

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

October 19, 2026

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.)

2450 Holcombe Blvd, TMC Partners Office 1.311

Houston, Texas

(Address of principal executive offices)

77021

(Zip Code)

(713) 400-6400

Registrant's telephone number, including area code

(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 Information

On October 19, 2026, Marker Therapeutics, Inc. (“**Marker**” or the “**Company**”) issued a press release announcing that it was awarded a \$2.6 Million Grant by the Food & Drug Administration (“**FDA**”) under the FDA’s Orphan Products development program to advance the Company’s lead investigational MAR-T cell therapy, MT-601, in patients with locally advanced unresectable pancreatic cancer.

A copy of the Press Release is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
<u>99.1</u>	<u>Press release, dated October 19, 2026.</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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: October 19, 2026

By: /s/ Juan Vera

Juan Vera

President and Chief Executive Officer



Marker Therapeutics Awarded \$2.6 Million FDA Orphan Products Development Grant to Advance MT-601 in Pancreatic Cancer

Competitive selection reinforces independent recognition of the scientific rationale and development potential of Marker's multi-antigen recognizing T cell platform

Houston, TX – October 19, 2026 – Marker Therapeutics, Inc. (Nasdaq: MRKR), is a clinical-stage immuno-oncology company developing multi-antigen recognizing (MAR)-T cell therapies under an exclusive worldwide license from Baylor College of Medicine for patients with cancer. Today, Marker announced that the Company has been awarded \$2.6 million from the U.S. Food and Drug Administration (FDA) through its Orphan Products Clinical Trials grants program. The funding will support a Phase 1 clinical study evaluating the Company's lead investigational MAR-T cell therapy, MT-601, in patients with locally advanced unresectable pancreatic cancer.

The FDA's Orphan Products Clinical Trials grants program is a highly competitive federal funding initiative designed to support clinical research that may advance the development of treatments for rare diseases. Applications undergo independent scientific peer review, including evaluation of scientific rationale, clinical trial design, feasibility, and potential contribution to product development. In fiscal year 2026, the FDA received 66 applications and selected six projects for funding.

"We are honored to be among the six recipients selected for funding through the FDA's highly competitive Orphan Products Clinical Trials grants program," said Juan Vera, MD, President and Chief Executive Officer of Marker Therapeutics. "This award represents meaningful independent recognition and external validation of the scientific rationale underlying our MAR-T platform and its potential application in pancreatic cancer. Our technology is designed to recognize multiple tumor-associated antigens, offering a differentiated approach to addressing tumor heterogeneity and antigen escape, while maintaining the favorable safety profile observed in more than 200 patients treated across our clinical programs in hematologic malignancies and solid tumors. The additional non-dilutive funding from the FDA will further support our efforts to advance MT-601 in an area of significant unmet medical need."

The FDA grant award further expands Marker's track record of securing competitive federal and state research funding to support the development of the Company's innovative MAR-T cell therapies. In addition to the FDA Orphan Products Clinical Trials grant, Marker has secured non-dilutive funding from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program and the Cancer Prevention and Research Institute of Texas (CPRIT) to support the pancreatic cancer program.

The clinical development of MT-601 in pancreatic cancer builds on encouraging results from a Phase 1/2 study conducted at Baylor College of Medicine and published in *Nature Medicine* earlier this year (Musher BL, Vasileiou S, Smaglo BG et al. Nat Med. 2026). The findings also received national coverage on *Good Morning America* (January 22, 2026). The study demonstrated a favorable safety profile and disease control rate of 84.6% in patients receiving multi-antigen targeted T cells in combination with frontline chemotherapy, with a median duration of response of 7.5 months and a median overall survival of 14.1 months.



“These encouraging clinical findings provide a strong foundation for the development of MT-601 in pancreatic cancer, particularly given the limited outcomes with current treatment options,” commented Dr. Vera. “For context, a recent clinical trial evaluating standard frontline chemotherapy regimens in metastatic pancreatic cancer reported median overall survival of 9.2-11.1 months and median duration of response of 5-7.3 months. Through our company-sponsored study, we aim to build on our previous observations from the Baylor study by incorporating an expanded antigen-targeting profile, higher T cell doses, and lymphodepletion to potentially enhance T cell expansion, persistence, and clinical outcomes. The FDA grant provides important non-dilutive funding and further recognition of the scientific rationale and development potential of our program. We anticipate clinical initiation of our study in pancreatic cancer in the first quarter of 2027 and look forward to advancing MT-601 as a potential treatment option for patients with a significant unmet medical need.”

About the FDA Orphan Products Clinical Trials Grants Program

The U.S. Food and Drug Administration's (FDA) Orphan Products Clinical Trials grants program supports clinical research evaluating the safety and efficacy of investigational products for rare diseases and conditions. The program provides competitive, non-dilutive funding to advance promising therapies through clinical development. Applications undergo a rigorous scientific peer-review process assessing scientific merit, clinical study design, feasibility, and potential impact on patients with unmet medical needs. Since its inception in 1983, the program has supported clinical research contributing to the approval of more than 85 medical products for rare diseases.

About MAR-T cells

The multi-antigen recognizing (MAR) T cell platform (formerly known as multiTAA-specific T cells) is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient's/donor's blood capable of recognizing a broad range of tumor antigens. Unlike other T cell therapies, MAR-T cells allow the recognition of hundreds of different epitopes within up to six tumor-specific antigens, thereby reducing the possibility of tumor escape. Since MAR-T cells are not genetically engineered, Marker believes that its product candidates will be easier and less expensive to manufacture, with an improved safety profile compared to current engineered T cell approaches and may provide patients with meaningful clinical benefits.

About MT-601

The Company's lead product, MT-601, is a multi-antigen recognizing (MAR) T cell product that utilizes a non-genetically modified approach that specifically targets six different tumor antigens upregulated in tumor cells (Survivin, PRAME, WT-1, NY-ESO-1, SSX-2, MAGEA-4). Marker is currently investigating MT-601 in the Phase 1 APOLLO trial (clinicaltrials.gov identifier: NCT05798897) for the treatment of patients with lymphoma who have relapsed after or are ineligible to receive anti-CD19 CAR-T cell therapies. Due to the broad target recognition profile of MT-601, the Company is exploring its potential application beyond lymphoma in patients with pancreatic cancer. The Company's pancreatic cancer program is supported by the National Cancer Institute of the National Institutes of Health (Award Number R44CA295168), the Cancer Prevention and Research Institute of Texas (CPRIT, Award Number DP250150), and the Food and Drug Administration Orphan Products Clinical Trials Grants program (Award Number 1R01FD008756-01).

**About Marker Therapeutics, Inc.**

Marker Therapeutics, Inc. is a Houston, TX-based clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumors. The Company was founded at Baylor College of Medicine, and clinical trials that enrolled more than 200 patients across various hematological and solid tumor indications showed that the Company's autologous and allogeneic MAR-T cell products were well tolerated and demonstrated durable clinical responses. Marker's goal is to introduce novel T cell therapies to the market and improve patient outcomes. To achieve these objectives, the Company prioritizes the preservation of financial resources and focuses on operational excellence. Marker's unique T cell platform is strengthened by non-dilutive funding from U.S. state and federal agencies supporting cancer research, including the National Cancer Institute of National Institutes of Health, U.S. Department of War, the FDA Orphan Drug program and the Cancer Prevention Research Institute of Texas (CPRIT).

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; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including neldaleucel (MT-601) for the treatment of patients with pancreatic cancer or lymphoma. 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 its forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release except as may be required by law.

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