**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**

**March 9, 2021**
Date of Report (Date of earliest event reported)

# MARKER THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

| **Delaware** | **001-37939** | **45-4497941** |
|---|---|---|
| (State or other jurisdiction of incorporation) | (Commission File Number) | (IRS Employer Identification No.) |

| **3200 Southwest Freeway**<br>**Suite 2500**<br>**Houston, Texas** | **77027** |
|---|---|
| (Address of principal executive offices) | (Zip Code) |

**(713) 400-6400**
Registrant's telephone number, including area code

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

Check the appropriate box below if the Form 8-K 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(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.001 per share | MRKR | The Nasdaq Stock Market LLC |

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 March 9, 2021, Marker Therapeutics, Inc. (the "Company") reported financial results for the fiscal year ended December 31, 2020 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

The information in this Item 2.02 of this Current Report on 8-K (including Exhibit 99.1) is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

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

(d) Exhibits.

| Exhibit No. | Description |
|---|---|
| 99.1 | Press release issued on March 9, 2021 |
| 104 | Inline XBRL for the cover page of this Current Report on Form 8-K |

**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.

**Marker Therapeutics, Inc.**

Dated: March 9, 2021

By: /s/ Anthony Kim
Anthony Kim
*Chief Financial Officer*

**Exhibit 99.1**

**Marker Therapeutics Reports Fiscal Year 2020 Operating and Financial Results**

- *Dosed first patient in the Company's Phase 2 trial of MT-401, its lead MultiTAA-specific T cell product candidate, for the treatment of post-transplant acute myeloid leukemia –*

- *Completed construction of new in-house cGMP manufacturing facility in Houston to supply MultiTAA-specific T cell products, including MT-401, for clinical activities and potential commercialization; facility expected to be fully operational in 1H 2021 -*

**Houston, TX—March 9, 2021—**Marker Therapeutics, Inc. (Nasdaq:MRKR), a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications, today provided a corporate update and reported financial results for the fiscal year ended December 31, 2020.

“We are proud of our Company’s continued progress, which has positioned us for a busy and productive year ahead,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “Recently, we dosed the first patient in the safety lead-in portion of our Phase 2 trial in post-transplant acute myeloid leukemia (AML). In the fourth quarter, we completed construction of a new in-house cGMP manufacturing facility in Houston, which we anticipate will be fully operational in the first half of this year. We also continue to optimize the MT-401 cell therapy manufacturing process, which we believe could result in an increase in the number of T cells available for patient administration, superior T cell phenotype and antigen specificity, and the potential for improved patient outcomes.”

**RECENT PROGRAM UPDATES**

**MT-401: Multi-Antigen Targeted (MultiTAA)-Specific T Cell Product Candidate for AML**

**Phase 2 AML Trial**

- In March 2021, Marker dosed the first patient in the safety lead-in portion of its Phase 2 trial in AML. The safety lead-in is expected to enroll a total of six patients: three of which will be treated with MT-401 manufactured with a legacy reagent, and the remaining three to be treated with study drug manufactured with a new reagent from an alternate supplier.

- To date, Marker has activated seven clinical sites and is in the start-up phase with additional clinical sites to enroll patients for the safety lead-in portion of the AML trial. The Company has also received commitments from additional clinical sites to participate in the Phase 2 AML trial following the safety lead-in phase and anticipates activating a total of approximately 20 sites.

**Manufacturing and Process Improvements**

- Marker continues to streamline and simplify the MT-401 manufacturing process. The technical improvements include a 50% reduction in manufacturing time, a 90%+ reduction in the number of required operator interventions, and significant improvement in the consistency and reproducibility of the manufacturing process, while yielding a significant increase in the number of T cells available for patient administration. The Company believes the new process could yield a measurably improved product, with superior T cell phenotype and antigen specificity as compared to the original process. The new process improvements have been updated in the CMC section of the IND and will be used for all patients in the Marker AML Phase 2 clinical trial.

**BUSINESS UPDATES**

- The Company completed the construction and qualification of its cGMP manufacturing facility in Houston, TX, located near the George Bush Intercontinental Airport. The facility will allow production of MultiTAA-specific T cell products according to U.S. FDA guidelines and is designed to be scalable using modular processes. The facility will be used to support the manufacture of study drug for Marker's Phase 2 AML trial (MT-401) and for future hematological and solid tumor trials, in addition to the potential commercialization of any approved products. The Company has initiated the technology transfer process and expects the facility to be fully operational in the first half of 2021.

**FISCAL YEAR 2020 FINANCIAL RESULTS**

**Cash Position and Guidance:** At December 31, 2020, Marker had cash and cash equivalents of $21.4 million. The Company raised $6.2 million through the previously executed $30 million common stock purchase agreement with Aspire Capital Fund, LLC. The remaining $23.8 million available to Marker from Aspire Capital, along with current cash available, funds operations into Q1 2022.

**R&D Expenses:** Research and development expenses were $18.9 million for the year ended December 31, 2020, compared to $12.8 million for the year ended December 31, 2019.

**G&A Expenses:** General and administrative expenses were $10.5 million for the year ended December 31, 2020, compared to $10.0 million for the year ended December 31, 2019.

**Net Loss:** Marker reported a net loss of $28.7 million for the year ended December 31, 2020, compared to a net loss of $21.4 million for the year ended December 31, 2019.

**About Marker Therapeutics, Inc.**

Marker Therapeutics, Inc. is a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. Marker's cell therapy technology is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens (i.e. tumor targets) and kill tumor cells expressing those targets. This population of T cells is designed to attack multiple tumor targets following infusion into patients and to activate the patient's immune system to produce broad spectrum anti-tumor activity. Because Marker does not genetically engineer its T cell therapies, we believe that our product candidates will be easier and less expensive to manufacture, with reduced toxicities, compared to current engineered CAR-T and TCR-based approaches, and may provide patients with meaningful clinical benefit. As a result, Marker believes its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

To receive future press releases via email, please visit: https://www.markertherapeutics.com/email-alerts.

**Forward-Looking Statement Disclaimer**

This release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Statements in this news release concerning the Company's expectations, plans, business outlook or future performance, and any other statements concerning assumptions made or expectations as to any future events, conditions, performance or other matters, are "forward-looking statements." Forward-looking statements include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our research, development and regulatory activities and expectations relating to our non-engineered multi-tumor antigen specific T cell therapies; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the timing, conduct and success of our clinical trials, including the Phase 2 trial of MT-401, as well as clinical trials conducted by our collaborators; the timing and success of the technology transfer process related to our planned manufacturing facility and the receipt of regulatory approval for the related cGMP; our manufacturing processes and our ability to use our current and planned manufacturing facilities to support clinical and commercial demand. Forward-looking statements are by their nature subject to risks, uncertainties and other factors which could cause actual results to differ materially from those stated in such statements. Such risks, uncertainties and factors include, but are not limited to the risks set forth in the Company's most recent Form 10-K, 10-Q and other SEC filings which are available through EDGAR at www.sec.gov. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its impact on our business and the global economy. The Company assumes no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

**Consolidated Balance Sheets**

| | December 31, 2020 | December 31, 2019 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 21,352,382 | $ 43,903,949 |
| Prepaid expenses and deposits | 2,057,924 | 1,526,442 |
| Interest receivable | 559 | 56,189 |
| Other receivable | 1,000,000 | - |
| Total current assets | 24,410,865 | 45,486,580 |
| Non-current assets: | | |
| Property, plant and equipment, net | 3,570,736 | 417,528 |
| Construction in progress | 6,789,098 | - |
| Right-of-use assets, net | 10,844,116 | 455,174 |
| Total non-current assets | 21,203,950 | 872,702 |
| | | |
| **Total assets** | **$ 45,614,815** | **$ 46,359,282** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 6,013,010 | $ 1,757,680 |
| Lease liability | 388,792 | 204,132 |
| Warrant liability | - | 31,000 |
| Total current liabilities | 6,401,802 | 1,992,812 |
| Non-current liabilities: | | |
| Lease liability, net of current portion | 11,868,440 | 280,247 |
| Total non-current liabilities | 11,868,440 | 280,247 |
| | | |
| Total liabilities | 18,270,242 | 2,273,059 |
| | | |
| Commitments and contingencies | - | - |
| | | |
| Stockholders' equity: | | |
| Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at December 31, 2020 and 2019, respectively | - | - |
| Common stock, $0.001 par value, 150 million shares authorized, 50.7 million and 45.7 million shares issued and outstanding as of December 31, 2020 and 2019, respectively | 50,731 | 45,728 |
| Additional paid-in capital | 383,533,326 | 371,573,909 |
| Accumulated deficit | (356,239,484) | (327,533,414) |
| Total stockholders' equity | 27,344,573 | 44,086,223 |
| | | |
| **Total liabilities and stockholders' equity** | **$ 45,614,815** | **$ 46,359,282** |

**Marker Therapeutics, Inc.**
**Consolidated Statements of Operations**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Revenues:** | | |
| Grant income | $ 466,785 | $ 213,194 |
| Total revenues | 466,785 | 213,194 |
| **Operating expenses:** | | |
| Research and development | 18,880,751 | 12,764,804 |
| General and administrative | 10,471,846 | 9,977,196 |
| Total operating expenses | 29,352,597 | 22,742,000 |
| Loss from operations | (28,885,812) | (22,528,806) |
| **Other income (expense):** | | |
| Change in fair value of warrant liabilities | 31,000 | 18,000 |
| Interest income | 148,742 | 1,082,842 |
| **Net loss** | **$ (28,706,070)** | **$ (21,427,964)** |
| | | |
| Net loss per share, basic and diluted | $ (0.61) | $ (0.47) |
| Weighted average number of common shares outstanding | 47,039,862 | 45,587,734 |

**Marker Therapeutics, Inc.**
**Consolidated Statements of Cash Flows**

| | For the Years Ended December 31, | |
|---|---|---|
| | **2020** | **2019** |
| **Cash Flows from Operating Activities:** | | |
| **Net loss** | $ (28,706,070) | $ (21,427,964) |
| **Reconciliation of net loss to net cash used in operating activities:** | | |
| Depreciation and amortization | 485,641 | 105,123 |
| Changes in fair value of warrant liabilities | (31,000) | (18,000) |
| Stock-based compensation | 5,228,409 | 5,356,972 |
| Amortization on right-of-use assets | 590,039 | 181,459 |
| **Changes in operating assets and liabilities:** | | |
| Prepaid expenses and deposits | (531,482) | (1,384,725) |
| Interest receivable | 55,630 | 51,988 |
| Accounts payable and accrued expenses | 4,222,470 | (963,967) |
| Lease liability | (173,268) | (185,179) |
| Net cash used in operating activities | (18,859,631) | (18,284,293) |
| **Cash Flows from Investing Activities:** | | |
| Purchase of property and equipment | (3,638,849) | (374,983) |
| Purchase of construction in progress | (6,789,098) | - |
| Net cash used in investing activities | (10,427,947) | (374,983) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuance of common stock | 6,186,011 | - |
| Proceeds from exercise of stock options | - | 57,744 |
| Proceeds from exercise of warrants | 550,000 | 758,733 |
| Net cash provided by financing activities | 6,736,011 | 816,477 |
| Net decrease in cash | (22,551,567) | (17,842,799) |
| | | |
| Cash and cash equivalents at beginning of the period | 43,903,949 | 61,746,748 |
| **Cash and cash equivalents at end of the period** | $ 21,352,382 | $ 43,903,949 |

**Contacts**

**Investors**
Solebury Trout
Brian Korb
(646) 378-2923
bkorb@soleburytrout.com

**Media**
Solebury Trout
Amy Bonanno
(914) 450-0349
abonanno@soleburytrout.com

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