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

August 7, 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

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 August 7, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release announcing non-clinical data of its lead multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401, in an Off-the-Shelf ("***OTS***") setting and provided an update on clinical readiness for the OTS program. 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 August 7, 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: August 7, 2023

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

Exhibit 99.1

Marker Therapeutics Reports Non-Clinical Proof-of-Concept Data and Update on Clinical Readiness for the MT-401 Off-the-Shelf Program

Houston, TX – August 7, 2023 – Marker Therapeutics, Inc. (Nasdaq: MRKR), 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 announced non-clinical data of its lead multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401, in an Off-the-Shelf (OTS) setting and provided an update on clinical readiness for the OTS program.

Non-Clinical Proof-of-Concept Data of MT-401 OTS

In a set of *in vitro* experiments, the Research and Development team at Marker demonstrated anti-tumor activity of MT-401 OTS in a partially human leukocyte antigen (HLA) matched setting to kill THP-1 cells, an aggressive treatment-resistant Acute Myeloid Leukemia (AML) cell line.

The results of this non-clinical study have been posted on the Investor Relations section of the Marker website and are briefly summarized below:

- THP-1 cells were genetically modified to be bioluminescent, allowing long-term, undisturbed tracking of AML cell growth.
- THP-1 cell growth was followed for 5 days in the presence or absence of MT-401 OTS (manufactured from healthy donors matching 2/8 HLA alleles to THP-1 cells).
- Leukemic cell growth was significantly reduced when treated with MT-401 OTS.
- Meanwhile, untreated THP-1 cells continued to grow in the absence of treatment.
- Microscopic analysis confirmed the MT-401 OTS-induced killing of AML cells.
- MT-401 OTS demonstrated a significant anti-tumor effect *in vitro* with just 2/8 matched HLA alleles, suggesting that this low level of matching criteria may be useful for future OTS clinical studies.
- The low level of allele matching would open the door to an OTS AML killing cell bank that could be suitable for many patients.

“We recently developed this long-term *in vitro* model to monitor the interaction of cancer cells with multiTAA-specific T cells and to further investigate the tumor killing capacity of the MT-401 OTS product,” said Eric A. Smith, Ph.D., Director of Research and Development of Marker Therapeutics. “In collaboration with Alexandre Carisey, Ph.D., Assistant Professor Baylor College of Medicine, we used live cell confocal microscopy to visualize the potential of MT-401 OTS to eliminate tumor cells and confirm our previous observations. These non-clinical data highlight that MT-401 OTS has the potential to kill tumor cells in a partially HLA-matched setting and underscore the potential of MT-401 OTS as a treatment option in patients with relapsed/refractory (r/r) AML. In the post allogeneic hematopoietic stem cell transplant (HSCT) setting, MT-401 OTS could expedite the availability of treatment by eliminating the need to find the original transplant donor.”

Clinical Readiness of MT-401 OTS

The use of antigen-specific cells in a partially HLA-matched setting has been validated and extensively tested in the clinic by others (Leen et al., Blood, 2013; Tzannou et al, Blood Adv, 2019; Tzannou et al, J Clin Oncol, 2017). The favorable safety profile of these OTS products is achieved by enriching antigen-specific T cells and reducing alloreactive cells, thereby reducing the risk of graft-versus-host disease (GVHD).

The U.S. Food and Drug Administration (FDA) has cleared the clinical protocol to investigate MT-401 OTS as a treatment in patients with r/r AML. Marker has established a cellular inventory of 8 lines manufactured from healthy donors, with ongoing efforts to further expand the inventory. At full scale production, a single donor could provide treatment for approximately 40 patients, and the current stability program indicates that OTS multiTAA-specific T cell products are stable for more than a year in liquid nitrogen, permitting future on-demand availability for broad-scale implementation.

Marker anticipates that the first patient will be treated with MT-401 OTS during the first half of 2024.

“One of the biggest limitations to cell therapy is manufacturing of individualized products,” said Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “Our OTS multiTAA-specific T cell strategy would remove this limitation by manufacturing a cell bank inventory from healthy donors that were carefully selected to cover a large patient population. This strategy has been tested extensively in the clinic at Baylor College of Medicine in the context of virus-specific T cells (VST). Applying this strategy to tumor-specific T cells will enable Marker to manufacture at a large scale and characterize the multiTAA-specific T cell products ahead of time. This will not only expedite administration and significantly reduce manufacturing cost, but also drastically reduce the time between patient identification and treatment, to as little as 72 hours. This quick turnaround time would be beneficial for treating patients with rapid cancer progression, such as those with measurable residual disease in the AML setting, which typically advances rapidly into Frank Relapse with dismal outcomes.”

“Our OTS strategy is intended to address the commercial bottlenecks such as costs and time to treatment, imposed by the manufacture of individualized T cell products and the donor-to-donor variability of starting material. If MT-401 OTS is successful in clinical trials, we will consider expanding the OTS multiTAA-specific T cell program to other indications with unmet medical needs,” concluded Dr. Vera.

About Acute Myeloid Leukemia (AML)

AML is a life-threatening and debilitating disease that is rapidly progressive and fatal if untreated. Despite achievement of initial responses with induction regimens, relapse rates remain high particularly those with higher risk disease. Allogeneic hematopoietic stem cell transplant (HSCT) remains the only curative treatment for many patients. However, recurrence post-HSCT is common and outcomes are dismal with an estimated median survival of less than one year (Estey and Döhner, Lancet, 2006), underlining the urgency for more effective and accessible treatment options.

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 and 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 MT-401 OTS

The investigational allogeneic MT-401 Off-the-Shelf (OTS) product utilizes a non-genetically modified approach that specifically targets four different antigens upregulated in AML cells (WT-1, Survivin, PRAME, NY-ESO-1). OTS products match a patient's human leukocyte antigen (HLA) genotype with the appropriately HLA identified and cryopreserved MT-401 OTS product in the cell bank inventory.

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 in place 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, Marker believes that its 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; the timing, conduct and success of our clinical trials of our product candidates, including MT-401 OTS for the treatment of patients with AML; and our manufacturing strategies. 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 except as may be required by law.

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