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 12, 2024
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, Suite BCM-A, MS: BCM251
Houston, Texas **77021**
(Address of principal executive offices) (Zip Code)

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

9350 Kirby Drive, Suite 300
Houston, Texas 77054
(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 August 12, 2024, Marker Therapeutics, Inc. (the "Company") issued a press release announcing that the Company was awarded a $2 million grant from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program to support the clinical investigation of MT-601 in patients with non-Hodgkin's lymphoma (NHL) who have relapsed following anti-CD19 chimeric antigen receptor (CAR) 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 August 12, 2024.
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: August 12, 2024

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

Exhibit 99.1

Marker Therapeutics Awarded $2 Million Grant from NIH in Support of Phase 1 Study Investigating MT-601 in CAR-Relapsed Patients with Non-Hodgkin's Lymphoma

Marker Therapeutics to receive non-dilutive funding from NIH Small Business Innovation Research Program based on preliminary clinical results and non-clinical data in lymphoma

Houston, TX – August 12, 2024 – 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 Company has been awarded a $2 million grant from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program to support the clinical investigation of MT-601 in patients with non-Hodgkin's lymphoma (NHL) who have relapsed following anti-CD19 chimeric antigen receptor (CAR) T cell therapy.

The SBIR grant has been awarded based in part on Marker's preliminary clinical data in patients with lymphoma (Press Release, September 11, 2023) as well as non-clinical data demonstrating the anti-tumor activity of MT-601 on anti-CD19 CAR resistant lymphoma cells (Press Release, May 31, 2023). The proceeds of the grant will support the nationwide multi-center Phase 1 APOLLO study (ClinicalTrials.gov identifier: NCT05798897), evaluating the safety and efficacy of MT-601, a multi-tumor associated antigen (multiTAA)-specific T cell product, in patients with relapsed NHL including those previously treated with anti-CD19 CAR-T cell therapy. Including this SBIR grant, the Company has been awarded over $19 million in non-dilutive funding proceeds.

"We are pleased to receive the SBIR grant from the NIH to support our clinical Phase 1 study in CAR-relapsed patients with non-Hodgkin's lymphoma," said Juan Vera, M.D., President and CEO of Marker Therapeutics. "Although anti-CD19 CAR-T cells are rapidly expanding as a treatment option in patients with hematological malignancies, approximately 40-60% of patients will relapse within the first year of therapy with currently no standard of care for patients post CD19-targeting CAR-T cells. The NIH award process is highly competitive, and we believe that the decision the NIH made suggests the potential scientific merit and the capacity of Marker's APOLLO study to address an unmet medical need."

Dr. Vera continued: "While our results of the APOLLO study are preliminary, as we move through the dose escalation part of the study, we are encouraged by the objective responses observed in all three study participants treated at City of Hope (Press Release, April 8, 2024) and the lack of cytokine release syndrome (CRS) or immune effector cell associated neurotoxicity syndrome (ICANS) observed. We will continue to closely monitor all patients for long-term treatment effects and durability of response, and with the non-dilutive funding support from NIH we look forward to treating additional participants in this Phase 1 study."

"This grant award is a testimony of our continued commitment to apply for non-dilutive funding and allows us to leverage our data to drive innovation and growth while maximizing shareholder value. Obtaining non-dilutive funding is an ongoing effort, and we are actively applying for additional opportunities as they become available," 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 MT-601

The Company's lead product, MT-601, is a multi-tumor associated antigen (multiTAA)-specific T cell product that utilizes a non-genetically modified approach that specifically targets six different tumor antigens upregulated in lymphoma cells (Survivin, PRAME, WT-1, NY-ESO-1, SSX-2, MAGE-A4). Marker is currently investigating MT-601 in the Company-sponsored Phase 1 APOLLO trial (clinicaltrials.gov identifier: NCT05798897) for the treatment of lymphoma patients who are relapsed after or where CD19 CAR-T cell therapy is not an option.

About APOLLO

The APOLLO trial (clinicaltrials.gov Identifier: NCT05798897) is a Phase 1, multicenter, open-label study designed to evaluate the safety and efficacy of MT-601 in participants with lymphoma who relapsed after anti-CD19 CAR-T cell therapy or where anti-CD19 CAR-T cell therapy is not an option. The primary objective of this exploratory Phase 1 clinical trial is to evaluate the safety and preliminary efficacy of MT-601 in participants with various lymphoma subtypes. Under the APOLLO trial, it is anticipated that nine clinical sites across the United States will cumulatively enroll up to approximately 30 participants during the dose escalation phase.

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. Unlike other T cell therapies, multiTAA-specific 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 multiTAA-specific 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 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. Clinical trials that enrolled more than 200 patients across various hematological and solid tumor indications showed that the Company's autologous and allogeneic multiTAA-specific 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 and success of our clinical trials of our product candidates, including MT-601 for the treatment of patients with 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 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.

Contacts
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