

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

March 31, 2025

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, Suite BCM-A, MS: BCM251

Houston, Texas

(Address of principal executive offices)

77021

(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 2.02 Results of Operations and Financial Condition.

On March 31, 2025, Marker Therapeutics, Inc. (the “*Company*”) reported financial results for the year ended December 31, 2024 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this report and incorporated by reference.

The information in this Item 2.02 of this Current Report on 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, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 31, 2025
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: March 31, 2025

By: /s/ Juan Vera

Juan Vera

President and Chief Executive Officer



Marker Therapeutics Reports Year-End 2024 Corporate and Financial Results

Lead program investigating MT-601 in patients with refractory lymphomas, including anti-CD19 CAR-T cell therapy, demonstrated safety and efficacy in 9 patients with 78% having objective responses, including durable complete responses

Secured over \$13 million in non-dilutive funding from the Cancer Prevention & Research Institute of Texas (CPRIT) and the National Institute of Health (NIH) Small Business Innovation Research (SBIR) to support pancreatic and lymphoma clinical programs

Approval from United States Adopted Name (USAN) council and International Nonproprietary Names (INN) expert committee for “neldaleucel” as nonproprietary name for MT-601

Strategic financing to support clinical advancements to investigate MT-601 in patients with lymphoma

Houston, TX — March 31, 2025 – MARKER THERAPEUTICS, INC. (Nasdaq: MRKR), a clinical-stage immuno-oncology company focusing on developing next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumors, today announced corporate updates and financial results for the year ended December 31, 2024.

“In 2024, we made substantial progress advancing MT-601, our lead multi antigen recognizing (MAR)-T cell therapy, and laid the groundwork for continued momentum in 2025,” said Juan Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “Preliminary data from our Phase 1 APOLLO study showed encouraging safety and efficacy results in lymphoma patients who relapsed after anti-CD19 CAR-T cell therapy. With a 78% objective response rate and favorable safety profile, we believe MT-601 has the potential to provide a transformative treatment option for this patient population. We look forward to sharing additional insights during a webinar in the second quarter of 2025.”

“We also strengthened our financial position through a strategic private placement and additional non-dilutive funding from the NIH and CPRIT. As we move further into 2025, our focus remains on cash preservation and disciplined execution to maximize the impact of our clinical programs,” concluded Dr. Vera.

2024 PROGRAM UPDATES & OPERATIONAL HIGHLIGHTS

MT-601 (Lymphoma)

- MT-601, Marker’s lead MAR-T cell therapy, is being evaluated in the nationwide multicenter Phase 1 APOLLO study ([CLINICALTRIALS.GOV](https://clinicaltrials.gov/ct2/show/study/NCT05798897) identifier: NCT05798897) in patients with anti-CD19 CAR-T relapsed lymphoma or where CAR-T cells are not an option.
- The Company provided an update on the APOLLO study ([Press Release, December 19, 2024](#)). Key findings from the study include:
 - o Safety: MT-601 was well tolerated across all study participants. No immune-effector cell associated neurotoxicity syndrome (ICANS) and one case of Grade 1 cytokine release syndrome (CRS) were observed. No dose limiting toxicities (DLTs) have been reported to date.



- o Efficacy: In the first dose cohort, 7 out of 9 patients achieved objective responses (78%) at first response assessment, with 4 patients demonstrating complete response (CR; 44.4%).
- o Time in Follow-Up: Three patients have been followed for 6 to 12 months, with ongoing follow-up underway. All study participants are monitored closely to ensure comprehensive data collection and patient safety.

- The Company is enrolling additional study participants in the Phase 1 APOLLO trial and expects to report further data in the second half of 2025.

MT-601 (Pancreatic)

- Marker received \$2 million from NIH SBIR and \$9.5 million from CPRIT to support the development of MT-601 in metastatic pancreatic cancer.
- Clinical program launch is anticipated in the second half of 2025.

MT-401-OTS (Acute Myeloid Leukemia or Myelodysplastic Syndrome)

- The Company previously secured non-dilutive funding to support the clinical investigation of MT-401 as an “Off-the-Shelf” (MT-401-OTS) product in patients with Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS). MT-401-OTS is manufactured from healthy donors and a cellular inventory has been established with ongoing efforts to expand.
- The Company anticipates clinical program initiation during the second half of 2025.

2024 CORPORATE HIGHLIGHTS

- Announced clinical pipeline prioritization in January 2024 to strategically focus on MT-601 in patients with lymphoma. This announcement also included program updates that highlighted the potential of the Company’s MT-401-OTS program for patients with AML ([Press Release, January 8, 2024](#)).
 - The United States Adopted Names (USAN) and International Nonproprietary Names (INN) committees approved “*neldaleucel*” as the nonproprietary (generic) name for MT-601.
 - On December 23, 2024, the Company announced a \$16.1 million private placement to support the clinical advancements of the Phase 1 APOLLO study. The financing involved participation from new and existing investors, including esteemed firms such as Blue Owl, New Enterprise Associates (NEA) and Aisling Capital.
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FISCAL YEAR 2024 FINANCIAL HIGHLIGHTS

Cash Position and Guidance: At December 31, 2024, Marker had cash and cash equivalents of \$19.2 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the first quarter of 2026, assuming no additional grant funds are received. We anticipate receiving additional grant funding, which we expect could extend our runway beyond Q1 2026.

R&D Expenses: Research and development expenses were \$13.5 million for the year ended December 31, 2024, compared to \$10.4 million for the year ended December 31, 2023.

G&A Expenses: General and administrative expenses were \$4.2 million for the year ended December 31, 2024, compared to \$7.5 million for the year ended December 31, 2023.

Net Loss: Marker reported a net loss of \$10.7 million for the year ended December 31, 2024, compared to a net loss of \$8.2 million for the year ended December 31, 2023.

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 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.

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; the timing, conduct, interim results announcements and outcomes of our clinical trials of our product candidates, including MT 601 for the treatment of patients with 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.



Marker Therapeutics, Inc.
Consolidated Balance Sheets
(Audited)

	December 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 19,192,440	\$ 15,111,450
Prepaid expenses and deposits	483,717	988,126
Other receivables	2,346,703	1,027,815
Total current assets	22,022,860	17,127,391
Total assets	\$ 22,022,860	\$ 17,127,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,753,954	\$ 1,745,193
Related party payable	1,710,500	1,329,655
Total current liabilities	3,464,454	3,074,848
Total liabilities	3,464,454	3,074,848
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at December 31, 2024 and 2023, respectively	-	-
Common stock, \$0.001 par value, 30 million shares authorized, 10.7 million and 8.9 million shares issued and outstanding as of December 31, 2024 and 2023, respectively (see Note 8)	10,708	8,891
Additional paid-in capital	465,564,876	450,329,515
Accumulated deficit	(447,017,178)	(436,285,863)
Total stockholders' equity	18,558,406	14,052,543
Total liabilities and stockholders' equity	\$ 22,022,860	\$ 17,127,391



Marker Therapeutics, Inc.
Consolidated Statements of Operations
(Audited)

	For the Year Ended December 31,	
	2024	2023
Revenues:		
Grant income	\$ 6,591,080	\$ 3,311,133
Total revenues	6,591,080	3,311,133
Operating expenses:		
Research and development	13,467,845	10,416,789
General and administrative	4,241,607	7,475,722
Total operating expenses	17,709,452	17,892,511
Loss from operations	(11,118,372)	(14,581,378)
Other income (expenses):		
Interest income	437,010	539,158
Loss from continuing operations before income taxes	(10,681,362)	(14,042,220)
Income tax expense	49,953	3,675
Net loss from continuing operations	(10,731,315)	(14,045,895)
Discontinued operations:		
Loss from discontinued operations, net of tax	-	(2,922,406)
Gain on disposal of discontinued operations	-	8,731,487
Income from discontinued operations	-	5,809,081
Net loss	\$ (10,731,315)	\$ (8,236,814)
Net loss per share:		
Loss from continuing operations, basic and diluted	\$ (1.19)	\$ (1.59)
Income from discontinued operations, basic and diluted	\$ -	\$ 0.66
Net loss per share, basic and diluted	\$ (1.19)	\$ (0.94)
Weighted average number of common shares outstanding:		
Basic	8,980,207	8,809,382
Diluted	8,980,207	8,809,382



Marker Therapeutics, Inc.
Consolidated Statements of Cash Flows
(Audited)

	For the Year Ended	
	December 31,	
	2024	2023
Cash Flows from Operating Activities:		
Net loss	\$ (10,731,315)	\$ (8,236,814)
Less: gain from discontinued operations, net of tax	-	5,809,081
Net loss from continuing operations	(10,731,315)	(14,045,895)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	245,864	858,269
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	504,409	861,113
Other receivables	(1,318,888)	1,374,189
Related party payable	380,845	1,329,655
Accounts payable and accrued expenses	8,761	(718,393)
Net cash used in operating activities - continuing operations	(10,910,324)	(10,341,062)
Net cash used in operating activities - discontinued operations	-	(6,098,899)
Net cash used in operating activities	(10,910,324)	(16,439,961)
Cash Flows from Investing Activities:		
Net cash provided by investing activities - discontinued operations	-	18,664,122
Net cash provided by investing activities	-	18,664,122
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	14,929,155	1,014,640
Proceeds from stock options exercise	62,159	90,477
Net cash provided by financing activities	14,991,314	1,105,117
Net increase in cash and cash equivalents	4,080,990	3,329,278
Cash and cash equivalents at beginning of the period	15,111,450	11,782,172
Cash and cash equivalents at end of the period	\$ 19,192,440	\$ 15,111,450

Media and Investor Contact

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