

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

August 11, 2022

Date of Report (Date of earliest event reported)

MARKER THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

001-37939

(Commission File Number)

45-4497941

(IRS Employer Identification No.)

**3200 Southwest Freeway
Suite 2500**

Houston, Texas

(Address of principal executive offices)

77027

(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 August 11, 2022, Marker Therapeutics, Inc. (the “*Company*”) reported financial results for the quarter ended June 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 11, 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: August 11, 2022

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



Marker Therapeutics Reports Q2 2022 Operating and Financial Results

Houston, TX— August 11, 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 second quarter ended June 30, 2022.

“We are proud of our progress this year in advancing our Company-sponsored clinical program in AML, and early results support the ability of MT-401, a multiTAA-specific T cell product, to drive results for patients with AML,” said Peter L. Hoang, Marker’s President and Chief Executive Officer. “This quarter, we continued to dose patients in the Phase 2 AML study, and we expect to provide a topline readout of active disease patients in Q3 2022. The recent \$8 million upfront cash payment to Marker by Wilson Wolf has aided the efficient execution of Marker’s programs.”

Mr. Hoang continued: “In addition, we recently announced that FDA cleared our IND investigating the safety and efficacy of MT-601 in patients with relapsed/refractory lymphoma, and that we are on track to file another IND by year-end to investigate the safety and efficacy of MT-601 in patients with pancreatic cancer, which has already received FDA Orphan Drug Designation. We anticipate dosing the first patients in these trials, in addition to dosing patients in our off-the-shelf therapy for AML, next year.”

“We are very optimistic about the ability of MT-401 to drive results for patients with measurable residual disease given the results we have seen to date in the ARTEMIS study,” said Dr. Mythili Koneru, Marker’s Chief Medical Officer. “Of note, we were very pleased to note that the second patient we treated with MRD+ disease was found to be MRD- by that patient’s week 8 follow-up. The ability to administer MT-401 without the need for lymphodepletion, coupled with our improved accelerated manufacturing process, enable us to treat patients who have MRD+ disease. We believe that the results observed to date support the notion that patients with AML would have meaningful benefit from a multi-antigen targeted T cell therapy approach.”

PROGRAM UPDATES AND EXPECTED MILESTONES

Acute Myeloid Leukemia (MT-401)

- Marker has enrolled 13 evaluable patients in total, including 6 in the Safety Lead-in cohorts.
- 5 patients have been treated with MT-401 manufactured by a revised process and have completed dose-limiting toxicity (DLT) periods with no DLTs reported.
- One additional MRD+ patient was treated and became MRD- at 8 weeks after the first infusion.
- 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)

- On August 4, 2022, Marker announced that the U.S. Food and Drug Administration (FDA) cleared the Company's Investigational New Drug (IND) application for MT-601, a multi-tumor-associated antigen (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.
- Marker expects to initiate a Phase 1 trial in 2023.

Pancreatic Cancer (MT-601)

- Marker is on track to file an IND for MT-601 for the treatment of pancreatic cancer in 2022.
- 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.

SECOND QUARTER 2022 FINANCIAL RESULTS

- **Cash Position and Guidance:** At June 30, 2022, Marker had cash and cash equivalents of \$25.8 million.
- **R&D Expenses:** Research and development expenses were \$6.6 million for the quarter ended June 30, 2022, compared to \$7.4 million for the quarter ended June 30, 2021.
- **G&A Expenses:** General and administrative expenses were \$3.5 million for the quarter ended June 30, 2022, compared to \$3.6 million for the quarter ended June 30, 2021.
- **Net Loss:** Marker reported a net loss of \$9.2 million for the quarter ended June 30, 2022, compared to a net loss of \$10.9 million for the quarter ended June 30, 2021.

Organizational Restructuring

On August 10, 2022, the Company implemented changes to the Company's organizational structure as part of an operational cost reduction plan to conserve the Company's available capital. In connection with these changes, the Company reduced headcount in its general and administrative function by approximately 23.5%, including the separation of the Company's Chief Financial Officer. The Company estimates that the severance and termination-related costs will total approximately \$0.7 million and will be recorded in the third quarter of 2022. The Company expects that the payment of these costs will be substantially complete in September of 2023.

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)

	June 30, 2022	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 25,821,708	\$ 42,351,145
Restricted cash	-	1,146,186
Prepaid expenses and deposits	2,826,699	2,484,634
Other receivables	627,629	237
Total current assets	<u>29,276,036</u>	<u>45,982,202</u>
Non-current assets:		
Property, plant and equipment, net	13,740,158	10,096,861
Construction in progress	-	2,225,610
Right-of-use assets, net	9,303,544	9,830,461
Total non-current assets	<u>23,043,702</u>	<u>22,152,932</u>
Total assets	<u>\$ 52,319,738</u>	<u>\$ 68,135,134</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 4,735,251	\$ 11,134,913
Related party deferred revenue	8,000,000	-
Lease liability	738,389	620,490
Deferred revenue	-	1,146,186
Total current liabilities	<u>13,473,640</u>	<u>12,901,589</u>
Non-current liabilities:		
Lease liability, net of current portion	10,819,825	11,247,950
Total non-current liabilities	<u>10,819,825</u>	<u>11,247,950</u>
Total liabilities	<u>24,293,465</u>	<u>24,149,539</u>
Stockholders' equity:		
Preferred stock - \$0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at June 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 June 30, 2022 and December 31, 2021, respectively	83,599	83,079
Additional paid-in capital	445,215,725	442,020,871
Accumulated deficit	(417,273,051)	(398,118,355)
Total stockholders' equity	<u>28,026,273</u>	<u>43,985,595</u>
Total liabilities and stockholders' equity	<u>\$ 52,319,738</u>	<u>\$ 68,135,134</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2022	2021	2022	2021
Revenues:				
Grant income	\$ 790,508	\$ -	\$ 1,754,830	\$ -
Total revenues	<u>790,508</u>	<u>-</u>	<u>1,754,830</u>	<u>-</u>
Operating expenses:				
Research and development	\$ 6,555,299	\$ 7,350,035	13,581,365	12,993,064
General and administrative	3,515,183	3,559,150	7,248,184	6,697,108
Total operating expenses	<u>10,070,482</u>	<u>10,909,185</u>	<u>20,829,549</u>	<u>19,690,172</u>
Loss from operations	(9,279,974)	(10,909,185)	(19,074,719)	(19,690,172)
Other income (expenses):				
Arbitration settlement	-	-	(118,880)	-
Interest income	35,786	2,403	38,903	3,940
Net loss	<u>\$ (9,244,188)</u>	<u>\$ (10,906,782)</u>	<u>\$ (19,154,696)</u>	<u>\$ (19,686,232)</u>
Net loss per share, basic and diluted	<u>\$ (0.11)</u>	<u>\$ (0.13)</u>	<u>\$ (0.23)</u>	<u>\$ (0.28)</u>
Weighted average number of common shares outstanding, basic and diluted	<u>83,592,043</u>	<u>83,030,470</u>	<u>83,351,184</u>	<u>69,823,729</u>

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

	For the Six Months Ended	
	June 30,	
	2022	2021
Cash Flows from Operating Activities:		
Net loss	\$ (19,154,696)	\$ (19,686,232)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,156,113	1,032,971
Stock-based compensation	3,131,801	3,029,125
Amortization on right-of-use assets	517,059	504,232
Changes in operating assets and liabilities:		-
Prepaid expenses and deposits	(342,065)	(743,876)
Other receivables	(627,392)	1,000,273
Accounts payable and accrued expenses	(4,255,034)	108,230
Related party deferred revenue	8,000,000	-
Deferred revenue	(1,146,186)	-
Lease liability	(300,368)	(130,503)
Net cash used in operating activities	<u>(13,020,768)</u>	<u>(14,885,780)</u>
Cash Flows from Investing Activities:		
Purchase of property and equipment	(1,229,298)	(842,048)
Purchase of construction in progress	(3,489,130)	(958,965)
Net cash used in investing activities	<u>(4,718,428)</u>	<u>(1,801,013)</u>
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	<u>63,573</u>	<u>52,555,845</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(17,675,623)</u>	<u>35,869,052</u>
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	<u>\$ 25,821,708</u>	<u>\$ 57,221,434</u>

Investors and Media Contacts

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