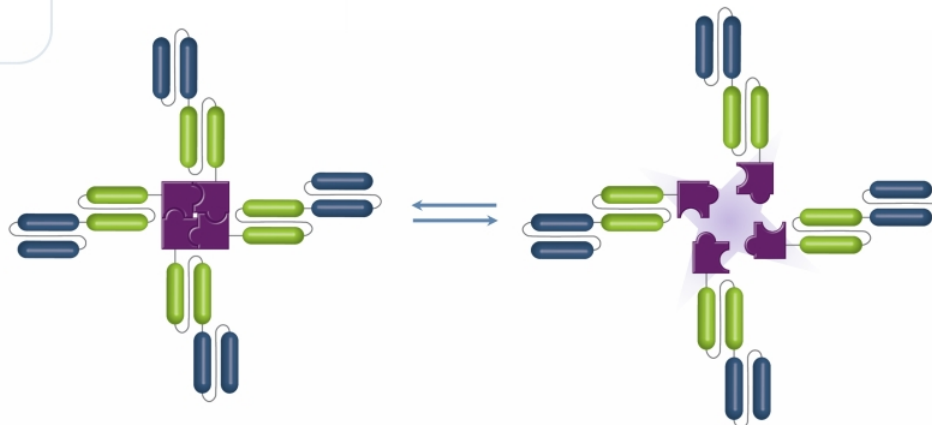
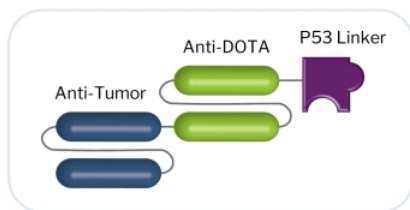
Novel SADA Platform Potential Capabilities

- ✓ Pretargeting tumor potentially mir toxicity and potentially enhances r of unbound protein
- ✓ Potential to work with short $T_{1/2}$ is
- ✓ Potentially broader site options wi dose administered by Medical Onc large infusion centers
- ✓ Potential COGS improvements

* Pending successful development and approval.

Self-Assembly DisAssembly (SADA) Technology: High Affinity Tumor Targets and Rapid Clearance from Blood Stream

SADA domains uniquely selected to allow proteins to change size based on concentration

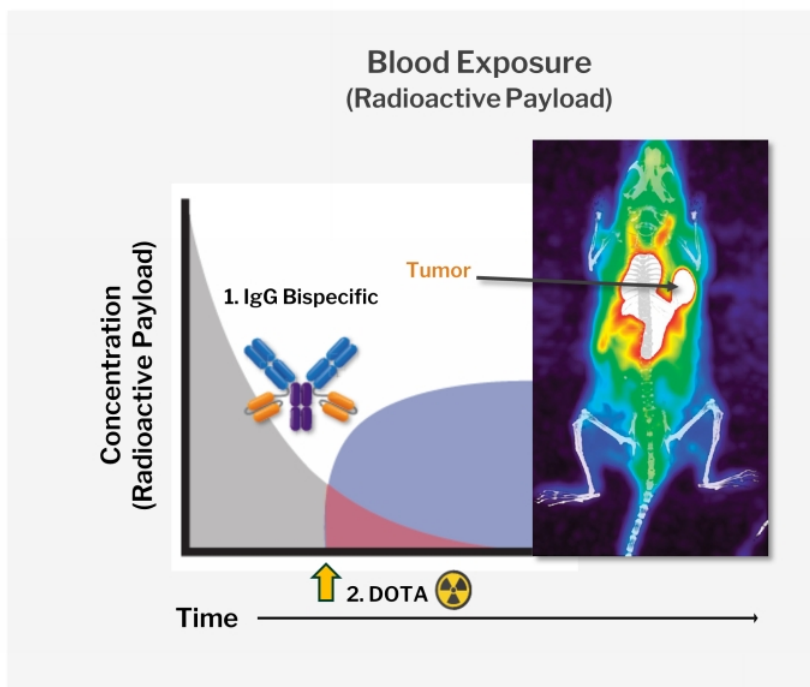


Self-Assembled Tetramer
~200 kDa
Strong Tumor Binding

DisAssembled Monomer
< 70kDa
Rapid Clearance

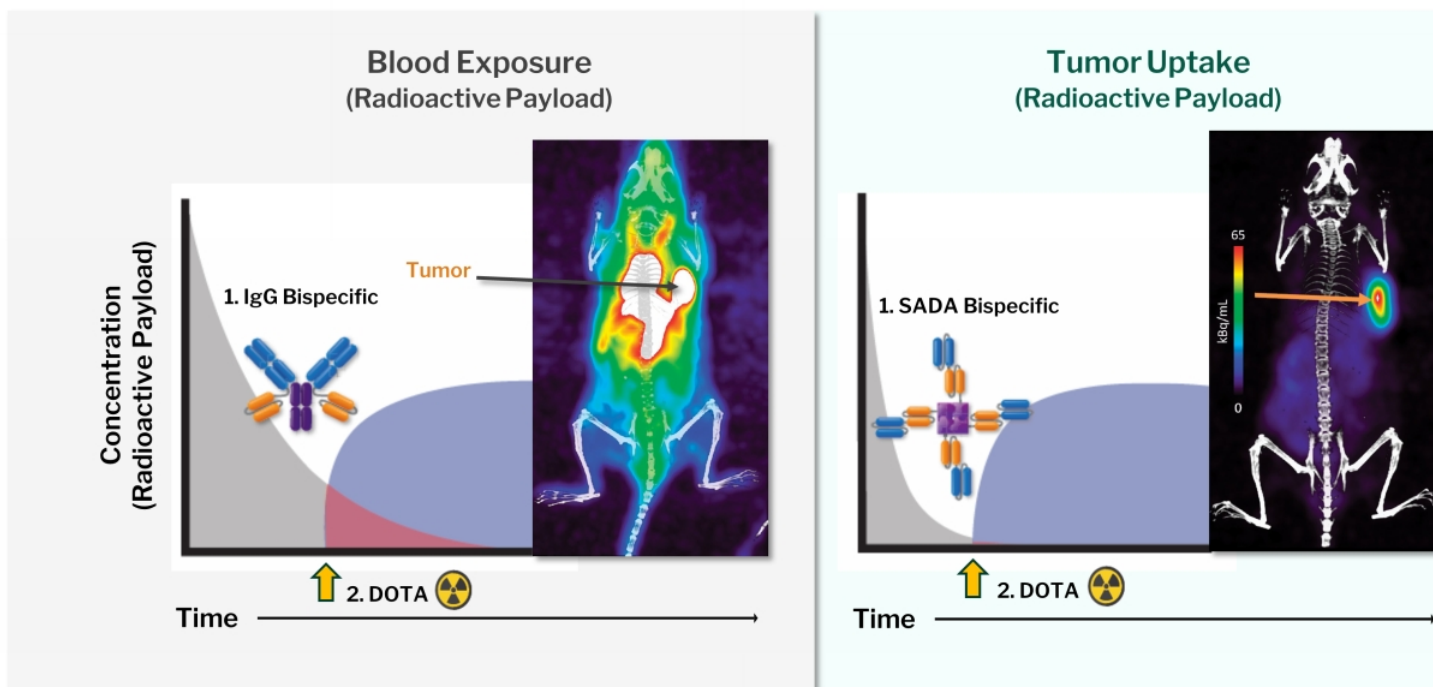
Adapted from Santich et al. Clin Canc Res 2020

Conventional GD2 Antibody's Persistence in Blood Stream Leads to Substantial Unwanted Exposure and Increased Toxicity



Adapted from Santich et al. Clin Canc Res 2021

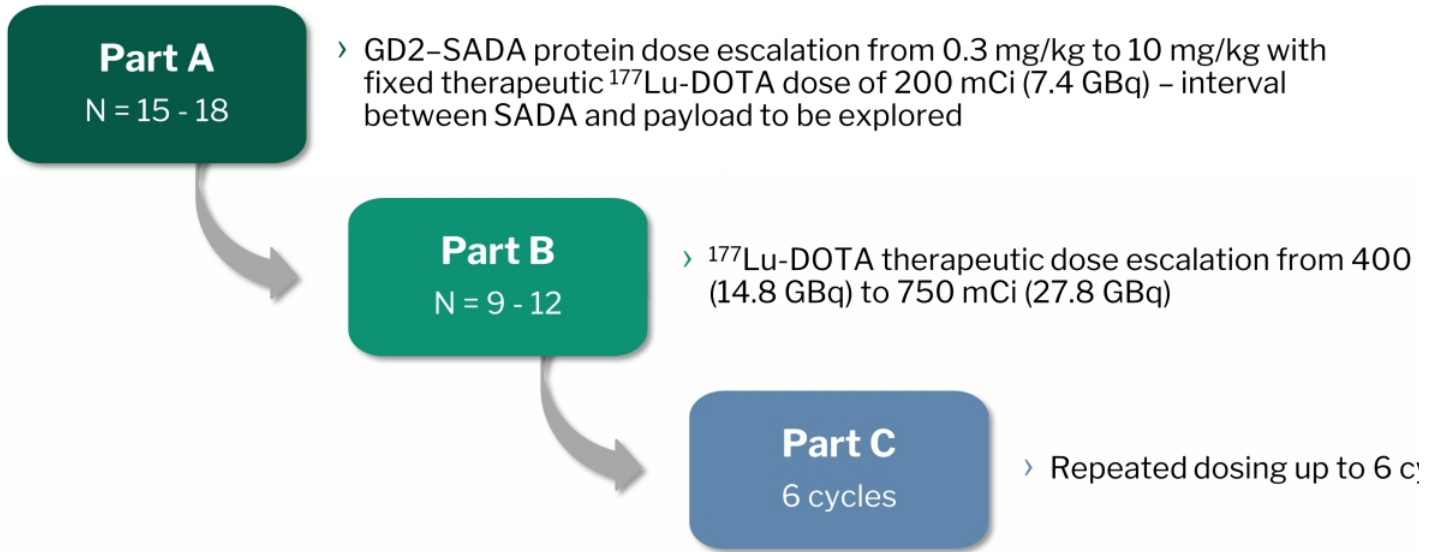
GD2-SADA Achieves High Tumor Uptake with Minimal Exposure All Other Tissues



Adapted from Santich et al. Clin Canc Res 2021
These early results are not complete and are not necessarily indicative of the full results or ultimate success of the trials or SADA development program.

Study 1001: GD2-SADA Ongoing Phase I Clinical Trial (Study 1001) Dosing Patients in Part A

Theranostic approach using a 30 mCi ¹⁷⁷Lu-DOTA imaging dose before exposing to therapy

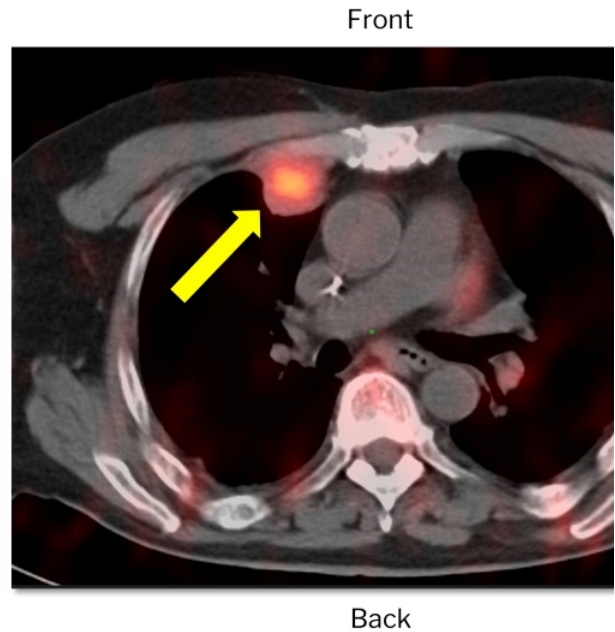


Trial Update:

- › Solid tumors (SCLC, malignant melanoma, sarcoma)
- › Completed cohorts 1, 2 and 3
- › 9 patients dosed 30 mCi, 3 patients
- › 6 sites enrolled; adding additional sites

Study 1001: SPECT/CT Scan Demonstrating Tumor Binding of ^{177}Lu -GD2 SADA*

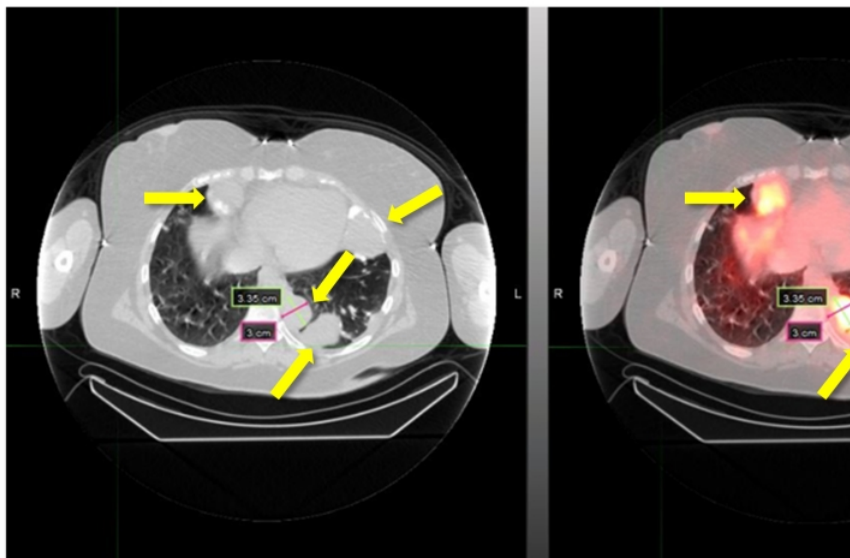
- Example of tumor targeting in Osteosarcoma using ^{177}Lu -DOTA dose of **30 mCi** (imaging dose) in patient
- Arrow indicates tumor metastasis located in the Thoracic cavity – with ^{177}Lu -DOTA uptake
- Scan performed 24 hours after radionuclide administration



*These early results are not complete and are not necessarily indicative of the full results or ultimate success of the SADA trials or the SADA development program.
Limitation: Patient-level data are for descriptive purposes and should not be considered indicative of typical product efficacy or duration; interpret with caution

Study 1001: SPECT/CT Scan on Osteosarcoma Patient Demonstrate Positive Tumor Uptake After Exposure*

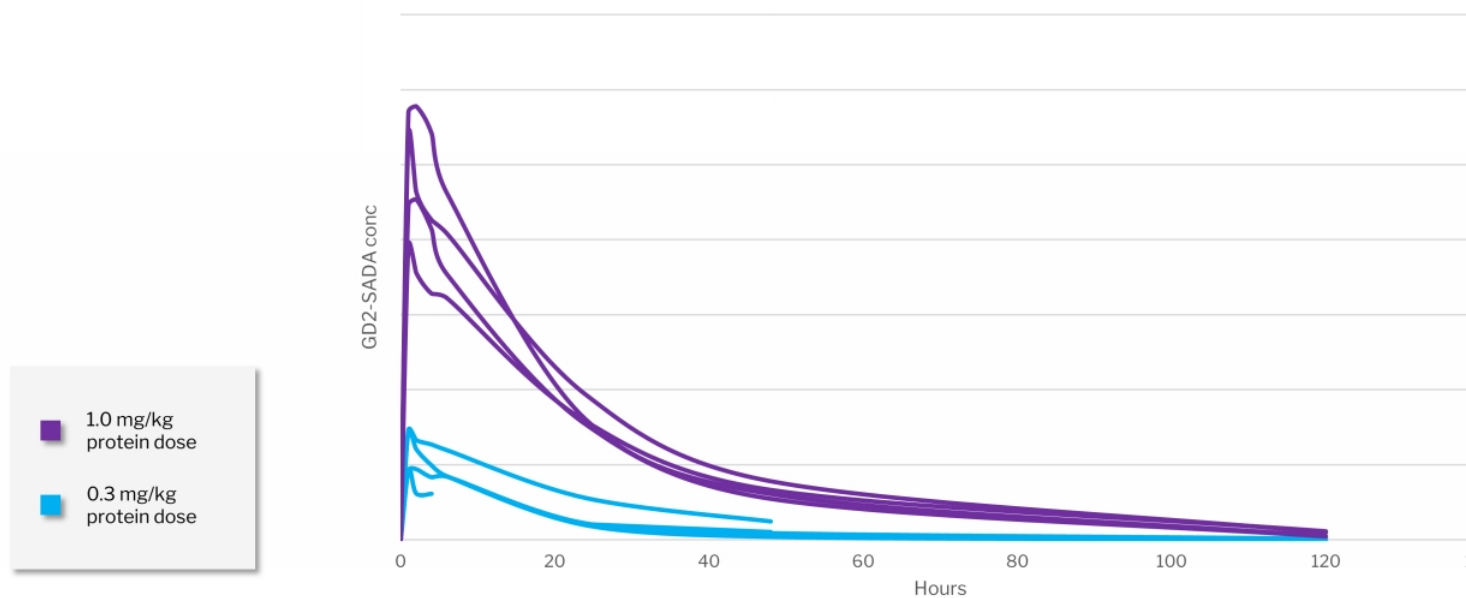
- Patient treated with 0.3 mg/kg GD2-SADA, followed by 200 mCi ^{177}Lu -DOTA (lowest therapeutic radionuclide dose) 48-hours later
- Scan performed 24 hours after radionuclide administration
- 4 target lesions marked on CT scan (left image) – all targeted by ^{177}Lu -DOTA SADA (right image)



*These early results are not complete and are not necessarily indicative of the full results or ultimate success of the SADA trials or the SADA development program. Limitation: Patient-level data are for descriptive purposes and should not be considered indicative of typical product efficacy or duration; interpret with caution

Ongoing GD2-SADA Phase I Trial: Initial PK Data*

Non-QC data



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Novel SADA Platform Potentially Provides Simplicity and Enhanced Precision for Physicians and Patients*



Ongoing GD2-SADA Phase I Trial (Study 1001)

- › Evidence of tumor uptake
- › No DLTs or pain observed to date
- › Demonstrated PoC that GD2-SADA targets and binds to tumor in humans



CD38-SADA Phase I Trial

- › IND cleared by U.S. FDA
- › First-in-human in patient with Hodgkin Lymphoma
- › Trial initiation expected in 2023



Additional early-stage programs include:

- › HER2-SADA
- › B7H3-SADA

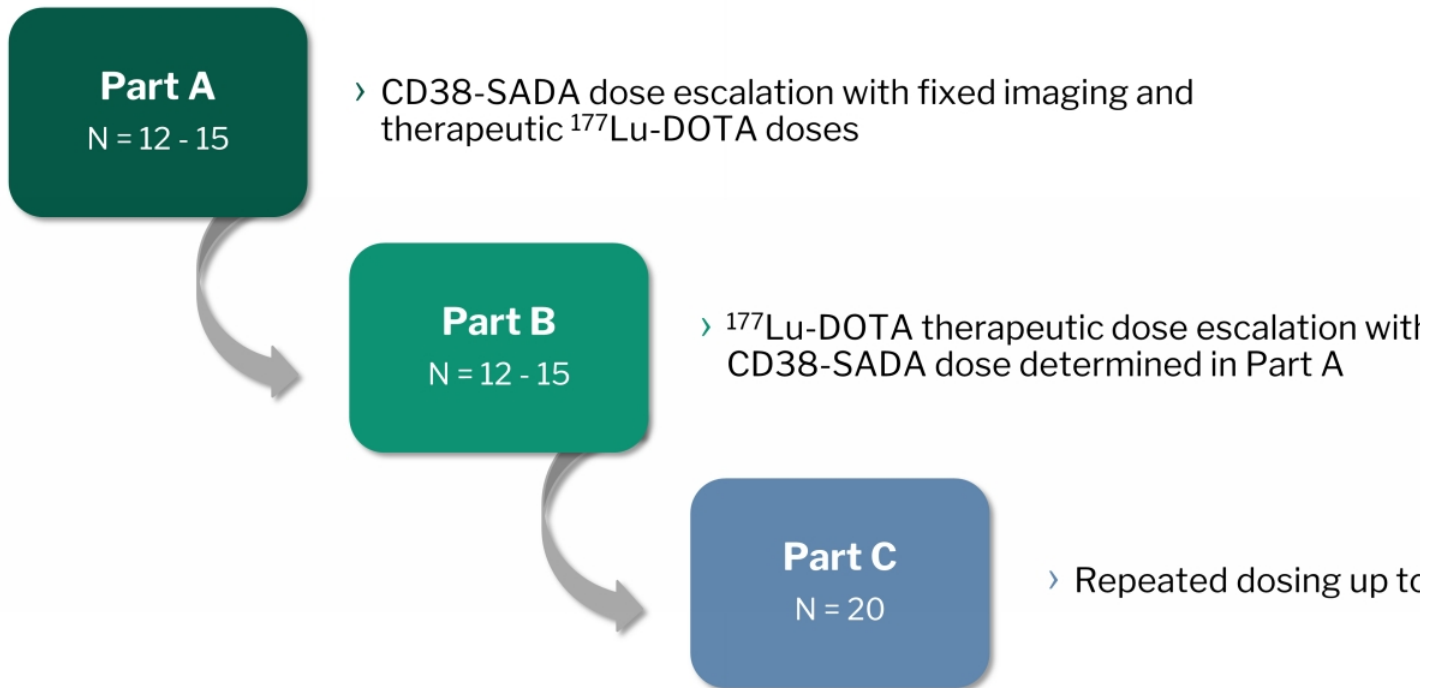


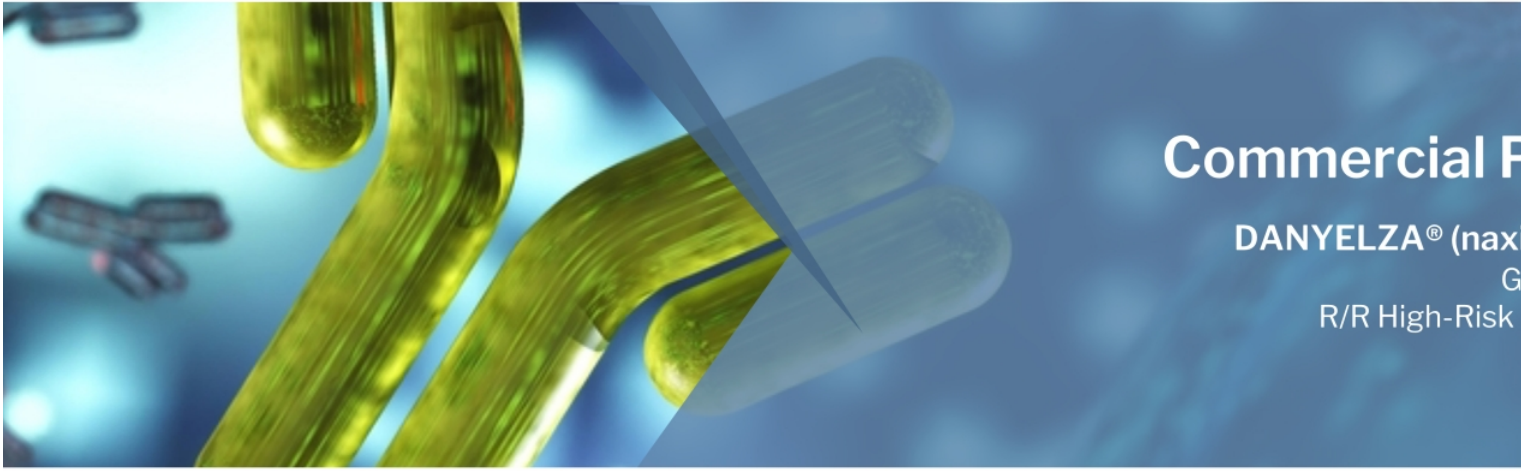
- › Potential to shift radioimmunotherapy treatment paradigm for patients with cancer, providing physicians with simplified and enhanced precision of the platform

*These early results are not complete and are not necessarily indicative of the full results or ultimate success of the SADA trials or the SADA development program.

Planned CD38-SADA Phase I Clinical Trial (Study 1201): Study I

Theragnostic approach using a ^{177}Lu -DOTA imaging dose before exposure to a therapeutic ^{177}Lu -I





Commercial F

DANYELZA® (nax

G

R/R High-Risk

DANYELZA: Only FDA-Approved Medicine for R/R NB Patients



FDA Approval for R/R Neuroblastoma (NB)

- Differentiated therapy:
 - › Humanized antibody
 - › Rapid infusion, modest toxicity
 - › Administered in outpatient treatment setting
- U.S. addressable market:
 - › 2L NB: **300** patients



Neuroblastoma

- NB forms in certain types of nerve tissue, most frequently starting from adrenal glands; can also develop in the neck, chest, abdomen or spine
- NB is the **most common cancer in infants**



Global Commercial Launch Performance

- Q3 2023 net sales of **\$20.0 million**
- **59 sites** across the U.S. have utilized DANYELZA*
- Ex-U.S. commercial ramp progressing in China; Strong EU demand through WEP
- Additional regulatory approvals in LATAM

Solid Drive Up

- New DANYELZA rolled out in
- **167 new patients** date since
- Increasing GD2 market

DANYELZA
(naxitamab)

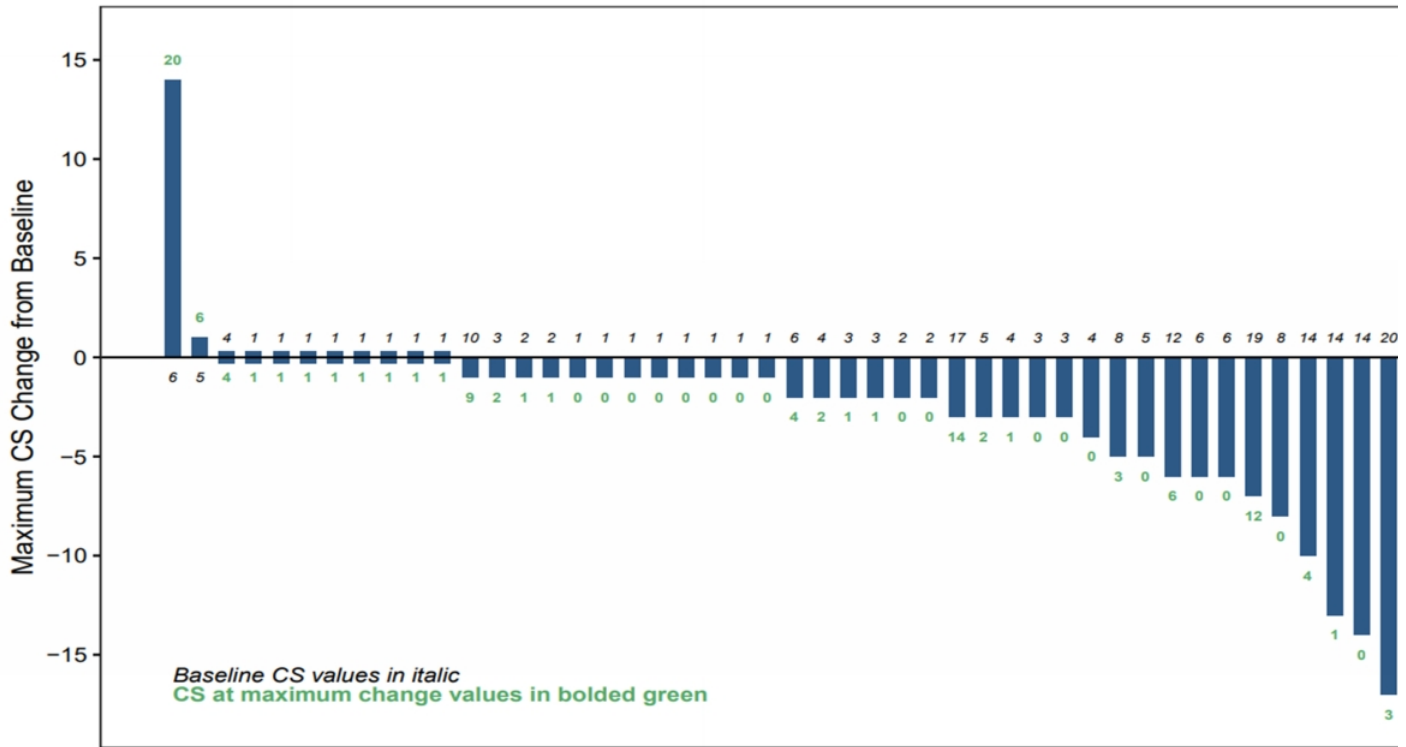
* As of January 4, 2024

** YTD through September 30, 2023



This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Study 201 Prespecified Interim Analysis: Waterfall Plot of Change in Curie Score in all Relapsed/Refractory Patients with Bone Disease



Ongoing Naxitamab Clinical Trials

Beat Childhood Cancer RESEARCH CONSORTIUM

- Phase II BCC multi-center trial evaluating naxitamab + standard induction therapy in patients with newly diagnosed High-Risk Neuroblastoma
- 13 sites initiated; target 40-50 sites in U.S. and Canada
- 6 patients dosed; target 76 total patients

➤ Anticipate transitioning to a multi-center randomized trial in Q2 2024



Memorial Sloan Kettering Cancer Center

- Multi-center Phase II trial investigating naxitamab in patients with relapsed osteosarcoma
- Anticipated data readout from MSKCC in Q4 2024

➤ Following data readout from MSKCC, Y-mAbs prepared to initiate pivotal randomized Phase II trial



THE OHIO STATE COMPREHENSIVE CANCER CENTER

- ISS Phase Ib/II trial investigating naxitamab + nivolumab + ipilimumab + pembrolizumab + durvalumab + nivolumab + ipilimumab + pembrolizumab + durvalumab + nivolumab + ipilimumab + pembrolizumab + durvalumab in patients with metastatic cancer
- Target enrollment complete
- Anticipate first patient in Q1 2024

➤ Consider multi-center based on the results

Clinicaltrials.gov: BCC trial NCT05489887, MSK trial NCT02502786, OSU trial NCT06026657

Ongoing and Potential New Studies for Naxitamab: Expanding in New Indications

Cancer Indications		Treatable Patient Population (U.S.)	GD2 Expression	2022	2023	2024	2025
High-Risk Neuroblastoma	Relapsed / Refractory	300	~ 99-100%	R/R HRNB Confirmatory Study 201*			
	Front-line Induction	450		1 st line Induction BCC-018 Phase II	1 st line Induction BCC s		
Osteosarcoma Relapsed/Recurrent		200	~ 88%	Relapsed Osteosarcoma MSKCC Study 15-096			
Soft-Tissue Sarcomas Including Ewings		2,900 (1 st -line population)	> 90%	ISS – Ongoing Phase II (Ewings)			
Breast Cancer Triple Negative / Advanced		8,900 (2 nd line & 3 rd line +)	> 50%	ISS – Ongoing Phase Ib/II			
Melanoma Newly Unresectable and Metastatic		11,400 (2 nd line & 3 rd line +)	> 50%	ISS – Area of Interest			

* This indication is approved under accelerated approval. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).
 ** Subject to data readout of MSKCC study 15-096.

DANYELZA Addresses Significant Unmet Needs in R/R High-R with Expansion Potential Across Broader Patient Populations



Studies 12-230 and 201 formed primary basis of approval in November 2020. Reached 100 patients in Study 201



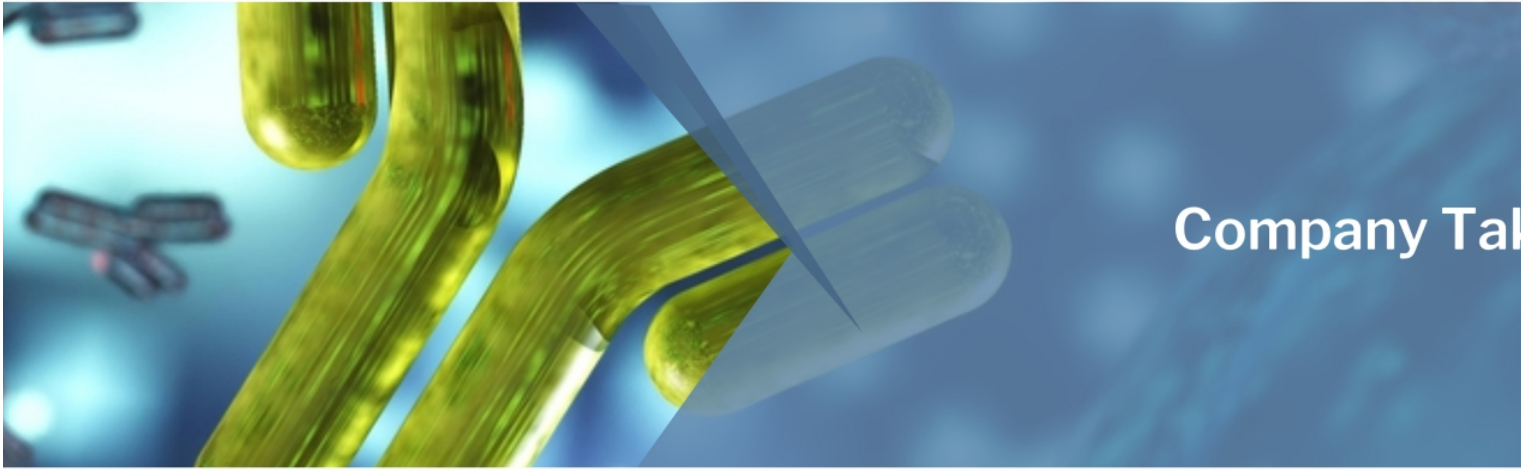
Granted ODD and BTD. study ongoing



U.S. commercialization in high-risk NB. Launch in China by SciClone; LATAM partner Adium; EU access via WEP



Multiple potential advanced other GD2 targeting anti-therapies: Modest toxicity, infusion time, ability to be administered in outpatient



Company Talk



Strongly Positioned to Drive Future Value

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Anticipated 2024 Milestones



**GD2-SADA Phase I
Part A Data Readout
CD38-SADA Phase I
Study Initiation
MSK Data Readout of
Phase II Osteosarcoma
Trial Anticipated**

Cap Effic

**Indep
Commer
Biotech Co
Cash of ~\$
Financia
into
Maintai
Guid**

* As of September 30, 2023

A microscopic background featuring a large, textured green sphere on the left, several green rod-shaped bacteria on the right, and various blue and red structures in the background. A white rectangular box is centered over the image.

THANK YOU
