**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 10, 2021**
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**<br>**Suite 2500**<br>**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 10, 2021, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the quarter ended September 30, 2021 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, dated November 10, 2021 |
| 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 10, 2021

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

**Exhibit 99.1**

**Marker Therapeutics Reports Third Quarter 2021 Operating and Financial Results**

*Enrollment of first 20 patients of the Company's Phase 2 AML trial anticipated in Q4 2021*

*Topline readout of Group 2 active disease anticipated in Q1 2022*

*Company to host year-end conference call and webcast in Q1 2022*

**Houston, TX—November 10, 2021—**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, 2021.

"This quarter, we continued our momentum in advancing Marker's Phase 2 trial of MT-401, Marker's lead MultiTAA-specific T cell therapy, for the treatment of post-transplant acute myeloid leukemia, or AML," said Peter L. Hoang, President & CEO of Marker Therapeutics. "We are pleased to announce that the first patients in Marker's Phase 2 AML trial have been dosed with study drug. Further, we are on track to enroll the first 20 patients of the trial in the fourth quarter, with the first data readout expected in the first quarter of 2022. We look forward to providing year-end updates in a conference call and webcast early next year."

**PROGRAM UPDATES**

- The Company continues to enroll patients and activate clinical sites across the U.S. in Marker's Phase 2 trial of MT-401, its lead MultiTAA-specific T cell product candidate, for the treatment of post-transplant AML. The trial is expected to enroll approximately 120 patients in the adjuvant setting and 40 patients with active disease at approximately 20 clinical sites.

**BUSINESS UPDATES**

- The Company's new cGMP manufacturing facility in Houston, Texas is fully operational and is supporting ongoing operations. The facility will also manufacture Marker's MultiTAA-specific T cell products for future hematological and solid tumor trials, in addition to producing the potential commercial supply of any products, if approved.
- In August, the Company announced that it received notice of a Product Development Research award totaling approximately $13.1 million from the Cancer Prevention and Research Institute of Texas (CPRIT) to support the Company's Phase 2 AML trial.

**ANTICIPATED PROGRAM MILESTONES**

**AML Trial Milestones**

- Enrollment of first 20 patients of the Phase 2 AML trial expected in Q4 2021
- Topline readout of Group 2 active disease anticipated in Q1 2022

**THIRD QUARTER 2021 FINANCIAL RESULTS**

- **Cash Position and Guidance:** At September 30, 2021, Marker had cash and cash equivalents of $48.7 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses and capital expenditure requirements into the first quarter of 2023.

- **R&D Expenses:** Research and development expenses were $6.8 million for the quarter ended September 30, 2021 compared to $4.8 million for the quarter ended September 30, 2020. The increase was primarily attributable to increases in clinical trial and sponsored research expenses and headcount-related expenses due to growth of research and development operations.

- **G&A Expenses:** General and administrative expenses were $3.2 million for the quarter ended September 30, 2021 compared to $2.6 million for the quarter ended September 30, 2020.

- **Net Loss:** Marker reported a net loss of $12.4 million for the quarter ended September 30, 2021, compared to a net loss of $7.4 million for the quarter ended September 30, 2020.

**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 Statements**

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 timing, conduct and success of our clinical trials, including the Phase 2 trial of MT-401; our ability to use our manufacturing facilities to support clinical and commercial demand; the timing and use of the CPRIT award; and our future operating expenses and capital expenditure requirements. 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**
**(Unaudited)**

| | September 30, 2021 | December 31, 2020 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 48,705,297 | $ 21,352,382 |
| Prepaid expenses and deposits | 2,701,327 | 2,057,924 |
| Other receivables | 243 | 1,000,559 |
| Total current assets | 51,406,867 | 24,410,865 |
| Non-current assets: | | |
| Property, plant and equipment, net | 9,846,745 | 3,570,736 |
| Construction in progress | 600,005 | 6,789,098 |
| Right-of-use assets, net | 10,086,158 | 10,844,116 |
| Total non-current assets | 20,532,908 | 21,203,950 |
| **Total assets** | **$ 71,939,775** | **$ 45,614,815** |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 7,645,287 | $ 6,013,010 |
| Lease liability | 581,588 | 388,792 |
| Total current liabilities | 8,226,875 | 6,401,802 |
| Non-current liabilities: | | |
| Lease liability, net of current portion | 11,430,892 | 11,868,440 |
| Total non-current liabilities | 11,430,892 | 11,868,440 |
| Total liabilities | 19,657,767 | 18,270,242 |
| Commitments and contingencies | - | - |
| Stockholders' equity: | | |
| Preferred stock - $0.001 par value, 5 million shares authorized and 0 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively | - | - |
| Common stock, $0.001 par value, 150 million shares authorized, 83.1 million and 50.7 million shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively | 83,079 | 50,731 |
| Additional paid-in capital | 440,553,968 | 383,533,326 |
| Accumulated deficit | (388,355,039) | (356,239,484) |
| Total stockholders' equity | 52,282,008 | 27,344,573 |
| **Total liabilities and stockholders' equity** | **$ 71,939,775** | **$ 45,614,815** |

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

| | For the Three Months Ended September 30, | | For the Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| **Revenues:** | | | | |
| Grant income | $ - | $ - | $ - | $ 466,785 |
| Total revenues | - | - | - | 466,785 |
| **Operating expenses:** | | | | |
| Research and development | 6,784,390 | 4,803,605 | 19,777,454 | 12,897,275 |
| General and administrative | 3,239,148 | 2,572,562 | 9,936,256 | 7,946,846 |
| Total operating expenses | 10,023,538 | 7,376,167 | 29,713,710 | 20,844,121 |
| Loss from operations | (10,023,538) | (7,376,167) | (29,713,710) | (20,377,336) |
| **Other income:** | | | | |
| Change in fair value of warrant liabilities | - | - | - | 31,000 |
| Arbitration settlement | (2,406,576) | - | (2,406,576) | - |
| Interest income | 791 | 4,667 | 4,731 | 147,493 |
| **Net loss** | **$ (12,429,323)** | **$ (7,371,500)** | **$ (32,115,555)** | **$ (20,198,843)** |
| | | | | |
| Net loss per share, basic and diluted | $ (0.15) | $ (0.16) | $ (0.43) | $ (0.43) |
| Weighted average number of common shares outstanding, basic and diluted | 83,078,675 | 46,867,119 | 74,290,598 | 46,509,391 |

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

| | For the Nine Months Ended September 30, | |
|---|---|---|
| | **2021** | **2020** |
| **Cash Flows from Operating Activities:** | | |
| **Net loss** | $ (32,115,555) | $ (20,198,843) |
| **Reconciliation of net loss to net cash used in operating activities:** | | |
| Depreciation and amortization | 1,584,495 | 272,725 |
| Changes in fair value of warrant liabilities | - | (31,000) |
| Stock-based compensation | 4,497,145 | 3,974,536 |
| Amortization on right-of-use assets | 757,958 | 337,530 |
| **Changes in operating assets and liabilities:** | | |
| Prepaid expenses and deposits | (643,403) | (840,703) |
| Other receivables | 1,000,316 | 56,054 |
| Accounts payable and accrued expenses | 2,742,154 | 2,065,929 |
| Lease liability | (244,752) | (166,723) |
| Net cash used in operating activities | (22,421,642) | (14,530,495) |
| **Cash Flows from Investing Activities:** | | |
| Purchase of property and equipment | (1,262,092) | (2,005,160) |
| Purchase of construction in progress | (1,519,196) | (3,147,566) |
| Net cash used in investing activities | (2,781,288) | (5,152,726) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuance of common stock, net | 52,552,758 | 2,186,009 |
| Proceeds from exercise of warrants | - | 550,000 |
| Proceeds from exercise of stock options | 3,087 | - |
| Net cash provided by financing activities | 52,555,845 | 2,736,009 |
| Net increase (decrease) in cash | 27,352,915 | (16,947,212) |
| | | |
| Cash and cash equivalents at beginning of the period | 21,352,382 | 43,903,949 |
| **Cash and cash equivalents at end of the period** | $ 48,705,297 | $ 26,956,737 |

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