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

March 17, 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 March 17, 2022, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended December 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, dated March 17, 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: March 17, 2022

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

Exhibit 99.1

Marker Therapeutics Reports Fiscal Year 2021 Operating and Financial Results

Enrollment of first 20 patients of the Company's Phase 2 acute myeloid leukemia (AML) trial completed in Q4 2021

Topline readout of 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—March 17, 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 fiscal year ended December 31, 2021.

"In 2021, we completed enrollment of the first 20 patients in our Phase 2 AML trial investigating our lead product candidate, MT-401," said Peter L. Hoang, Marker's President and Chief Executive Officer. "We also developed a new nine-day manufacturing process which increased the potency and antigen specificity and diversity of our products and significantly reduced the time it takes to manufacture our patient-specific T cell therapies. In February 2022, we reported initial results from the six-patient safety lead-in phase of the Phase 2 AML trial, which demonstrated that MT-401 was well-tolerated and satisfied the safety requirements with FDA. We expect to report topline data from the active disease group in the main phase of the Phase 2 trial next quarter. In addition, we look forward to expanding our pipeline beyond AML and expect to file INDs for lymphoma and pancreatic cancer by the end of the year."

PROGRAM UPDATES AND EXPECTED MILESTONES

Acute Myeloid Leukemia (AML)

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) in one MRD positive patient and induced epitope spreading across multiple AML-associated antigens in that patient.
- The safety lead-in satisfied safety requirements with the FDA and the main Phase 2 stage of the AML trial began enrolling in July 2021.
- Enrollment of the first 20 patients of the Phase 2 AML trial was completed in Q4 2021.
- Topline readout of Group 2 active disease is anticipated in Q2 2022.

Off-the-Shelf (MT-401-OTS)

- Marker announced in February 2022 that it intends to expand its AML program with the development of 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 approval of 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 in 2023.

Additional Clinical Programs (MT-601)

- Marker recently announced 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.
- 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.

BUSINESS UPDATES

- On December 9, 2021, Marker announced the appointment of Katharine Knobil, M.D., to the Company's Board of Directors.
- Marker began manufacturing MT-401 for its Phase 2 AML trial at the Company's cGMP manufacturing facility in the fourth quarter of 2021.
- The Company developed and is implementing a new nine-day MultiTAA-specific T cell manufacturing process for its current Company-sponsored Phase 2 AML trial as well as future clinical trials using a patient-specific manufacturing approach. The new T cell manufacturing process is designed to improve potency, increase antigen specificity and diversity and significantly reduce manufacturing time.

FISCAL YEAR 2021 FINANCIAL RESULTS

Cash Position and Guidance: At December 31, 2021, Marker had cash, cash equivalents and restricted cash of $43.5 million. The Company believes that its existing cash, cash equivalents and restricted cash will fund its operating expenses and capital expenditure requirements into the first quarter of 2023

R&D Expenses: Research and development expenses were $27.8 million for the year ended December 31, 2021, compared to $18.9 million for the year ended December 31, 2020.

G&A Expenses: General and administrative expenses were $12.9 million for the year ended December 31, 2021, compared to $10.5 million for the year ended December 31, 2020.

Net Loss: Marker reported a net loss of $41.9 million for the year ended December 31, 2021, compared to a net loss of $28.7 million for the year ended December 31, 2020.

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 and our planned trials of MT-401-OTS and MT-601; our ability to use our manufacturing facilities to support clinical and commercial demand; the success of our new manufacturing process; 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.
Consolidated Balance Sheets
(Audited)

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	$ 42,351,145	$ 21,352,382
Restricted cash	1,146,186	-
Prepaid expenses and deposits	2,484,634	2,057,924
Other receivables	237	1,000,559
Total current assets	45,982,202	24,410,865
Non-current assets:		
Property, plant and equipment, net	10,096,861	3,570,736
Construction in progress	2,225,610	6,789,098
Right-of-use assets, net	9,830,461	10,844,116
Total non-current assets	22,152,932	21,203,950
Total assets	**$ 68,135,134**	**$ 45,614,815**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 11,134,913	$ 6,013,010
Lease liability	620,490	388,792
Deferred revenue	1,146,186	-
Total current liabilities	12,901,589	6,401,802
Non-current liabilities:		
Lease liability, net of current portion	11,247,950	11,868,440
Total non-current liabilities	11,247,950	11,868,440
Total liabilities	24,149,539	18,270,242
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at December 31, 2021 and 2020, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 83.1 million and 50.7 million shares issued and outstanding as of December 31, 2021 and 2020, respectively	83,079	50,731
Additional paid-in capital	442,020,871	383,533,326
Accumulated deficit	(398,118,355)	(356,239,484)
Total stockholders' equity	43,985,595	27,344,573
Total liabilities and stockholders' equity	**$ 68,135,134**	**$ 45,614,815**

Marker Therapeutics, Inc.
Consolidated Statements of Operations
(Audited)

	For the Years Ended December 31,	
	2021	**2020**
Revenues:		
Grant income	$ 1,241,710	$ 466,785
Total revenues	1,241,710	466,785
Operating expenses:		
Research and development	27,794,879	18,880,751
General and administrative	12,924,826	10,471,846
Total operating expenses	40,719,705	29,352,597
Loss from operations	(39,477,995)	(28,885,812)
Other income:		
Change in fair value of warrant liabilities	-	31,000
Arbitration settlement	(2,406,576)	-
Interest income	5,700	148,742
Net loss	**$ (41,878,871)**	**$ (28,706,070)**
Net loss per share, basic and diluted	$ (0.55)	$ (0.61)
Weighted average number of common shares outstanding, basic and diluted	76,505,675	47,039,862

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

	For the Years Ended December 31,	
	2021	**2020**
Cash Flows from Operating Activities:		
Net loss	$ (41,878,871)	$ (28,706,070)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	2,148,983	485,641
Changes in fair value of warrant liabilities	-	(31,000)
Stock-based compensation	5,964,048	5,228,409
Amortization on right-of-use assets	1,013,655	590,039
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(426,710)	(531,482)
Other receivables	1,000,322	55,630
Accounts payable and accrued expenses	4,141,414	3,047,410
Deferred revenue	1,146,186	-
Lease liability	(388,792)	(173,268)
Net cash used in operating activities	(27,279,765)	(20,034,691)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,572,161)	(3,422,754)
Purchase of construction in progress	(1,558,970)	(5,830,133)
Net cash used in investing activities	(3,131,131)	(9,252,887)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	52,552,758	6,186,011
Proceeds from exercise of warrants	-	550,000
Proceeds from exercise of stock options	3,087	-
Net cash provided by financing activities	52,555,845	6,736,011
Net increase (decrease) in cash, cash equivlants and restricted cash	22,144,949	(22,551,567)
Cash, cash equivalents and restricted cash at beginning of the year	21,352,382	43,903,949
Cash, cash equivalents and restricted cash at end of the year	$ 43,497,331	$ 21,352,382

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Investors and Media Contacts

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