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 10, 2022
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.)

4551 Kennedy Commerce Dr. **Houston, Texas**	**77027**
(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 10, 2022, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended September 30, 2022 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 10, 2022
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 10, 2022

By: /s/ Peter Hoang
Peter Hoang
President and Chief Executive Officer

Exhibit 99.1

Marker Therapeutics Reports Q3 2022 Operating and Financial Results

Company awarded $2 million U.S. FDA Orphan Products Grant to support Phase 2 ARTEMIS trial of its lead T cell therapy candidate MT-401 in patients with post-transplant AML

Houston, TX— November 10, 2022—Marker Therapeutics, Inc. (Nasdaq: MRKR), 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, today provided a corporate update and reported financial results for the third quarter ended September 30, 2022.

“This quarter we reached a major milestone in treating the first six patients in our Phase 2 AML trial with T cells derived from our new manufacturing process, which are designed for increased potency against tumor antigens,” said Peter L. Hoang, Marker’s President and Chief Executive Officer. “We are also pleased to receive a grant from the FDA Orphan Products program to support the Phase 2 treatment arm evaluating MT-401 in patients with minimal residual disease. We believe the MRD-positive patient population represents a significant opportunity for MT-401 as we continue to dose more patients in the trial and measure long-term response.”

PROGRAM UPDATES AND EXPECTED MILESTONES

Acute Myeloid Leukemia (MT-401)

- In September 2022, Marker announced that it had been awarded a $2 million grant from the U.S. Food and Drug Administration (FDA) Orphan Products Grants program to support the Phase 2 ARTEMIS trial of the company’s lead multi-tumor-associated antigen (MultiTAA) T cell product candidate, MT-401, in patients with post-transplant AML. The FDA grant will support the Company’s treatment arm evaluating MT-401 in patients with post-transplant AML with minimal residual disease. MT-401 was granted Orphan Drug Designation for the treatment of patients with AML following allogeneic stem cell transplant in 2020.

- The Company has treated all six patients in Cohorts 4 and 5 using MT-401 manufactured with Marker’s new T cell manufacturing process. The new manufacturing process is designed to produce a more potent product with increased antigen specificity and diversity and a reduction in manufacturing time. To date, all six patients have completed dose-limiting toxicity (DLT) periods with no DLTs reported. The Company expects to announce an efficacy analysis from the six patients in Cohorts 4 and 5 by year-end.

- Marker remains on track to dose the first patient in 2023 with MT-401-OTS, a scalable, off-the-shelf product candidate with the potential to match patients to treatment in under three days. The Company is in the process of developing a patient cell bank inventory.

Lymphoma (MT-601)

- In August 2022, Marker announced that the U.S. FDA cleared the Company's Investigational New Drug Application (IND) for a Phase 1 study of MT-601, a multiTAA-specific T cell product targeting six antigens, for the treatment of patients with relapsed/refractory non-Hodgkin lymphoma who have failed or are ineligible to receive anti-CD19 CAR T cell treatment.

- The Company expects some sites to open before the end of the year and to enroll the first patient in the Phase 1 trial in Q1 of 2023.

Pancreatic Cancer (MT-601)

- The Company intends to initiate a Phase 1 multicenter study of MT-601 administered in combination with front-line chemotherapy to patients with locally advanced unresectable or metastatic pancreatic cancer in 2023.

THIRD QUARTER 2022 FINANCIAL RESULTS

- **Cash Position and Guidance**: At September 30, 2022, Marker had cash and cash equivalents of $18.1 million.

- **Revenues**: For the quarter ended September 30, 2022, Marker recorded $1.0 million of grant income and $2.95 million of related party service revenue.

- **R&D Expenses:** Research and development expenses were $7.3 million for the quarter ended September 30, 2022, compared to $6.8 million for the quarter ended September 30, 2021.

- **G&A Expenses:** General and administrative expenses were $3.7 million for the quarter ended September 30, 2022, compared to $3.2 million for the quarter ended September 30, 2021.

- **Net Loss:** Marker reported a net loss of $6.9 million for the quarter ended September 30, 2022, compared to a net loss of $12.4 million for the quarter ended September 30, 2021.

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. Marker's cell therapy technology 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 its T cell therapies, we believe that our 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 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; the timing, conduct and success of our clinical trials of our product candidates; our ability to use our manufacturing facilities to support clinical and commercial demand; and our future operating expenses and capital expenditure requirements. 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. Such risks and uncertainties may be amplified by the COVID-19 pandemic and its impact on our business and the global economy. 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)

	September 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 18,076,379	$ 42,351,145
Restricted cash	—	1,146,186
Prepaid expenses and deposits	2,665,668	2,484,634
Other receivables	1,681,019	237
Total current assets	22,423,066	45,982,202
Non-current assets:		
Property, plant and equipment, net	13,059,816	10,096,861
Construction in progress	—	2,225,610
Right-of-use assets, net	5,631,683	9,830,461
Total non-current assets	18,691,499	22,152,932
Total assets	**$ 41,114,565**	**$ 68,135,134**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 5,746,404	$ 11,134,913
Related party deferred revenue	5,050,000	—
Lease liability	490,449	620,490
Deferred revenue	—	1,146,186
Total current liabilities	11,286,853	12,901,589
Non-current liabilities:		
Lease liability, net of current portion	7,225,990	11,247,950
Total non-current liabilities	7,225,990	11,247,950
Total liabilities	18,512,843	24,149,539
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at September 30, 2022 and December 31,2021, respectively	—	—
Common stock, $0.001 par value, 300 million and 150 million shares authorized, 83.6 million and 83.1 million shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	83,599	83,079
Additional paid-in capital	446,710,757	442,020,871
Accumulated deficit	(424,192,634)	(398,118,355)
Total stockholders' equity	22,601,722	43,985,595
Total liabilities and stockholders' equity	**$ 41,114,565**	**$ 68,135,134**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenues:				
Grant income	$ 999,571	$ —	$ 2,754,401	$ —
Related partry service revenue	2,950,000	—	2,950,000	—
Total revenues	3,949,571	—	5,704,401	—
Operating expenses:				
Research and development	7,290,899	6,784,390	20,872,264	19,777,454
General and administrative	3,678,005	3,239,148	10,926,189	9,936,256
Total operating expenses	10,968,904	10,023,538	31,798,453	29,713,710
Loss from operations	(7,019,333)	(10,023,538)	(26,094,052)	(29,713,710)
Other income (expenses):				
Arbitration settlement	—	(2,406,576)	(118,880)	(2,406,576)
Interest income	99,750	791	138,653	4,731
Net loss	**$ (6,919,583)**	**$ (12,429,323)**	**$ (26,074,279)**	**$ (32,115,555)**
Net loss per share, basic and diluted	$ (0.08)	$ (0.15)	$ (0.31)	$ (0.43)
Weighted average number of common shares outstanding, basic and diluted	83,599,187	83,078,675	83,434,760	74,290,598

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

	For the Nine Months Ended September 30,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (26,074,279)	$ (32,115,555)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,975,996	1,584,495
Stock-based compensation	4,626,833	4,497,145
Amortization on right-of-use assets	739,446	757,958
Loss on disposal of assets	25,995	—
Gain on lease termination	(278,681)	—
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(181,034)	(643,403)
Other receivables	(1,680,782)	1,000,316
Accounts payable and accrued expenses	(3,310,051)	2,742,154
Related party deferred revenue	5,050,000	—
Deferred revenue	(1,146,186)	—
Lease liability	(413,988)	(244,752)
Net cash used in operating activities	(20,666,731)	(22,421,642)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,328,664)	(1,262,092)
Purchase of construction in progress	(3,489,130)	(1,519,196)
Net cash used in investing activities	(4,817,794)	(2,781,288)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	63,573	52,552,758
Proceeds from exercise of stock options	—	3,087
Net cash provided by financing activities	63,573	52,555,845
Net (decrease) increase in cash, cash equivalents and restricted cash	(25,420,952)	27,352,915
Cash, cash equivalents and restricted cash at beginning of the period	43,497,331	21,352,382
Cash, cash equivalents and restricted cash at end of the period	$ 18,076,379	$ 48,705,297

Contacts

Investors
Xuan Yang
xyang@soleburystrat.com

Media
Amy Bonanno
abonanno@soleburystrat.com