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 12, 2021
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 12, 2021, Marker Therapeutics, Inc. (the "Company") reported financial results for the quarter ended March 31, 2021 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 issued on May 12, 2021.
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 12, 2021

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

Exhibit 99.1

Marker Therapeutics Reports First Quarter 2021 Operating and Financial Results

Marker continues to advance Phase 2 AML trial, recently dosing first patient

Company closed financing extending cash runway into Q1 2023

Company to host conference call and webcast today at 5:00 p.m. ET

Houston, TX—May 12, 2021—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, 2021.

“We had a productive first quarter supported by our recently completed financing, strengthening our overall cash position and enabling continued growth and expansion of our Multi-TAA pipeline,” Peter L. Hoang, President & CEO of Marker Therapeutics. “In addition, we continue to make strong progress on both the clinical and manufacturing fronts. In March, we dosed the first patient in the safety lead-in portion of our Phase 2 trial in post-transplant acute myeloid leukemia, or AML, and continue to activate clinical sites. In parallel, we continue to optimize the MT-401 cell therapy manufacturing process, which we believe could result in an increase in the number of T cells available for patient administration—among other benefits—as we prepare to operationalize our new in-house cGMP facility in the first half of the year.”

PROGRAM UPDATES

- In March 2021, Marker dosed the first patient in the safety lead-in portion of its Phase 2 trial in AML, which is expected to enroll a total of six patients: three of which will be treated with MT-401 manufactured with a legacy reagent, and the remaining three to be treated with study drug manufactured with a new reagent from an alternate supplier.

- The clinical operations team has made considerable progress in opening sites to enroll patients for the safety lead-in portion of the AML trial. The Company has also received commitments from additional clinical sites to participate in the Phase 2 AML trial following the safety lead-in phase and anticipates activating a total of approximately 20 sites.

- Marker continues to streamline and simplify the MT-401 manufacturing process, which could potentially result in a product with a superior T cell phenotype and improved antigen specificity as compared to the original process. The new process improvements have been updated in the CMC section of the IND and will be used for all patients in the Marker AML Phase 2 clinical trial.

- Marker presented early results of robotic automation of T cell generation for the treatment of AML at the American Society of Gene & Cell Therapy 24th Annual Meeting on May 11, 2021. The results will also be presented at the upcoming International Society for Cell & Gene Therapy 2021 Annual Meeting, taking place virtually May 26-28, 2021.

BUSINESS UPDATES

- In March, Marker closed an underwritten public offering of 32,282,857 shares of its common stock at a public offering price of $1.75 per share. The gross proceeds to Marker from the offering, before deducting the underwriting discounts and commissions and other offering expenses, were approximately $56.5 million.

- The Company is preparing to open its new cGMP manufacturing facility in Houston, TX, which will be used to manufacture study drug for Marker's Phase 2 AML trial (MT-401) and for future hematological and solid tumor trials, in addition to the potential commercialization of any approved products. Marker initiated the technology transfer from Baylor College of Medicine to the cGMP facility in Q1 2021 and expects the facility to be fully operational in the first half of 2021.

ANTICIPATED PROGRAM MILESTONES

AML Trial Milestones

- Complete safety lead-in (6 patients) in Q2 2021
- Initiate main portion of Phase 2 trial in Q3 2021
- Complete enrollment of 20 patients in main portion of Phase 2 trial in Q4 2021
- Topline readout of Group 2 (active disease) in Q1 2022

Manufacturing Milestones

- Receive regulatory approval for Marker cGMP in Q2 2021
- Manufacture MT-401 at Marker cGMP for Phase 2 AML trial in Q3 2021

FIRST QUARTER 2021 FINANCIAL RESULTS

- **Cash Position and Guidance:** At March 31, 2021, Marker had cash and cash equivalents of $64.5 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses and capital expenditure requirements into Q1 2023.

- **R&D Expenses:** Research and development expenses were $5.6 million for the quarter ended March 31, 2021 compared to $3.8 million for the quarter ended March 31, 2020. The increase was primarily attributable to increases in headcount-related expenses and infrastructure expenses due to growth of research and development operations.

- **G&A Expenses:** General and administrative expenses were $3.1 million for the quarter ended March 31, 2021 compared to $2.8 million for the quarter ended March 31, 2020.

- **Net Loss:** Marker reported a net loss of $8.8 million for the quarter ended March 31, 2021, compared to a net loss of $6.5 million for the quarter ended March 31, 2020.

Conference Call and Webcast
The Company will host a webcast and conference call to discuss its first quarter 2021 financial results and provide a corporate update today at 5:00 p.m. EDT. The webcast will be accessible in the Investors section of the Company's website at markertherapeutics.com. Individuals can participate in the conference call by dialing 877-407-8913 (domestic) or 201-689-8201 (international) and referring to the "Marker Therapeutics First Quarter 2021 Earnings Call."

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, as well as clinical trials conducted by our collaborators; the timing and success of the technology transfer process related to our planned manufacturing facility and the receipt of regulatory approval for the related cGMP; our manufacturing processes and our ability to use our current and planned manufacturing facilities to support clinical and commercial demand. 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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 64,507,575	$ 21,352,382
Prepaid expenses and deposits	1,962,924	2,057,924
Other receivables	1,000,867	1,000,559
Total current assets	67,471,366	24,410,865
Non-current assets:		
Property, plant and equipment, net	10,298,225	3,570,736
Construction in progress	-	6,789,098
Right-of-use assets, net	10,592,490	10,844,116
Total non-current assets	20,890,715	21,203,950
Total assets	**$ 88,362,081**	**$ 45,614,815**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 3,674,259	$ 6,013,010
Lease liability	473,077	388,792
Total current liabilities	4,147,336	6,401,802
Non-current liabilities:		
Lease liability, net of current portion	11,719,826	11,868,440
Total non-current liabilities	11,719,826	11,868,440
Total liabilities	15,867,162	18,270,242
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at March 31, 2021 and December 31, 2020, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 83.0 million and 50.7 million shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	83,014	50,731
Additional paid-in capital	437,430,839	383,533,326
Accumulated deficit	(365,018,934)	(356,239,484)
Total stockholders' equity	72,494,919	27,344,573
Total liabilities and stockholders' equity	**$ 88,362,081**	**$ 45,614,815**

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

	For the Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 5,643,029	$ 3,816,618
General and administrative	3,137,958	2,826,995
Total operating expenses	8,780,987	6,643,613
Loss from operations	(8,780,987)	(6,643,613)
Other income (expense):		
Change in fair value of warrant liabilities	-	31,000
Interest income	1,537	126,969
Net loss	**$ (8,779,450)**	**$ (6,485,644)**
Net loss per share, basic and diluted	$ (0.16)	$ (0.14)
Weighted average number of common shares outstanding, basic and diluted	56,470,247	46,084,383

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

	For the Three Months Ended March 31,	
	2021	**2020**
Cash Flows from Operating Activities:		
Net loss	$ (8,779,450)	$ (6,485,644)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	502,743	35,265
Changes in fair value of warrant liabilities	-	(31,000)
Stock-based compensation	1,377,038	1,344,592
Amortization on right-of-use assets	251,626	47,361
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	95,000	(189,650)
Other receivables	(308)	31,584
Accounts payable and accrued expenses	(2,442,581)	1,197,613
Lease liability	(64,329)	(49,187)
Net cash used in operating activities	(9,060,261)	(4,099,066)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(441,134)	(99,821)
Net cash used in investing activities	(441,134)	(99,821)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	52,656,588	-
Proceeds from exercise of warrants	-	550,000
Net cash provided by financing activities	52,656,588	550,000
Net increase (decrease) in cash	43,155,193	(3,648,887)
Cash and cash equivalents at beginning of the period	21,352,382	43,903,949
Cash and cash equivalents at end of the period	$ 64,507,575	$ 40,255,062

SOURCE: Marker Therapeutics, Inc.

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