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

July 10, 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 July 10, 2023, Marker Therapeutics, Inc. (the "***Company***") issued a press release announcing that *zedenoleucel*, its multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401, was granted Orphan Drug Designation by the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) for the treatment of patients with acute myeloid leukemia (AML). 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 July 10, 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: July 10, 2023

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

Exhibit 99.1

European Medicines Agency Grants Orphan Drug Designation for MT-401 developed by Marker Therapeutics for the Treatment of AML Patients

Houston, TX – July 10, 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, announced that *zedenoleucel*, its multi-tumor-associated antigen (multiTAA)-specific T cell product candidate, MT-401, was granted Orphan Drug Designation by the Committee for Orphan Medicinal Products of the European Medicines Agency (EMA) for the treatment of patients with acute myeloid leukemia (AML).

AML is a life-threatening and chronically debilitating disease that is rapidly progressive and fatal if untreated. Relapse rates after initial treatment are high, and the next step for eligible patients is an allogeneic hematopoietic stem cell transplant (HSCT). Unfortunately, AML relapse after HSCT is frequent and outcomes are dismal. Patients who relapse after HSCT have an estimated median survival of less than one year (Estey and Döhner, Lancet, 2006), highlighting the urgent need for new therapies.

MT-401 utilizes a novel non-genetically modified approach that recognizes multiple antigens expressed on tumor cells, thereby designed to minimize tumor escape. MT-401 is currently being studied in a Phase 2 clinical trial for the treatment of relapsed AML following allogeneic HSCT, and was designed to specifically target four different antigens that are upregulated in AML but have limited expression on normal cells.

In the European Union, orphan drug designation is granted to drugs intended for the treatment of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 individuals in the European Union. Orphan drug designation by the EMA provides crucial support to expedite the development and market readiness of necessary drugs for such rare diseases. This designation will help Marker Therapeutics continue to develop MT-401 to fill a significant void in the treatment of AML and provides Marker Therapeutics with a range of potential benefits, including ten years of market exclusivity following approval, reduced regulatory fees, and invaluable scientific advice from the EMA during the drug development phase.

"The orphan drug designation for MT-401 by the EMA is a significant regulatory milestone," said Nadia Agopyan, Ph.D., RAC, Senior Vice President, Regulatory Affairs of Marker Therapeutics. "It acknowledges not just the potential therapeutic impact of MT-401, but also the urgent need to deliver innovative treatment options to patients living with AML. In 2020, MT-401 was also granted orphan designation by the U.S. Food and Drug Administration for the treatment of patients with AML. We are deeply committed to working with regulatory authorities to expedite the drug development and approval process."

“We are extremely proud to have been granted Orphan Drug Designation by the EMA for MT-401,” said Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “In our Phase 2 clinical trial of patients with post-transplant AML, we have observed promising results from patients with measurable residual disease, suggesting that the unique and differentiated targeting technology of MT-401 can be a potential treatment for patients with AML before relapse.”

"This is an important milestone for Marker and a significant step forward in our mission to improve the lives of patients with AML, especially of those with relapsed AML where no therapeutic options have been approved. Our team at Marker is committed to accelerating the development of MT-401 and believes that this designation brings us one step closer to offering a new, potentially life-altering therapy for relapsed AML patients after stem cell transplant,” concluded Dr. Vera.

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 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. Marker’s cell therapy technology 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 for the treatment of patients with AML; and the potential benefits of orphan drug designation to MT401. 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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