

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 14, 2024

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 November 14, 2024, Marker Therapeutics, Inc. (the “*Company*”) reported financial results for the quarter ended September 30, 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.

Exhibit No. **Description**

[99.1](#) [Press Release dated November 14, 2024.](#)
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: November 14, 2024

By: /s/ Juan Vera
Juan Vera
President and Chief Executive Officer



Marker Therapeutics Reports Third Quarter 2024 Financial Results and Provides Business Updates

Marker Therapeutics to receive two grants from NIH Small Business Innovation Research (SBIR) program to support clinical investigation of MT-601 in patients with lymphoma and metastatic pancreatic cancer

Houston, TX — November 14, 2024 – 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 reported corporate updates and financial results for the third quarter ended September 30, 2024.

“As we approach the end of 2024, we continue to build momentum across our clinical and corporate programs,” said Juan Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “During the third quarter, we made significant progress in our ongoing Phase 1 APOLLO study investigating MT-601 in patients with lymphoma who have relapsed after anti-CD19 chimeric antigen receptor (CAR)-T cell therapy or where CAR-T cells are not an option. Enrollment is ongoing and we expect to be able to report preliminary safety and efficacy data by the end of this year. We, along with our study investigators, have been encouraged by the promising activity shown in this platform and look forward to continuing assessments from the trial.”

“We also recently strengthened our financial position with the receipt of two, \$2 million Small Business Innovation Research (SBIR) grants from the National Institutes of Health (NIH). The non-dilutive funding will be used to support further development of MT-601 in patients with non-Hodgkin’s lymphoma who have relapsed following anti-CD19 CAR-T cell therapy, as well as assist in funding the clinical investigation of MT-601 in pancreatic cancer. We continue to make meaningful progress and remain focused on execution as we move our programs through the clinical trials,” added Dr. Vera.

PROGRAM UPDATES & EXPECTED MILESTONES

MT-601 (Lymphoma)

- Marker’s lead program is investigating MT-601 in the nationwide multicenter Phase 1 APOLLO study ([CLINICALTRIALS.GOV](https://clinicaltrials.gov/ct2/show/study/NCT05798897) identifier: NCT05798897) in patients with lymphoma who have relapsed after anti-CD19 CAR-T cell therapy or where CAR-T cells are not an option.
 - The Company previously reported that one of the Principal Investigators presented preliminary safety and efficacy with sustained objective responses observed in three study participants treated at City of Hope National Medical Center ([PRESS RELEASE, APRIL 8, 2024](#)). Treatment was well tolerated among all study participants with no observation of severe adverse effects such as immune effector cell associated neurotoxicity syndrome (ICANS).
 - All study participants continue to be observed for long-term treatment effects and durability of response.
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- The Company is enrolling additional study participants in the Phase 1 APOLLO trial and expects to provide an update on safety and durability during the fourth quarter of 2024.
- Marker Therapeutics was awarded a \$2 million grant from NIH Small Business Innovation Research Program (SBIR) to support the clinical investigation of MT-601 in patients with lymphoma who have relapsed following anti-CD19 CAR-T cell therapy ([PRESS RELEASE, AUGUST 12, 2024](#)).

MT-601 (Pancreatic)

- The Company was awarded a \$2 million grant from NIH Small Business Innovation Research (SBIR) Program to support the clinical investigation of MT-601 in patients with metastatic pancreatic cancer.
- The Company expects to start the clinical program of MT-601 in patients with metastatic pancreatic cancer in 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-OTS in patients with Acute Myeloid Leukemia (AML) or Myelodysplastic Syndrome (MDS) and anticipates clinical program initiation during the first half of 2025.

THIRD QUARTER 2024 FINANCIAL HIGHLIGHTS

Cash Position and Guidance: At September 30, 2024, Marker had cash and cash equivalents of \$9 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses into October 2025. This estimate is subject to the Company's ability to effectively manage its costs and utilize drawdowns of available grant funds.

R&D Expenses: Research and development expenses were \$3.5 million for the quarter ended September 30, 2024, compared to \$2.0 million for the quarter ended September 30, 2023 as a result of our increased clinical trial activity in the quarter.

G&A Expenses: General and administrative expenses were \$0.9 million for the quarter ended September 30, 2024, compared to \$1.4 million for the quarter ended September 30, 2023 reflecting the savings from the reorganization that was completed in late 2023.

Net Loss: Marker reported a net loss from continuing operations of \$2.3 million for the quarter ended September 30, 2024, compared to \$3.0 million for the quarter ended September 30, 2023.

About multiTAA-specific T cells

The multi-tumor associated antigen (multiTAA)-specific T cell platform 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, multiTAA-specific 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 multiTAA-specific 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. Clinical trials that enrolled more than 200 patients across various hematological and solid tumor indications showed that the Company's autologous and allogeneic multiTAA-specific 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; and the timing, conduct and success 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.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30,	December 31,
	2024	2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 8,999,664	\$ 15,111,450
Prepaid expenses and deposits	1,166,274	988,126
Other receivables	744,410	1,027,815
Total current assets	10,910,348	17,127,391
Total assets	\$ 10,910,348	\$ 17,127,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,557,335	\$ 1,745,193
Related party payable	903,438	1,329,655
Total current liabilities	3,460,773	3,074,848
Total liabilities	3,460,773	3,074,848
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value, 30 million shares authorized, 8.9 million shares issued and outstanding as of September 30, 2024 and December 31, 2023 (see Note 9)	8,923	8,891
Additional paid-in capital	450,620,206	450,329,515
Accumulated deficit	(443,179,554)	(436,285,863)
Total stockholders' equity	7,449,575	14,052,543
Total liabilities and stockholders' equity	\$ 10,910,348	\$ 17,127,391



Marker Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(Unaudited)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenues:				
Grant income	\$ 1,926,020	\$ 257,606	\$ 4,339,317	\$ 2,254,601
Total revenues	<u>1,926,020</u>	<u>257,606</u>	<u>4,339,317</u>	<u>2,254,601</u>
Operating expenses:				
Research and development	3,471,216	2,044,980	8,381,661	7,799,472
General and administrative	854,677	1,412,672	3,214,611	6,098,716
Total operating expenses	<u>4,325,893</u>	<u>3,457,652</u>	<u>11,596,272</u>	<u>13,898,188</u>
Loss from operations	(2,399,873)	(3,200,046)	(7,256,955)	(11,643,587)
Other income (expenses):				
Interest income	91,681	218,085	363,264	337,819
Loss from continuing operations	<u>(2,308,192)</u>	<u>(2,981,961)</u>	<u>(6,893,691)</u>	<u>(11,305,768)</u>
Discontinued operations:				
Loss from discontinued operations, net of tax	—	—	—	(2,922,406)
Gain on disposal of discontinued operations before income taxes	—	—	—	8,794,426
Income from discontinued operations	<u>—</u>	<u>—</u>	<u>—</u>	<u>5,872,020</u>
Net (loss) income	<u><u>\$ (2,308,192)</u></u>	<u><u>\$ (2,981,961)</u></u>	<u><u>\$ (6,893,691)</u></u>	<u><u>\$ (5,433,748)</u></u>
Net (loss) earnings per share:				
Loss from continuing operations, basic and diluted	\$ (0.26)	\$ (0.34)	\$ (0.77)	\$ (1.29)
Income from discontinued operations, basic	\$ —	\$ —	\$ —	\$ 0.67
Income from discontinued operations, diluted	\$ —	\$ —	\$ —	\$ 0.66
Net loss per share	<u><u>\$ (0.26)</u></u>	<u><u>\$ (0.34)</u></u>	<u><u>\$ (0.77)</u></u>	<u><u>\$ (0.62)</u></u>
Weighted average number of common shares outstanding:				
Basic	<u>8,923,170</u>	<u>8,825,881</u>	<u>8,914,487</u>	<u>8,782,340</u>
Diluted	<u>8,923,170</u>	<u>8,825,881</u>	<u>8,914,487</u>	<u>8,834,512</u>



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

	For the Nine Months Ended	
	September 30,	
	2024	2023
Cash Flows from Operating Activities:		
Net loss	\$ (6,893,691)	\$ (5,433,748)
Less: gain from discontinued operations, net of tax	—	5,872,020
Net loss from continuing operations	(6,893,691)	(11,305,768)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	195,320	714,899
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(178,148)	(80,116)
Other receivables	283,405	2,318,691
Related party payable	(426,217)	367,915
Accounts payable and accrued expenses	812,142	(159,567)
Deferred revenue	—	107,530
Net cash used in operating activities - continuing operations	(6,207,189)	(8,036,416)
Net cash used in operating activities - discontinued operations	—	(6,035,961)
Net cash used in operating activities	(6,207,189)	(14,072,377)
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	36,902	1,014,640
Proceeds from stock options exercise	58,501	85,342
Net cash provided by financing activities	95,403	1,099,982
Net (decrease) increase in cash and cash equivalents	(6,111,786)	5,691,727
Cash and cash equivalents at beginning of the period	15,111,450	11,782,172
Cash and cash equivalents at end of the period	\$ 8,999,664	\$ 17,473,899

Contacts

Investors

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