

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

**May 29, 2020**

Date of Report (Date of earliest event reported)

**MARKER THERAPEUTICS, INC.**

(Exact name of registrant as specified in its charter)

**Delaware**

(State or other jurisdiction of incorporation)

**001-37939**

(Commission File Number)

**45-4497941**

(IRS Employer Identification No.)

**3200 Southwest Freeway**

**Suite 2240**

**Houston, Texas**

(Address of principal executive offices)

**77027**

(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 May 29, 2020, Marker Therapeutics, Inc. issued a press release announcing interim results from its Phase 1 clinical trial of its MultiTAA-specific T cell therapy in patients with pancreatic adenocarcinoma. 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.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release issued on May 29, 2020</u></a>

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**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.

Dated: May 29, 2020

**Marker Therapeutics, Inc.**

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

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**Marker Therapeutics Reports Interim Results of its MultiTAA-Specific T Cell Therapy in Patients with Pancreatic Adenocarcinoma at the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting**

*— Results demonstrate potential of MultiTAA-specific T cell therapy in combination with chemotherapy as a first-line treatment option for patients with advanced or metastatic pancreatic adenocarcinoma —*

*— Evidence of epitope-spreading was observed in all responders, suggesting that MultiTAA T cell therapy triggered the recruitment of a broader endogenous immune system response —*

*— Company to host investor event and webcast on Monday, June 1 at 8:00am EDT —*

**Houston, TX – May 29, 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 updated clinical results from an ongoing investigator-sponsored Phase 1 trial led by the Baylor College of Medicine, evaluating the Company’s MultiTAA-specific T cell therapy in patients with advanced or metastatic pancreatic adenocarcinoma. Data from a cohort of patients receiving MultiTAA-specific T cell therapy in combination with standard-of-care chemotherapy in the first-line setting (Arm A), were reviewed today by lead investigator, Brandon G. Smaglo, M.D., FACP, as part of a poster session during the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. ASCO is being held from Friday, May 29 through Sunday, May 31, 2020.

“Pancreatic cancer is one of the most deadly forms of cancer today, with the mortality rate remaining relatively unchanged over the past several decades despite ongoing research and treatment advances,” said Dr. Brandon G. Smaglo. “With a growing body of data, we continue to be encouraged by the potential of MultiTAA-specific T cell therapy, in combination with standard-of-care chemotherapy, to safely produce durable responses in patients with advanced pancreatic cancer. In this study, a number of patient responses occurred after the period in which a chemotherapy-driven response would typically occur, suggesting MultiTAA’s potential to produce added benefit in this patient population. Additionally, we also observed induction of the endogenous immune system – or epitope spreading – suggesting that the benefits of MultiTAA may extend beyond the targeted antigens and further contribute to a long-lasting anti-tumor effect.”

**Presentation Title:**

*“A phase I trial targeting advanced or metastatic pancreatic cancer using a combination of standard chemotherapy and adoptively transferred nonengineered, multiantigen specific T cells in the first-line setting (TACTOPS)”*

**Study Design:**

Arm A is evaluating the safety and potential efficacy of using MultiTAA-specific T cells in the first-line setting for chemo-responsive patients with pancreatic adenocarcinoma. Patients in Arm A receive at least three months of standard-of-care chemotherapy (gemcitabine/nab-paclitaxel or FOLFIRINOX) – the period during which a response to chemotherapy would typically occur – before receiving up to six administrations of MultiTAA-specific T cells in conjunction with chemotherapy.

**Summary of Interim Results**

Between June 2018 and December 2019, 13 patients have been treated, each of whom received up to 6 monthly infusions of  $1 \times 10^7$  MultiTAA-specific T cells/m<sup>2</sup> in conjunction with ongoing first-line chemotherapy and without prior protocol-associated lymphodepletion. For 12 of the 13 patients, sufficient cells for all six planned doses were generated; two doses were available for the remaining patient.

- Out of the 13 evaluable patients (best overall response):
  - o 4 patients experienced objective responses after administration of MultiTAA cells;
    - § 1 patient experienced a radiographic complete response occurring at month 9 after starting chemotherapy;
    - § 3 patients experienced partial responses per RECIST occurring at 6-9 months after starting chemotherapy;
  - o 6 patients experienced stable disease;
  - o 1 patient experienced a mixed response (some lesions increased in size and others decreased for a net zero change in size of tumor lesions);
  - o 2 patients experienced disease progression;
- For 9 of the 13 patients, the cancer was controlled for a period longer than historical controls relative to the type of chemotherapy used
- 5 patients enrolled in the study were not administered MultiTAA-specific T cells, either because of disease progression (4 patients) which made them ineligible for treatment, or because insufficient starting material from the patient was available for manufacturing (1 patient);
- Evidence of epitope-spreading was observed in all responders, suggesting that the MultiTAA T cell therapy triggered the recruitment of a broader endogenous immune system response for improved anti-tumor activity;
- No infusion-related reactions, cytokine release syndrome or neurotoxicity was observed.

Mythili Koneru, M.D., Ph.D., Chief Medical Officer of Marker Therapeutics commented: “We are pleased with these interim results, which demonstrate the potential of our therapy to simultaneously recognize and target multiple antigens. As the tumor microenvironment varies from patient to patient, the ability to address these differences may offer a significant benefit to patients. While these results represent a small patient population, we look forward to generating additional data that may support MultiTAA’s future development in this challenging disease area.”

The TACTOPS poster and corresponding recorded presentation by Dr. Smaglo will be available on demand through the ASCO20 Virtual Scientific Program on the ASCO website beginning on May 29, 2020, at 8:00 a.m. EDT.

#### **Conference Call and Webcast**

Marker will host a conference call and webcast on Monday, June 1st at 8:00 am EDT featuring Dr. Brandon Smaglo, as well as Marker senior management, to discuss the data. The webcast will be accessible in the **Investors** section of the Company's website at markertherapeutics.com. Individuals can participate in the conference call by dialing 877-407-8913 (domestic) or 201-689-8201 (international).

The archived webcast will be available for replay on the Marker website following the event.

#### **About MultiTAA-Specific T Cell Therapy**

Marker's Multi-Antigen Targeted (MultiTAA) platform is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient's blood capable of recognizing a broad range of tumor antigens. In early clinical trials, the multi-antigen approach has been well tolerated and shown to enhance tumor destroying capability and is one of the first therapies to consistently demonstrate epitope spreading – inducing the patient's own T cells to expand, potentially contributing to a lasting anti-tumor effect. Unlike other cell therapies which require pre-conditioning regimens and hospitalization, MultiTAA is 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 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 potential benefits of orphan drug designation; and the timing and success of our clinical trials, 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](http://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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