**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): May 6, 2021**

**Y-MABS THERAPEUTICS, INC.**



**(Exact name of registrant as specified in its charter)**

|  |  |  |
| --- | --- | --- |
| **Delaware** | **001-38650** | **47-4619612** |
| **(State or other jurisdiction of** | **(Commission** | **(I.R.S. Employer** |
| **incorporation or organization)** | **File Number)** | **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 May 6, 2021, Y-mAbs Therapeutics, Inc., announced its financial results for the quarter ended March 31, 2021. A copy of the press release 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 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](#page4) | |  |  | [Press Release, dated May 6, 2021.](#page4) | |
|  |  |  |  |  |  |
| 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: May 6, 2021 | By: /s/ Thomas Gad | |
|  |  | Thomas Gad |
|  |  | Founder, Chairman, President and Head of Business Development & |
|  |  | Strategy |
|  |  |  |

**Exhibit 99.1**



**Y-mAbs Announces First Quarter Financial Results and Recent Corporate Developments**

New York, NY, May 6, 2021 (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 reported financial results for the first quarter of 2021.

“We are very pleased with our first quarter 2021 financial results, as we have been commercializing DANYELZA® (naxitamab-gqgk) throughout the U.S. since the beginning of February and we are very pleased with our progress to date. In addition, we successfully completed a follow-on offering with gross proceeds of approximately $115 million and netted another $62 million from closing the sale of our Priority Review Voucher, after sharing the total sales price of $105 million with MSK pursuant to the terms of our license agreement. With a cash balance of $252 million, we believe we are well positioned to advance our pipeline in the coming years,” stated Thomas Gad, founder, Chairman and President.

Dr. Claus Moller, Chief Executive Officer, continued, “We successfully submitted the European Marketing Authorization Application for omburtamab to the European Medicines Agency (“EMA”) in April. In parallel, we are making good progress in the clinic and have continued to advance the earlier stage programs in our pipeline, including GPA33-SADA, where we reported radioactivity uptake with a tumor to blood ratio of 122 in a mouse model. We are planning for the first SADA IND later this year and target an IND for GPA33-SADA in 2022.”

**Recent Corporate Developments**

* Subsequent to the end of the first quarter, on April 27, 2021, Y-mAbs announced the submission to EMA of a European Marketing Authorization Application for omburtamab for the treatment of pediatric patients with CNS/leptomeningeal metastasis from neuroblastoma.
* Also subsequent to the end of the first quarter, on April 20, 2021, Y-mAbs announced a regulatory update for resubmission of the BLA for omburtamab, reconfirming our aim to resubmit the BLA late in the second quarter or in the third quarter 2021.
* After the close of the first quarter, on April 12, 2021, Y-mAbs announced data from GPA33-SADA, which in a xenograft model of colorectal peritoneal carcinomatosis showed radioactivity uptake with a tumor to blood ratio of 122 measured 24 hours after injection. An IND for the GPA33-SADA is targeted for next year.
* On February 22, 2021, Y-mAbs announced the closing of a follow-on shelf public offering, including the full exercise of the underwriters’ overallotment option, resulting in gross proceeds to the Company of approximately $115.0 million.

**Financial Results**

Y-mAbs reported net income of $33.4 million, or $0.80 per basic share or $0.75 per diluted share, for the quarter ended March 31, 2021, compared to a net loss of $26.2 million, or ($0.66) per basic and diluted share, reported for the quarter ended March 31, 2020. The increased net income was caused by the DANYELZA revenues and the recording of the net proceeds from monetization of the DANYELZA Priority Review Voucher.





**Revenues**

Y-mAbs reported net revenues of $5.4 million for the quarter ended March 31, 2021 from the sales of DANYELZA. No revenues were reported for the quarter ended March 31, 2020.

**Operating Expenses**

*Research and Development*



Research and development expenses were $21.6 million for the three months ended March 31, 2021, compared to $18.6 million for the three months ended

March 31, 2020, an increase of $3.0 million. The increase in research and development expenses primarily reflects the following:

* $2.0 million increase in outsourced manufacturing;
* $2.5 million increase in personnel costs; and
* $0.8 million increase in clinical trials.

These increases were partially offset by a $3.1 million decrease in outsourced research and supplies.

*Selling, General, and Administration*

Selling, general, and administrative expenses were $12.0 million for the three months ended March 31, 2021, compared to $8.1 million for the three months ended March 31, 2020, an increase of $3.9 million. The increase in selling general and administrative expenses primarily reflects the following:

* $3.3 million increase in personnel costs.

**Cash and Cash Equivalents**

The Company had approximately $252.3 million in cash and cash equivalents as of March 31, 2021.

**Webcast and Conference Call**

The Company will host a conference call on Friday, May 7, 2021 at 9 a.m. Eastern Time. To participate in the call, please dial 877-407-0792 (domestic) or 201-689-8263 (international) and reference the access code 13718796. A webcast will be available at: http://public.viavid.com/index.php?id=144412

**About Y-mAbs**

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 has a broad and advanced product pipeline, including one FDA approved product, DANYELZA® (naxitamab-gqgk), which targets tumors that express GD2, and one pivotal-stage product candidate, 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 and development, commercialization and product distribution plans; 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; rate and degree of market acceptance and clinical utility as well as pricing and reimbursement levels; retaining and hiring key employees; our commercialization, marketing and manufacturing capabilities and strategy; our intellectual property position and strategy; 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; developments relating to our competitors and our industry; 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; 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 pandemic caused by the novel coronavirus known as COVID-19 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 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.





“DANYELZA” and “Y-mAbs” are registered trademarks of Y-mAbs Therapeutics, Inc.

**Contact:**

Y-mAbs Therapeutics, Inc.

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New York, NY 10169

USA

+1 646 885 8505

E-mail: info@ymabs.com



ASSETS

CURRENT ASSETS

Cash and cash equivalents

Accounts receivable, net

Inventories

Other current assets

Total current assets

Property and equipment, net

Operating lease right-of-use assets

Other assets

TOTAL ASSETS

LIABILITIES AND STOCKHOLDERS’ EQUITY

**Y-MABS THERAPEUTICS, INC.**



**Consolidated Balance Sheets**

**(unaudited)**

(in thousands, except share data)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | March 31, | |  |  | December 31, |
|  |  | 2021 |  |  |  | 2020 |
| $ | | 252,271 | | $ | | 114,634 |
|  |  | 5,997 | |  |  | — |
|  |  | 1,005 | |  |  | — |
|  |  | 4,736 | |  |  | 7,729 |
|  |  | 264,009 |  |  |  | 122,363 |
|  |  | 2,095 | |  |  | 1,825 |
|  |  | 3,979 | |  |  | 4,569 |
|  |  | 4,833 | |  |  | 3,290 |
|  | $ | 274,916 |  |  | $ | 132,047 |
|  |  |  |  |  |  |  |



|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| LIABILITIES |  |  |  |  |  |  |  |  |
| Accounts payable | $ | | 6,543 | | $ | | 9,372 | |
| Accrued liabilities |  |  | 8,486 | |  |  | 8,197 | |
| Operating lease liabilities, current portion |  |  | 1,971 | |  |  | 1,966 | |
| Total current liabilities |  |  | 17,000 |  |  |  | 19,535 |  |
| Accrued milestone and royalty payments |  |  | 2,250 | |  |  | 2,695 | |
| Operating lease liabilities, long-term portion |  |  | 1,515 | |  |  | 2,013 | |
| Other liabilities |  |  | 1,934 | |  |  | 1,968 | |
| TOTAL LIABILITIES |  |  | 22,699 |  |  |  | 26,211 |  |
|  |  |  |  |  |  |  |  |  |
| STOCKHOLDERS’ EQUITY |  |  |  |  |  |  |  |  |
| Preferred stock, $0.0001 par value, 5,500,000 shares authorized at March 31, 2021 and December 31, 2020; |  |  |  |  |  |  |  |  |
| none issued at March 31, 2021 and December 31, 2020 |  |  | — | |  |  | — | |
| Common stock, $0.0001 par value, 100,000,000 shares authorized at March 31, 2021 and December 31, 2020; |  |  |  |  |  |  |  |  |
| 43,548,419 and 40,688,447 shares issued at March 31, 2021 and December 31, 2020, respectively |  |  | 4 | |  |  | 4 | |
| Additional paid in capital |  |  | 504,091 | |  |  | 391,558 | |
| Accumulated other comprehensive income / (loss) |  |  | (91) | |  |  | (526) | |
| Accumulated deficit |  |  | (251,787) | |  |  | (285,200) | |
| TOTAL STOCKHOLDERS’ EQUITY |  |  | 252,217 |  |  |  | 105,836 |  |
|  |  |  |  |  |  |  |  |  |
| TOTAL LIABILITIES AND STOCKHOLDERS’ EQUITY | $ | | 274,916 | | $ | | 132,047 | |
|  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |



**Y-MABS THERAPEUTICS, INC.**

**Consolidated Statements of Net Income/(Loss) and Comprehensive Income/(Loss)**

**(unaudited)**

(In thousands, except share and per share data)

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Three months ended March 31, | | | | | |
|  |  |  | 2021 |  |  |  | 2020 |  |
| REVENUE |  |  |  |  |  |  |  |  |
| Product revenue, net | $ | | 5,383 | | $ | | — | |
| OPERATING COSTS AND EXPENSES |  |  |  |  |  |  |  |  |
| Cost of goods sold |  |  | 93 | |  |  | — | |
| Research and development |  |  | 21,579 | |  |  | 18,622 | |
| Selling, general, and administrative |  |  | 11,970 | |  |  | 8,125 | |
| Total operating costs and expenses |  |  | 33,642 |  |  |  | 26,747 |  |
| Loss from operations |  |  | (28,259 | ) |  |  | (26,747 | ) |
|  |  |  |  |  |  |  |  |  |

OTHER INCOME



Gain from sale of priority review voucher

Interest and other income, net

NET INCOME / (LOSS)



|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  | 62,010 | |  |  | — | |  |
|  |  | (338) | |  |  | 568 | ) |  |
|  | $ | 33,413 |  |  | $ | (26,179 |  |
|  |  |  |  |  |  |  |  |  |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Other comprehensive income |  |  |  |  |  |  |  |  |  |  |
| Foreign currency translation |  |  | 435 | |  |  | 25 | |  |  |
| COMPREHENSIVE INCOME / (LOSS) |  | $ | 33,848 |  |  | $ | (26,154 | ) | |  |
|  |  |  |  |  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |  |  |  |  |
| Net income/(loss) per share attributable to common stockholders, basic | $ | | 0.80 | | $ | | (0.66) | | |  |
| Weighted average common shares outstanding, basic |  |  |  |  |  |  |  |  |  |  |
|  |  | 41,870,759 |  |  | 39,753,583 |  |  |
| Net income/(loss) per share attributable to common stockholders, diluted |  | $ | 0.75 |  |  | $ | (0.66 | ) | |  |
| Weighted average common shares outstanding, diluted |  |  |  |  |  |  |  |  |  |  |
|  |  | 44,383,791 |  |  | 39,753,583 |  |  |
|  |  |  |  |  |  |  |  |  |  |  |

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