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

October 6, 2025
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.)

2450 Holcombe Blvd, TMC Partners Office 1.311
Houston, Texas **77021**
(Address of principal executive offices) (Zip Code)

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

(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 Information

On October 6, 2025, Marker Therapeutics, Inc. ("**Marker**" or the "**Company**") issued a press release announcing that the first patient had been treated in the Company's Off-the-Shelf ("**OTS**") Program evaluating Marker's Multi-Antigen Recognizing (MAR)-T cell therapy.

A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release, dated October 6, 2025.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: October 6, 2025

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

Exhibit 99.1

Marker Therapeutics Announces First Patient Treated in Off-the-Shelf Program

Marker Therapeutics initiated Phase 1 RAPID study to investigate Multi-Antigen Recognizing (MAR) T cells as an Off-the-Shelf (OTS) product to accelerate time to treatment

OTS product was well tolerated - safety data consistent with other MAR-T cell studies

Houston, TX — October 6, 2025 – 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 that the first patient has been treated in the Company's OTS program, with encouraging preliminary safety data.

Marker is evaluating the safety and efficacy of escalating doses of MT-401, a multi-antigen recognizing (MAR) T cell product targeting four antigens, as an OTS product in the Phase 1 RAPID study (clinicaltrials.gov Identifier: NCT06552416). The first study participant received the OTS product at the initial dose level ($100x10^6$ cells) and was monitored for 28 days. The therapy was well tolerated with no treatment-related adverse events. This observation is consistent with the favorable safety profile and tolerability previously reported for MAR-T cells. The OTS product will be initially tested in patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS), with the potential to be expanded to other indications.

"The initiation of our OTS program represents a major achievement," said Juan Vera, M.D., President and CEO of Marker Therapeutics. "One of the biggest limitations to cell therapy is the time-consuming manufacturing of individualized products. With our OTS product, we are aiming to remove this bottleneck and provide a fast treatment option for patients with aggressive and rapidly progressing diseases. We believe that using commercially available leukapheresis material from healthy donors can facilitate large-scale manufacturing and expedite treatment as fast as 72 hours, while also enabling broader scalability and accessibility of cell therapies at a lower per-dose cost."

"Having a rapid available alternative to individualized T cell production allows us to broaden our clinical investigation of MAR-T cells and to extend the OTS program to other indications," commented Dr. Vera. "Looking ahead, we will remain focused on advancing our clinical investigation of MAR-T cells in lymphoma. We recently reported promising clinical efficacy and durability data from our APOLLO study where we have observed an objective response rate of 66%, with durable complete responses in patients with non-Hodgkin lymphoma, and we believe our lymphoma program has the potential to qualify for expedited approval."

Marker has secured non-dilutive funding from the Food and Drug Administration (FDA), the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program and the Cancer Prevention and Research Institute of Texas (CPRIT) to support the clinical investigation of the OTS product. Using these allocated non-dilutive funds will allow the Company to proceed with the OTS program without affecting the Company's runway and its efforts to advance its lead asset, MT-601, in the ongoing Phase 1 APOLLO study in patients with lymphoma. Marker recently reported an update from the APOLLO study (Press Release, August 26, 2025) highlighting a favorable safety profile and durable clinical responses.

To facilitate the OTS program, the Company has established a cellular inventory from commercially available leukapheresis material that was carefully selected to cover a large patient population with partially human leukocyte antigen (HLA) matched material. This approach has been validated and extensively tested in the clinic (Leen et al., Blood, 2013; Tzannou et al, Blood Adv, 2019; Tzannou et al, J Clin Oncol, 2017). Data from the ongoing RAPID trial will help inform future clinical developments of MAR-T cell products and guide their potential use as an OTS product in other indications.

“Behind this milestone is a set of scientific data and a significant body of research and development. This strategy has been tested extensively in the clinic at Baylor College of Medicine in the context of virus-specific T cells (VST). As we enroll additional patients in the Phase 1 RAPID study, we will continue to closely monitor the safety and long-term treatment effects of our OTS product. The collected data from this trial will serve as a foundation for refining and understanding the performance of MAR-T cells as an OTS product to potentially expand the OTS approach to other product candidates in our pipeline with the goal to accelerate time to treatment in other indications,” concluded Dr. Vera.

About MAR-T cells

The multi-antigen recognizing (MAR) T cell platform (formerly known as multiTAA-specific T cells) 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. Unlike other T cell therapies, MAR-T cells allow the recognition of hundreds of different epitopes within up to six tumor-specific antigens, thereby reducing the possibility of tumor escape. Since MAR-T cells are not genetically engineered, Marker believes that its product candidates will be easier and less expensive to manufacture, with an improved safety profile compared to current engineered T cell approaches and may provide patients with meaningful clinical benefits.

About the Off-the-Shelf Program

MT-401-OTS is an Off-the-Shelf (OTS) multi-antigen recognizing (MAR) T cell product that targets four different tumor antigens upregulated in cancer cells (Survivin, PRAME, NY-ESO-1, WT-1). MT-401-OTS is currently investigated in the Company-sponsored Phase 1 multicenter, open-label RAPID trial (clinicaltrials.gov identifier: NCT06552416) for the treatment of patients with relapsed acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). The Company’s OTS program is supported by the National Cancer Institute of the National Institutes of Health (Award Number 1R44CA285177), the Food and Drug Administration Department of Health and Human Services (R01FD007272), and the Cancer Prevention and Research Institute of Texas (CPRIT, Award Number DP210042).

About Marker Therapeutics, Inc.

Marker Therapeutics, Inc. is a Houston, TX-based clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumors. The Company was founded at Baylor College of Medicine, and clinical trials that enrolled more than 200 patients across various hematological and solid tumor indications showed that the Company’s autologous and allogeneic MAR-T cell products were well tolerated and demonstrated durable clinical responses. Marker’s goal is to introduce novel T cell therapies to the market and improve patient outcomes. To achieve these objectives, the Company prioritizes the preservation of financial resources and focuses on operational excellence. Marker’s unique T cell platform is strengthened by non-dilutive funding from U.S. state and federal agencies supporting cancer research.

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, interim results announcements and outcomes of our clinical trials of our product candidates, including MT-601 for the treatment of patients with lymphoma or MT-401-OTS for the treatment of patients with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). 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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