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 9, 2020
Date of Report (Date of earliest event reported)

MARKER THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-37939**	**45-4497941**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

3200 Southwest Freeway **Suite 2240** **Houston, Texas**	**77027**
(Address of principal executive offices)	(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 9, 2020, Marker Therapeutics, Inc. (the "Company") reported financial results for the quarter ended September 30, 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.

Exhibit No.	**Description**
99.1	Press release issued on November 9, 2020.
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: November 9, 2020

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

Exhibit 99.1

Marker Therapeutics Reports Third Quarter 2020 Operating and Financial Results

- Initiated first Marker-sponsored study, a Phase 2 trial of MT-401 for the treatment of post-transplant acute myeloid leukemia, and enrolled the first patient in the safety lead-in portion -

- Received alternate reagent and expect to submit required data to enable removal of partial clinical hold for IND for MT-401 by Q1 2021 -

- Company to host conference call and webcast today at 5:00 PM EST -

Houston, TX—November 9, 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 third quarter ended September 30, 2020.

“This quarter, our Company reached a significant milestone by initiating our first Marker-sponsored study—a Phase 2 trial of zelenoleucel or MT-401, our lead MultiTAA-specific T cell product candidate for the treatment of post-transplant acute myeloid leukemia,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “We have enrolled the first patient in the safety lead-in portion of the trial, and are in the process of scheduling the donor in order to manufacture the product.”

Continued Mr. Hoang: “During this unprecedented time, we have made significant progress by enrolling additional clinical sites for our AML trial, advancing our manufacturing process, reducing production time by 50% and improving the potency of our MT-401 product, and entering the final phase of the construction of our new in-house cGMP manufacturing facility. I am extremely proud of the dedication and resolve that our team has shown during these challenging months. I want to acknowledge their hard work across the organization that went into achieving these milestones.”

PROGRAM UPDATES

MT-401: Multi-Antigen Targeted (MultiTAA)-Specific T Cell Product Candidate for AML

Phase 2 AML Trial
The Company initiated the safety lead-in portion of its Phase 2 study of zelenoleucel (MT-401) in patients with acute myeloid leukemia (AML) following an allogeneic stem cell transplant in both the adjuvant and active disease settings. The Company anticipates treating the first patient by Q1 2021. The safety lead-in is expected to enroll a total of six patients: three of which will be treated with MT-401 manufactured with a legacy reagent, and the remaining three to be treated with study drug manufactured with a new reagent from an alternate supplier.

Marker has activated four clinical sites and is in the start-up phase with additional clinical sites to enroll patients for the safety lead-in portion of the AML trial. The Company has also received commitments from additional clinical sites to participate in the Phase 2 AML trial following the safety lead-in phase and anticipates activating a total of approximately 20 sites.

The study remains on partial clinical hold pending the review of final data and subsequent acceptance of certificates of analysis for the new reagent by the U.S. FDA. The Company received the remaining reagent from the alternate supplier in Q3 2020 and is currently conducting the comparability analyses between the previous and new reagents, as required by FDA. Marker intends to submit all required data to FDA by Q1 2021 to enable removal of the partial clinical hold.

Over the past year, the Company has continued to streamline and simplify the MT-401 manufacturing process. The technical improvements include a 50% reduction in manufacturing time, a 95% reduction in the number of required operator interventions, and significant improvement in the consistency and reproducibility of the manufacturing process, while yielding a significant increase in the number of T cells available for patient administration. The Company expects the new process to yield a measurably improved product, with superior T cell phenotype and antigen specificity as compared to the original process. The new process improvements have been updated in the CMC section of the IND and will be used for all patients in the Marker AML clinical trial.

BUSINESS UPDATES

- Construction of the cGMP manufacturing facility has entered its final phase. The facility, located in Houston near the George Bush Intercontinental Airport, will be used to support the manufacture of study drug for Marker's Phase 2 AML trial and for future hematological and solid tumor trials, in addition to the potential commercialization of any approved products. The construction is expected to be completed by year-end with clinical activities to be initiated in the first half of 2021.

THIRD QUARTER 2020 FINANCIAL RESULTS

Cash Position and Guidance: At September 30, 2020, Marker had cash and cash equivalents of $27.0 million. The Company raised $2.2 million through the previously executed $30 million common stock purchase agreement with Aspire Capital Fund, LLC. The remaining $27.8 million available to Marker from Aspire Capital along with current cash available, funds operations into Q1 2022.

R&D Expenses: Research and development expenses were $4.8 million for the quarter ended September 30, 2020, compared to $3.1 million for the quarter ended September 30, 2019.

G&A Expenses: General and administrative expenses were $2.6 million for the quarter ended September 30, 2020, compared to $2.5 million for the quarter ended September 30, 2019.

Net Loss: Marker reported a net loss of $7.4 million for the quarter ended September 30, 2020, compared to a net loss of $5.5 million for the quarter ended September 30, 2019.

Conference Call and Webcast
The Company will host a webcast and conference call to discuss its third quarter 2020 financial results and provide a corporate update today at 5:00 PM EST.

The webcast will be accessible in the Investors section of the Company's website at 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 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**

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; the effectiveness of these programs or the possible range of application and potential curative effects and safety in the treatment of diseases; the impact of the COVID-19 pandemic; the timing, conduct and success of our clinical trials, as well as clinical trials conducted by our collaborators; our manufacturing processes and our ability to use our in-house manufacturing facility to support clinical and commercial demand. 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

	September 30, 2020 (Unaudited)	December 31, 2019 (Audited)
ASSETS		
Current assets:		
Cash and cash equivalents	$ 26,956,737	$ 43,903,949
Prepaid expenses and deposits	2,367,145	1,526,442
Interest receivable	135	56,189
Other receivable	1,000,000	-
Total current assets	30,324,017	45,486,580
Non-current assets:		
Property, plant and equipment, net	2,629,628	417,528
Construction in progress	4,557,581	-
Right-of-use assets, net	11,059,962	455,174
Total non-current assets	18,247,171	872,702
Total assets	**$ 48,571,188**	**$ 46,359,282**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable and accrued liabilities	$ 5,746,149	$ 1,757,680
Lease liability	278,333	204,132
Warrant liability	-	31,000
Total current liabilities	6,024,482	1,992,812
Non-current liabilities:		
Lease liability, net of current portion	11,948,781	280,247
Total non-current liabilities	11,948,781	280,247
Total liabilities	17,973,263	2,273,059
Commitments and contingencies	-	-
Stockholders' equity:		
Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at September 30, 2020 and December 31, 2019, respectively	-	-
Common stock, $0.001 par value, 150 million shares authorized, 48.0 million and 45.7 million shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	48,025	45,728
Additional paid-in capital	378,282,157	371,573,909
Accumulated deficit	(347,732,257)	(327,533,414)
Total stockholders' equity	30,597,925	44,086,223
Total liabilities and stockholders' equity	**$ 48,571,188**	**$ 46,359,282**

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2020	**2019**	**2020**	**2019**
Revenues:				
Grant income	$ -	$ -	$ 466,785	$ -
Total revenues	-	-	466,785	-
Operating expenses:				
Research and development	4,803,605	3,118,530	12,897,275	9,103,670
General and administrative	2,572,562	2,536,204	7,946,846	8,063,099
Total operating expenses	7,376,167	5,654,734	20,844,121	17,166,769
Loss from operations	(7,376,167)	(5,654,734)	(20,377,336)	(17,166,769)
Other income (expense):				
Change in fair value of warrant liabilities	-	(64,000)	31,000	(80,000)
Interest income	4,667	259,248	147,493	897,967
Net loss	**$ (7,371,500)**	**$ (5,459,486)**	**$ (20,198,843)**	**$ (16,348,802)**
Net loss per share, basic and diluted	$ (0.16)	$ (0.12)	$ (0.43)	$ (0.36)
Weighted average number of common shares outstanding	46,867,119	45,655,387	46,509,391	45,541,434

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

	For the Nine Months Ended September 30,	
	2020	**2019**
Cash Flows from Operating Activities:		
Net loss	$ (20,198,843)	$ (16,348,802)
Reconciliation of net loss to net cash used in operating activities:		
Depreciation and amortization	272,725	70,908
Changes in fair value of warrant liabilities	(31,000)	80,000
Stock-based compensation	3,974,536	4,073,505
Amortization on right-of-use assets	337,530	134,919
Changes in operating assets and liabilities:		
Prepaid expenses and deposits	(840,703)	(1,764,345)
Interest receivable	56,054	30,032
Accounts payable and accrued expenses	3,955,609	137,161
Lease liability	(166,723)	(136,812)
Net cash used in operating activities	(12,640,815)	(13,723,434)
Cash Flows from Investing Activities:		
Purchase of property and equipment	(2,484,825)	(362,121)
Purchase of construction in progress	(4,557,581)	-
Net cash used in investing activities	(7,042,406)	(362,121)
Cash Flows from Financing Activities:		
Proceeds from issuance of common stock	2,186,009	-
Proceeds from exercise of stock options	-	57,744
Proceeds from exercise of warrants	550,000	758,733
Net cash provided by financing activities	2,736,009	816,477
Net decrease in cash	(16,947,212)	(13,269,078)
Cash and cash equivalents at beginning of the period	43,903,949	61,746,748
Cash and cash equivalents at end of the period	$ 26,956,737	$ 48,477,670

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