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 4, 2022
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.)

3200 Southwest Freeway **Suite 2500** **Houston, Texas**	**77027**
(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 4, 2022, Marker Therapeutics, Inc. issued a press release (the "Press Release") announcing that the FDA cleared the Company's Investigational New Drug application for MT-601. A copy of this Press Release is furnished herewith as Exhibit 99.1 to this Form 8-K and is incorporated herein by reference.

The information contained in this Item 7.01 of the Form 8-K, including Exhibit 99.1, is furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and is not incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as shall be expressly set forth by specific reference in any such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 4, 2022
104	The cover page from Marker Therapeutics, Inc.'s Form 8-K filed on August 4, 2022, formatted in Inline XBRL

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Marker Therapeutics, Inc.

Dated: August 4, 2022

By: /s/ Anthony Kim
Anthony Kim
Chief Financial Officer

Exhibit 99.1

Marker Therapeutics Announces FDA Clearance of IND for MT-601, the six-antigen targeted T Cell Therapy for the treatment of relapsed/refractory Non-Hodgkin Lymphoma

Company expects to initiate Phase 1 trial of MT-601 in r/r NHL in 2023

Houston, TX—August 4, 2022—Marker Therapeutics, Inc. (Nasdaq: MRKR), 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, today announced that the U.S. Food and Drug Administration (FDA) has cleared the Company's Investigational New Drug (IND) application for MT-601, a multi-tumor-associated antigen (multiTAA)-specific T cell product targeting six antigens, for the treatment of patients with relapsed/refractory non-Hodgkin lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell treatment.

"This new clinical trial will build upon results that were observed in the Phase I/II TACTAL study conducted by BCM, which assessed the safety and efficacy of five-antigen-directed multiTAA-specific T cell product," stated Dr. Mythili Koneru, Marker's Chief Medical Officer. "In the TACTAL study, BCM observed long-term CR rates that were comparable to recently approved CD19 CAR-T therapies, even at very low cell doses. Unlike CD19 CAR-T cell therapies, patients receiving multiTAA-specific T cell product had superior durability of response, without the severe toxicities that commonly occur with other adoptive cell therapies, such as cytokine release syndrome or neurotoxicity. Based on these results, we believe that multiTAA-specific T cell products can be easily administered in an outpatient setting without hospitalization."

In the TACTAL study, patients were treated with five-antigen-directed multiTAA-T cell product. Based upon the safety profile observed with multiTAA-specific T cell therapies containing WT-1 in multiple cancer indications, the FDA cleared in the IND the addition of WT-1 as the sixth tumor-associated antigen to the MT-601 product that will be used to treat patients in the Marker sponsored study. In addition, the FDA has cleared Marker to initiate its study at a dose level of 200 million cells per infusion, versus the dose range of 10-40 million cells per infusion used in the TACTAL study. This increase in the cell dose will be possible due to Marker's development and adoption of a 9-day manufacturing process, which also accelerates the time to treatment.

Dr. Koneru continued: "We believe that the most important finding of the TACTAL study was that the administration of multiTAA therapy consistently drove an enhanced immunological response from the patient's own immune system, which we believe was due to the lack of lymphodepletion which allowed the patient's own immune system to play a part. We believe that this phenomenon, known as epitope spreading, was critical in driving more durable responses than have been observed with other cell therapies like TCRs and CAR-Ts. It is notable that none of the patients who developed a CR in the TACTAL study relapsed during the follow up period, and several patients have been in CR for over five years at their last follow-up. This contrasts strongly with the experience of CD-19 CAR-Ts, where up to 40% of patients are expected to relapse within 12 months of developing a complete response."

Marker's MT-601 Phase 1 trial will focus on r/r NHL patients who have failed CD19 CAR-T therapy, or those who are ineligible for treatment with those therapies. MT-601 targets a series of tumor antigens other than CD19, offering patients a therapeutic alternative even if their tumor has escaped by downregulating the expression of CD19. For patients who cannot access CD19 therapies, MT-601 has the potential to generate objective responses, with tolerability and potentially longer duration of response.

"FDA clearance of our IND for MT-601 is a significant milestone as we advance our pipeline in a number of Company-sponsored trials," said Peter L. Hoang, Marker's President and Chief Executive Officer. "We believe that MT-601, which targets six tumor-associated antigens highly expressed in lymphoma, has the potential to build upon results of the TACTAL study. We look forward to initiating our Company-sponsored Phase 1 study next year."

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 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, including MT-601; 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, including the Phase 1 trial of MT-601. 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its impact on our business and the global economy. 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.

Investors and Media Contacts

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