

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 10, 2021

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 10, 2021, Marker Therapeutics, Inc. (the “*Company*”) reported financial results for the quarter ended June 30, 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.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release, dated August 10, 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: August 10, 2021

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



Marker Therapeutics Reports Second Quarter 2021 Operating and Financial Results

Marker continues to enroll patients and activate clinical sites in Phase 2 AML trial following completion of safety lead-in

Company's new in-house cGMP manufacturing facility in Houston is fully operational

Houston, TX—August 10, 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 second quarter ended June 30, 2021.

“Marker accomplished a number of strategic goals and clinical milestones this quarter, including completing the safety lead-in portion of our company-sponsored Phase 2 trial investigating Marker’s MultiTAA-specific T cell therapy in post-transplant acute myeloid leukemia, or AML,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “We are now enrolling patients as well as activating additional clinical sites in the main portion of the trial. In parallel, we opened a new in-house cGMP manufacturing facility in Houston and recently announced that the facility is fully operational. We look forward to manufacturing study drug at the new facility next quarter, which we expect will yield quality product, reduce manufacturing costs and expand patient access to Marker’s MultiTAA-specific cell therapies.”

PROGRAM UPDATES

- In June 2021, Marker completed the six-patient safety lead-in portion of the Company's Phase 2 trial of MT-401, its lead MultiTAA-specific T cell product candidate, for the treatment of post-transplant AML.
- The Company continues to enroll patients in the main portion of the trial and activate clinical sites across the U.S. The trial is expected to enroll approximately 120 patients in the adjuvant setting and 40 patients with active disease at approximately 20 clinical sites.

BUSINESS UPDATES

- Marker recently announced that the Company’s new cGMP manufacturing facility in Houston, TX, located near the George Bush Intercontinental Airport, is fully operational. The facility will manufacture Marker’s MultiTAA-specific T cell products for the Company’s Phase 2 AML trial as well as future hematological and solid tumor trials, in addition to producing the potential commercial supply of any approved products.
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ANTICIPATED PROGRAM MILESTONES

AML Trial Milestones

- 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

- Manufacture MT-401 at Marker's new cGMP facility for Phase 2 AML trial in Q3 2021

SECOND QUARTER 2021 FINANCIAL RESULTS

- **Cash Position and Guidance:** At June 30, 2021, Marker had cash and cash equivalents of \$57.2 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses and capital expenditure requirements into the first quarter of 2023.
- **R&D Expenses:** Research and development expenses were \$7.4 million for the quarter ended June 30, 2021 compared to \$4.3 million for the quarter ended June 30, 2020. The increase was primarily attributable to increases in clinical trial and sponsored research expenses and headcount-related expenses due to growth of research and development operations.
- **G&A Expenses:** General and administrative expenses were \$3.6 million for the quarter ended June 30, 2021 compared to \$2.5 million for the quarter ended June 30, 2020.
- **Net Loss:** Marker reported a net loss of \$10.9 million for the quarter ended June 30, 2021, compared to a net loss of \$6.3 million for the quarter ended June 30, 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, as well as clinical trials conducted by our collaborators; our manufacturing processes and our ability to use our current and planned 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, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,221,434	\$ 21,352,382
Prepaid expenses and deposits	2,801,800	2,057,924
Other receivables	286	1,000,559
Total current assets	<u>60,023,520</u>	<u>24,410,865</u>
Non-current assets:		
Property, plant and equipment, net	10,107,579	3,570,736
Construction in progress	-	6,789,098
Right-of-use assets, net	10,339,884	10,844,116
Total non-current assets	<u>20,447,463</u>	<u>21,203,950</u>
Total assets	<u>\$ 80,470,983</u>	<u>\$ 45,614,815</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 5,100,943	\$ 6,013,010
Lease liability	558,657	388,792
Total current liabilities	<u>5,659,600</u>	<u>6,401,802</u>
Non-current liabilities:		
Lease liability, net of current portion	11,568,072	11,868,440
Total non-current liabilities	<u>11,568,072</u>	<u>11,868,440</u>
Total liabilities	<u>17,227,672</u>	<u>18,270,242</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock - \$0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at June 30, 2021 and December 31, 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 June 30, 2021 and December 31, 2020, respectively	83,079	50,731
Additional paid-in capital	439,085,948	383,533,326
Accumulated deficit	(375,925,716)	(356,239,484)
Total stockholders' equity	<u>63,243,311</u>	<u>27,344,573</u>
Total liabilities and stockholders' equity	<u>\$ 80,470,983</u>	<u>\$ 45,614,815</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2021	2020	2021	2020
Revenues:				
Grant income	\$ -	\$ 466,785	\$ -	\$ 466,785
Total revenues	-	466,785	-	466,785
Operating expenses:				
Research and development	7,350,035	4,277,052	12,993,064	8,093,670
General and administrative	3,559,150	2,547,289	6,697,108	5,374,284
Total operating expenses	10,909,185	6,824,341	19,690,172	13,467,954
Loss from operations	(10,909,185)	(6,357,556)	(19,690,172)	(13,001,169)
Other income:				
Change in fair value of warrant liabilities	-	-	-	31,000
Interest income	2,403	15,857	3,940	142,826
Net loss	\$ (10,906,782)	\$ (6,341,699)	\$ (19,686,232)	\$ (12,827,343)
Net loss per share, basic and diluted	\$ (0.13)	\$ (0.14)	\$ (0.28)	\$ (0.28)
Weighted average number of common shares outstanding, basic and diluted	83,030,470	46,572,739	69,823,729	46,328,561

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

	For the Six Months Ended June 30,	
	2021	2020
Cash Flows from Operating Activities:		
Net loss	\$ (19,686,232)	\$ (12,827,343)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	1,032,971	124,627
Changes in fair value of warrant liabilities	-	(31,000)
Stock-based compensation	3,029,125	2,705,365
Amortization on right-of-use assets	504,232	96,973
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(743,876)	(1,106,072)
Other receivables	1,000,273	52,749
Accounts payable and accrued expenses	(912,067)	2,770,341
Lease liability	(130,503)	(187,068)
Net cash used in operating activities	(15,906,077)	(8,401,428)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(780,716)	(1,299,193)
Purchase of construction in progress	-	(2,629,141)
Net cash used in investing activities	(780,716)	(3,928,334)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock, net	52,552,758	-
Proceeds from exercise of warrants	-	550,000
Proceeds from exercise of stock options	3,087	-
Net cash provided by financing activities	52,555,845	550,000
Net increase (decrease) in cash	35,869,052	(11,779,762)
Cash and cash equivalents at beginning of the period	21,352,382	43,903,949
Cash and cash equivalents at end of the period	\$ 57,221,434	\$ 32,124,187

Contacts**Investors**

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