

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

November 12, 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 November 12, 2019, Marker Therapeutics, Inc. (the “Company”) reported financial results for the quarter ended September 30, 2019 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>
<u>99.1</u>	<u>Press release issued on November 12, 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: November 12, 2019

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



Marker Therapeutics Reports Third Quarter 2019 Operating and Financial Results

Conference Call and Webcast Today at 5:00pm EST

Houston, TX – November 12, 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 third quarter ended September 30, 2019.

“We continue to make progress in advancing our next-generation T-cell based immunotherapies for the treatment of hematological malignancies and solid tumors,” said Peter L. Hoang, President and CEO of Marker Therapeutics. “Our partner-sponsored MultiTAA T-cell therapy trials at the Baylor College of Medicine continue to show promising results. In addition, we continue to expand our team and build out our infrastructure to support future Marker-sponsored clinical trials. We expect the next 12 to 18 months to be an exciting and productive time for our Company.”

Continued Mr. Hoang: “We recently filed an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) for our MultiTAA T-cell therapy as part of a planned Marker Phase 2 study in post-allogeneic hematopoietic stem cell transplant patients with acute myeloid leukemia in both the adjuvant and active disease setting. The FDA reviewed our submission and requested additional information regarding certain quality and technical specifications for two reagents supplied by third party vendors that are used in our manufacturing process. Because the FDA requires these data in order to clear the IND, the Marker AML trial has been placed on clinical hold until our complete response to the technical questions is satisfactory to the FDA. While these reagents are not present in the final product, we worked with respective manufacturers of these reagents to satisfy the FDA’s questions and subsequently submitted a complete response to the FDA in late October. We currently project to initiate our Phase 2 trial in 2020 and look forward to providing an update on our clinical path forward upon receiving the FDA’s feedback.”

PROGRAM UPDATES

Multi-Antigen Targeted (MultiTAA) T-Cell Therapies

Marker Submits Response to FDA Clinical Hold on AML Trial

The Company worked with regulatory and quality groups at the respective manufacturers to address the FDA’s request and submitted a complete response to the issues raised by the FDA on October 28, 2019. The FDA will respond within 30 days after receiving Marker’s complete response, indicating whether the hold is lifted and, if not, specifying the reasons the clinical trial remains on hold. Marker expects to initiate its Phase 2 clinical trial of MultiTAA therapy for the treatment of post-transplant AML in 2020.

T Cell-Based Vaccines

Phase 2 Triple Negative Breast Cancer Trial Progressing

Marker continues to advance its T cell-based vaccine program in triple negative breast cancer. To date, results have shown:

- Based on a preliminary analysis of 34 patients enrolled in the triple negative breast cancer trial, 31 patients showed meaningful immune response to vaccine treatment;
- Of 80 patients treated at 11 clinical sites, 14 have shown disease progression, as of September 30, 2019, following treatment with TPIV200.

Phase 2 Platinum-Sensitive Advanced Ovarian Cancer Trial Update

Marker will be discontinuing the development of TPIV200 in patients with platinum-sensitive advanced ovarian cancer based on an unblinded review of interim results from its Phase 2 study conducted by an independent Data and Safety Monitoring Board (DSMB). Although the DSMB did not express any safety concerns with respect to TPIV200, Marker has elected to suspend the trial because it did not meet the threshold for probability of success based upon the Company's pre-specified criteria. Pending full review of the data, Marker anticipates closing the trial in the first quarter of 2020.

CORPORATE UPDATES

- Nadia Agopyan, Ph.D., RAC, former Director of Regulatory Affairs, Global Regulatory Lead at Kite Pharma, appointed as Vice President of Regulatory Affairs
- Steve Elms, Managing Partner at Aisling Capital, appointed to Board of Directors

THIRD QUARTER 2019 FINANCIAL RESULTS

Net loss for the quarter ended September 30, 2019 was \$5.5 million, compared to a net loss of \$4.4 million for the quarter ended September 30, 2018.

Research and development expenses during the three months ended September 30, 2019 were \$3.1 million, compared to \$1.9 million during the three months ended September 30, 2018. The increase of \$1.2 million was primarily attributable to increases in personnel-related expenses, relating to the build-up of Marker's internal infrastructure.

General and administrative expenses were \$2.5 million during the three months ended September 30, 2019 as compared to \$2.6 million during the three months ended September 30, 2018. The decrease was primarily attributable to \$0.6 million of merger-related expenses incurred during the three months ended September 30, 2018, offset by increased expenses in headcount-related and legal and other professional expenses.

CASH POSITION AND GUIDANCE

At September 30, 2019, Marker had cash and cash equivalents of \$48.5 million. The Company believes that its existing cash and cash equivalents will fund its current operations through at least the fourth quarter of 2020.

Conference Call and Webcast

The Company will host a webcast and conference call to discuss its third quarter 2019 financial results and provide an update on recent corporate activities today at 5:00 p.m. EST.

The webcast will be accessible in the [Investors](#) section of the Company's website at www.markertherapeutics.com. Individuals can participate in the conference call by dialing 877-407-8913 (domestic) or 201-689-8201 (international) and referring to the "Marker Therapeutics Third Quarter 2019 Earnings Call."

The archived webcast will be available for replay on the Marker website following the event.

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 cancer 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://www.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; 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)

	September 30, 2019	December 31, 2018
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 48,477,670	\$ 61,746,748
Prepaid expenses and deposits	1,906,062	141,717
Interest receivable	78,145	108,177
Total current assets	<u>50,461,877</u>	<u>61,996,642</u>
Non-current assets:		
Property, plant and equipment, net	438,881	147,668
Right-of-use assets, net	501,714	-
Total non-current assets	<u>940,595</u>	<u>147,668</u>
Total assets	<u>\$ 51,402,472</u>	<u>\$ 62,144,310</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,858,808	\$ 2,754,572
Lease liability	199,266	-
Warrant liability	129,000	49,000
Total current liabilities	<u>3,187,074</u>	<u>2,803,572</u>
Non-current liabilities:		
Lease liability, net of current portion	333,480	-
Total non-current liabilities	<u>333,480</u>	<u>-</u>
Total liabilities	<u>3,520,554</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 September 30, 2019 and December 31, 2018, respectively	-	-
Common stock, \$0.001 par value, 150 million shares authorized, 45.7 million and 45.4 million shares issued and outstanding as of September 30, 2019 and December 31, 2018, respectively	45,723	45,440
Additional paid-in capital	370,290,447	365,400,748
Accumulated deficit	(322,454,252)	(306,105,450)
Total stockholders' equity	<u>47,881,918</u>	<u>59,340,738</u>
Total liabilities and stockholders' equity	<u>\$ 51,402,472</u>	<u>\$ 62,144,310</u>

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenues:				
Grant income	\$ -	\$ -	\$ -	\$ 205,994
Total revenues	-	-	-	205,994
Operating expenses:				
Research and development	3,118,530	1,877,260	9,103,670	5,303,647
General and administrative	2,536,204	2,551,146	8,063,099	7,202,036
Total operating expenses	5,654,734	4,428,406	17,166,769	12,505,683
Loss from operations	(5,654,734)	(4,428,406)	(17,166,769)	(12,299,689)
Other income (expense):				
Change in fair value of warrant liabilities	(64,000)	40,000	(80,000)	(98,000)
Interest income	259,248	-	897,967	-
Net loss	\$ (5,459,486)	\$ (4,388,406)	\$ (16,348,802)	\$ (12,397,689)
Net loss per share, basic and diluted	\$ (0.12)	\$ (0.32)	\$ (0.36)	\$ (1.03)
Weighted average number of common shares outstanding	45,655,387	13,733,406	45,541,434	12,082,176

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

	For the Nine Months Ended	
	September 30,	
	2019	2018
Cash Flows from Operating Activities:		
Net loss	\$ (16,348,802)	\$ (12,397,689)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	70,908	-
Changes in fair value of warrant liabilities	80,000	98,000
Stock-based compensation	4,073,505	1,947,733
Amortization on right-of-use assets	134,919	-
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(1,764,345)	(45,817)
Interest receivable	30,032	-
Accounts payable and accrued expenses	137,161	2,080,459
Lease liability	(136,812)	-
Net cash used in operating activities	(13,723,434)	(8,317,314)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(362,121)	-
Net cash used in investing activities	(362,121)	-
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, net of offering costs	758,733	4,344,171
Net cash provided by financing activities	816,477	7,482,296
Net decrease in cash	(13,269,078)	(835,018)
Cash and cash equivalents at beginning of period	61,746,748	5,129,289
Cash and cash equivalents at end of period	\$ 48,477,670	\$ 4,294,271

Contacts

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