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

May 31, 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.)

4551 Kennedy Commerce Dr. **Houston, Texas**	**77032**
(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 May 31, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release reporting pre-clinical data from the Company's multiple tumor-associated antigens (multiTAA)-specific T cell product candidate MT-601 in lymphoma cells, including CD19 CAR T refractory cells. 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 May 31, 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: May 31, 2023

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

Exhibit 99.1

Marker Therapeutics Reports Pre-Clinical Data of its MT-601 MultiTAA-Specific T Cell Product Candidate in Lymphoma Cells

MT-601 showed anti-tumor activity against CD19 CAR T refractory lymphoma cells in vitro

Houston, TX — May 31, 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 pre-clinical data from the Company's multiple tumor-associated antigens (multiTAA)-specific T cell product candidate MT-601 in lymphoma cells, including CD19 CAR T refractory cells.

Although CAR T cell therapies targeting the CD19 antigen have gained acceptance as treatment for patients with relapsed/refractory lymphoma because of their significant benefit relative to the standard of care, up to 60% of patients treated with CAR T therapies relapse within a year (Chong EA et al, N Engl J Med, 2021).

MultiTAA-specific T cell therapy was investigated in the Baylor TACTAL study, which enrolled patients with both Hodgkin's and non-Hodgkin's lymphoma (Vasileiou et al, J Clin Oncol, 2021). The multiTAA-specific T cell product used in the TACTAL study was directed against five antigens and showed more durable clinical responses. For example, some patients who attained a complete remission (CR) with the multiTAA-specific T cell treatment were still in remission at the 72 months follow-up, suggesting a longer-lasting clinical benefit relative to published results for CD19 CAR T therapies.

Given the high probability of antigen-loss associated relapse seen with CD19 CAR T therapy, Marker believes that its multiTAA-specific T cell product may result in durable responses due to its ability to overcome antigen loss by targeting more than one antigen. Data from the TACTAL study has demonstrated that multiTAA-specific T cell products recognize cancer cells by up to five antigens presented on cancer cells and continue to kill even when cancer cells morph by downregulating the targeted antigen to escape recognition.

Marker recently started to evaluate the safety and efficacy of MT-601, a multiTAA-specific T cell product that recognizes six antigens, including WT-1, a TAA that was not part of the targeted antigens in the TACTAL study, in patients with non-Hodgkin's lymphoma who have either relapsed after receiving anti-CD19 CAR T cell treatment or are ineligible for anti-CD19 CAR T cell treatment (ClinicalTrials.gov Identifier: NCT05798897). Marker believes that killing induced by a product directed against six TAAs instead of five TAAs can potentially provide a more durable solution. Prior to starting the clinical trial Marker assessed the killing capacity of MT-601 *in vitro* in a lymphoma cell line and demonstrated that MT-601 kills lymphoma cells regardless of their CD19 expression levels.

"We have recently developed a long-term *in vitro* model to monitor the interaction of T cells with cancerous cells. Data from a lymphoma cell line utilizing this model demonstrated that MT-601 inhibited growth of lymphoma cells as well as the growth of CD19 CAR resistant lymphoma cells," said Eric A. Smith, Ph.D., Director of Research and Development at Marker Therapeutics. Marker has posted further details about this preclinical study on the Investor Relations section of its website.

Dr. Smith continued “Specifically, we have developed an *in vitro* model which reproduces the CD19 antigen-negative tumor that causes relapse and observed the following:

- In this *in vitro* model, 98% of lymphoma cells were eliminated after initial administration of a CD19-targeting CAR T cell product.
- While the CAR T cells significantly controlled lymphoma cell growth, we observed that 3 weeks after the start of anti-CD19 CAR T cell administration, a population of lymphoma cells that were resistant to CD19 CAR T cell administration started to grow.
- These CD19 CAR resistant lymphoma cells were tested for CD19 expression and were shown to be negative for the CD19 surface antigen, which explained why they were no longer controlled with a second administration of anti-C19 CAR T cells, thus recapitulating the antigen-negative relapse observations in CAR relapsed/refractory lymphoma patients.
- However, when MT-601, with its broad antigen recognition (Survivin, NY-ESO-1, WT-1, PRAME, MAGE-A4, SSX2) was added to this anti-CD19 CAR T cell resistant cell population complete growth inhibition was observed.

These data highlight that MT-601 has the potential to eliminate tumors that are CD19 CAR T cell refractory, indicating that MT-601 might offer a viable therapeutic option for lymphoma patients that have relapsed from previous CAR T cell interventions.”

“We are encouraged by the promising results of our pre-clinical study of MT-601,” said Juan F. Vera, M.D., President and Chief Executive Officer at Marker Therapeutics. “These pre-clinical findings reinforce previous TACTAL clinical observations, highlighting the potential benefit of our innovative multiTAA-specific T cell therapy in CD19 CAR T refractory lymphoma patients. Our Investigational New Drug (IND) application for MT-601 for the treatment of patients with relapsed non-Hodgkin lymphoma has been cleared by the FDA and we are excited to further explore the potential benefits of MT-601 in our multicenter Phase 1 clinical trial, which was initiated in the first quarter of 2023. We are continuing our detailed review of the scope of clinical opportunities provided by MT-601 and look forward to providing an update about our clinical strategy and anticipated milestones as soon as possible.”

About multiTAA-specific T cells

Marker's 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 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 the multiTAA-specific T cell product was well tolerated, demonstrated durable clinical responses, and consistent epitope spreading. The latter is typically not observed with other T cell therapies and enables the patient's own T cells to expand, potentially contributing 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 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 of our product candidates, including MT-601 for the treatment of patients with relapsed non-Hodgkin lymphoma. 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 our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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