**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): December 28, 2020 (December 24, 2020)**

**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 1.01. Entry Into Material Agreement**

On December 24, 2020, Y-mAbs Therapeutics, Inc., (the “Company”) entered into a definitive agreement (the “Agreement”) to sell its Priority Review Voucher (“PRV”) to United Therapeutics Corporation (Nasdaq: UTHR), based on an agreed valuation of $105 million. The transaction remains subject to customary closing conditions, including anti-trust review. A copy of the Company’s press release announcing the Agreement is attached hereto as Exhibit 99.1.

The information furnished pursuant to Item 1.01 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.

The foregoing summary of the Agreement is qualified in its entirety by the full text of the Agreement, a copy of which will be filed as an exhibit, with certain portions subject to confidential treatment, to the Company's Annual Report on Form 10-K for the year ended December 31, 2020, and incorporated herein by reference.

**Item 9.01. Financial Statements and Exhibits.**

|  |  |  |
| --- | --- | --- |
|  |  | (d) Exhibits |
| **Exhibit No.** | **Description** |
| [99.1](#page4) |  | [Press Release, dated December 28, 2020 issued by Y-mAbs Therapeutics, Inc.](#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: December 28, 2020 | By: /s/ Thomas Gad |
|  |  | Thomas Gad |
|  |  | Founder, Chairman, President and Head of Business Development & |
|  |  | Strategy |
|  |  |  |

**Exhibit 99.1**



**Y-mAbs Announces Sale of Priority Review Voucher**

New York, NY, December 28, 2020 (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 that it has entered into a definitive agreement to sell its Priority Review Voucher (“PRV”) to United Therapeutics Corporation (Nasdaq: UTHR), based on an agreed valuation of $105 million.

The PRV was granted in conjunction with the approval by the U.S. Food and Drug Administration (“FDA”) of DANYELZA®, for the treatment of refractory/relapsed high-risk neuroblastoma.

Under the terms of the Company’s license agreement with Memorial Sloan Kettering Cancer Center (“MSK”), Y-mAbs is entitled to retain 60% of the net proceeds from monetization of the PRV, and the remaining 40% will be paid to MSK. The transaction remains subject to customary closing conditions, including anti-trust review.

“We are pleased to announce the sale of the PRV, which will provide an important source of non-dilutive capital to fund additional investment in our pipeline. These efforts will be critical to our growth over the coming year, and we are committed to our mission of becoming a world leader in developing better and safer antibody-based oncology products addressing unmet pediatric and adult medical needs,” said Thomas Gad, founder, Chairman and President.

Jefferies LLC acted as exclusive financial advisor to Y-mAbs on this transaction.

Researchers at MSK developed DANYELZA, which is exclusively licensed by MSK to Y-mAbs. As a result of this licensing arrangement, MSK has institutional financial interests related to the compound and Y-mAbs.

**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 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: the risk that we may not close the transaction for the sale of our PRV voucher and would not have the additional funds provided by such sale to reinvest into our research and development programs; 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:**

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