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

June 26, 2023
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.)

9350 Kirby Drive, Suite 300 **Houston, Texas**	**77054**
(Address of principal executive offices)	(Zip Code)

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

4551 Kennedy Commerce Dr.
Houston, Texas 77032
(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 June 26, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release reporting non-clinical data on the Company's lead multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401 in acute myeloid leukemia ("***AML***") cells after treatment with hypomethylating agents. The Company also announced that it was awarded a $2 million grant from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program to support the development of MT-401 for the treatment of patients with AML after hematopoietic stem cell transplant. 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 No.	**Description**
99.1	Press release, dated June 26, 2023
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: June 26, 2023

By: /s/ Juan Vera
Juan Vera
President and Chief Executive Officer

Exhibit 99.1

Marker Therapeutics Reports MT-401 Non-Clinical Data in AML Cells after Hypomethylating Agent Administration

Marker Therapeutics Awarded $2 Million Grant from NIH in Support of the Development of MT-401 for the Treatment of AML Patients

Houston, TX – June 26, 2023 – Marker Therapeutics, Inc. (Nasdaq: MRKR) (Marker or the Company), a clinical-stage immuno-oncology company focusing on developing next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications, today reports non-clinical data on its lead multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401, which showed increased anti-tumor activity against an acute myeloid leukemia (AML) cell line after treatment with hypomethylating agents (HMA). Marker further announces that the Company has been awarded a $2 million grant from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program to support the development of MT-401 for the treatment of patients with AML after hematopoietic stem cell transplant (HSCT).

The multiTAA-specific T cell technology from Marker uses a novel non-genetically modified T cell therapy approach that recognizes multiple antigens expressed on tumor cells, thereby designed to minimize tumor escape. MT-401 was designed to specifically target four different antigens (Survivin, PRAME, WT-1 and NY-ESO-1), which are upregulated in AML but have limited expression on normal cells.

In March 2023, Marker reported clinical updates from the Company sponsored ARTEMIS clinical trial (clinicaltrials.gov identifier: NCT04511130) highlighting the potential benefit of MT-401 in patients with AML who have measurable residual disease (MRD+) after HSCT. Given the promising responses in patients who are MRD+, Marker has been investigating clinical opportunities to further improve AML patient outcomes.

One such opportunity is to combine multiTAA-specific T cell therapy with agents that make cancer cells more visible to cancer killing cells. This opportunity has practical merit because HMAs that do this, such as 5’-Azacytidine and Decitabine, are commonly used as therapies for AML. It also has scientific merit because these agents inhibit DNA methylation, a process which regulates gene expression. By reducing DNA methylation, HMAs can restore physiological gene expression patterns, including the upregulation of tumor suppressor genes, and the inhibition of oncogenes. HMAs have also been found to upregulate the expression of tumor antigens, including MT-401-specific tumor antigens, previously silenced by DNA methylation (Wong et al, Front Oncol, 2021).

Due to this mechanism of action, Laura S. Angelo, Ph.D., and her team at Marker investigated in a set of *in vitro* experiments, the capacity of MT-401 to inhibit or kill THP-1 cells, an aggressive treatment-resistant AML cell line, after the cells were exposed to HMA. The results of this non-clinical study have been posted on the Investor Relations section of the Marker website, and highlights are briefly summarized below:

- In this *in vitro* model of treatment resistant AML, tumor cells exposed to HMA for 72 hours upregulated tumor-associated antigen targets of MT-401, including Survivin.
- The THP-1 cell line was bioluminescent modified to allow real-time long-term assessment of cancer cell growth.
- THP-1 cells continued to grow both in the absence and presence of DMSO, the vehicle used to dissolve 5'-Azacytidine.
- The growth of THP-1 cells was reduced in the presence of 5'-Azacytidine (after exposure to the drug for 72 hours).
- The growth of THP-1 cells was also reduced in the presence of MT-401 (manufactured from donors that were partially HLA-matched to THP-1 cells).
- THP-1 cell growth, however, was significantly decreased when MT-401 was added after exposure to 5'-Azacytidine compared to MT-401 or 5'-Azacytidine administration alone, suggesting a synergistic effect between the two agents.
- These *in vitro* data demonstrate that administration of MT-401 following HMA infusion enhanced AML cell killing and could offer a new therapeutic option for AML patients post-HSCT.

"These non-clinical findings highlight that the potential for treatment of AML cells with HMA to upregulate expression of specific tumor antigens and increase tumor inhibition and killing. These benefits could therefore significantly enhance the potential clinical outcome of our multiTAA-specific T cell product," said Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. "In light of these encouraging results we are planning to incorporate these findings into our current AML clinical study to improve and empower our multiTAA-specific T cell outcomes. Details about the revised clinical study design will be announced in Q3 of 2023."

Based on this non-clinical data, Marker received a $2 million grant from the NIH. The awarded SBIR grant will support a nationwide multi-center Phase 2b clinical trial in AML patients following HSCT to evaluate the effect of MT-401 administered after pre-treatment with HMAs. This proposed Phase 2b study includes evaluation of efficacy and safety of MT-401, as well as immune monitoring of patient samples. AML is considered an orphan indication and in 2020, MT-401 was granted orphan designation by the U.S. Food and Drug Administration for treatment of patients with acute myeloid leukemia (orphan drug designation number DRU-2020-7363).

"We are pleased to receive the SBIR grant from the NIH to support our clinical Phase 2b study in AML patients, a rare disease with limited treatment options after a stem cell transplant," said Dr. Angelo, PI of the study.

"We previously observed promising results in our Phase 2 ARTEMIS trial for patients with AML who are MRD+ post-transplant, suggesting that MT-401 can effectively positively impact this patient population before relapse. The SBIR grant will greatly contribute to further advance our clinical trial and to investigate the benefit of HMA administration before MT-401 therapy in patients after HSCT, and for whom no treatments have been approved," concluded Dr. Vera.

About the NIH SBIR Program

The NIH Small Business Innovation Research (SBIR) Program sets aside more than $1.2 billion from its Research & Development Funding to specifically support early-stage small businesses throughout the United States. Many companies leverage the NIH SBIR funding to attract the partners and investors needed to take an innovation to market. The Small Business program focuses on a variety of high-impact technologies including research tools, diagnostics, digital health, drugs, and medical devices, and can provide the seed funding needed to bring scientific innovations from bench to bedside.

About multiTAA-specific T cells

The multi-tumor associated antigen (multiTAA)-specific T cell platform is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient's/donor’s blood capable of recognizing a broad range of tumor antigens. Clinical trials that enrolled more than 180 patients with various hematological malignancies and solid tumors showed that autologous and allogeneic multiTAA-specific T cell products were well tolerated, demonstrated durable clinical responses, and consistent epitope spreading. The latter is typically not observed with other T cell therapies and enables the potential contribution to a lasting anti-tumor effect. Unlike other cell therapies which require hospitalization and close monitoring, multiTAA-specific T cells are designed to be administered in an outpatient setting.

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. The cell therapy technology Marker has, 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 the T cells, 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 the Company's intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the Company's research, development and regulatory activities and expectations relating to the Company's 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 the Company's clinical trials of our its product candidates, including MT-401 for the treatment of patients with AML. 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. The Company assumes no obligation to update its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

Contacts

TIBEREND STRATEGIC ADVISORS, INC.

Investors
Daniel Kontoh-Boateng
(862) 213-1398
dboateng@tiberend.com

Media
Casey McDonald
(646) 577-8520
cmcdonald@tiberend.com