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 6, 2025

Y-MABS THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-38650**	**47-4619612**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(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:

☐ 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**	**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 9, 2025, Y-mAbs Therapeutics, Inc. (the "Company") announced a business realignment plan, as described in greater detail in Items 2.05 and 7.01 below, designed to optimize the Company's operations by aligning dedicated internal resources to two business units, with the goal of increasing operational flexibility and speed, and accelerating clinical development programs within the Company's radiopharmaceutical platform. In addition, the Company reported preliminary estimated unaudited total net revenue of approximately $88 million for the year ended December 31, 2024, within the previously announced estimated guidance range of between approximately $87 million and $95 million. In addition, the Company announced that it expects its operating expenses for the year ended December 31, 2024, including the impact of any business realignment charges recorded in the 2024 fiscal year, to be within the previously announced estimated guidance range of between $115 million and $120 million. The Company also reported preliminary estimated unaudited cash and cash equivalents as of December 31, 2024 of approximately $67 million with a total annual cash investment of approximately $11 million for the 2024 fiscal year, which is below the previously announced estimated guidance range of between $15 million to $20 million.

The full text of the Company's press release issued in connection with the announcement is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The preliminary 2024 financial results and expectations set forth above are unaudited and based on management's initial review of the Company's results as of and for the year ended December 31, 2024, and are subject to revision based upon the Company's year-end closing procedures and the completion of the audit by the Company's external auditors of the Company's December 31, 2024 financial statements. Actual results may differ materially from these preliminary results as a result of the completion of year-end closing procedures, final adjustments, and other developments arising between now and the time that the Company's financial results are finalized. In addition, these preliminary results are not a comprehensive statement of the Company's financial results as of and for the year ended December 31, 2024, should not be viewed as a substitute for complete financial statements prepared in accordance with U.S. generally accepted accounting principles, and are not necessarily indicative of the Company's results for any future period.

The information in this Item 2.02 of this Current Report on Form 8-K is being furnished to the Securities and Exchange Commission and 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 liability under that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended (the "Securities Act"), except as expressly set forth by specific reference in such a filing.

ITEM 2.05. COSTS ASSOCIATED WITH EXIT OR DISPOSAL ACTIVITIES.

On January 6, 2025, the Company's Board of Directors approved a business realignment plan designed to optimize the Company's operations by aligning dedicated internal resources to two business units, with the goal of increasing operational flexibility and speed, and accelerating clinical development within its radiopharmaceutical platform. Pursuant to the plan, the Company will have two business units, one that is focused on expanding market access to DANYELZA and progressing the clinical and commercial development of naxitamab in other indications and for potential label expansion, and another that is focused on progressing the radiopharmaceutical platform, including Self-Assembly Disassembly Pretargeted ("SADA PRIT") technology platform and the Company's early-stage pipeline, with a shared general administrative function.

In connection with this business realignment, the Company expects a reduction in its current workforce by up to approximately 13%, depending on whether a number of the impacted employees accept newly created positions. This percentage substantially reflects the following: first, a small adjustment of the DANYELZA commercial team to focus the team on potential growth opportunities within the GD2 market, and second the relocation of some SADA development functions to the United States from Denmark, with such reduction anticipated to be completed by the end of the second quarter of 2025. Affected employees will be offered separation benefits in exchange for their execution of a severance agreement and general release. The separation benefits include but are not limited to severance payments, payout of 2025 statutory bonuses, outplacement services, along with temporary healthcare coverage assistance.

As a result of the reduction in workforce and realignment plan, the Company expects to incur restructuring expenses of up to approximately $2.6 million, consisting predominantly of cash-related notice and severance payments of up to

approximately $2.1 million and acceleration of stock-based compensation of up to approximately $0.5 million. The Company anticipates that the restructuring expenses will impact its results of operations during the fourth quarter of 2024 and first quarter of 2025 and that the cash payments will occur through the first half of 2026. The charges that the Company expects to incur are subject to a number of assumptions, and actual expenses may differ materially from the estimates disclosed above.

ITEM 5.02. DEPARTURE OF DIRECTORS OR CERTAIN OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF CERTAIN OFFICERS; COMPENSATORY ARRANGEMENTS OF CERTAIN OFFICERS.

In connection with this business realignment described in above, Susan Smith, the Company's Senior Vice President and Chief Commercial Officer, will be departing from the Company on April 9, 2025.

ITEM 7.01 REGULATION FD DISCLOSURE.

In connection with the business realignment described above, effective January 7, 2025, the Board of Directors of the Company appointed Doug Gentilcore to serve as the Company's SVP, Danyelza Business Unit Head. The Company has also appointed Natalie Tucker, previously the Company's Vice President of Business Development and Chief of Staff, to be promoted to the role of SVP, Radiopharmaceutical Business Head.

On January 10, 2025, the Company issued a press release announcing Strategic Business Updates and 2025 Priorities, including the business realignment discussed above and the anticipated timing of certain trial data regulatory matters. The full text of the Company's press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on Form 8-K is being furnished to the Securities and Exchange Commission and shall not be deemed "filed" for purposes of Section 18 of the Exchange Act or otherwise subject to liability under that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Cautionary Statement Regarding Forward-Looking Statements

Statements in this Current Report on Form 8-K about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about: our business model, expectations with respect to estimated charges and expenses in connection with the business realignment plan, including the amounts and timing thereof, preliminary estimated financial results and expectations for the year ended December 31, 2024, including estimated operating expenses, cash and cash equivalents and net revenue; the realignment plan,/ including the reduction in workforce and operations and resources, and the expected impacts, anticipated expenses and benefits thereof, including operational flexibility and speed, and acceleration of clinical development within the radiopharmaceutical platform expectations with respect to trial data and regulatory matters; implied and express statements regarding the future of the Company's business; the Company's strategies, development, regulatory, commercialization and product distribution plans; and other statements that are not historical facts. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "guidance," "hope," "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. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with our financial condition and need for additional capital; the risk that our reported results may differ materially from our preliminary estimated operating expense, cash and cash equivalent and DANYELZA net product revenue results as a result of the completion of year-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized; the risks that actual results of the business realignment plan will not be as expected, including the impact on employees and other parties; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of our product candidates; development of

our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; risks related to our ability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock; risks associated with ongoing geopolitical conflicts; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30, and September 30, 2024, and in our other SEC filings. Any forward-looking statements contained in this Current Report on Form 8-K speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 10, 2025, issued by Y-mAbs Therapeutics, Inc.
104	Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, 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 10, 2025

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

Y-mAbs Provides Strategic Business Update and 2025 Priorities

Company establishes two business units with goal of accelerating clinical development of its Radiopharmaceuticals Platform and optimizing the commercial potential of DANYELZA

Preliminary Part A data from GD2-SADA Phase 1 trial demonstrates tolerability and validity of SADA PRIT platform pre-targeting approach; Company expects to present Part A data in the second quarter of 2025

Company reports preliminary estimated unaudited Total Net Revenue of approximately $88 million for the year ended December 31, 2024, within Full Year 2024 top line guidance range

Company reports preliminary estimated unaudited cash, cash equivalents and marketable securities of approximately $67 million as of December 31, 2024, anticipated to support operations into 2027

Company presenting at 43rd Annual J.P. Morgan Healthcare Conference on Wednesday, January 15, 2024 at 5:15 p.m. PT

New York, NY, January 10, 2025 – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB), a commercial-stage biopharmaceutical company focused on the development and commercialization of novel radioimmunotherapy and antibody-based therapeutic products for the treatment of cancer, today announced strategic business updates and 2025 priorities in the Company's mission to improve and extend people's lives.

Business Update

Y-mAbs is internally realigning operations with the establishment of two business units: Radiopharmaceuticals and DANYELZA.

- Radiopharmaceuticals
  - Novel Self-Assembly DisAssembly Pre-targeted Radioimmunotherapy ("SADA PRIT") platform designed to improve upon traditional radioimmunotherapy by delivering high therapeutic dose while minimizing off-target exposure, increase physician participation and decrease manufacturing and infrastructure costs.
  - SADA PRIT technology utilizes a pre-targeted payload delivery method where antibody constructs assemble in tetramers and bind to the tumor target.
  - Platform can deliver a variety of payloads and could potentially be developed against multiple tumor targets, as well as for radiopharmaceutical purposes.
  - Y-mAbs is currently evaluating its SADA PRIT technology in two clinical trials in the U.S.

- DANYELZA
  - DANYELZA is a GD2 antibody and the only FDA-approved treatment for the treatment of patients one-year of age and older with high-risk relapsed/refractory neuroblastoma in the bone and bone marrow.
  - Initially commercially launched in 2021, DANYELZA is commercialized across both U.S. and international markets.

The business realignment is designed to support the optimization of internal resources and provide flexibility and agility to advance the Company's novel SADA PRIT platform programs through clinical development while simultaneously driving commercial growth of DANYELZA.

"Our mission at Y-mAbs has been clear from day one: bring important new cancer therapies to patients as quickly as possible. Since the successful commercial launch of DANYELZA, we are proud to have positively impacted the lives of children with high-risk relapsed/refractory neuroblastoma, giving the hope of a better future to families around the world," said Michael Rossi, President and Chief Executive Officer. "As we look ahead towards the potential of our novel Radiopharmaceutical platform and high value therapeutic areas, as well as the potential of DANYELZA, we believe now is the right time to focus our efforts into two business units. By doing so, we expect to expand our radiopharmaceutical capabilities, accelerate clinical execution, further improve capital efficiencies, and better align strategic priorities."

With these updates to our business strategy, the Company anticipates a reduction in its current workforce of up to approximately 13%, depending on whether a portion of impacted employees accept newly created positions. The Company also intends to move some roles from Denmark to the U.S. to more efficiently coordinate the advancement of its radiopharmaceutical platform, and implement a small adjustment to the DANYELZA commercial team to focus the team on potential growth opportunities within the anti-GD2 market.

Recent Pipeline Advancement

GD2-SADA (Trial 1001): Y-mAbs has dosed 21 patients at six sites to date in Part A of the GD2-SADA Phase 1 trial in adults with solid tumors. Tumor types include small cell lung cancer (SCLC), malignant melanoma, sarcomas and adult neuroblastoma. Preliminary data from the Part A GD2-SADA Phase 1 trial has demonstrated this novel pre-targeting approach to be well-tolerated with no dose-limiting toxicities (DLTs) and no treatment-related adverse events (AEs) reported. Part A remains ongoing as the Company aggregates final data on patients in open cohorts and continues to study further patients incorporating various elements to further optimize the platform aiming to maximize tumor uptake and retention. The Company expects to share data from Part A in the second quarter of 2025.

"The preliminary data from Part A of our GD2-SADA Phase 1 trial demonstrates the viability of the pre-targeted approach of the platform. We continue to gather learnings from the 21 patients dosed to date, which we anticipate will allow us to improve tumor uptake, determine the optimal therapeutic dose, and establish the ideal construct to further advance Trial 1001 in the clinic," said Norman LaFrance, M.D., Chief Development Officer. "We believe in the significant potential of our SADA PRIT platform, and we are excited to be at the forefront of this next-generation, pre-targeted radiotherapy technology."

CD38-SADA (Trial 1201): To date, six sites have been selected, and three sites have been activated. The Company expects to dose the first non-Hodgkin Lymphoma (NHL) patient in Study 1201 in the first quarter of 2025.

Unaudited Preliminary FY2024 Results

Y-mAbs reported preliminary estimated unaudited full year 2024 total net revenue of approximately $88 million, within the Company's previously announced guidance range of between $87 million and $95 million, and preliminary estimated unaudited cash, cash equivalents and marketable securities as of December 31, 2024 of approximately $67 million, with preliminary estimated total cash investment for the full year 2024 of approximately $11 million, which is below the Company's guidance range of between $15 million and $20 million.

Anticipated 2025 Milestones

- Part A data from GD2-SADA Phase 1 trial (Trial 1001) expected to be presented in the second quarter of 2025
- GD2-SADA optimization data expected to be presented in the second quarter of 2025
- Expect to present updates with respect to reprioritized SADA PRIT pipeline, including new high-value target indications and timelines, in the second quarter of 2025
- Expect to dose first patient in CD38-SADA Phase 1 trial (Trial 1201) in the first quarter of 2025
- Potential for marketing approval for DANYELZA in new ex-US market in 2025
- Plan to provide full year 2025 guidance in conjunction with full year 2024 earnings report in the first quarter of 2025

Upcoming Investor Presentation

The company previously announced that Mr. Rossi will present at the 43rd Annual J.P. Morgan Healthcare Conference in San Francisco, CA on Wednesday, January 15, 2025 at 5:15 p.m. PT. A live webcast will be available under the Events section of the Company's investor relations website at ir.ymabs.com. The webcast will be archived and available for replay for 30 days after the event.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, radioimmunotherapy and antibody-based therapeutic cancer products. The Company's technologies include its investigational Self-Assembly DisAssembly ("SADA") Pretargeted Radioimmunotherapy Platform ("PRIT") and bispecific antibodies generated using the Y-BiClone platform. The Company's broad and advanced product pipeline includes the anti-GD2 therapy DANYELZA® (naxitamab-gqgk), the first FDA-approved treatment for patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow after a partial response, minor response, or stable disease to prior therapy.

Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects, as well as any other statements regarding matters that are not historical facts, may constitute "forward-looking statements" within the meaning of The Private Securities Litigation Reform Act of 1995. Such statements include, but are not limited to, statements about: our business model, expectations with respect to estimated charges and expenses in connection with the business realignment plan, including the amounts and timing thereof, preliminary estimated financial results and expectations for the year ended December 31, 2024, including estimated operating expenses, cash and cash equivalents and net revenue; the realignment plan, including the reduction in workforce and operations and resources, and the expected impacts, anticipated expenses and benefits thereof, including operational flexibility and acceleration of clinical development within the radiopharmaceutical platform; implied and express statements regarding the future of the Company's business; the Company's strategies, development, regulatory, commercialization and product distribution plans; expectations with respect to the Company's products and product candidates, including market access expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA PRIT technology platform and product candidates based on such technology; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA and the SADA PRIT technology, including anticipated collection and presentation of data, and the timing thereof; current and future clinical and pre-clinical studies and our research and development programs; expectations related to the timing of the initiation and completion of regulatory submissions; regulatory, marketing and reimbursement approvals; and other statements that are not historical facts. Words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "goal," "guidance," "hope," "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. Our product candidates and related technologies are novel approaches to cancer treatment that present significant challenges. Actual results may differ materially from those indicated by such forward-looking statements as a result of various factors, including but not limited to: risks associated with our financial condition and need for additional capital; the risk that our reported results may differ materially from our preliminary estimated operating expense, cash and cash equivalent and DANYELZA net product revenue results as a result of the completion of year-end closing procedures, final adjustments, and other developments arising between now and the time that our financial results are finalized; the risks that actual results of the business realignment plan will not be as expected, including the impact on employees and other parties; risks associated with our development work; cost and success of our product development activities and clinical trials; the risks of delay in the timing of our regulatory submissions or failure to receive approval of our drug candidates; the risks related to commercializing any approved pharmaceutical product including the rate and degree of market acceptance of our product candidates; development of our sales and marketing capabilities and risks associated with failure to obtain sufficient reimbursement for our products; the risks related to our dependence on third parties including for conduct of clinical testing and product manufacture; risks related to our ability to enter into partnerships; the risks related to government regulation; risks related to market approval, risks associated with protection of our intellectual property rights; risks related to employee matters and managing growth; risks related to our common stock; risks associated with ongoing geopolitical conflicts; and other risks and uncertainties affecting the Company including those described in the "Risk Factors" section included in our Annual Report on Form 10-K for the year ended December 31, 2023, our Quarterly Reports on Form 10-Q for the quarters ended March 31, June 30, and September 30, 2024, and in our other SEC filings. Any forward-looking statements contained in this press release

speak only as of the date hereof, and the Company undertakes no obligation to update any forward-looking statement, whether as a result of new information, future events or otherwise.

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