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 3, 2023

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 4, 2022, Y-mAbs Therapeutics, Inc. (the "Company") announced a strategic restructuring plan designed to extend its cash runway and prioritize resources on the commercialization and potential label extension of DANYELZA and development of the SADA technology platform. The restructuring plan includes an estimated 28% reduction in annual operating expenses for 2023 compared to previously announced guidance of estimated annual operating expenses of $162-$167 million for 2022. In addition, the Company announced certain preliminary unaudited results for fiscal year ended December 31, 2022. In particular, the Company expects its cash and cash equivalents as of December 31, 2022 to be approximately $106.0 million and DANYELZA net product revenues for 2022 to be approximately $47-48 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 above information relating to 2022 operating expenses is subject to revision in connection with the Company's financial closing procedures and finalization and audit of the Company's financial statements for the fiscal year ended December 31, 2022. Actual operating expenses for the fiscal year ended 2022 may differ from the above information. In addition, the preliminary financial results pertaining to expected 2022 cash and cash equivalents and DAYELZA net product revenues 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, 2022, 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, 2022 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, 2022, 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 (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.

ITEM 2.05. COSTS ASSOCIATED WITH EXIT OR DISPOSAL ACTIVITIES.

On January 3, 2023, the Company's Board of Directors approved updates to the Company's plan with respect to its development activities and a restructuring of its development and commercial organization, including a reduction of workforce, designed to focus resources on the commercialization of DANYELZA and the development of its SADA (Self-Assembly DisAssembly) technology and reduce operating expenses, which is expected to preserve financial resources and extend the Company's cash runway into the first quarter of 2026 based on the revised business plan as currently contemplated.

Beginning on January 4, 2023, the Company intends to commence executing this restructuring and revised business plan, which includes reducing its development activities by deprioritizing other pipeline programs, including activities relating to development of omburtamab, a GD2-GD3 Vaccine and CD33 bispecific antibody constructs. This restructuring and revised business plan was initiated largely in response to the complete response letter issued by the U.S. Food and Drug Administration ("FDA") on November 30, 2022, for the Biologics License Application for the investigational medicine ^{131}I-omburtamab for the treatment of central nervous system /leptomeningeal metastasis from neuroblastoma. Going forward, the Company plans to focus its sales and marketing efforts on increasing commercialization of DANYELZA® (naxitamab-gqgk), and its development activities on its SADA program.

The Company currently 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 are expected to be offered separation benefits, including severance payments 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, the Company expects to incur restructuring expenses of approximately $5.0 million, consisting predominantly of cash related notice and severance payments of approximately $3.0 million and acceleration of stock-based compensation of approximately $2.0 million. The Company anticipates that the majority of such restructuring expenses will be recognized and paid in the first quarter of 2023. 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.

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, including financial outlook for 2023, including expectations with respect to estimated charges and restructuring expenses, including the amounts and timing thereof, estimated operating expenses, total cash burn and DANYELZA product revenue and sufficiency of cash resouces, in addition to expected revenues, operating expenses and cash position for 2022, the restructuring, including the reduction in workforce and revised business plan, and the expected impacts, expenses and benefits thereof, including potential cost-savings from the reduction in force, expected reduction of operating expenses and any expectations with respect to cost savings to be derived therefrom; implied and express statements regarding the future of the Company's business; the Company's plans and strategies, development, commercialization and product distribution plans; expectations with respect to omburtamab, including the anticipated Type A meeting with the FDA; expectations with respect to our products and product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA Technology, including the development of the first tumor binding dataset and potential benefits thereof and potential partnership relating thereto; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA and the SADA Technology, including anticipated collection of data in in GD2-SADA multicenter trial against small-cell lung cancer, sarcoma, and malignant melanoma and anticipated IND relating to the CD38-SADA construct against non-hodgkin's lymphoma, and the timing thereof; expectations that DANYELZA and the SADA technology represent potential key near and long-term growth drivers; 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; including satisfaction of conditions to approvals; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements, cash burn; and other statements that are not historical facts. Words such as ''anticipate,'' ''believe,'' ''contemplate,'' ''continue,'' ''could,'' ''estimate,'' ''expect,'' ''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 risks that actual results of the restructuring plan and revised business plan will not be as expected; 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; our inability 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 the COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto; including inflation and uncertain global credit and capital markets; 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, 2021, our Quarterly Reports on Firm 10-Q for the quarters ending March 31, 2022, June 30, 2022 and September 30, 2022, 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.

ITEM 7.01 REGULATION FD DISCLOSURE.

On January 4, 2023, the Company issued a press release related to the restructuring and revised business plan discussed above in addition to the Company's financial outlook for 2023. The full text of the Company's press release is filed 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.

ITEM 9.01. FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 4, 2023, 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 4, 2023

By: /s/ Thomas Gad
Thomas Gad
Founder, President, Interim Chief Executive Officer, and Head of Business Development & Strategy

Exhibit 99.1

Y-mAbs Announces Restructuring Plan and Provides Financial Outlook Following Complete Response Letter from FDA

- **Estimated 28% reduction in annual operating expenses for 2023 compared to previously announced guidance for 2022 of $162-167 million;**
- **Estimated total cash burn for 2023, including restructuring expenses, expected to be $50-55 million, expected to extend cash runway into Q1 2026 based on revised business plan;**
- **Estimated 2023 DANYELZA net product revenues expected to be $60-65 million;**
- **Focusing resources on DANYELZA growth and label expansion, and development of SADA technology; and**
- **Estimated 35% reduction of Y-mAbs workforce as part of the restructuring in addition to reprioritization of pipeline programs.**

New York, NY, January 4, 2023 (GLOBE NEWSWIRE) – Y-mAbs Therapeutics, Inc. (the "Company" or "Y-mAbs") (Nasdaq: YMAB) a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic products for the treatment of cancer, today announced a strategic restructuring plan designed to extend its cash runway and prioritize resources on the commercialization and potential label extension of DANYELZA and development of the SADA (Self-Assembly DisAssembly ("SADA") PRIT 2-STEP) technology platform. The Company plans to discuss omburtamab at its upcoming Type A meeting with the FDA; however, the Company has assumed a deprioritization of the omburtamab program, including all indications, in designing its restructuring plan and in its estimates for 2023. In addition, the Company plans to deprioritize other pipeline programs, including activities relating to GD2-GD3 Vaccine and CD33 bispecific antibody constructs, as part of the restructuring plan.

"We believe that this restructuring of the organization aligns our resources to efficiently leverage both the DANYELZA franchise and support development activities for our highly differentiated novel SADA platform, which we view as the key near and long-term potential growth drivers of Y-mAbs. We believe this sharpened focus should propel us through key anticipated milestones, including continuation and potential expansion of the commercialization of DANYELZA for neuroblastoma patients and potential indication expansion," said Thomas Gad, founder, President, and Interim CEO. "We also look forward to potentially dosing the first patient with GD2-SADA and generating data that we believe could potentially represent a transformative therapeutic option for patients based on the novel mechanism of action of our SADA constructs. We also expect to submit the IND for CD38-SADA targeting non-Hodgkin's lymphoma. We are excited for 2023 and aim at further de-risking our SADA platform while continuing to grow our top line revenue for DANYELZA in the U.S. and adding ex-U.S. sales as we are excited about the potential launch in China after SciClone Pharmaceuticals received an approval late last year. Additionally, we anticipate a Type A meeting with the FDA in January 2023 to discuss the future of omburtamab."

Mr. Gad continued, "We expect the reduction in our workforce and our revised business plan to result in a reduction in operating expenses and extension of our cash runway into Q1 2026. I want to extend my sincere appreciation and gratitude to all of our colleagues for the work that has brought us to this point, and for their dedication and service to Y-mAbs while striving to develop new treatments for patients with cancer."

Strategic Objectives for 2023 and Beyond

- Aiming to drive growth for our commercial drug, DANYELZA in the US through market growth and potential label expansion to target an estimated US market opportunity of $400 million for high-risk neuroblastoma and osteosarcoma alone
- Seeking initial validation of the tumor binding capability of our novel SADA platform in solid tumors in the GD2-SADA multicenter trial through the collection of imaging data in patients with small-cell lung cancer, sarcoma, and malignant melanoma
- Targeting an IND submission in Q2 2023 for CD38-SADA construct against non-Hodgkin's lymphoma to potentially validate SADA in blood cancers
- Seeking partnerships based on the SADA technology platform
- Discussing potential regulatory pathway for omburtamab at Type A meeting with the FDA

2023 Financial Outlook

- The restructuring plan announced today is expected to result in a reduction of Y-mAbs workforce by approximately 35% by the end of May 2023
- Operating expenses, including restructuring costs which are expected to be recognized in Q1 2023, are expected to decrease by approximately 28% to $115-120 million, compared to previously announced 2022 guidance for operating expenses of $162-167 million
- As a result of the estimated decrease in operating expenses, we estimate that our cash and cash equivalents should support our operations as currently planned, taking into account the restructuring plan, into the first quarter of 2026
- The total cash burn for the 2023 fiscal year is expected to be in the range of $50-55 million, which is based on an expected 2022 year-end cash position of approximately $106 million
- Estimated DANYELZA net product revenues for the 2023 fiscal year are expected to be between $60-65 million, compared to approximately $47-48 million expected for fiscal year 2022

Researchers at Memorial Sloan Kettering Cancer Center ("MSK") developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. MSK has institutional financial interests related to the compound and Y-mAbs.

Preliminary Financial Results

The preliminary financial results pertaining to expected cash and cash equivalents as of December 31, 2022 and DANYELZA net product revenues for fiscal year 2022 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, 2022, 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, 2022 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, 2022, 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.

About DANYELZA® (naxitamab-gqgk)

DANYELZA® (naxitamab-gqgk) is indicated, in combination with granulocyte-macrophage colony-stimulating factor ("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. This indication was approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefits in a confirmatory trial. DANYELZA® includes a Boxed Warning for serious infusion-related reactions, such as cardiac arrest and anaphylaxis, and neurotoxicity, such as severe neuropathic pain and transverse myelitis. See full Prescribing Information for complete Boxed Warning and other important safety information.

About Y-mAbs

Y-mAbs is a commercial-stage biopharmaceutical company focused on the development and commercialization of novel, antibody-based therapeutic cancer products. In addition to conventional antibodies, the Company's technologies include bispecific antibodies generated using the Y-BiClone platform and the SADA platform. The Company's broad and advanced product pipeline includes one FDA-approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one product candidate at the registration-stage, OMBLASTYS® (omburtamab), which targets tumors that express B7-H3.

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, including financial outlook for 2023, including estimated operating expenses, total cash burn and DANYELZA product revenue and sufficiency of cash resouces, in addition to expected revenues, operating expenses, and cash position for 2022, the restructuring, including the reduction in workforce and revised business plan, and the expected impacts, expenses and benefits thereof, including potential cost-savings from the reduction in force, expected reduction of operating expenses and any expectations with respect to cost savings to be derived therefrom; implied and express statements regarding the future of the Company's business; the Company's plans and strategies, development, commercialization and product distribution plans; expectations with respect to omburtamab, including the anticipated Type A meeting with the FDA; expectations with respect to our products and product candidates, including potential territory and label expansion of DANYELZA and the potential market opportunity related thereto and potential benefits thereof, and the potential of the SADA Technology, including the development of the first tumor binding dataset and potential benefits thereof and potential partnership relating thereto; expectations relating to key anticipated development milestones, including potential expansion of international commercialization efforts with respect to DANYELZA and the SADA Technology, including anticipated collection of data in in GD2-SADA multicenter trial against small-cell lung cancer, sarcoma, and malignant melanoma and anticipated IND relating to the CD38-SADA construct against non-hodgkin's lymphoma, and the timing thereof; expectations that DANYELZA and the SADA technology represent potential key near and long-term growth drivers; 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; including satisfaction of conditions to approvals; additional product candidates and technologies; collaborations or strategic partnerships and the potential benefits thereof; expectations related to the use of our cash and cash equivalents, and the need for, timing and amount of any future financing transaction; our financial performance, including our estimates regarding revenues, expenses, capital expenditure requirements, cash burn; and other statements that are not historical facts. 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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 risks that actual results of our restructuring plan and revised business plan will not be as expected; 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; our inability 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 the COVID-19 pandemic; risks associated with the conflict between Russia and Ukraine and sanctions related thereto; including inflation and uncertain global credit and capital markets; 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, 2021, our Quarterly Reports on Firm 10-Q for the quarters ending March 31, 2022, June 30, 2022 and September 30, 2022, 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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