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

November 22, 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.)

4551 Kennedy Commerce Dr. **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 November 22, 2022, Marker Therapeutics, Inc. (the "***Company***") issued a press release (the "***Press Release***") announcing that the U.S. Food and Drug Administration had cleared the Company's Investigational New Drug application for MT-601 for the treatment of pancreatic cancer. 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 November 22, 2022
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: November 22, 2022

By: /s/ Peter Hoang
Peter Hoang
President and Chief Executive Officer

Exhibit 99.1

Marker Therapeutics Announces FDA Clearance of IND for MT-601, its Six-Antigen T Cell Therapy for the Treatment of Pancreatic Cancer

Houston, TX— November 22, 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 locally advanced unresectable or metastatic pancreatic cancer in combination with front-line chemotherapy.

"Based on the encouraging results seen in the Phase 1 TACTOPS study conducted by our partners at Baylor College of Medicine, we are eager to initiate a Marker-sponsored Phase 1 clinical trial next year," said Dr. Mythili Koneru, Marker's Chief Medical Officer. "Interim results from the TACTOPS study presented at ASCO in 2020 showed that treatment with multiTAA therapy in combination with front-line standard-of-care chemotherapy resulted in clinical responses greater than expected with chemotherapy alone. We look forward to investigating MT-601, a potentially more potent multiTAA-specific T cell therapy product that targets six antigens found on pancreatic cancer tumor cells, in a similar patient population."

Marker intends to initiate a multicenter Phase 1 trial for the treatment of patients with locally advanced unresectable or metastatic pancreatic cancer in combination with front-line chemotherapy in 2023.

Compared to the TACTOPS study, Marker is using a new, streamlined manufacturing process for MT-601. This new manufacturing process has already demonstrated major improvements to MT-401, Marker's multiTAA-specific T cell product for AML. The new manufacturing process allows production in 9 days compared to the original process of >30 days. This is accompanied by a 90% decrease in the number of interventions during production and an improved final T cell product versus the original product in the TACTOPS trial. Marker's IND for MT-601 for the treatment of pancreatic cancer reflected this improved manufacturing process.

"The FDA's clearance of our IND for MT-601 is a significant milestone for Marker as we prepare for our third planned clinical trial evaluating our multiTAA-specific T cell therapy next year," said Peter L. Hoang, President and Chief Executive Officer of Marker Therapeutics. "Our pioneering multi-antigen approach to cancer treatment has the potential to significantly benefit patients, and we are pleased to advance development of our pancreatic cancer program through the initiation of our Company-sponsored Phase 1 trial in 2023."

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; the timing, conduct and success of our clinical trials of our product candidates, including the Phase 2 trial of MT-601; our ability to use our manufacturing facilities to support clinical and commercial demand; and our future operating expenses and capital expenditure requirements. 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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