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 22, 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.)

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 March 22, 2023, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the fiscal year ended December 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 March 22, 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: March 22, 2023

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

Exhibit 99.1

Marker Therapeutics Reports Fiscal Year 2022 Corporate and Financial Results

2022 CLINICAL AND REGULATORY HIGHLIGHTS

- Awarded $2 million grant from U.S. Food and Drug Administration (FDA) for the Phase 2 ARTEMIS trial of MT-401 in post-transplant acute myeloid leukemia (AML)
- Investigational New Drug (IND) application cleared by FDA for multicenter Phase 1 trial of MT-601 for the treatment of metastatic pancreatic cancer in combination with front-line chemotherapy
    - Received FDA Orphan Drug Designation for MT-601 for the treatment of pancreatic cancer
- IND for MT-601 for the treatment of non-Hodgkin lymphoma cleared by FDA, focused on patients who have failed or are ineligible for CAR-T therapy

2022 CORPORATE AND FINANCIAL HIGHLIGHTS

- Entered into a services agreement with Wilson Wolf Manufacturing Corporation, which included an $8.0 million upfront cash payment from Wilson Wolf
- Entered into a common stock purchase agreement with Lincoln Park Capital for up to $25 million

Houston, TX – March 22, 2023 – 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 fiscal year 2022 financial results and provided updates for its clinical development programs.

“2022 was a critical year for Marker Therapeutics as we advanced the company on several fronts, including key enhancements to our multiTAA clinical development pipeline and strategic initiatives, including with Wilson Wolf, to leverage our differentiated manufacturing capabilities to generate alternative sources of funding for our clinical programs,” said Peter L. Hoang, President and Chief Executive Officer at Marker Therapeutics. “We believe these initiatives will unlock multiple value building opportunities for Marker throughout 2023. We continue to advance our MT-401 Phase 2 ARTEMIS clinical trial and are encouraged by recent data involving measurable residual disease (MRD) positive patients, which suggest MT-401 produced with our new T cell manufacturing process could be well suited for this underserved subset of patients with AML. We anticipate reporting a more expansive data readout from the MRD positive group in the second half of 2023.

Mr. Hoang continued: “We also made considerable progress with our MT-601 program, securing FDA clearance for INDs in non-Hodgkin lymphoma and pancreatic cancer. We have initiated enrollment for the lymphoma Phase 1 clinical study of MT-601 and expect to report topline data in early 2024 and expect to initiate enrollment for the pancreatic study by the fourth quarter of 2023. We continue to be energized by the manufacturing services agreement with Wilson Wolf and believe we are on track to earn the additional $1 million bonus provided for in the agreement. Additionally, we see the potential to build on the success of this project with additional revenue-generating opportunities whereby we leverage our unique expertise in technical operations to provide the company with non-dilutive capital to fund our clinical programs.”

MT-401 PHASE 2 ARTEMIS (AML)

New manufacturing process for MT-401:

- In 2022, Marker implemented an improved manufacturing process that reduced production time to 9 days (compared to the original process of >30 days).
- This new process enabled a >90% reduction in the number of operator interventions during production and an improved final T cell product candidate compared to the original product candidate that was used in the ongoing ARTEMIS trial.
- These process improvements have yielded an MT-401 product candidate that has five times the measurable specificity and four times the potency in terms of tumor killing as compared to the prior manufacturing process. Marker has now treated 12 patients with MT-401 manufactured using the Company's improved process, with 16 patients treated with MT-401 manufactured using the original process, for a total of 28 patients.

Adjuvant Patients:

- To date, a total of 11 patients in the adjuvant arm of the ARTEMIS study have been randomized to treatment with MT-401 using a new manufacturing process or to standard-of-care.
- All patients are too early for evaluation, but the Data Monitoring Committee has reviewed the existing safety data and has not identified any concerns.

Marker continues to see promising data with MRD+ patients:

- A total of four patients with measurable residual disease (MRD+) have been treated and are currently evaluable.
  - Two MRD+ patients were treated with MT-401 manufactured using the original manufacturing process and showed elimination of detectable disease.
- In this update, Marker can report on the status of two additional MRD+ patients that were treated with MT-401 manufactured with the improved process:
  - The first MRD+ patient was treated at 100 x 10^6 cells per infusion and was able to remain in stable disease for six months, allowing the patient to bridge to a second allogeneic transplant.
  - The second MRD+ patient was dosed at 200 x 10^6 cells per infusion and the PCR value, which proved to be a valuable tool for detecting MRD, has decreased by 70% only four weeks after the last infusion. This patient's disease status will continue to be closely monitored and evaluated.
- Marker also treated one additional MRD+ patient with product manufactured using the improved process. This patient is too early for evaluation. Additional MRD+ patients have been enrolled and are awaiting treatment.
- Marker anticipates reporting a data readout of the MRD+ patient subset in the second half of 2023.

Measurable residual disease is an important biomarker in hematological malignancies, such as AML, that is used for prognostic, predictive and monitoring assessments. This term refers to a small number of malignant cancer cells remaining in a patient's body after completion of therapy, despite the absence of clinical and radiological evidence of disease. MRD detection relies on highly sensitive laboratory techniques, such as next-generation sequencing, polymerase chain reaction (PCR), or flow cytometry. The assessment is crucial in AML management as it can provide prognostic information and guide therapeutic decisions, such as the need for additional treatment or close surveillance. Importantly, MRD is a transitional phase prior to development of frank relapse and considered a negative prognostic factor. Thus, the achievement of MRD negativity, defined as the absence of detectable malignant cells, is a favorable prognostic factor and an important treatment goal in AML.

The standard first-line treatment for the last decade had been combination chemotherapy using cytarabine and an anthracycline. However, approximately half of the patients eventually relapse. Eligible patients subsequently proceed to hematopoietic stem cell transplantation (HSCT), but disease relapse after transplant is frequent and remains a major cause of death. To date, there is no approved therapy for post-transplant MRD+ patients, highlighting the need for novel therapies. Therefore, the positive clinical responses observed in MRD+ patients treated with MT-401 may provide a more effective approach to treatment.

“Our ARTEMIS trial showed promising clinical responses in post-transplant MRD positive patients highlighting the potential benefit of our multiTAA-specific T cell therapy in patients where no treatments have been approved,” said Dr. Juan F. Vera, Chief Scientific Officer and Chief Operating Officer of Marker Therapeutics. “We will continue to track the patients’ disease status and look forward to investigating MT-401 in a larger patient population.”

Dr. Vera continued: “Our improved T cell manufacturing process used for multiTAA-specific T cells enables a 9-day ex vivo T cell production, providing a fast turnaround for patient treatment to reach MRD positive patients before relapse.”

Frank Relapse Patients:

- To date, a total of 15 frank relapse patients have been treated.
- In addition to the 11 patients previously reported, who were treated with MT-401 manufactured using the original manufacturing process, four additional patients with frank relapse have been treated with MT-401 manufactured using the improved manufacturing process:
  - Of the four patients treated with the improved manufacturing process, one of these patients received a dose of 100 x 10^6 cells per infusion, while the other three patients were dosed at 200 x 10^6 cells per infusion.
  - None of the frank relapse patients showed an objective response to therapy.
- Marker has suspended further enrollment of frank relapse patients while re-evaluating additional modifications for this patient cohort, including potentially higher cell doses.

MT-601 (Lymphoma)

- IND cleared by FDA for the multicenter Phase 1 trial of MT-601 for the treatment of patients with non-Hodgkin lymphoma
- Phase 1 clinical trial initiated in Q1 2023 with a clinical readout expected in the first quarter of 2024

MT-601 (Pancreatic):

- IND cleared by FDA for the multicenter Phase 1 trial of MT-601 for the treatment of patients with metastatic pancreatic cancer in combination with front-line chemotherapy
- Phase 1 clinical trial expected to initiate by Q4 2023.

FISCAL YEAR 2022 FINANCIAL RESULTS

Cash Position and Guidance: At December 31, 2022, Marker had cash and cash equivalents of $11.8 million. The Company believes that its existing cash, cash equivalents and restricted cash will fund its operating expenses and capital expenditure requirements into the third quarter of 2023.

R&D Expenses: Research and development expenses were $26.1 million for the year ended December 31, 2022, compared to $27.8 million for the year ended December 31, 2021.

G&A Expenses: General and administrative expenses were $12.8 million for the year ended December 31, 2022, compared to $12.9 million for the year ended December 31, 2021.

Net Loss: Marker reported a net loss of $29.9 million for the year ended December 31, 2022, compared to a net loss of $41.9 million for the year ended December 31, 2021.

About Marker's Phase 2 ARTEMIS Trial
The multicenter Phase 2 AML study is evaluating the clinical efficacy of MT-401 in patients with AML following an allogeneic stem-cell transplant in both the adjuvant and active disease setting. In the adjuvant setting, approximately 150 patients will be randomized 1:1 to either MT-401 at 90 days post-transplant versus standard-of-care observation, while approximately 40 patients with active disease will receive MT-401 as part of the single-arm group.

The primary objectives of the trial are to evaluate relapse-free survival in the adjuvant group and determine the complete remission rate and duration of complete remission in active disease patients. Additional objectives include, for the adjuvant group, overall survival and graft-versus-host disease relapse-free survival while additional objectives for the active disease group include overall response rate, duration of response, progression-free survival, and overall survival.

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 collaboration with Wilson Wolf Manufacturing Corporation; 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, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,782,172	$ 42,351,145
Restricted cash	-	1,146,186
Prepaid expenses and deposits	2,435,079	2,484,634
Other receivables	2,402,004	237
Total current assets	16,619,255	45,982,202
Non-current assets:		
Property, plant and equipment, net	12,323,143	10,096,861
Construction in progress	-	2,225,610
Right-of-use assets, net	5,479,786	9,830,461
Total non-current assets	17,802,929	22,152,932
Total assets	**$ 34,422,184**	**$ 68,135,134**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 4,704,611	$ 11,134,913
Related party deferred revenue	2,500,000	-
Deferred revenue	-	1,146,186
Lease Liability	577,198	620,490
Total current liabilities	7,781,809	12,901,589
Non-current liabilities:		
Lease liability, net of current portion	7,039,338	11,247,950
Total non-current liabilities	7,039,338	11,247,950
Total liabilities	14,821,147	24,149,539
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at December 31, 2022 and 2021, respectively	-	-
Common stock, $0.001 par value, 30 million and 15 million shares authorized, 8.4 million and 8.3 million shares issued and outstanding as of December 31, 2022 and 2021, respectively	8,406	8,308
Additional paid-in capital	447,641,680	442,095,642
Accumulated deficit	(428,049,049)	(398,118,355)
Total stockholders' equity	19,601,037	43,985,595
Total liabilities and stockholders' equity	**$ 34,422,184**	**$ 68,135,134**

Marker Therapeutics, Inc.

Consolidated Statements of Operations

(Audited)

	For the Years Ended December 31,	
	2022	**2021**
Revenues:		
Grant income	$ 3,513,544	$ 1,241,710
Related party service revenue	5,500,000	-
Total revenues	9,013,544	1,241,710
Operating expenses:		
Research and development	26,139,323	27,794,879
General and administrative	12,820,004	12,924,826
Total operating expenses	38,959,327	40,719,705
Loss from operations	(29,945,783)	(39,477,995)
Other income (expenses):		
Arbitration settlement	(232,974)	(2,406,576)
Interest income	248,063	5,700
Net loss	**$ (29,930,694)**	**$ (41,878,871)**
Net loss per share, basic and diluted	$ (3.58)	$ (5.47)
Weighted average number of common shares outstanding, basic and diluted	8,351,003	7,650,567

Marker Therapeutics, Inc.

Condensed Consolidated Statements of Cash Flows

(Audited)

	For the Years Ended December 31,	
	2022	**2021**
Cash Flows from Operating Activities:		
Net loss	$ (29,930,694)	$ (41,878,871)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	2,789,106	2,148,983
Stock-based compensation	5,344,006	5,964,048
Amortization on right-of-use assets	891,343	1,013,655
Loss on disposal of fixed assets	25,995	-
Gain on lease termination	(278,681)	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	49,555	(426,710)
Other receivables	(2,401,767)	1,000,322
Accounts payable and accrued expenses	(4,300,939)	4,141,414
Related party deferred revenue	2,500,000	-
Deferred revenue	(1,146,186)	1,146,186
Lease liability	(513,891)	(388,792)
Net cash used in operating activities	(26,972,153)	(27,279,765)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,456,006)	(1,572,161)
Purchase of construction in progress	(3,489,130)	(1,558,970)
Net cash used in investing activities	(4,945,136)	(3,131,131)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	202,130	52,552,758
Proceeds from exercise of stock options	-	3,087
Net cash provided by financing activities	202,130	52,555,845
Net (decrease) increase in cash, cash equivalents and restricted cash	(31,715,159)	22,144,949
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	$ 11,782,172	$ 43,497,331

Contacts

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