

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 8, 2019

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 2240**

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 8, 2019, Marker Therapeutics, Inc. (the “Company”) reported financial results for the second quarter ended June 30, 2019 and other recent corporate updates. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on 8-K 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>
<u>99.1</u>	<u>Press release issued on August 8, 2019.</u>

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 8, 2019

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



Marker Therapeutics Reports Second Quarter 2019 Operating and Financial Results

Houston, TX—August 8, 2019—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, 2019.

“We are encouraged by the data generated to date with our MultiTAA T cell therapies—particularly in pancreatic cancer—a disease that has not seen meaningful improvements in treatment outcomes in more than 40 years,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “These data suggest that our therapy—which targets multiple antigens—continues to demonstrate epitope spreading, potentially contributing to the T cells’ ability to expand and produce a lasting anti-tumor effect, with no added toxicities. We will continue to follow these patients and enroll new patients to further evaluate durability.”

Continued Mr. Hoang: “Encouraged by results from our investigator-sponsored trials, we are now looking forward to initiating our first Marker-sponsored trial with MultiTAA T cell therapies in patients with post-transplant acute myeloid leukemia, and look forward to continuing our discussions with the FDA regarding our Phase 2 trial.”

PROGRAM HIGHLIGHTS AND CURRENT UPDATES

Multi-Antigen Targeted (MultiTAA) T Cell Therapies

Encouraging Interim Pancreatic Cancer Data Reported at AACR Meeting in July

Marker recently reported interim data from an ongoing investigator-sponsored Phase 1/2 clinical trial led by Baylor College of Medicine (BCM), evaluating the Company’s MultiTAA T cell therapy in patients with pancreatic adenocarcinoma. Investigators plan to enroll a total of 45 patients with advanced or borderline resectable pancreatic cancer in the three-arm trial and a total of 19 patients had received infusions of MultiTAA T cell therapy as of July 5, 2019. The results from these patients—which were reviewed in an oral presentation during a plenary session at AACR’s Cell Therapy meeting in July—suggested that MultiTAA T cell therapy may contribute to more durable responses without added toxicity when used in combination with standard-of-care chemotherapy, or as a second-line therapy for patients who are chemo-refractory. Additionally, in patients with borderline surgically resectable disease—a challenging setting due to the associated dense fibrotic tissue—interim data suggest that MultiTAA T cells are capable of meaningfully infiltrating the tumor. Marker plans to follow these patients and enroll new patients to further evaluate durability.

Marker Preparing for Company-Sponsored Phase 2 Clinical Trial in AML

The multicenter trial will evaluate clinical efficacy of Marker’s MultiTAA T cell therapy in patients with AML in both the adjuvant and active disease setting following an allogeneic hematopoietic stem cell transplant (HSCT). The dose in the Phase 2 trial is expected to be the maximum tolerated dose currently determined in the BCM-sponsored Phase 1 trial. In the adjuvant setting, patients will be randomized to either MultiTAA T cell therapy at approximately 90 days post-transplant or standard of care observation, while the active disease patients will receive MultiTAA T cells upon relapse as part of a single-arm group.

T Cell-Based Vaccines

The Company continues to advance its T cell-based vaccine programs in ovarian cancer and triple negative breast cancer.

Phase 2 Ovarian Cancer Clinical Trial Highlights

- TPIV200 is being studied as a maintenance therapy for patients in their first remission after surgery and platinum-based chemotherapy.
- Trial is fully enrolled, with a total of 120 patients randomized and treated at 17 clinical sites.
- Company expects to reach planned interim analysis trigger of 55 patients who have progressed before the end of 2019 and to report results of this interim analysis in the fourth quarter of 2019.

Phase 2 Triple Negative Breast Cancer Trial Highlights

- Based on preliminary analysis of 34 patients evaluated to date in the dose-finding, four-arm trial—including low and high-dose TPIV200 with or without cyclophosphamide—31 showed meaningful immune response to the vaccine treatment (subject to final review by independent biostatistical analysis).
- Of 80 patients treated at 11 clinical sites, 14 have shown disease progression, as of June 30, 2019, following treatment with TPIV200.

CORPORATE UPDATE

- On August 6, Steve Elms was appointed to Marker's Board of Directors. Mr. Elms currently serves as Managing Partner at Aisling Capital.

SECOND QUARTER 2019 FINANCIAL RESULTS

Net loss for the quarter ended June 30, 2019 was \$5.6 million, compared to a net loss of \$4.8 million for the quarter ended June 30, 2018.

Research and development expenses were \$3.2 million for the quarter ended June 30, 2019, an increase of \$1.4 million, compared to \$1.8 million for the quarter ended June 30, 2018. The increase was primarily attributable to increases in personnel-related expenses, including stock-based compensation expenses and consulting expenses, relating to the build-up of Marker's internal infrastructure as the Company advances the clinical development of its MultiTAA T cell product candidates.

General and administrative expenses were \$2.7 million for the quarter ended June 30, 2019, a decrease of \$0.4 million, compared to \$3.1 million for the quarter ended June 30, 2018. The decrease was primarily attributable to \$1.2 million of merger-related expenses incurred during the three months ended June 30, 2018, offset by increased expenses relating to \$0.3 million of headcount-related expenses, \$0.4 million of non-merger-related legal and other professional expenses and \$0.1 million of office-related and insurance expenses.

CASH POSITION AND GUIDANCE

At June 30, 2019, Marker had cash and cash equivalents of \$53.4 million. The Company believes that its existing cash and cash equivalents will fund the Company's current operations into late 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.

Marker is also advancing a number of innovative peptide and gene-based immuno-therapeutics for the treatment of metastatic solid tumors, including the Folate Receptor Alpha program (TPIV200) for breast and ovarian cancers and the HER2/neu program (TPIV100/110) for breast cancer, currently in Phase 2 clinical trials.

To receive future press releases via email, please visit: <https://markertherapeutics.com/email-alerts/>

Forward-Looking Statement Disclaimer

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 and our TPIV200 and TPIV100/110 programs; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; and, the timing and success of our clinical trials, as well as clinical trials conducted by our collaborators. 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. 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, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 53,444,906	\$ 61,746,748
Prepaid expenses and deposits	491,467	141,717
Interest receivable	98,154	108,177
Total current assets	<u>54,034,527</u>	<u>61,996,642</u>
Non-current assets:		
Property, plant and equipment, net	413,239	147,668
Right-of-use assets, net	547,455	-
Total non-current assets	<u>960,694</u>	<u>147,668</u>
Total assets	<u>\$ 54,995,221</u>	<u>\$ 62,144,310</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,946,782	\$ 2,754,572
Lease liability	194,482	-
Warrant liability	65,000	49,000
Total current liabilities	<u>3,206,264</u>	<u>2,803,572</u>
Non-current liabilities:		
Lease liability, net of current portion	385,169	-
Total non-current liabilities	<u>385,169</u>	<u>-</u>
Total liabilities	<u>3,591,433</u>	<u>2,803,572</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, 2019 and December 31, 2018, respectively	-	-
Common stock, \$0.001 par value, 150 million shares authorized, 45.5 million and 45.4 million shares issued and outstanding as of June 30, 2019 and December 31, 2018, respectively	45,513	45,440
Additional paid-in capital	368,353,041	365,400,748
Accumulated deficit	(316,994,766)	(306,105,450)
Total stockholders' equity	<u>51,403,788</u>	<u>59,340,738</u>
Total liabilities and stockholders' equity	<u>\$ 54,995,221</u>	<u>\$ 62,144,310</u>

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

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2019	2018	2019	2018
Revenues:				
Grant income	\$ -	\$ 205,994	\$ -	\$ 205,994
Total revenues	<u>-</u>	<u>205,994</u>	<u>-</u>	<u>205,994</u>
Operating expenses:				
Research and development	3,152,445	1,826,837	5,985,140	3,426,387
General and administrative	2,721,120	3,052,954	5,526,895	4,650,890
Total operating expenses	<u>5,873,565</u>	<u>4,879,791</u>	<u>11,512,035</u>	<u>8,077,277</u>
Loss from operations	(5,873,565)	(4,673,797)	(11,512,035)	(7,871,283)
Other income (expense):				
Change in fair value of warrant liabilities	(7,000)	(139,000)	(16,000)	(138,000)
Interest income	310,174	-	638,719	-
Net loss	<u>\$ (5,570,391)</u>	<u>\$ (4,812,797)</u>	<u>\$ (10,889,316)</u>	<u>\$ (8,009,283)</u>
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.41)	\$ (0.24)	\$ (0.71)
Weighted average number of common shares outstanding	<u>45,501,078</u>	<u>11,838,371</u>	<u>45,483,513</u>	<u>11,233,755</u>

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

	For the Six Months Ended	
	June 30,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	\$ (10,889,316)	\$ (8,009,283)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	39,811	-
Changes in fair value of warrant liabilities	16,000	138,000
Stock-based compensation	2,889,243	1,096,472
Amortization on right-of-use assets	89,178	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(349,750)	(57,566)
Interest receivable	10,023	-
Accounts payable and accrued expenses	225,135	2,086,840
Lease liability	(89,907)	-
Net cash used in operating activities	<u>(8,059,583)</u>	<u>(4,745,537)</u>
Cash Flows from Investing Activities:		
Purchase of property and equipment	(305,382)	-
Net cash used in investing activities	<u>(305,382)</u>	<u>-</u>
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock and warrants in private placement, net of offering costs	-	3,120,000
Proceeds from exercise of stock options	57,744	18,125
Proceeds from exercise of warrants	5,379	4,261,085
Net cash provided by financing activities	<u>63,123</u>	<u>7,399,210</u>
Net (decrease) increase in cash	<u>(8,301,842)</u>	<u>2,653,673</u>
Cash and cash equivalents at beginning of period	61,746,748	5,129,289
Cash and cash equivalents at end of period	<u><u>\$ 53,444,906</u></u>	<u><u>\$ 7,782,962</u></u>

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