**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**

**March 25, 2024**
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.) |

| **9350 Kirby Drive, Suite 300**<br>**Houston, Texas** | **77054** |
|---|---|
| (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 March 25, 2024, Marker Therapeutics, Inc. (the "***Company***") reported financial results for the fiscal year ended December 31, 2023 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 March 25, 2024. |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document). |

**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: March 25, 2024

By: /s/ Juan Vera
Juan Vera
*President and Chief Executive Officer*

**Exhibit 99.1**

**Marker Therapeutics Reports Year-End 2023 Corporate and Financial Results**

Lead program in patients with lymphoma demonstrated preliminary safety and efficacy results with sustained complete response in first study participant treated with MT-601 (Neldaleucel) following CAR T relapse

Secured non-dilutive funding of $2 million from National Institute of Health (NIH) to support clinical program for treatment of patients with Acute Myeloid Leukemia (AML)

Received Orphan Drug Designation (ODD) from European Medicines Agency (EMA) for multiTAA-specific T cell product candidate MT-401 (Zedenoleucel) for the treatment of patients with AML

Implemented leadership transition resulting in appointments of Juan Vera, M.D. as President and Chief Executive Officer and Monic Stuart, M.D., MPH as Chief Medical Officer

Executed comprehensive non-dilutive agreement with Cell Ready™ effecting a significant reduction in overhead expenses and extending Marker's runway into the fourth quarter of 2025

Strategic prioritization of clinical pipeline with focus on MT-601 (Neldaleucel) in patients with lymphoma

**Houston, TX — March 25, 2024** – Marker Therapeutics, Inc. (Nasdaq: MRKR), a clinical-stage immuno-oncology company focusing on developing next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumors, today reported recent corporate developments and financial results for the year ended December 31, 2023.

"The progress achieved in 2023 we believe establishes a robust foundation for Marker and sets the stage for continued advancement in our clinical programs and business operations in the upcoming year," commented Juan Vera, M.D. President and Chief Executive Officer of Marker Therapeutics. "A pinnacle of last year's success was the Phase 1 lymphoma study milestone, where we observed a sustained complete response in our first study participant treated with MT-601 following CAR T relapse. This patient relapsed within 90 days of CAR T therapy but has remained in a complete remission for at least six months after MT-601 treatment, indicating that MT-601 has superior durability in this study participant. The promising clinical and non-clinical observations from our lymphoma study reinforced our strategic decision, made public this January, to prioritize the development of MT-601 in patients with lymphoma who have failed or are ineligible for CAR T therapy. Focusing on this unique niche of patients and by targeting multiple antigens, our approach differs significantly from competitors, and we believe that MT-601 could address an unmet medical need in this patient population with a better safety profile and at lower costs when compared to gene-modified cell therapy approaches."

Further bolstering Marker's position is the award of $2 million in non-dilutive funding from the NIH last year, which is instrumental in supporting the advancement of the Company's MT-401 "Off-the-Shelf" (MT-401-OTS) program in patients with Acute Myeloid Leukemia (AML).

Dr. Vera added, "This award is expected to enable us to proceed with the OTS program without affecting our ongoing study for patients with lymphoma. Decreasing time to treatment is critical for rapidly progressing cancers, such as patients with minimal residual disease (MRD) in AML."

Utilizing an OTS product manufactured from healthy donors will help to bypass the treatment delay that is associated with patient-specific manufacture and should shorten the time until the product is made available to patients, while reducing manufacturing costs. Additionally, receiving Orphan Drug Designation (ODD) by the European Medicines Agency (EMA) substantiates the potential impact of MT-401 in patients with AML and presents an opportunity to develop the therapy on an expedited basis.

Marker also executed a comprehensive non-dilutive agreement with Cell Ready which included a sale of select cell manufacturing assets from Marker for approximately $19 million in cash. This major transaction, which we expect will enable a reduction of overhead expenses of about $11 million annually, not only improves our financial health but, we believe, also positions us uniquely in the cell therapy industry — a sector where such significant non-dilutive funding and operational savings are remarkably rare. This strategic foresight, together with the drawdowns available from our grant funds, should extend the cash runway into the fourth quarter of 2025.

“These accomplishments underline our commitment to driving scientific innovation, our vision in making major impact with our novel multiTAA technology for patients in need, and our emphasis on cash preservation and operational excellence. As we have pivoted into 2024, we remain poised to advance our clinical endeavors with the goal of introducing transformative therapies to the market and improving patient outcomes,” concluded Dr. Vera.

**2023 PROGRAM UPDATES & OPERATIONAL HIGHLIGHTS**

**MT-601 (Lymphoma)**

*Non-Clinical Data on MT-601*

- Marker developed a long-term in vitro killing assay 1) to investigate resistance mechanisms after CAR T cell treatment, and 2) to analyze if MT-601 (targeting 6 TAAs) can eliminate CAR-resistant lymphoma cells.

- Anti-CD19 CAR T cell treatment killed 98% of lymphoma cells in vitro. However, after three weeks, CD19-negative tumor cells started to grow. Further anti-CD19 CAR T cell treatments were ineffective as these tumor cells lack target antigen (CD19) expression (Pre-Clinical Data in Lymphoma, May 31, 2023).

- Treatment with MT-601 demonstrated long-term growth inhibition (over three weeks) of CAR-resistant lymphoma cells, highlighting that MT-601 has the potential to effectively treat CD19 CAR-resistant tumors (Press Release, May 31, 2023).

*Clinical Highlights*

- Phase 1 multicenter APOLLO trial (clinicaltrials.gov identifier: NCT05798897), investigating MT-601 in patients with lymphoma who relapsed or are ineligible for anti-CD19 CAR T cell therapies, was selected as lead program based on promising preliminary clinical results and non-clinical proof-of-concept data.

- The first study participant, a 57-year-old female with diffuse large B cell lymphoma (DLBCL), was enrolled in the Phase 1 dose escalation stage of the trial after failing 4 prior lines of therapy, including relapsing within 90 days of anti-CD19 CAR T cell therapy. Without prior lymphodepletion, the participant was treated with MT-601. In December 2023, the Company announced that the study participant tolerated initial dose level well and had maintained a complete response to therapy six months after initial treatment with MT-601 (Press Release, December 11, 2023).

- The Company is enrolling additional patients in the Phase 1 APOLLO trial and expects to report further data in the first half of 2024.

- MT-601 designated non-proprietary name “Neldaleucel” by United States Adopted Name (USAN) Counsel and International Nonproprietary Names (INN) Expert Committee.

**MT-601 (Pancreatic)**

- Investigational New Drug (IND) application cleared by U.S. Food and Drug Administration (FDA) for multicenter Phase 1 trial of MT-601 in patients with metastatic pancreatic cancer in combination with front-line chemotherapy.

- Clinical advancement will be pending additional financial support from non-dilutive grant activities.

**MT-401-OTS (Acute Myeloid Leukemia or Myelodysplastic Syndrome)**

- U.S. FDA has granted an Investigational New Drug (IND) to investigate MT-401 as an “Off-the-Shelf” (MT-401-OTS) product in patients with AML or Myelodysplastic Syndrome (MDS). MT-401-OTS is manufactured from healthy donors and a cellular inventory has been established with ongoing efforts to expand.

- Marker announced non-clinical proof-of-concept data supporting the clinical benefits of MT-401-OTS in AML.

- The Company has secured $2M in non-dilutive funding from the NIH Small Business Innovation Research (SBIR) program. These funds will support the clinical investigation of MT-401-OTS in patients with AML without affecting the ongoing Phase 1 APOLLO study in patients with lymphoma.

- Granted ODD from the Committee for Orphan Medicinal Products of the EMA for the treatment of patients with AML in 2023. ODD was received from the U.S. FDA in 2020.

- Clinical program initiation of MT-401-OTS anticipated for the second half of 2024.

**2023 CORPORATE HIGHLIGHTS**

- Announced clinical pipeline prioritization in January 2024 to strategically focus on MT-601 in patients with lymphoma. This announcement also included program updates that highlighted the potential of the Company’s MT-401-OTS program for AML.

- Appointed Juan Vera, M.D., as President and Chief Executive Officer and Monic Stuart, M.D., MPH, as Chief Medical Officer. Dr. Vera was also appointed the Company’s Principal Financial and Accounting Officer.

- On June 26, 2023, Marker completed a non-dilutive transaction with Cell Ready, under which Cell Ready purchased certain cell manufacturing assets from Marker for approximately $19 million in cash. On February 22, 2024, Marker entered into a Master Services Agreement for Product Supply with Cell Ready. Under this agreement, Cell Ready will perform a wide variety of services for Marker, including research and development, and manufacturing in support of Marker’s clinical trials.

- Terminated common stock purchase agreement with Lincoln Park Capital.

- Extended financial runway into the fourth quarter of 2025.

**FISCAL YEAR 2023 FINANCIAL HIGHLIGHTS**

**Cash Position and Guidance**: At December 31, 2023, Marker had cash and cash equivalents of $15.1 million. The Company believes that its existing cash and cash equivalents will fund its operating expenses into the fourth quarter of 2025, inclusive of available drawdowns from grant funds.

**R&D Expenses**: Research and development expenses were $10.4 million for the year ended December 31, 2023, compared to $12.0 million for the year ended December 31, 2022.

**G&A Expenses**: General and administrative expenses were $7.5 million for the year ended December 31, 2023, compared to $11.3 million for the year ended December 31, 2022.

**Net Loss**: Marker reported a net loss of $8.2 million for the year ended December 31, 2023, compared to a net loss of $29.9 million for the year ended December 31, 2022.

**About multiTAA-specific T cells**

The multi-tumor associated antigen (multiTAA)-specific T cell platform is a novel, non-genetically modified cell therapy approach that selectively expands tumor-specific T cells from a patient's/donor's blood capable of recognizing a broad range of tumor antigens. Since multiTAA-specific T cells are not genetically engineered, Marker believes that its 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 benefits. As a result, Marker believes that its portfolio of T cell therapies has a compelling product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

**About Marker Therapeutics, Inc.**

Marker Therapeutics, Inc. is a Houston, TX-based clinical-stage immuno-oncology company specializing in the development of next-generation T cell-based immunotherapies for the treatment of hematological malignancies and solid tumors. Clinical trials that enrolled more than 200 patients across various hematological and solid tumor indications showed that the Company's autologous and allogeneic multiTAA-specific T cell products were well tolerated and demonstrated durable clinical responses. Marker's goal is to introduce novel T cell therapies to the market and improve patient outcomes. To achieve these objectives, the Company prioritizes the preservation of financial resources and focuses on operational excellence. Marker's unique T cell platform is strengthened by non-dilutive funding from U.S. state and federal agencies supporting cancer research.

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; and the timing, conduct and success of our clinical trials of our product candidates, including MT-601 and MT-401-OTS. 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.**
**Consolidated Balance Sheets**
**(Audited)**

| | December 31, 2023 | December 31, 2022 |
|---|---|---|
| **ASSETS** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 15,111,450 | $ 11,782,172 |
| Prepaid expenses and deposits | 988,126 | 1,849,239 |
| Other receivables | 1,027,815 | 2,402,004 |
| Current assets of discontinued operations | - | 585,840 |
| Total current assets | 17,127,391 | 16,619,255 |
| Non-current assets of discontinued operations | - | 17,802,929 |
| **Total assets** | **$ 17,127,391** | **$ 34,422,184** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY** | | |
| Current liabilities: | | |
| Accounts payable and accrued liabilities | $ 1,745,193 | $ 2,521,193 |
| Related party payable | 1,329,655 | - |
| Current liabilities of discontinued operations | - | 5,260,616 |
| Total current liabilities | 3,074,848 | 7,781,809 |
| Non-current liabilities of discontinued operations | - | 7,039,338 |
| Total liabilities | 3,074,848 | 14,821,147 |
| | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value, 5 million shares authorized, 0 shares issued and outstanding at December 31, 2023 and 2022, respectively | - | - |
| Common stock, $0.001 par value, 30 million shares authorized, 8.9 million and 8.4 million shares issued and outstanding as of December 31, 2023 and 2022, respectively (see Note 10) | 8,891 | 8,406 |
| Additional paid-in capital | 450,329,515 | 447,641,680 |
| Accumulated deficit | (436,285,863) | (428,049,049) |
| Total stockholders' equity | 14,052,543 | 19,601,037 |
| **Total liabilities and stockholders' equity** | **$ 17,127,391** | **$ 34,422,184** |

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

| | For the Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Revenues:** | | |
| Grant income | $ 3,311,133 | $ 3,513,544 |
| Total revenues | 3,311,133 | 3,513,544 |
| **Operating expenses:** | | |
| Research and development | 10,416,789 | 11,968,428 |
| General and administrative | 7,475,722 | 11,336,120 |
| Total operating expenses | 17,892,511 | 23,304,548 |
| Loss from operations | (14,581,378) | (19,791,004) |
| **Other income (expenses):** | | |
| Arbitration settlement | - | (232,974) |
| Interest income | 539,158 | 248,063 |
| Loss from continuing operations before income taxes | (14,042,220) | (19,775,915) |
| Income tax expense | 3,675 | - |
| **Net loss from continuing operations** | (14,045,895) | (19,775,915) |
| | | |
| **Discontinued operations:** | | |
| Loss from discontinued operations | (2,922,406) | (10,154,779) |
| Gain on disposal of discontinued operations, net of $63,000 in tax | 8,731,487 | - |
| Income (loss) from discontinued operations | 5,809,081 | (10,154,779) |
| **Net loss** | **$ (8,236,814)** | **$ (29,930,694)** |
| | | |
| Net earnings (loss) per share: | | |
| Loss from continuing operations, basic and diluted | $ (1.59) | $ (2.37) |
| Income (loss) from discontinued operations, basic and diluted | $ 0.66 | $ (1.22) |
| Net loss per share, basic and diluted | $ (0.94) | $ (3.58) |
| | | |
| Weighted average number of common shares outstanding: | | |
| Basic | 8,809,382 | 8,351,003 |
| Diluted | 8,809,382 | 8,351,003 |

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

| | For the Years Ended December 31, | |
|---|---|---|
| | **2023** | **2022** |
| **Cash Flows from Operating Activities:** | | |
| Net loss | $ (8,236,814) | $ (29,930,694) |
| Less: gain (loss) from discontinued operations, net of $63,000 in tax | 5,809,081 | (10,154,779) |
| Net loss from continuing operations | (14,045,895) | (19,775,915) |
| **Reconciliation of net loss to net cash used in operating activities:** | | |
| Stock-based compensation | 858,269 | 3,304,634 |
| Gain on lease termination | - | (278,681) |
| **Changes in operating assets and liabilities:** | | |
| Prepaid expenses and deposits | 861,113 | 104,147 |
| Other receivables | 1,374,189 | (2,401,767) |
| Accounts payable and accrued expenses | 611,262 | (1,319,710) |
| Deferred revenue | - | (1,146,186) |
| Net cash used in operating activities - continuing operations | (10,341,062) | (21,513,478) |
| Net cash used in operating activities - discontinued operations | (6,098,899) | (5,458,675) |
| Net cash used in operating activities | (16,439,961) | (26,972,153) |
| **Cash Flows from Investing Activities:** | | |
| Net cash provided by (used in) investing activities - discontinued operations | 18,664,122 | (4,945,136) |
| Net cash provided by (used in) investing activities | 18,664,122 | (4,945,136) |
| **Cash Flows from Financing Activities:** | | |
| Proceeds from issuance of common stock, net | 1,014,640 | 202,130 |
| Proceeds from stock options exercise | 90,477 | - |
| Net cash provided by financing activities | 1,105,117 | 202,130 |
| Net increase (decrease) in cash and cash equivalents | 3,329,278 | (31,715,159) |
| Cash and cash equivalents at beginning of the year | 11,782,172 | 43,497,331 |
| **Cash and cash equivalents at end of the year** | $ 15,111,450 | $ 11,782,172 |

**Contacts**

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