

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 10, 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 August 10, 2020, Marker Therapeutics, Inc. (the “Company”) reported financial results for the quarter ended June 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.

| <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 August 10, 2020.</u></a>   |
| 104                         | Inline XBRL for the cover page of this Current Report on Form 8-K |

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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: August 10, 2020

By: /s/ Anthony Kim

Anthony Kim

*Chief Financial Officer*

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

**Houston, TX—August 10, 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 second quarter ended June 30, 2020.

“We continue to make progress toward advancing our planned Phase 2 trial with our novel MultiTAA-specific T cell therapy in patients with acute myeloid leukemia, or AML,” said Peter L. Hoang, President & CEO of Marker Therapeutics. “While the COVID-19 pandemic has impacted hospital systems globally, we have augmented our process development for our MT-401 product, continued the buildout of our manufacturing facility and added further clinical sites for our Phase 2 AML trial. With a novel cell therapy product candidate that has demonstrated the ability to induce broad and durable immune responses in earlier clinical studies, Marker remains well-positioned to provide a potential treatment option for patients suffering from this devastating disease.”

### PROGRAM UPDATES

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

##### Phase 2 AML Trial Update

The Company continues to identify and add clinical trial sites in preparation for the Phase 2 AML trial initiation. The study is currently subject to a partial clinical hold on the use of a new reagent in the manufacturing process until the FDA reviews and accepts the final data and certificates of analysis for the new reagent. The alternate supplier has been delayed in providing the reagent but expects to ship the reagent to Marker in Q3. Once Marker receives the reagent and completes the required analyses for FDA, the Company will provide additional clarification around the timing of the AML trial enrollment.

##### USAN Council Approval of “Zelenoleucel” for MT-401

Marker recently announced that the United States Adopted Names (USAN) Council approved “zelenoleucel” as the nonproprietary (generic) name for MT-401, a MultiTAA-specific T cell product candidate for the treatment of patients with AML following allogeneic stem cell transplant in both adjuvant and active disease settings.

##### Pancreatic Cancer Data Presented During ASCO

Updated clinical results from an ongoing investigator-sponsored Phase 1 trial led by the Baylor College of Medicine, evaluating the Company’s MultiTAA-specific T cell therapy in patients with advanced or metastatic pancreatic adenocarcinoma, were presented during the 2020 American Society of Clinical Oncology (ASCO) Virtual Annual Meeting. Data from a cohort of patients receiving MultiTAA-specific T cell therapy in combination with standard-of-care chemotherapy in the first-line setting (Arm A) were presented.

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- Out of the 13 evaluable patients (best overall response): four patients experienced objective responses, including one complete response; six patients experienced stable disease; one patient experienced a mixed response (some lesions increased in size and others decreased for a net zero change in size of tumor lesions).
- Patients had durable cancer control with 9 of the 13 patients exceeding historical control of overall survival.
- Evidence of epitope-spreading was observed in all responders, suggesting that the MultiTAA T cell therapy triggered the recruitment of a broader endogenous immune system response for improved anti-tumor activity.
- No infusion-related reactions, cytokine release syndrome or neurotoxicity was observed.

## **BUSINESS UPDATES**

On June 30, 2020, Marker announced that the Company executed a lease agreement to establish an in-house cGMP manufacturing facility in Houston, TX. The facility is expected to be completed by year-end and operational in 2021. Marker will continue to manufacture its MultiTAA-specific T cell therapy at the Baylor College of Medicine to support the Company-sponsored AML trial until the in-house cGMP manufacturing facility is operational.

## **SECOND QUARTER 2020 FINANCIAL RESULTS**

**Cash Position and Guidance:** At June 30, 2020, Marker had cash and cash equivalents of \$32.1 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses and capital expenditure requirements into Q2 2021.

**R&D Expenses:** Research and development expenses were \$4.3 million for the quarter ended June 30, 2020, compared to \$3.2 million for the quarter ended June 30, 2019.

**G&A Expenses:** General and administrative expenses were \$2.5 million for the quarter ended June 30, 2020, compared to \$2.7 million for the quarter ended June 30, 2019.

**Net Loss:** Marker reported a net loss of \$6.3 million for the quarter ended June 30, 2020, compared to a net loss of \$5.6 million for the quarter ended June 30, 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 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.

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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; 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

|   | June 30,<br>2020<br>(Unaudited) | December 31,<br>2019<br>(Audited) |
|---|---------------------------------|-----------------------------------|
| <b>ASSETS</b>   |                                 |                                   |
| Current assets:   |                                 |                                   |
| Cash and cash equivalents   | \$ 32,124,187                   | \$ 43,903,949                     |
| Prepaid expenses and deposits   | 2,632,514                       | 1,526,442                         |
| Interest receivable   | 3,440                           | 56,189                            |
| Total current assets  | <u>34,760,141</u>               | <u>45,486,580</u>                 |
| Non-current assets:   |                                 |                                   |
| Property, plant and equipment, net  | 1,592,094                       | 417,528                           |
| Construction in progress  | 2,629,141                       | -                                 |
| Right-of-use assets, net  | 9,542,228                       | 455,174                           |
| Total non-current assets  | <u>13,763,463</u>               | <u>872,702</u>                    |
| <b>Total assets</b>   | <b><u>\$ 48,523,604</u></b>     | <b><u>\$ 46,359,282</u></b>       |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>   |                                 |                                   |
| Current liabilities:  |                                 |                                   |
| Accounts payable and accrued liabilities  | \$ 4,528,021                    | \$ 1,757,680                      |
| Lease liability   | 456,065                         | 204,132                           |
| Warrant liability   | -                               | 31,000                            |
| Total current liabilities   | <u>4,984,086</u>                | <u>1,992,812</u>                  |
| Non-current liabilities:  |                                 |                                   |
| Lease liability, net of current portion   | <u>9,025,273</u>                | <u>280,247</u>                    |
| Total non-current liabilities   | <u>9,025,273</u>                | <u>280,247</u>                    |
| Total liabilities   | <u>14,009,359</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 June 30, 2020 and December 31, 2019, respectively                           | -                               | -                                 |
| Common stock, \$0.001 par value, 150 million shares authorized, 46.6 million and 45.7 million shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively | 46,617                          | 45,728                            |
| Additional paid-in capital  | 374,828,385                     | 371,573,909                       |
| Accumulated deficit   | (340,360,757)                   | (327,533,414)                     |
| Total stockholders' equity  | <u>34,514,245</u>               | <u>44,086,223</u>                 |
| <b>Total liabilities and stockholders' equity</b>   | <b><u>\$ 48,523,604</u></b>     | <b><u>\$ 46,359,282</u></b>       |

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

|  | For the Three Months Ended |                       | For the Six Months Ended |                        |
|--|----------------------------|-----------------------|--------------------------|------------------------|
|  | June 30,                   |                       | June 30,                 |                        |
|  | 2020                       | 2019                  | 2020                     | 2019                   |
| <b>Revenues:</b>                                     |                            |                       |                          |                        |
| Grant income   | \$ 466,785                 | \$ -                  | \$ 466,785               | \$ -                   |
| Total revenues                                       | <u>466,785</u>             | <u>-</u>              | <u>466,785</u>           | <u>-</u>               |
| <b>Operating expenses:</b>                           |                            |                       |                          |                        |
| Research and development                             | 4,277,052                  | 3,152,445             | 8,093,670                | 5,985,140              |
| General and administrative                           | 2,547,289                  | 2,721,120             | 5,374,284                | 5,526,895              |
| Total operating expenses                             | <u>6,824,341</u>           | <u>5,873,565</u>      | <u>13,467,954</u>        | <u>11,512,035</u>      |
| Loss from operations                                 | (6,357,556)                | (5,873,565)           | (13,001,169)             | (11,512,035)           |
| <b>Other income (expense):</b>                       |                            |                       |                          |                        |
| Change in fair value of warrant liabilities          | -                          | (7,000)               | 31,000                   | (16,000)               |
| Interest income                                      | 15,857                     | 310,174               | 142,826                  | 638,719                |
| <b>Net loss</b>                                      | <u>\$ (6,341,699)</u>      | <u>\$ (5,570,391)</u> | <u>\$ (12,827,343)</u>   | <u>\$ (10,889,316)</u> |
| Net loss per share, basic and diluted                | \$ (0.14)                  | \$ (0.12)             | \$ (0.28)                | \$ (0.24)              |
| Weighted average number of common shares outstanding | <u>46,572,739</u>          | <u>45,501,078</u>     | <u>46,328,561</u>        | <u>45,483,513</u>      |



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

|   | For the Six Months Ended    |                             |
|---|-----------------------------|-----------------------------|
|   | June 30,                    |                             |
|   | 2020                        | 2019                        |
| <b>Cash Flows from Operating Activities:</b>                                |                             |                             |
| Net loss  | \$ (12,827,343)             | \$ (10,889,316)             |
| <b>Reconciliation of net loss to net cash used in operating activities:</b> |                             |                             |
| Depreciation and amortization   | 124,627                     | 39,811                      |
| Changes in fair value of warrant liabilities                                | (31,000)                    | 16,000                      |
| Stock-based compensation  | 2,705,365                   | 2,889,243                   |
| Amortization on right-of-use assets   | 96,973                      | 89,178                      |
| <b>Changes in operating assets and liabilities:</b>                         |                             |                             |
| Prepaid expenses and deposits   | (1,106,072)                 | (349,750)                   |
| Interest receivable   | 52,749                      | 10,023                      |
| Accounts payable and accrued expenses                                       | 2,770,341                   | 225,135                     |
| Lease liability   | (187,068)                   | (89,907)                    |
| Net cash used in operating activities                                       | <u>(8,401,428)</u>          | <u>(8,059,583)</u>          |
| <b>Cash Flows from Investing Activities:</b>                                |                             |                             |
| Purchase of property and equipment  | (1,299,193)                 | (305,382)                   |
| Purchase of construction in progress  | (2,629,141)                 | -                           |
| Net cash used in investing activities                                       | <u>(3,928,334)</u>          | <u>(305,382)</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>(11,779,762)</u>         | <u>(8,301,842)</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><u>\$ 32,124,187</u></u> | <u><u>\$ 53,444,906</u></u> |

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