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

August 14, 2024
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.)

2450 Holcombe Blvd, Suite BCM-A, MS: BCM251
Houston, Texas **77021**
(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 2.02 Results of Operations and Financial Condition.

On August 14, 2024, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended June 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 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 August 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: August 14, 2024

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

Exhibit 99.1

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

Preliminary safety and efficacy with sustained objective responses observed in patients with lymphoma treated with MT-601 in Phase 1 APOLLO study

MT-601 was well tolerated with no observation of cytokine release syndrome (CRS) or immune effector cell associated neurotoxicity syndrome (ICANS)

Marker Therapeutics to receive $2 million funding from NIH Small Business Innovation Research (SBIR) program to support clinical investigation of MT-601 in patients with lymphoma

Houston, TX — August 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 second quarter ended June 30, 2024.

"The second quarter of 2024 was characterized by ongoing momentum in our clinical programs," said Juan Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. "Following the positive outcomes reported in the first quarter, we continued to advance our Phase 1 APOLLO study investigating MT-601 in patients with lymphoma who have relapsed after anti-CD19 CAR-T cell therapy or where CAR-T therapy is not an option. In April, Geoffrey Shouse, D.O., Ph.D., the Principal Investigator at City of Hope National Medical Center, presented encouraging data from the APOLLO study, at the 11th Global Summit on Hematologic Malignancies. The data showed that three out of three participants had objective responses, and that treatment was well tolerated among all patients with no significant treatment-related adverse events, further signifying the potential benefit of MT-601 in patients with lymphoma. We are gratified by these preliminary results and expect to provide a more comprehensive clinical update on the APOLLO study in the upcoming quarter."

"Additionally, after the close of the quarter, we announced that Marker has been awarded a $2 million Small Business Innovation Research (SBIR) grant from the National Institutes of Health (NIH) to support our Phase 1 APOLLO study evaluating the safety and efficacy of MT-601 in patients with non-Hodgkin's lymphoma (NHL) who have relapsed following anti-CD19 CAR-T cell therapy. We were pleased to receive this highly competitive grant, which reinforces the potential scientific merit and the capacity of the APOLLO study to address an unmet medical need," 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 identifier: NCT05798897) in patients with lymphoma who relapsed after anti-CD19 CAR-T cell therapy or where CAR-T cells are not an option.

- The Company previously reported 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 cytokine release syndrome (CRS) or immune effector cell associated neurotoxicity syndrome (ICANS).

- All study participants continue to be observed for long-term treatment effects and durability of response. The Company is enrolling additional study participants in the Phase 1 APOLLO trial and expect to provide an update on safety and durability during the third quarter.

- The Company 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-CD CAR-T cell therapy (Press Release, August 12, 2024).

MT-601 (Pancreatic)

- Investigational New Drug (IND) application cleared by U.S. Food and Drug Administration (FDA) for multicenter Phase 1 trial to investigate MT-601 in combination with front-line chemotherapy in patients with metastatic pancreatic cancer.

- Clinical advancement will be pending additional financial support from non-dilutive funding activities.

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

- U.S. FDA has granted an IND to investigate 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 Marker has established a cellular inventory for MT-401-OTS with ongoing efforts to further expansion.

- Marker has non-clinical proof-of-concept data supporting the potential clinical benefits of MT-401-OTS in patients with AML or MDS (Press Release, August 7, 2023).

- The Company secured non-dilutive funding to support the clinical investigation of MT-401-OTS and anticipates the clinical program initiation of MT-401-OTS during the fourth quarter of 2024.

SECOND QUARTER 2024 FINANCIAL HIGHLIGHTS

Cash Position and Guidance: At June 30, 2024, Marker had cash and cash equivalents of $7.8 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the fourth quarter of 2025, inclusive of available drawdowns from grant funds.

R&D Expenses: Research and development expenses were $2.3 million for the quarter ended June 30, 2024, compared to $2.4 million for the quarter ended June 30, 2023.

G&A Expenses: General and administrative expenses were $1.1 million for the quarter ended June 30, 2024, compared to $2.5 million for the quarter ended June 30, 2023.

Net Loss: Marker reported a net loss from continuing operations of $2.2 million for the quarter ended June 30, 2024, compared to $4.1 million for the quarter ended June 30, 2023.

"The financial performance in the past quarter demonstrates the benefits that we are seeing from our restructuring efforts that we initiated in the second quarter of 2023, including our agreement with Cell Ready, and the favorable impact that they are having on our business, especially our Operating Expenses. Unlike most small, pre-revenue companies in the Cell Therapy space, our extremely efficient structure, combined with our successful grant funding initiatives, are allowing us to maximize our cash runway and to focus the majority of our available funds on our clinical programs," concluded Dr. Vera.

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)

	June 30, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,800,464	$ 15,111,450
Prepaid expenses and deposits	1,384,394	988,126
Other receivables	2,490,147	1,027,815
Total current assets	11,675,005	17,127,391
Total assets	**$ 11,675,005**	**$ 17,127,391**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 1,679,672	$ 1,745,193
Related party payable	292,569	1,329,655
Total current liabilities	1,972,241	3,074,848
Total liabilities	1,972,241	3,074,848
Stockholders' equity:		
Preferred stock, $0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	-	-
Common stock, $0.001 par value, 30 million shares authorized, 8.9 million shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively (see Note 8)	8,922	8,891
Additional paid-in capital	450,565,204	450,329,515
Accumulated deficit	(440,871,362)	(436,285,863)
Total stockholders' equity	9,702,764	14,052,543
Total liabilities and stockholders' equity	**$ 11,675,005**	**$ 17,127,391**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Revenues:				
Grant income	$ 1,169,236	$ 762,658	$ 2,413,297	$ 1,996,995
Total revenues	1,169,236	762,658	2,413,297	1,996,995
Operating expenses:				
Research and development	2,335,430	2,377,993	4,910,446	5,754,492
General and administrative	1,141,871	2,518,725	2,359,934	4,686,044
Total operating expenses	3,477,301	4,896,718	7,270,380	10,440,536
Loss from operations	(2,308,065)	(4,134,060)	(4,857,083)	(8,443,541)
Other income (expenses):				
Interest income	115,388	35,080	271,584	119,734
Loss from continuing operations	(2,192,677)	(4,098,980)	(4,585,499)	(8,323,807)
Discontinued operations:				
Loss from discontinued operations, net of tax	-	(2,179,657)	-	(2,922,406)
Gain on disposal of discontinued operations	-	8,794,426	-	8,794,426
Income from discontinued operations	-	6,614,769	-	5,872,020
Net income/(loss)	**$ (2,192,677)**	**$ 2,515,789**	**$ (4,585,499)**	**$ (2,451,787)**
Net loss per share:				
Loss from continuing operations, basic and diluted	$ (0.25)	$ (0.47)	$ (0.51)	$ (0.95)
Income from discontinued operations, basic and diluted	$ -	$ 0.75	$ -	$ 0.67
Net income/(loss) per share, basic and diluted	$ (0.25)	$ 0.29	$ (0.51)	$ (0.28)
Weighted average number of common shares outstanding:				
Basic	8,918,233	8,798,956	8,910,097	8,760,209
Diluted	8,918,233	8,798,956	8,910,097	8,760,209

Marker Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows
(Unaudited)

	For the Six Months Ended June 30,	
	2024	**2023**
Cash Flows from Operating Activities:		
Net loss	$ (4,585,499)	$ (2,451,787)
Less: income from discontinued operations, net of tax	-	5,872,020
Net loss from continuing operations	(4,585,499)	(8,323,807)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	142,018	539,858
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(396,268)	(238,223)
Other receivables	(1,462,332)	655,904
Related party payable	(1,037,086)	-
Accounts payable and accrued expenses	(65,521)	197,030
Net cash used in operating activities - continuing operations	(7,404,688)	(7,169,238)
Net cash used in operating activities - discontinued operations	-	(5,775,680)
Net cash used in operating activities	(7,404,688)	(12,944,918)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	-	18,664,122
Net cash provided by (used in) investing activities	-	18,664,122
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	36,902	619,974
Proceeds from stock options exercise	56,800	736
Net cash provided by financing activities	93,702	620,710
Net (decrease)/increase in cash and cash equivalents	(7,310,986)	6,339,914
Cash and cash equivalents at beginning of the period	15,111,450	11,782,172
Cash and cash equivalents at end of the period	$ 7,800,464	$ 18,122,086

Contacts
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