**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**

**February 16, 2022**
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 8.01 Other Events.**

On February 16, 2022, Marker Therapeutics, Inc. (the "***Company***") issued a press release announcing updates regarding the Company's clinical program and pipeline expansion. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

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

(d) Exhibits.

| **Exhibit No.** | **Description** |
|---|---|
| 99.1 | Press release, dated February 16, 2022 |

**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: February 16, 2022

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

**Exhibit 99.1**

**Marker Therapeutics Announces Clinical Program Updates and Pipeline Expansion**

*Results from safety lead-in stage of Marker's Phase 2 AML trial demonstrate that MT-401 was well-tolerated, eliminated measurable residual disease (MRD) in one MRD+ patient and induced epitope spreading*

*New T cell manufacturing process for MT-401 and other product candidates designed to improve potency, increase antigen specificity and diversity and significantly reduce manufacturing time*

*Company announces clinical updates, including plans to file additional INDs by year end, with clinical trials in solid tumors and blood cancers to be initiated in 2023*

*Company to host conference call and webcast at 5:00 p.m. EST today*

**Houston, TX—February 16, 2022—**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 announced an update on the Company's clinical programs, manufacturing processes and pipeline.

"We are excited to announce an improved T cell manufacturing process, expansion of our pipeline into solid tumor and off-the-shelf cell therapies, and encouraging results from the six-patient safety lead-in stage of our Phase 2 AML trial, where one MRD positive patient converted to MRD negative following treatment with MT-401, Marker's lead MultiTAA-specific T cell product candidate," said Peter L. Hoang, Marker's President and Chief Executive Officer. "Our new T cell manufacturing process, which will be implemented in AML and additional planned trials, is designed to produce a much more potent product with increased antigen specificity and diversity and further reduces manufacturing time to just nine days."

Mr. Hoang continued: "Further, we are pleased to announce a planned expansion of our pipeline into pancreatic cancer, our first Company-sponsored trial evaluating MultiTAA cell therapy for the treatment of solid tumors, and a Company-sponsored Phase 1 trial in lymphoma. We are also excited to expand our AML trial with MT-401-OTS, a scalable, off-the-shelf product candidate with the potential to match patients to treatment in under three days. Looking ahead, we plan to develop additional off-the-shelf product candidates in other hematological malignancies and solid tumors, with the goal of significantly improving access to promising cell therapies."

Safety Lead-in Results from Phase 2 AML Trial

The results of the safety lead-in stage of the Marker Phase 2 AML trial support the potential for MT-401 as a treatment option for patients with AML in the post-transplant setting. The purpose of the safety lead-in was to test the safety for patients using a new reagent in the manufacturing process. Three patients were treated with MT-401 using the legacy reagent and three additional patients were treated with MT 401 using the new reagent. The safety lead-in enrolled five patients with active disease: one MRD positive patient and five frank relapse patients.

The initial results from the safety lead-in are as follows:

- No dose limiting toxicities, cytokine release syndrome or neurotoxicity were observed. The results were consistent with the safety data observed in more than 150 patients treated in the Phase 1/2 studies at the Baylor College of Medicine.
- 1 MRD+ patient became MRD- after infusion with MT-401
- No objective responses from the frank relapse patients
- Immuno-monitoring data indicates the evidence of epitope spreading after infusion of MT-401 in the patient who converted from MRD+ to MRD-

The safety lead-in satisfied safety requirements with the FDA and the main Phase 2 stage of the AML trial began enrolling in July 2021.

MultiTAA-Specific T Cell Therapy Manufacturing

The Company developed and is implementing a new nine-day MultiTAA-specific T cell manufacturing process for its current Company-sponsored Phase 2 AML trial as well as future clinical trials using a patient-specific manufacturing approach. The new manufacturing process marks additional manufacturing improvements compared to the processes used in the Baylor College of Medicine Phase 1/2 trials (36-day manufacturing time) and the current AML trial (20-day manufacturing time). The new nine-day manufacturing process enables increased antigen specificity and diversity, which has exhibited a strong linear correlation to anti-tumor activity *in vitro*. The new process produces a patient product that is four times more potent, with the potential to greatly improve tumor killing.

Pipeline Expansion

The Company plans to initiate additional Marker-sponsored clinical trials across other indications. The Company has initiated activities to support the advancement of the pipeline but beginning any additional clinical trial is subject to the receipt of additional funding:

- Patient-specific product candidates
    - MT-601, a six-antigen product, for the treatment of pancreatic cancer and lymphoma
    - The Company intends to file Investigational New Drug applications (INDs) for MT-601 in pancreatic cancer and lymphoma in 2022 and expects to initiate these trials in 2023

- Off-the-shelf (OTS) product candidates
    - Patients will be dosed using “banked” products based on human leukocyte antigen (HLA) matching
    - The OTS platform is designed to eliminate manufacturing wait time and patient product can be shipped to patients immediately
    - High scalability where one donor has the potential to provide more than 100 patient products
    - An OTS program in AML is already approved under the Company’s current Phase 2 AML IND. The Company is currently in the process of developing its patient cell bank inventory and expects to dose the first patient in 2023.
    - The Company expects to expand OTS clinical trials in other hematological malignancies and solid tumors
- Preclinical / development activities
    - Analyzing potential of a 12-antigen product
    - Assessing potential of combination therapies for MT-401 and MT-601

**Webcast and Conference Call**

Marker will host a conference call and webcast at 5:00 p.m. EST today to discuss the clinical program updates. The webcast will be accessible in the Investors section of the Company's website at www.markertherapeutics.com. Individuals can participate in the conference call by dialing 877-869-3847 (domestic) or 201-689-8261 (international) and referring to the "Marker Therapeutics Clinical Program Update Call." The archived webcast will be available for replay on the Marker website following the event.

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**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 Statements**

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 and our preclinical pipeline; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the potential commercialization of our current and future product candidates; our manufacturing processes and the efficiencies and cost thereof; our ability to use our cGMP manufacturing facility to support clinical and commercial demand; and our ability to secure additional funding on favorable terms. 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.

**Investors and Media Contacts**

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