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

February 11, 2020
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 2240
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 8.01 Other Events.

On February 11, 2020, Marker Therapeutics, Inc. (the "Company") issued a press release providing an update regarding the Company's planned Phase 2 trial of its MultiTAA T cell therapy for the treatment of acute myeloid leukemia. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release issued on February 11, 2020

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: February 11, 2020

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

Exhibit 99.1

Marker Therapeutics Announces Update to its Clinical Program in AML

U.S. FDA lifts clinical hold on Phase 2 AML trial; places partial hold on the trial for the use of a reagent from an alternative vendor until final data and certificate of analysis are accepted by FDA

Houston, TX – February 11, 2020– 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 lifted the clinical hold on Marker's planned trial investigating safety and efficacy of its novel MultiTAA T cell therapy in patients with post-transplant acute myeloid leukemia (AML).

Marker previously announced on November 12, 2019, that the FDA placed the trial on clinical hold. The FDA requested additional information and technical specifications for two legacy reagents supplied by third parties used in the MultiTAA-specific T cell manufacturing process. The technical specifications and data requested by the FDA could not be produced by the original suppliers. The Company identified alternative suppliers, satisfying the Agency's request.

Based on data Marker provided, the FDA permitted the Company to initiate its AML trial, beginning with a safety lead-in portion. The FDA placed a partial clinical hold on the trial for the use of the MultiTAA-specific T cell product manufactured using one of the reagents supplied by the alternative supplier, until the final data and certificate of analysis for the reagent are reviewed and accepted by the Agency. The safety lead-in portion of the trial is expected to enroll approximately six patients as part of the amended trial design. Three patients will be dosed with MultiTAA-specific T cells manufactured using the legacy reagent, and three patients will be dosed with T cells manufactured using the reagent from the alternative supplier.

Marker currently estimates that the alternative supplier will deliver the final reagent, along with the final data and certificate of analysis required by the FDA, by the end of the second quarter of 2020. Marker anticipates to complete enrollment of the first three patients and submission of the final technical specifications and comparability data of the new reagents to the FDA during the second half of 2020, thereby satisfying the requirements for lifting the partial hold on the clinical trial. Given this expected timing, Marker does not currently expect the partial clinical hold to significantly impact site and patient enrollment of the AML trial.

The safety lead-in will be followed by the 160-patient randomized portion of the study at approximately 20 transplant centers. Group 1 will comprise 120 adjuvant (disease-free) patients, with the primary endpoint of relapse-free survival of patients receiving MultiTAA-specific T cell therapy versus a control group. Group 2 will comprise 40 active disease patients in a single arm, with primary endpoints of complete remission and duration of complete remission.

“With a clear path identified for getting our study of MultiTAA-specific T cell therapy underway in patients with AML, we’re focused on addressing the remaining requirements from the FDA and enrolling up to 20 clinical centers to conduct our Phase 2 trial,” stated Peter L. Hoang, President and CEO of Marker Therapeutics. “We appreciate the productive dialogue with the FDA throughout the process and look forward to advancing MultiTAA-specific T cell therapy for patients with post-transplant AML in a randomized and multicenter clinical trial.”

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 Statement Disclaimer
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 the MultiTAA programs or the possible range of application and potential curative effects and safety in the treatment of diseases; expectations regarding our supplier’s delivery of the final reagent, data and certificate of analysis required to advance the MultiTAA program for AML; and expectations regarding, among other things, the timing, design and success of our clinical trials, including the AML trial, as well as clinical trials conducted by our collaborators. 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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