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

January 5, 2021
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 January 5, 2021, Marker Therapeutics, Inc. (the "***Company***") issued a press release entitled "Marker Therapeutics Announces FDA Lifted Partial Clinical Hold on Phase 2 AML Clinical Trial." A copy of the press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 of this Current Report on 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, or subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, whether made before or after today's date, regardless of any general incorporation language in such filing, except as shall be expressly set forth by specific references in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	**Description**
99.1	Press release, dated January 5, 2021

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: January 5, 2021

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

Exhibit 99.1

Marker Therapeutics Announces FDA Lifted Partial Clinical Hold on Phase 2 AML Clinical Trial

Houston, TX—January 5, 2021—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) lifted the partial clinical hold on the Company's Phase 2 trial investigating the safety and efficacy of MT-401, Marker's lead multi-tumor-associated antigen (MultiTAA)-specific T cell product candidate for the treatment of post-transplant acute myeloid leukemia (AML).

"We are pleased to move forward with our Phase 2 AML trial of MT-401, which we believe may provide a safe and effective treatment option for patients with post-transplant AML over the standard of care," said Mythili Koneru, M.D., Ph.D., Chief Medical Officer of Marker Therapeutics. "During the partial clinical hold, we continued to open clinical centers to enroll patients in the first half of the safety lead-in of our Phase 2 trial. With the FDA's decision, we will now be able to seamlessly enroll patients in the second half of the safety lead-in, as well as the remainder of the trial. We look forward to working with our clinical sites to continue enrolling patients."

The multicenter Phase 2 AML study is evaluating clinical efficacy of MT-401 in patients with AML in both the adjuvant and active disease setting, following an allogeneic stem-cell transplant. In the adjuvant setting, approximately 120 patients will be randomized 1:1 to either MT-401 at 90 days post-transplant versus standard-of-care observation, while about 40 patients with active disease will receive MT-401 as part of the single-arm group. The trial also includes a safety lead-in expected to enroll six patients.

The primary objectives of the trial are to evaluate relapse-free survival in the adjuvant group and determine the complete remission rate and duration of complete remission in active disease patients. Additional objectives include, for the adjuvant group, overall survival and graft-versus-host disease relapse-free survival while additional objectives for the active disease group include overall response rate, duration of response, progression-free survival and overall survival.

In April 2020, the FDA granted Orphan Drug designation to MT-401 for the treatment of patients with AML following allogeneic stem cell transplant.

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 these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the impact of the COVID-19 pandemic; the timing, conduct and success of our clinical trials, including the Phase 2 trial of MT-401, as well as clinical trials conducted by our collaborators; our manufacturing processes and our ability to use our in-house manufacturing facility to support clinical and commercial demand. 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.

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