

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

May 9, 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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On May 9, 2019, Marker Therapeutics, Inc. (the “Company”) issued a press release announcing its financial results for the first quarter ended March 31, 2019 and an update on recent developments. A copy of that press release is furnished herewith as Exhibit 99.1 and is incorporated herein by reference.

The information furnished under this Item 2.02, including the accompanying Exhibit 99.1, shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 (the “Exchange Act”), or otherwise subject to the liability of such section, nor shall such information be deemed to be incorporated by reference in any subsequent filing by the Company under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language of such filing, except as specifically stated in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on May 9, 2019.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 9th day of May, 2019.

MARKER THERAPEUTICS, INC.
(Registrant)

BY: /s/ Anthony Kim

Anthony Kim

Chief Financial Officer



Marker Therapeutics Reports First Quarter 2019 Operating and Financial Results

—Company on track to submit IND for Phase 2 AML clinical trial in the third quarter, with first patient enrolled by year end—

—MultiTAA T cell therapies continue to generate positive clinical results across various indications in investigator-sponsored trials—

—Company to report update from Phase 1/2 clinical trial in pancreatic cancer in Q3 2019—

Houston, TX –May 9th, 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 first quarter ended March 31, 2019.

“We continued to make significant progress this quarter. Based on our early interactions with the U.S. FDA, we are confident in our submission package for our IND for post-transplant acute myeloid leukemia (AML). In light of the feedback from the FDA, we plan to submit an IND for a Phase 2 clinical trial in the third quarter, which should enable us to enroll the first patient by the end of the year,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “Depending on the results and upon further discussions with the FDA, we believe that if results are positive, this has the potential to serve as a pivotal trial—particularly if results are consistent with data generated to date from our MultiTAA therapies in investigator-sponsored trials. We look forward to initiating our first company-sponsored trial in such an important disease area, for which there are limited treatment options. Additionally, we anticipate reporting an update from our solid tumor program in pancreatic cancer in the third quarter.”

PROGRAM HIGHLIGHTS AND CURRENT UPDATES

Multi-Antigen Targeted (MultiTAA) T Cell Therapies

Company Prepares IND for Potentially Pivotal Trial in Post-Transplant AML

Based on interactions with the U.S. Food and Drug Administration (FDA) on the clinical trial design of the planned Marker-sponsored Phase 2 clinical trial in post-transplant AML, the Company remains on track to submit an Investigational New Drug (IND) application in the third quarter, and anticipates first patient enrolled by the end of 2019. The multicenter trial will evaluate clinical efficacy of Marker’s MultiTAA-specific T cells in patients with AML in both the adjuvant and active disease setting, following an allogeneic hematopoietic stem cell transplant (HSCT). The dose to be administered in the trial is expected to be the maximum tolerated dose currently determined in the Baylor College of Medicine-sponsored Phase 1 trial. In the adjuvant setting, patients will be randomized to either MultiTAA therapy at approximately 90 days post-transplant or standard of care observation, while the active disease patients will receive MultiTAA T cells as part of a single-arm group at approximately 90 days post-transplant.

- **MultiTAA T Cell Therapies Continue to Generate Positive Clinical Data Across Various Indications**

In several ongoing investigator-sponsored Phase 1 clinical trials led by Baylor College of Medicine (BCM), Marker's MultiTAA therapies have demonstrated the potential to mediate a meaningful anti-tumor effect, as well as significant *in vivo* expansion of T cells. Across all hematological indications studied in these trials—including AML, lymphoma, acute lymphoblastic leukemia (ALL), and multiple myeloma—MultiTAA therapy has appeared to be well-tolerated, with no incidence of cytokine release syndrome, neurotoxicity or any other serious adverse events related to the therapy.

- **Company to Report Update from Phase 1/2 Trial in Pancreatic Cancer in Q3 2019**

Marker plans to report additional interim data from BCM's ongoing Phase 1/2 clinical trial in pancreatic cancer in the third quarter of 2019. The Phase 1/2 trial is a three-arm trial which includes chemo-responsive patients (Arm A), chemo-refractory patients (Arm B) and an exploratory arm for patients who have surgically-resectable disease (Arm C). Patients in the chemo-responsive arm have completed at least three months of standard-of-care chemotherapy, and are receiving up to six administrations of MultiTAA T cells in alternation with chemotherapy. Patients in the chemo-refractory arm are either ineligible for chemotherapy or have progressed on chemotherapy, and are receiving up to six doses of MultiTAA T cells as a monotherapy. The surgically-resectable patients are receiving a dose of T cells prior to surgical resection which allows Marker to assess the tumor samples for T-cell infiltration, epitope spreading and other important characteristics. These patients are eligible to receive five additional doses of T cells after surgical resection.

T Cell Based Vaccines

- **Ovarian Cancer Data**

As of January 2019, the Company has completed enrollment in its Phase 2 clinical trial in ovarian cancer using TPIV200 as a maintenance therapy for patients in their first remission after surgery and platinum-based chemotherapy, with a total of 120 patients enrolled, randomized, and treated at 17 clinical sites. The trial completed enrollment six months faster than anticipated and the Company expects to reach its planned interim analysis trigger of 55 patients who have progressed before the end of 2019 and to report the results of this interim analysis in the fourth quarter of 2019.

- **Triple Negative Breast Cancer Data**

The Company reported initial findings from its dose-finding, four-arm Phase 2 clinical trial in triple negative breast cancer, including low- and high-dose TPIV200 with or without cyclophosphamide. Of 27 patients evaluated for immunogenicity, 26 showed significant immune response to the vaccine treatment. Of 80 patients treated at 11 clinical sites, 14 have shown disease progression, as of April 30, 2019, following treatment with TPIV200.

FIRST QUARTER 2019 FINANCIAL RESULTS

Net loss for the quarter ended March 31, 2019 was \$5.3 million compared to a net loss of \$3.2 million for the quarter ended March 31, 2018.

Research and development expenses were \$2.8 million for the quarter ended March 31, 2019, an increase of \$1.2 million, compared to \$1.6 million for the quarter ended March 31, 2018. The increase was primarily attributable to increased headcount-related expenses, stock-based compensation expenses and consulting expenses resulting from the expansion of our internal infrastructure as we advance the clinical development of our MultiTAA T cell product candidates.

General and administrative expenses were \$2.8 million for the quarter ended March 31, 2019, an increase of \$1.2 million, compared to \$1.6 million for the quarter ended March 31, 2018. The increase was primarily attributable to an increase in general and administrative headcount and stock-based compensation expenses.

CASH POSITION AND GUIDANCE

At March 31, 2019, Marker had cash and cash equivalents of \$57.7 million. The Company believes that its existing cash and cash equivalents will fund the Company's current operations into late 2020.

UPCOMING NEAR-TERM POTENTIAL MILESTONES

- First update in solid tumor program planned for third quarter of 2019;
- IND submission for Company-sponsored Phase 2 AML clinical trial in the third quarter of 2019, with first patient enrolled by end of 2019;
- Interim analysis readout in the TPIV200 ovarian trial expected in fourth quarter of 2019; and
- Overall update on ongoing clinical trials in cell therapy to be provided by the end of 2019.

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 cells 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 therapeutic 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.

For additional information, please call toll free at (904) 862-6490 or visit: markertherapeutics.com

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

Follow us on Twitter @MRKRTherapeutic, or follow us on Facebook.

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 and development activities relating to our non-engineered multi-tumor antigen specific T cell therapies; 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.
Consolidated Balance Sheets
(Unaudited)

	March 31, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 57,706,579	\$ 61,746,748
Prepaid expenses and deposits	216,433	141,717
Interest receivable	112,200	108,177
Total current assets	<u>58,035,212</u>	<u>61,996,642</u>
Non-current assets:		
Property, plant and equipment, net	360,280	147,668
Right-of-use assets, net	592,422	-
Total non-current assets	<u>952,702</u>	<u>147,668</u>
TOTAL ASSETS	<u>\$ 58,987,914</u>	<u>\$ 62,144,310</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,694,019	\$ 2,754,572
Lease liability	189,791	-
Warrant liability	58,000	49,000
Total current liabilities	<u>2,941,810</u>	<u>2,803,572</u>
Non-current liabilities:		
Lease liability, net of current portion	435,192	-
Total non-current liabilities	<u>435,192</u>	<u>-</u>
Total liabilities	<u>3,377,002</u>	<u>2,803,572</u>
COMMITMENTS AND CONTINGENCIES		
Stockholders' equity:		
Preferred stock - \$0.001 par value, 5 million shares authorized at March 31, 2019 and December 31, 2018, respectively		
Series A, \$0.001 par value, 1.25 million shares designated, 0 shares issued and outstanding as of March 31, 2019 and December 31, 2018, respectively	-	-
Series B, \$0.001 par value, 1.5 million shares designated, 0 shares issued and outstanding as of March 31, 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 March 31, 2019 and December 31, 2018, respectively	45,484	45,440
Additional paid-in capital	366,989,803	365,400,748
Accumulated deficit	(311,424,375)	(306,105,450)
Total stockholders' equity	<u>55,610,912</u>	<u>59,340,738</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 58,987,914</u>	<u>\$ 62,144,310</u>

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

	For the Three Months Ended	
	March 31,	
	2019	2018
Operating expenses:		
Research and development	\$ 2,832,695	\$ 1,599,550
General and administrative	2,805,775	1,597,936
Total operating expenses	<u>5,638,470</u>	<u>3,197,486</u>
Loss from operations	(5,638,470)	(3,197,486)
Other income (expense):		
Change in fair value of warrant liabilities	(9,000)	1,000
Interest income	328,545	-
Net loss	<u>\$ (5,318,925)</u>	<u>\$ (3,196,486)</u>
Net loss per share, Basic and Diluted	<u>\$ (0.12)</u>	<u>\$ (0.30)</u>
Weighted average number of common shares outstanding	<u>45,465,754</u>	<u>10,622,420</u>

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

	For the Three Months Ended	
	March 31,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	\$ (5,318,925)	\$ (3,196,486)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	10,514	-
Changes in fair value of warrant liabilities	9,000	(1,000)
Stock-based compensation	1,525,976	136,193
Amortization on right-of-use assets	44,211	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(74,716)	(77,878)
Interest receivable	(4,023)	-
Accounts payable and accrued expenses	(27,628)	792,849
Lease liability	(44,575)	-
Net cash used in operating activities	<u>(3,880,166)</u>	<u>(2,346,322)</u>
Cash Flows from Investing Activities:		
Purchase of property and equipment	(223,126)	-
Net cash used in investing activities	<u>(223,126)</u>	<u>-</u>
Cash Flows from Financing Activities:		
Proceeds from exercise of stock options	57,744	18,125
Proceeds from exercise of warrants	5,379	-
Net cash provided by financing activities	<u>63,123</u>	<u>18,125</u>
Net decrease in cash	<u>(4,040,169)</u>	<u>(2,328,197)</u>
Cash and cash equivalents at beginning of period	61,746,748	5,129,289
Cash and cash equivalents at end of period	<u>\$ 57,706,579</u>	<u>\$ 2,801,092</u>

Contacts

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