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 13, 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.)

3200 Southwest Freeway **Suite 2500** **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 May 13, 2022, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended March 31, 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 May 13, 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: May 13, 2022

By: /s/ Anthony Kim
Anthony Kim
Chief Financial Officer

Exhibit 99.1

Marker Therapeutics Reports Q1 2022 Operating and Financial Results

Topline readout of Phase 2 AML trial Group 2 active disease anticipated in Q2 2022

Company plans to file INDs in lymphoma and pancreatic cancer by year end, with clinical trials to be initiated in 2023

Houston, TX—May 13, 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 first quarter ended March 31, 2022.

"2022 has already been an exciting year for Marker as we reported encouraging initial results from the six-patient safety lead-in portion of our Phase 2 AML trial—including elimination of MRD in one MRD positive patient—and announced plans for Company-sponsored trials of our second cell therapy product candidate, MT-601, in pancreatic cancer and lymphoma," said Peter L. Hoang, Marker's President and Chief Executive Officer. "We also implemented a new MultiTAA-specific T cell therapy manufacturing process, details of which were presented at the 2022 International Society for Cell & Gene Therapy (ISCT) annual meeting. After completing enrollment of the first 20 patients in the Phase 2 AML trial last year, we anticipate reporting topline data from the active disease group in the main phase of the trial next quarter."

PROGRAM UPDATES AND EXPECTED MILESTONES

Acute Myeloid Leukemia (MT-401)

- In February 2022, Marker announced the initial results of the safety lead-in stage of its Company-sponsored Phase 2 AML trial evaluating MT-401, Marker's lead MultiTAA-specific T cell product candidate. Results from the safety lead-in demonstrate that MT-401 was well-tolerated, eliminated measurable residual disease (MRD) based on peripheral blood analysis at Week 32 in one MRD positive patient and induced epitope spreading across multiple AML-associated antigens in that patient.

- Enrollment of the first 20 patients of the main Phase 2 stage of the AML trial was completed in Q4 2021. Topline readout of Group 2 active disease is anticipated in Q2 2022.

- Marker announced in February 2022 that it is developing MT-401-OTS, a scalable, off-the-shelf product candidate with the potential to match patients to treatment in under three days. Marker's open Investigational New Drug application (IND) for MT-401 for the treatment of AML includes an off-the-shelf program. The Company is in the process of developing a patient cell bank inventory and expects to dose the first patient with MT-401-OTS 2023.

Additional Clinical Programs (MT-601)

- In January 2022, Marker announced that the U.S. Food and Drug Administration granted Orphan Drug designation to MT-601 for the treatment of pancreatic cancer.

- Marker announced in February 2022 that the Company intends to file INDs for MT-601, Marker's second MultiTAA-specific T cell product candidate, in lymphoma and pancreatic cancer in 2022. The Company expects to initiate these trials in 2023.

BUSINESS UPDATES

- In April 2022, the Company announced that it entered into a services agreement with Wilson Wolf Manufacturing Corporation. The agreement includes an $8.0 million upfront cash payment by Wilson Wolf to Marker in exchange for services relating to Marker's expertise in the manufacture of cell therapies. Wilson Wolf has agreed to pay Marker an additional $1.0 million if the certain work, as defined in the services agreement, is completed within one year from the onset of the services agreement.

FIRST QUARTER 2022 FINANCIAL RESULTS

Cash Position and Guidance: At March 31, 2022, Marker had cash, cash equivalents and restricted cash of $28.8 million.

R&D Expenses: Research and development expenses were $7.0 million for the quarter ended March 31, 2022, compared to $5.6 million for the quarter ended March 31, 2021.

G&A Expenses: General and administrative expenses were $3.7 million for the quarter ended March 31, 2022, compared to $3.1 million for the quarter ended March 31, 2021.

Net Loss: Marker reported a net loss of $9.9 million for the quarter ended March 31, 2022, compared to a net loss of $8.8 million for the quarter ended March 31, 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, including the Phase 2 trial of MT-401; our ability to use our manufacturing facilities to support clinical and commercial demand; the timing and use of the CPRIT award; 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)

	March 31, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 28,637,217	$ 42,351,145
Restricted cash	181,864	1,146,186
Prepaid expenses and deposits	2,196,225	2,484,634
Other receivables	2,185	237
Total current assets	31,017,491	45,982,202
Non-current assets:		
Property, plant and equipment, net	10,276,936	10,096,861
Construction in progress	4,089,135	2,225,610
Right-of-use assets, net	9,572,572	9,830,461
Total non-current assets	23,938,643	22,152,932
Total assets	**$ 54,956,134**	**$ 68,135,134**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 7,348,680	$ 11,134,913
Lease liability	683,969	620,490
Deferred revenue	181,864	1,146,186
Total current liabilities	8,214,513	12,901,589
Non-current liabilities:		
Lease liability, net of current portion	11,035,857	11,247,950
Total non-current liabilities	11,035,857	11,247,950
Total liabilities	19,250,370	24,149,539
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 83.5 million and 83.1 million shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	83,451	83,079
Additional paid-in capital	443,651,176	442,020,871
Accumulated deficit	(408,028,863)	(398,118,355)
Total stockholders' equity	35,705,764	43,985,595
Total liabilities and stockholders' equity	**$ 54,956,134**	**$ 68,135,134**

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

	For the Three Months Ended March 31,	
	2022	**2021**
Revenues:		
Grant income	$ 964,322	$ -
Total revenues	964,322	-
Operating expenses:		
Research and development	$ 7,026,066	$ 5,643,029
General and administrative	3,733,001	3,137,958
Total operating expenses	10,759,067	8,780,987
Loss from operations	(9,794,745)	(8,780,987)
Other income (expenses):		
Arbitration settlement	(118,880)	-
Interest income	3,117	1,537
Net loss	**$ (9,910,508)**	**$ (8,779,450)**
Net loss per share, basic and diluted	$ (0.12)	$ (0.16)
Weighted average number of common shares outstanding, basic and diluted	83,107,649	56,470,247

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

	For the Three Months Ended March 31,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (9,910,508)	$ (8,779,450)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	576,331	502,743
Stock-based compensation	1,630,677	1,377,038
Amortization of right-of-use assets	257,889	251,626
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	288,409	95,000
Other receivables	(1,948)	(308)
Accounts payable and accrued expenses	(3,953,976)	(1,482,473)
Deferred revenue	(964,322)	-
Lease liability	(148,614)	(64,329)
Net cash used in operating activities	(12,226,062)	(8,100,153)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(826,583)	(442,277)
Cash used for construction in progress	(1,625,605)	(958,965)
Net cash used in investing activities	(2,452,188)	(1,401,242)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	-	52,656,588
Net cash provided by financing activities	-	52,656,588
Net (decrease) increase in cash, cash equivlants and restricted cash	(14,678,250)	43,155,193
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	$ 28,819,081	$ 64,507,575

Investors and Media Contacts

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