

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

May 11, 2020

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 May 11, 2020, Marker Therapeutics, Inc. (the “Company”) reported financial results for the quarter ended March 31, 2020 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.

<b><u>Exhibit No.</u></b>	<b><u>Description</u></b>
<a href="#"><u>99.1</u></a>	<a href="#"><u>Press release issued on May 11, 2020.</u></a>

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**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: May 11, 2020

By: /s/ Anthony Kim

Anthony Kim

*Chief Financial Officer*

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## Marker Therapeutics Reports First Quarter 2020 Operating and Financial Results

*Company to host conference call and webcast today at 5:00pm EDT*

**Houston, TX—May 11, 2020**—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, 2020.

“While we are eager to initiate our planned Phase 2 trial with our novel MultiTAA-specific T cell therapy in patients with acute myeloid leukemia (AML), we anticipate that the initiation of our trial will be delayed by the impacts the COVID-19 pandemic has had on our clinical trial partners and throughout our supply chain. As a result of the uncertainty, we believe it is prudent to withdraw our prior guidance on the timing of this trial until the outlook clarifies,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “Despite these pandemic-related effects, we remain optimistic that when the study opens, there will be significant patient interest. We are moving expediently in the interim to secure clinical trial sites and are monitoring the situation closely to prioritize the health and wellness of our employees and the patients we serve.”

Continued Mr. Hoang: “We continue to be encouraged by the potential of our MultiTAA-specific T cell therapy to change the treatment paradigm for patients with both liquid and solid tumors. Recently, we received Orphan Drug designation from the U.S. FDA for MT-401, our MultiTAA-specific T cell product candidate to treat patients with AML post-stem cell transplant, our lead indication. Additionally, we are looking forward to soon reporting an update from an ongoing academic-sponsored trial in pancreatic adenocarcinoma, which will be presented during the upcoming ASCO annual meeting.”

### PROGRAM UPDATES

#### Multi-Antigen Targeted (MultiTAA) T Cell Therapies

##### Phase 2 AML Trial Update

Due to the COVID-19 pandemic, Marker expects to be delayed in initiating its planned Phase 2 trial in post-transplant AML patients per previously communicated timelines. Under an amended trial protocol announced in February 2020, the U.S. FDA cleared the Company to initiate the trial, beginning with a safety lead-in. Marker has paused opening the study for enrollment of the first three patients, as the manufacturing facility it utilizes to supply study drug remains closed during the pandemic. The Company continues to identify potential trial sites in the interim, in addition to establishing its own manufacturing facility. The latter portion of the safety lead-in, which involves use of a new reagent, remains on hold until the FDA reviews and accepts the final data and certificate of analysis. The alternate supplier providing these has informed the Company that it will be delayed in providing the reagent.

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### **Orphan Drug Designation Granted for MultiTAA T Cell Therapy in AML**

In April, the FDA's Office of Orphan Products Development granted Orphan Drug designation to MT-401, Marker's MultiTAA-specific T cell product candidate for the treatment of patients with post-transplant AML. Orphan designation is granted to advance the evaluation and development of safe and effective therapies for the treatment of rare diseases or conditions affecting fewer than 200,000 people in the U.S.

### **Pancreatic Cancer Data Update During ASCO**

Updated data from an ongoing Phase 1/2 clinical trial being conducted with Marker's MultiTAA-specific T cell product at the Baylor College of Medicine (BCM) in patients with pancreatic adenocarcinoma will be presented during the Annual Meeting of the American Society of Clinical Oncology (ASCO)—which due to the COVID-19 pandemic, will be held virtually. As previously reported, in the front-line treatment arm in combination with standard-of-care chemotherapy, clinical benefit was observed in correlation with the post-infusion detection of tumor-reactive T cells in patients' peripheral blood. These T cells exhibited activity against both targeted antigens and non-targeted TAAs, indicating induction of antigen spreading. To date, there has not been any cytokine release syndrome or neurotoxicity observed in this trial.

### **T Cell-Based Vaccines**

#### **Phase 2 Triple Negative Breast Cancer Trial Results**

Marker's T cell-based vaccine program in triple negative breast cancer has delivered the following results as of September 30, 2019:

- 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, 16 have shown disease progression following treatment with TPIV200.

### **FINANCING UPDATE**

- On March 2, 2020, Marker announced that the Company entered into a Common Stock Purchase Agreement of up to \$30 million with Aspire Capital Fund, LLC, a Chicago-based institutional investor and long-term Marker shareholder.

### **FIRST QUARTER 2020 FINANCIAL RESULTS**

**Cash Position and Guidance:** At March 31, 2020, Marker had cash and cash equivalents of \$40.3 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses and capital expenditure requirements into the second quarter of 2021.

**R&D Expenses:** Research and development expenses were \$3.8 million for the quarter ended March 31, 2020 compared to \$2.8 million for the quarter ended March 31, 2019. The increase was primarily attributable to headcount-related personnel expenses.

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**G&A Expenses:** General and administrative expenses were \$2.8 million for the quarter ended March 31, 2020 and March 31, 2019.

**Net Loss:** Marker reported a net loss of \$6.5 million for the quarter ended March 31, 2020, compared to a net loss of \$5.3 million for the quarter ended March 31, 2019.

**Conference Call and Webcast**

The Company will host a webcast and conference call to discuss its first quarter 2020 financial results and provide a corporate update today at 5:00 p.m. EDT.

The webcast will be accessible in the Investors section of the Company’s website at [markertherapeutics.com](http://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 First Quarter 2020 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.

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

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**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 program; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the potential benefits of orphan drug designation; the impact of the COVID-19 pandemic; 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](http://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.*

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**Marker Therapeutics, Inc.**  
**Condensed Consolidated Balance Sheets**  
**(Unaudited)**

	March 31, 2020	December 31, 2019
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents	\$ 40,255,062	\$ 43,903,949
Prepaid expenses and deposits	1,716,092	1,526,442
Interest receivable	24,605	56,189
Total current assets	<u>41,995,759</u>	<u>45,486,580</u>
Non-current assets:		
Property, plant and equipment, net	482,084	417,528
Right-of-use assets, net	407,813	455,174
Total non-current assets	<u>889,897</u>	<u>872,702</u>
<b>Total assets</b>	<b><u>\$ 42,885,656</u></b>	<b><u>\$ 46,359,282</u></b>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable and accrued liabilities	\$ 2,955,293	\$ 1,757,680
Lease liability	209,081	204,132
Warrant liability	-	31,000
Total current liabilities	<u>3,164,374</u>	<u>1,992,812</u>
Non-current liabilities:		
Lease liability, net of current portion	226,111	280,247
Total non-current liabilities	<u>226,111</u>	<u>280,247</u>
Total liabilities	<u>3,390,485</u>	<u>2,273,059</u>
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock - \$0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	-	-
Common stock, \$0.001 par value, 150 million shares authorized, 46.5 million and 45.7 million shares issued and outstanding as of March 31, 2020 and December 31, 2019, respectively	46,532	45,728
Additional paid-in capital	373,467,697	371,573,909
Accumulated deficit	<u>(334,019,058)</u>	<u>(327,533,414)</u>
Total stockholders' equity	<u>39,495,171</u>	<u>44,086,223</u>
<b>Total liabilities and stockholders' equity</b>	<b><u>\$ 42,885,656</u></b>	<b><u>\$ 46,359,282</u></b>



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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Operating expenses:</b>		
Research and development	\$ 3,816,618	\$ 2,832,695
General and administrative	2,826,995	2,805,775
Total operating expenses	6,643,613	5,638,470
Loss from operations	(6,643,613)	(5,638,470)
<b>Other income (expense):</b>		
Change in fair value of warrant liabilities	31,000	(9,000)
Interest income	126,969	328,545
<b>Net loss</b>	<b>\$ (6,485,644)</b>	<b>\$ (5,318,925)</b>
Net loss per share, basic and diluted	\$ (0.14)	\$ (0.12)
Weighted average number of common shares outstanding	46,084,383	45,465,754

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

	<b>For the Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2020</b>	<b>2019</b>
<b>Cash Flows from Operating Activities:</b>		
Net loss	\$ (6,485,644)	\$ (5,318,925)
<b>Reconciliation of net loss to net cash used in operating activities:</b>		
Depreciation and amortization	35,265	10,514
Changes in fair value of warrant liabilities	(31,000)	9,000
Stock-based compensation	1,344,592	1,525,976
Amortization on right-of-use assets	47,361	44,211
<b>Changes in operating assets and liabilities:</b>		
Prepaid expenses and deposits	(189,650)	(74,716)
Interest receivable	31,584	(4,023)
Accounts payable and accrued expenses	1,197,613	(27,628)
Lease liability	(49,187)	(44,575)
Net cash used in operating activities	<u>(4,099,066)</u>	<u>(3,880,166)</u>
<b>Cash Flows from Investing Activities:</b>		
Purchase of property and equipment	(99,821)	(223,126)
Net cash used in investing activities	<u>(99,821)</u>	<u>(223,126)</u>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of stock options	-	57,744
Proceeds from exercise of warrants	550,000	5,379
Net cash provided by financing activities	<u>550,000</u>	<u>63,123</u>
Net decrease in cash	<u>(3,648,887)</u>	<u>(4,040,169)</u>
Cash and cash equivalents at beginning of the period	43,903,949	61,746,748
<b>Cash and cash equivalents at end of the period</b>	<u>\$ 40,255,062</u>	<u>\$ 57,706,579</u>

**Contacts**

**Investors**

Solebury Trout  
Chiara Russo  
(617) 221-9197  
crusso@soleburytrout.com

**Media**

Solebury Trout  
Amy Bonanno  
(914) 450-0349  
abonanno@soleburytrout.com

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