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

September 13, 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 **Suite 2500** **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 7.01 Regulation FD Disclosure.

On September 13, 2022, Marker Therapeutics, Inc. (the "***Company***") issued a press release to announce that the U.S. Food and Drug Administration (the "***FDA***") has awarded the Company a $2.0 million grant from the FDA's Orphan Products Grant program to support the Company's Phase 2 clinical trial of MT-401 for the treatment of post-transplant AML. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibit 99.1) is being furnished and 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 in any filing under the Securities Act of 1933, as amended, 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 Number	Exhibit Description
99.1	Press Release, dated September 13, 2022.
104	The cover page from Marker Therapeutics, Inc.'s Form 8-K filed on September 13, 2022, formatted in Inline XBRL.

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: September 13, 2022

By: /s/ Peter Hoang
Peter Hoang
President and Chief Executive Officer

Exhibit 99.1

Marker Therapeutics Awarded $2 Million Grant from U.S. FDA to Support Marker's Phase 2 ARTEMIS Trial of MT-401 in Post-Transplant AML

Award to fund clinical study of Marker's multi-antigen targeted T cell therapy for the treatment of post-transplant AML patients with minimal residual disease

Houston, TX—September 13, 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 that the Company has been awarded a $2 million grant from the U.S. Food and Drug Administration (FDA) Orphan Products Grants program to support its Phase 2 ARTEMIS trial of its lead multi-tumor-associated antigen (MultiTAA) T cell product candidate, MT-401, in patients with post-transplant acute myeloid leukemia (AML).

The FDA grant will support the Company's treatment arm evaluating MT-401 in patients with post-transplant AML with minimal residual disease. MT-401 was granted Orphan Drug Designation for the treatment of patients with AML following allogeneic stem cell transplant in 2020.

"We are pleased to receive this Orphan Products award from the FDA to further clinical development of our multi-antigen targeted T cell therapy in AML, a rare disease with limited treatment options after a stem cell transplant," said Dr. Mythili Koneru, Marker's Chief Medical Officer. "In our Phase II ARTEMIS study for patients with post-transplant AML, we have observed promising results amongst the MRD^{+} patients, suggesting that MT-401's unique and differentiated targeting technology can potentially reach MRD positive patients before relapse. This grant will enable us to further advance our development of MT-401 to potentially treat a patient population where no treatments have been approved. We look forward to further exploration in this patient population."

About Marker's Phase 2 ARTEMIS Trial

The multicenter Phase 2 AML study is evaluating the clinical efficacy of MT-401 in patients with AML following an allogeneic stem-cell transplant in both the adjuvant and active disease setting. In the adjuvant setting, approximately 120 patients will be randomized 1:1 to either MT-401 at 90 days post-transplant versus standard-of-care observation, while approximately 40 patients with active disease will receive MT-401 as part of the single-arm group.

The primary objectives of the trial are to evaluate relapse-free survival in the adjuvant group and determine the complete remission rate and duration of complete remission in active disease patients. Additional objectives include, for the adjuvant group, overall survival and graft-versus-host disease relapse-free survival while additional objectives for the active disease group include overall response rate, duration of response, progression-free survival and overall survival.

About the U.S. FDA Orphan Products Grants Program

The FDA's Orphan Products Grants Program awards grants to clinical investigators to support the development of safe and effective medical products for patients with rare diseases. The program has supported clinical research since 1983 and has funded clinical trials that have facilitated the approval of more than 70 products.

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; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct and success of our clinical trials, including the Phase 2 trial of MT-401. 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.

Contact:

Neda Safarzadeh
Vice President/Head of Investor Relations, PR & Marketing
Marker Therapeutics

(713) 400-6451
investor.relations@markertherapeutics.com

##