

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

May 15, 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.)

9350 Kirby Drive, Suite 300

Houston, Texas

(Address of principal executive offices)

77054

(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 May 15, 2024, Marker Therapeutics, Inc. (the “*Company*”) reported financial results for the quarter ended March 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 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 May 15, 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: May 15, 2024

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



Marker Therapeutics Reports First 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

Study participant with Non-Hodgkin's Lymphoma who relapsed within 90 days of anti-CD19 CAR T cell therapy remains in complete response nine months after MT-601 treatment

Company received approval from United States Adopted Name (USAN) council and International Nonproprietary Names (INN) expert committee for "neldaleucel" as nonproprietary name for MT-601

Houston, TX — May 15, 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 first quarter ended March 31, 2024.

“We are pleased to report a strong start to the first quarter of 2024, marked by continued advances in our clinical programs,” said Juan Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “Building on our positive results, we continue to observe objective responses in our Phase 1 APOLLO study investigating MT-601 in patients with lymphoma who have relapsed or are ineligible for CAR T therapy. We recently announced that our first patient treated in this study achieved a complete response, which was maintained nine months after initial treatment with MT-601. This patient relapsed within 90 days of CAR T therapy, indicating that MT-601 has superior durability in this study participant. In April, our Principal Investigator at City of Hope National Medical Center was invited to share his findings from the APOLLO trial at a medical conference, where he presented data from two additional study participants and that three out of three subjects treated at City of Hope demonstrated objective responses. While we plan to provide a more comprehensive clinical update on the APOLLO study in the second half of this year, we are encouraged by these preliminary results, which underscore the potential benefit of MT-601 in patients with lymphoma.”

“Another significant milestone this quarter was to receive approval from the United States Adopted Name (USAN) council and International Nonproprietary Names (INN) expert committee for “neldaleucel” as nonproprietary drug name for MT-601. Having made these steady advances, we are confident that we are well positioned to achieve our near- and long-term goals related to MT-601 in patients with lymphoma,” concluded Dr. Vera.



PROGRAM UPDATES & EXPECTED MILESTONES

MT-601 (Lymphoma)

- Phase 1 multicenter APOLLO trial (clinicaltrials.gov identifier: NCT05798897), investigating MT-601 in patients with lymphoma who relapsed or are ineligible for anti-CD19 CAR T cell therapies, was selected as lead program based on promising preliminary clinical results and non-clinical proof-of-concept data ([Press Release, January 8, 2024](#)).
- Three patients were treated at City of Hope National Medical Center as part of the APOLLO study:
 - First study participant treated with MT-601 had diffuse large B cell lymphoma (DLBCL) and failed four prior lines of therapy, including a relapse within 90 days of anti-CD19 CAR T cell therapy (Breyanzi) ([Press Release, June 12, 2023](#)). Without prior lymphodepletion, this participant achieved a complete response eight weeks after the second infusion of MT-601 and remains in complete response nine months after initial treatment with MT-601 ([Press Release, April 8, 2024](#)).
 - Another study participant had transformed follicular Non-Hodgkin's Lymphoma (NHL) and failed 12 lines of therapy, including bispecific T cell engager therapy (mosunetuzumab) for follicular NHL, and anti-CD19 CAR T cells (Yescarta) after transformation into DLBCL. At the time of MT-601 infusion, only follicular NHL persisted in this patient. Eight weeks after initial infusion with MT-601 without prior lymphodepletion, the study participant achieved a complete response, which remains three months following treatment with MT-601 ([Press Release, April 8, 2024](#)).
 - The third study participant treated had DLBCL with cutaneous involvement and was not eligible for CAR T cell therapy. This participant achieved a partial response eight weeks after MT-601 treatment without prior lymphodepletion with all lesions decreasing in size including one that has completely resolved ([Press Release, April 8, 2024](#)).
 - Treatment was well tolerated among all patients with no significant treatment-related adverse events including cytokine release syndrome or neurotoxicity.
 - All patients continue to be observed for durability of response.
- The Company is enrolling additional patients in the Phase 1 APOLLO trial and expects to report further data in the second half of 2024.
- MT-601 designated non-proprietary name "*neldaleuce*" by United States Adopted Name (USAN) Counsel and International Nonproprietary Names (INN) Expert Committee.

MT-601 (Pancreatic)

- Investigational New Drug (IND) application cleared by U.S. Food and Drug Administration (FDA) for multicenter Phase 1 trial of MT-601 in patients with metastatic pancreatic cancer in combination with front-line chemotherapy.
- Clinical advancement will be pending additional financial support from non-dilutive grant activities.

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

- To streamline resources and to reduce time to treatment, Marker decided to discontinue the patient-specific part of the Acute Myeloid Leukemia (AML) program and to focus on a ready for use "Off-the-Shelf" product ([Press Release, January 8, 2024](#)).
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- U.S. FDA has granted an Investigational New Drug (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 with ongoing efforts of expanding it further.
- Granted Orphan Drug Designation from the European Medicines Agency (EMA) and U.S. FDA.
- Marker has non-clinical proof-of-concept data supporting the clinical benefits of MT-401-OTS in AML and secured \$2M in non-dilutive funding from the NIH Small Business Innovation Research (SBIR) program to support the clinical investigation of MT-401-OTS in patients with AML.
- Clinical program initiation of MT-401-OTS anticipated for the second half of 2024.

FIRST QUARTER 2024 FINANCIAL HIGHLIGHTS

Cash Position and Guidance: At March 31, 2024, Marker had cash and cash equivalents of \$11.3 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 \$2.6 million for the quarter ended March 31, 2024, compared to \$3.4 million for the quarter ended March 31, 2023.

G&A Expenses: General and administrative expenses were \$1.2 million for the quarter ended March 31, 2024, compared to \$2.2 million for the quarter ended March 31, 2023.

Net Loss: Marker reported a net loss of \$2.4 million for the quarter ended March 31, 2024, compared to a net loss of \$4.9 million for the quarter ended March 31, 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. Since multiTAA-specific T cells are not genetically engineered, Marker believes that its 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 benefits. As a result, Marker believes that its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

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 and MT-401-OTS. 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 our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.



Marker Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2024	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 11,323,428	\$ 15,111,450
Prepaid expenses and deposits	917,009	988,126
Other receivables	1,851,462	1,027,815
Total current assets	14,091,899	17,127,391
Total assets	\$ 14,091,899	\$ 17,127,391
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 1,949,700	\$ 1,745,193
Related party payable	353,965	1,329,655
Total current liabilities	2,303,665	3,074,848
Total liabilities	2,303,665	3,074,848
Stockholders' equity:		
Preferred stock, \$0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	—	—
Common stock, \$0.001 par value, 30 million shares authorized, 8.9 million issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	8,910	8,891
Additional paid-in capital	450,458,009	450,329,515
Accumulated deficit	(438,678,685)	(436,285,863)
Total stockholders' equity	11,788,234	14,052,543
Total liabilities and stockholders' equity	\$ 14,091,899	\$ 17,127,391



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

	For the Three Months Ended March 31,	
	2024	2023
Revenues:		
Grant income	\$ 1,244,061	\$ 1,234,336
Total revenues	<u>1,244,061</u>	<u>1,234,336</u>
Operating expenses:		
Research and development	2,575,015	3,376,497
General and administrative	1,218,063	2,167,318
Total operating expenses	<u>3,793,078</u>	<u>5,543,815</u>
Loss from operations	(2,549,017)	(4,309,479)
Other income (expenses):		
Interest income	156,195	84,654
Loss from continuing operations	<u>(2,392,822)</u>	<u>(4,224,825)</u>
Discontinued operations:		
Loss from discontinued operations, net of tax	—	(742,751)
Income (loss) from discontinued operations	—	(742,751)
Net loss	<u>\$ (2,392,822)</u>	<u>\$ (4,967,576)</u>
Net earnings (loss) per share:		
Loss from continuing operations, basic and diluted	\$ (0.27)	\$ (0.48)
Income (loss) from discontinued operations, basic and diluted	\$ —	\$ (0.09)
Net loss per share, basic and diluted	<u>\$ (0.27)</u>	<u>\$ (0.57)</u>
Weighted average number of common shares outstanding:		
Basic	<u>8,901,962</u>	<u>8,721,031</u>
Diluted	<u>8,901,962</u>	<u>8,721,031</u>



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

	For the Three Months Ended	
	March 31,	
	2024	2023
Cash Flows from Operating Activities:		
Net loss	\$ (2,392,822)	\$ (4,967,576)
Less: loss from discontinued operations, net of tax	-	(742,751)
Net loss from continuing operations	(2,392,822)	(4,224,825)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	79,417	659,913
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	71,117	36,452
Other receivables	(823,647)	1,319,118
Related party receivable	—	(1,000,000)
Related party payable	(975,690)	
Accounts payable and accrued expenses	204,507	111,171
Net cash used in operating activities - continuing operations	(3,837,118)	(3,098,171)
Net cash used in operating activities - discontinued operations	—	(2,790,124)
Net cash used in operating activities	(3,837,118)	(5,888,295)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	—	(112,608)
Net cash provided by (used in) investing activities	—	(112,608)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	—	619,974
Proceeds from stock options exercise	49,096	—
Net cash provided by financing activities	49,096	619,974
Net increase (decrease) in cash and cash equivalents	(3,788,022)	(5,380,929)
Cash and cash equivalents at beginning of the period	15,111,450	11,782,172
Cash and cash equivalents at end of the period	\$ 11,323,428	\$ 6,401,243

Contacts

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