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 9, 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 November 9, 2023, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended September 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 November 9, 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: November 9, 2023

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

Exhibit 99.1

Marker Therapeutics Reports Third Quarter 2023 Financial Results and Provides Business Updates

Announced complete response in first patient with lymphoma treated with MT-601 in Phase 1 APOLLO trial following CAR T relapse

Received Orphan Drug Designation (ODD) from European Medicines Agency (EMA) for multiTAA-specific T cell product candidate MT-401 (zedenoleucel) for the treatment of patients with Acute Myeloid Leukemia (AML)

Demonstrated enhanced anti-tumor activity in an aggressive, treatment-resistant AML cell line and provided an update on clinical readiness of the MT-401 Off-the-Shelf (OTS) program

HOUSTON, November 9, 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 third quarter ended September 30, 2023.

“During the third quarter of 2023, we continued to diligently advance and execute our clinical objectives across our novel multiTAA-specific T cell pipeline,” commented Juan F. Vera, M.D., President and Chief Executive Officer of Marker Therapeutics. “Among the many highlights, we announced in September that we observed a complete response in the first patient with lymphoma treated with MT-601, our multiTAA-specific T cell product candidate targeting six antigens. This study participant was enrolled in our Phase 1 APOLLO trial after failing anti-CD19 CAR T cell therapy. The positive clinical outcome in this CAR T relapsed participant is supported by non-clinical proof-of-concept data and highlights the potential of MT-601 in patients who have relapsed after CAR T cell therapy. Together with the favorable clinical safety and tolerability profile, MT-601 may represent a suitable alternative for the treatment of patients with lymphoma.”

“In July, our MT-401 program was granted Orphan Drug Designation by the EMA for the treatment of patients with AML,” continued Dr. Vera. “We also reported non-clinical proof-of-concept data from our MT-401-OTS program, which indicated the potential anti-tumor activity of the product in a partially human leukocyte antigen (HLA) matched setting. With the clearance of our clinical protocol for MT-401-OTS from the U.S. FDA and the added validation from our non-clinical work, we anticipate initiating a clinical trial in 2024 to evaluate the potential of this novel therapy in patients with relapsed/refractory AML.”

“To maximize shareholder value and accelerate our patient-centric mission, we continue to engage in internal and external conversations with pertinent stakeholders to optimize our clinical development plan, which we expect to announce in the first quarter of 2024. With our healthy balance sheet and clinical progress shown to date, we believe we are well poised to achieve our near-and long-term growth objectives,” concluded Dr. Vera.

Program Updates and Expected Milestones:

MT-401 (Acute Myeloid Leukemia)

- Marker was granted ODD from the Committee for Orphan Medicinal Products of the EMA for the treatment of patients with AML. This follows the ODD from U.S. FDA in 2020.

- Marker reported non-clinical proof-of-concept data of MT-401 in an OTS setting and provided updates on clinical readiness for the MT-401-OTS program, which will investigate the treatment of patients with relapsed/refractory AML. Marker has established an inventory for MT-401-OTS and anticipates initial patient treatment in 2024.

- Marker reported non-clinical data to bolster the clinical investigation of MT-401 after hypomethylating agent (HMA) administration and received a $2 million grant from the NIH Small Business Innovation Research (SBIR) program in support of the clinical study.

MT-601 (Lymphoma)

- Complete response in the first patient with lymphoma treated with MT-601 in the Phase 1 multicenter APOLLO trial (clinicaltrials.gov identifier: NCT05798897) following participant's failure to respond to four prior lines of therapy including anti-CD19 CAR T cell therapy. The study participant was treated with 2 doses of MT-601 at a 200 million cell dose level without prior lymphodepletion and showed no clinically significant treatment-related adverse events. At the first assessment, eight weeks after the second infusion of MT-601, the participant demonstrated a complete metabolic response based on PET-CT scans. MT-601 treatment was well tolerated with no treatment-related adverse events.

- This clinical observation is supported by *in vitro* data demonstrating the anti-tumor activity of MT-601 in anti-CD19 CAR T resistant lymphoma cells, highlighting the therapeutic potential of MT-601.

- Marker is treating and evaluating additional patients in the Phase 1 APOLLO trial and anticipates reporting additional data in the first half of 2024.

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.

Third Quarter 2023 Financial Highlights:

- **Cash Position**: Cash and cash equivalents of $17.5 million at September 30, 2023.

- **R&D Expenses:** Research and development expenses were $2.0 million for the quarter ended September 30, 2023, compared to $3.6 million for the quarter ended September 30, 2022. The decrease in R&D expenses was primarily attributable to lower expenses from the sale of Marker's cell processing facility to Cell Ready, which was completed in June 2023.

- **G&A Expenses:** General and administrative expenses were $1.4 million for the quarter ended September 30, 2023, compared to $3.2 million for the quarter ended September 30, 2022. The decrease in G&A expenses was also primarily attributable to the sale of Marker's cell processing facility to Cell Ready.

- **Net Loss:** Marker reported a net loss of ($3.0) million for the quarter ended September 30, 2023, compared to a net loss of ($6.9) million, inclusive of the $(1.2) million loss from discontinued operations, reflected in the quarter ended September 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 T cell therapy technology developed by Marker 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, including MT-601 for the treatment of patients with lymphoma and MT-401 for the treatment of patients with AML; the potential benefits of orphan drug designation to MT401; 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)

	September 30, 2023	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,473,899	$ 11,782,172
Prepaid expenses and deposits	1,929,355	1,849,239
Other receivables	83,313	2,402,004
Current assets of discontinued operations	-	585,840
Total current assets	19,486,567	16,619,255
Non-current assets of discontinued operations	-	17,802,929
Total assets	**$ 19,486,567**	**$ 34,422,184**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 2,304,019	$ 2,521,193
Related party payable	367,915	-
Deferred revenue	107,530	-
Current liabilities of discontinued operations	-	5,260,616
Total current liabilities	2,779,464	7,781,809
Non-current liabilities of discontinued operations	-	7,039,338
Total liabilities	2,779,464	14,821,147
Stockholders' equity:		
Preferred stock, $0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	-	-
Common stock, $0.001 par value, 30 million shares authorized, 8.8 million and 8.4 million shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	8,888	8,406
Additional paid-in capital	450,181,012	447,641,680
Accumulated deficit	(433,482,797)	(428,049,049)
Total stockholders' equity	16,707,103	19,601,037
Total liabilities and stockholders' equity	**$ 19,486,567**	**$ 34,422,184**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues:				
Grant income	$ 257,606	$ 999,571	$ 2,254,601	$ 2,754,401
Total revenues	257,606	999,571	2,254,601	2,754,401
Operating expenses:				
Research and development	2,044,980	3,591,897	7,799,472	9,786,138
General and administrative	1,412,672	3,234,133	6,098,716	9,720,598
Total operating expenses	3,457,652	6,826,030	13,898,188	19,506,736
Loss from operations	(3,200,046)	(5,826,459)	(11,643,587)	(16,752,335)
Other income (expenses):				
Arbitration settlement	-	-	-	(118,880)
Interest income	218,085	99,750	337,819	138,653
Loss from continuing operations	(2,981,961)	(5,726,709)	(11,305,768)	(16,732,562)
Discontinued operations:				
Loss from discontinued operations, net of tax	-	(1,192,874)	(2,922,406)	(9,341,717)
Gain on disposal of discontinued operations	-	-	8,794,426	-
Income (loss) from discontinued operations	-	(1,192,874)	5,872,020	(9,341,717)
Net loss	**$ (2,981,961)**	**$ (6,919,583)**	**$ (5,433,748)**	**$ (26,074,279)**
Net earnings (loss) per share:				
Loss from continuing operations, basic and diluted	$ (0.34)	$ (0.69)	$ (1.29)	$ (2.01)
Income (loss) from discontinued operations, basic	$ -	$ (0.14)	$ 0.67	$ (1.12)
Income (loss) from discontinued operations, diluted	$ -	$ (0.14)	$ 0.66	$ (1.12)
Net loss per share	$ (0.34)	$ (0.83)	$ (0.62)	$ (3.13)
Weighted average number of common shares outstanding:				
Basic	8,825,881	8,359,920	8,782,340	8,343,477
Diluted	8,825,881	8,359,920	8,834,512	8,343,477

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

	For the Nine Months Ended September 30, 2023	
	2023	**2022**
Cash Flows from Operating Activities:		
Net loss	$ (5,433,748)	$ (26,074,279)
Less: gain (loss) from discontinued operations, net of tax	5,872,020	(9,341,717)
Net loss from continuing operations	(11,305,768)	(16,732,562)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation	714,899	2,921,765
Gain on lease termination	-	(278,681)
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(80,116)	(204,222)
Other receivables	2,318,691	(1,680,782)
Accounts payable and accrued expenses	208,348	(289,148)
Deferred revenue	107,530	(1,146,186)
Net cash used in operating activities - continuing operations	(8,036,416)	(17,409,816)
Net cash used in operating activities - discontinued operations	(6,035,961)	(3,256,915)
Net cash used in operating activities	(14,072,377)	(20,666,731)
Cash Flows from Investing Activities:		
Net cash provided by (used in) investing activities - discontinued operations	18,664,122	(4,817,794)
Net cash provided by (used in) investing activities	18,664,122	(4,817,794)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	1,014,640	63,573
Proceeds from stock options exercise	85,342	-
Net cash provided by financing activities	1,099,982	63,573
Net increase (decrease) in cash, cash equivalents and restricted cash	5,691,727	(25,420,952)
Cash, cash equivalents and restricted cash at beginning of the period	11,782,172	43,497,331
Cash, cash equivalents and restricted cash at end of the period	$ 17,473,899	$ 18,076,379

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