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, 2023
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.)

9350 Kirby Drive, Suite 300 **Houston, Texas**	**77054**
(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, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended June 30, 2023 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, 2023
104	Inline XBRL for the cover page of this Current Report on Form 8-K

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, 2023

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

Exhibit 99.1

Marker Therapeutics Reports Second Quarter 2023 Financial Results and Provides Business Update

Executed comprehensive non-dilutive agreement with Cell Ready™, resulting in an extended financial runway into the fourth quarter of 2025

Appointed Juan Vera, M.D. as President and Chief Executive Officer and Monic Stuart, M.D., MPH, as Chief Medical Officer to spearhead Marker's restructuring efforts and guide clinical advancement of Marker's multiTAA-specific T cell technology

Announced encouraging non-clinical data from MT-401 program demonstrating increased anti-tumor activity against an acute myeloid leukemia (AML) cell line after treatment with hypomethylating agents (HMA)

Received $2 million of non-dilutive funding from National Institute of Health (NIH) to support MT-401 program for treatment of patients with AML

Commenced treatment of first patient with lymphoma with MT-601 multiTAA-specific T cell-based therapy in Phase 1 trial following positive non-clinical data announcement

HOUSTON, August 14, 2023 (GLOBE NEWSWIRE) -- 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 tumor indications, today reported corporate updates and financial results for the second quarter ended June 30, 2023.

"The second quarter of 2023 proved to be a highly beneficial time at Marker from an operational and clinical standpoint, and I am excited by our comprehensive strategic advancements," commented Dr. Juan F. Vera, the new President and Chief Executive Officer of Marker Therapeutics. "Importantly, we extended our cash runway through 2025 by an agreement with Cell Ready, a newly formed contract development and manufacturing organization (CDMO). In exchange for certain cell manufacturing assets, Cell Ready provided Marker with approximately $19 million in cash and Cell Ready will absorb approximately $11 million of Marker's overhead expense annually while simultaneously ensuring that Marker's manufacturing and research and development (R&D) needs will be fully met. As a result, we are now able to aggressively and strategically advance our unique multiTAA-specific T cell therapies toward meaningful clinical milestones."

Dr. Vera added, “Our R&D work has yielded non-clinical evidence for our multiTAA-specific T cell programs. In May, we reported compelling, non-clinical data for the MT-601 product candidate in lymphoma cells that highlighted the potential merit of multiTAA-specific T cell therapy in patients with CD19-directed CAR T cell refractory lymphoma. Shortly after, the first patient, who has relapsed following multiple therapies, including anti-CD19 CAR T treatment, was treated in our Phase 1, multicenter (“APOLLO”) clinical trial.”

“We also continue to progress the MT-401 program in patients suffering from Acute Myeloid Leukemia (AML). In June, we announced positive, non-clinical, in vitro data that demonstrated enhanced MT-401-induced tumor killing in an AML cell line after standard-of-care treatment with hypomethylating agents (HMA), suggesting a synergistic effect of HMA boosting the anti-tumor response of MT-401,” said Dr. Vera. “As a result of this work, Marker was awarded a $2 million grant from the National Institutes of Health (NIH) Small Business Innovation Research (SBIR) program to support the development and investigation of MT-401 for the treatment of AML patients following standard-of-care therapy with HMA. On the regulatory front, we reached a significant milestone by receiving Orphan Drug Designation for MT-401 in July from the European Medicines Agency (EMA), which validates the potential therapeutic impact of MT-401 in patients with AML and potentially provides an expedited development pathway.”

“Having made these broad-based advances in the second quarter, the new management team and I believe that Marker’s future has never been brighter. These advances position Marker to unlock significant value. To this end, we are finalizing an updated clinical development plan, which we expect to unveil in the coming months,” concluded Dr. Vera.

Recent Clinical and Operational Highlights:

MT-401 (Acute Myeloid Leukemia)

- Marker reported non-clinical data showing enhanced anti-tumor activity of MT-401 in AML cells following HMA exposure.
- Based on non-clinical data, Marker was awarded a $2 million grant from the NIH SBIR program to support clinical investigation of MT-401 after HMA administration.
- After receiving Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA), Marker was granted ODD from the Committee for Orphan Medicinal Products of the EMA for the treatment of AML patients.
- Marker reported non-clinical proof-of-concept data for MT-401 in an Off-the-Shelf (OTS) setting and provided an update on clinical readiness for the OTS program. The U.S. FDA has cleared the clinical protocol to investigate MT-401 OTS in patients with relapsed AML. Marker has implemented a patient cellular inventory and anticipates the first AML patient to be treated with MT-401 OTS during the first half of 2024.

MT-601 (Lymphoma)

- Marker provided non-clinical data demonstrating the anti-tumor activity of MT-601 in anti-CD19 CAR T resistant lymphoma cells, indicating the potential clinical benefit of MT-601 in patients with CAR T refractory lymphoma.
- Initiation of the Phase 1 APOLLO trial (clinicaltrials.gov Identifier: NCT05798897) for treatment of patients with lymphoma who have relapsed after, or are ineligible for, anti-CD19 CAR T cell therapy. First patient with lymphoma was treated with MT-601 at a 200 million cell dose level and showed no treatment-related adverse events, suggesting a similar favorable safety profile and tolerability of multiTAA-specific T cell products as observed in previous clinical studies.

MT-601 (Pancreatic)

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

Executive Leadership

- Appointed Juan Vera, M.D., President and Chief Executive Officer and Monic Stuart, M.D., MPH, Chief Medical Officer, whose combined experience will significantly aid Marker in advancing its clinical programs.

Strategic and Financial Partnerships

- On June 26, 2023, Marker completed the previously announced non-dilutive transaction with Cell Ready, under which Cell Ready purchased certain cell manufacturing assets from Marker for approximately $19 million in cash. Marker anticipates that the cost savings from the transaction, including the assumption of facility leases by Cell Ready and the hiring by Cell Ready of over 50 of Marker's employees in its manufacturing, R&D, quality and regulatory affairs functions, will result in a reduction of Marker's operating expenses by approximately $11 million annually, and should extend Marker's cash runway into the fourth quarter of 2025.
- In April 2022, Marker entered into a service agreement with Wilson Wolf Manufacturing Corporation (Wilson Wolf Agreement). Pursuant to the Wilson Wolf Agreement, Marker received an additional $1 million in May 2023 as the work was completed within one year from the onset of the agreement, achieving the agreed milestone.

Second Quarter 2023 Financial Highlights:

- **Cash Position**: At June 30, 2023, Marker had cash and cash equivalents of $18.1 million.
- **R&D Expenses:** Research and development expenses from continuing operations were $2.4 million for the quarter ended June 30, 2023, compared to $2.9 million for the quarter ended June 30, 2022.
- **G&A Expenses:** General and administrative expenses from continuing operations were $2.5 million for the quarter ended June 30, 2023, compared to $3.1 million for the quarter ended June 30, 2022.
- **Net Income (Loss):** Marker reported net income of $2.5 million for the quarter ended June 30, 2023, compared to a net loss of ($9.2) million for the quarter ended June 30, 2022.

About Marker Therapeutics, Inc.

Marker Therapeutics, Inc. is a clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumor indications. The cell therapy technology Marker has in place is based on the selective expansion of non-engineered, tumor-specific T cells that recognize tumor associated antigens (i.e., tumor targets) and kill tumor cells expressing those targets. This population of T cells is designed to attack multiple tumor targets following infusion into patients and to activate the patient's immune system to produce broad spectrum anti-tumor activity. Because Marker does not genetically engineer the T cells, 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 benefit. As a result, Marker believes its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

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 Marker'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 and success of our clinical trials of our product candidates; our ability to recognize the benefits of the Cell Ready transaction; anticipated cost savings as a result of the Cell Ready transaction; and our future operating expenses and capital expenditure requirements, including our anticipated cash runway. 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 Marker's most recent Form 10-K, 10-Q and other SEC filings which are available through EDGAR at WWW.SEC.GOV. Marker 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, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,122,086	$ 11,782,172
Prepaid expenses and deposits	2,087,462	1,849,239
Other receivables	1,746,100	2,402,004
Current assets of discontinued operations	-	585,840
Total current assets	21,955,648	16,619,255
Non-current assets of discontinued operations		17,802,929
Total assets	**$ 21,955,648**	**$ 34,422,184**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,660,616	$ 2,521,193
Current liabilities of discontinued operations	260,280	5,260,616
Total current liabilities	2,920,896	7,781,809
Non-current liabilities of discontinued operations	-	7,039,338
Total liabilities	2,920,896	14,821,147
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	-	-
Common stock, $0.001 par value, 30 million shares authorized, 8.8 million and 8.4 million shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	8,799	8,406
Additional paid-in capital	449,526,789	447,641,680
Accumulated deficit	(430,500,836)	(428,049,049)
Total stockholders' equity	19,034,752	19,601,037
Total liabilities and stockholders' equity	**$ 21,955,648**	**$ 34,422,184**

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Grant income	$ 762,658	$ 790,508	$ 1,996,995	$ 1,754,830
Total revenues	762,658	790,508	1,996,995	1,754,830
Operating expenses:				
Research and development	2,377,993	2,923,877	5,754,492	6,194,241
General and administrative	2,518,725	3,135,168	4,686,044	6,486,465
Total operating expenses	4,896,718	6,059,045	10,440,536	12,680,706
Loss from operations	(4,134,060)	(5,268,537)	(8,443,541)	(10,925,876)
Other income (expenses):				
Arbitration settlement	-	-	-	(118,880)
Interest income	35,080	35,786	119,734	38,902
Loss from continuing operations	(4,098,980)	(5,232,751)	(8,323,807)	(11,005,854)
Discontinued operations:				
Loss from discontinued operations before income taxes	(2,179,657)	(4,011,437)	(2,922,406)	(8,148,842)
Gain on disposal of discontinued operations	8,794,426	-	8,794,426	-
Income (loss) from discontinued operations	6,614,769	(4,011,437)	5,872,020	(8,148,842)
Net income (loss)	**$ 2,515,789**	**$ (9,244,188)**	**$ (2,451,787)**	**$ (19,154,696)**
Net earnings (loss) per share, basic and diluted:				
Loss from continuing operations	$ (0.47)	$ (0.63)	$ (0.95)	$ (1.32)
Income (loss) from discontinued operations	$ 0.75	$ (0.48)	$ 0.67	$ (0.98)
Net earnings (loss) per share	$ 0.29	$ (1.11)	$ (0.28)	$ (2.30)
Weighted average number of common shares outstanding,				
Basic and diluted	8,798,956	8,359,205	8,760,209	8,335,119

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

	For the Six Months Ended June 30,	
	2023	**2022**
Cash Flows from Operating Activities:		
Net loss	$ (2,451,787)	$ (19,154,696)
Less: gain (loss) from discontinued operations, net of tax	5,872,020	(8,148,842)
Net loss from continuing operations	(8,323,807)	(11,005,854)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	539,858	1,986,402
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(238,223)	(309,254)
Other receivables	655,904	(627,392)
Accounts payable and accrued expenses	197,030	(1,061,562)
Deferred revenue	-	(1,146,186)
Net cash used in operating activities - continuing operations	(7,169,238)	(12,163,846)
Net cash used in operating activities - discontinued operations	(5,775,680)	(856,922)
Net cash used in operating activities	(12,944,918)	(13,020,768)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	18,664,122	(4,718,428)
Net cash provided by (used in) investing activities	18,664,122	(4,718,428)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	619,974	63,573
Proceeds from stock options exercise	736	-
Net cash provided by financing activities	620,710	63,573
Net increase (decrease) in cash, cash equivalents and restricted cash (1)	6,339,914	(17,675,623)
Cash, cash equivalents and restricted cash at beginning of the period (1)	11,782,172	43,497,331
Cash and cash equivalents at end of the period	$ 18,122,086	$ 25,821,708

(1) As of June 30, 2022 and December 31, 2021, the Company had $0 and $1,146,186 of restricted cash, respectively.

Contacts
TIBEREND STRATEGIC ADVISORS, INC.
Investors
Daniel Kontoh-Boateng
(862) 213-1398
DBOATENG@TIBEREND.COM

Media
Casey McDonald
(646) 577-8520
CMCDONALD@TIBEREND.COM