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 19, 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 January 19, 2022, Marker Therapeutics, Inc. (the "***Company***") issued a press release entitled "Marker Therapeutics Receives FDA Orphan Drug Designation for its Multi-Antigen Targeted T Cell Therapy for Pancreatic Cancer." 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 19, 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: January 19, 2022

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

Exhibit 99.1

Marker Therapeutics Receives FDA Orphan Drug Designation for its Multi-Antigen Targeted T Cell Therapy for Pancreatic Cancer

Houston, TX –January 19, 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 United States Food and Drug Administration (FDA) Office of Orphan Products Development has granted Orphan Drug designation to MT-601, a multi-tumor-associated antigen (MultiTAA)-specific T cell product optimized for the treatment of patients with pancreatic cancer.

“The FDA’s orphan drug designation underscores MT-601’s potential as a treatment for pancreatic cancer, a cancer typically diagnosed at an incurable advanced stage with a total overall 5-year survival rate of 10%,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “Our novel therapy has shown encouraging results in an ongoing Phase 1 trial sponsored by Marker’s partners at the Baylor College of Medicine. In results reported at the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting, our therapy has demonstrated the potential to safely produce durable responses in combination with chemotherapy as a first-line treatment option for patients with advanced or metastatic pancreatic adenocarcinoma. The results also revealed that epitope spreading was consistent in responders to Multi-TAA-specific T cells. Following MT-401 for the treatment of post-transplant acute myeloid leukemia (AML), MT-601 is Marker’s second novel MultiTAA-specific T cell product to receive orphan drug designation and the first in a solid tumor indication, underscoring the potential of Marker’s multi-antigen targeting T cell therapy approach in both solid tumors and blood cancers.”

Marker developed MT-601, a new product targeting six tumor-associated antigens (PRAME, NY-ESO-1, Survivin, MAGE-A4, SSX2, WT1) highly expressed in pancreatic cancer. The Company intends to initiate a Phase 1 multicenter study of MT-601 administered in combination with front-line chemotherapy to patients with locally advanced unresectable or metastatic pancreatic cancer. Marker designed the study to include an initial antigen escalation period followed by a dose escalation period and will enroll 20 – 25 patients for the study.

The Company plans to file an Investigational New Drug Application (IND) for MT-601 for the treatment of pancreatic cancer in 2022.

Orphan designation is granted by the FDA Office of Orphan Products Development to advance the evaluation and development of safe and effective therapies for the treatment of rare diseases or conditions affecting fewer than 200,000 people in the U.S. Under the Orphan Drug Act, the FDA may provide grant funding toward clinical trial costs, tax credits, FDA user-fee benefits, and seven years of market exclusivity in the United States following marketing approval by the FDA. The granting of an orphan designation request does not alter the standard regulatory requirements and process for obtaining marketing approval. For more information about orphan designation, please visit the FDA website at www.fda.gov.

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.

IR and Media Contacts

Marker Therapeutics
Neda Safarzadeh
Vice President/Head of Investor Relations, PR & Marketing
(713) 400-6451
investor.relations@markertherapeutics.com

Solebury Trout

Investors
Xuan Yang
xyang@soleburytrout.com

Media
Amy Bonanno
abonanno@soleburytrout.com