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 28, 2019
Date of Report

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))

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 8.01 Other Events.

On March 28, 2019, Marker Therapeutics, Inc. (“Marker” or the “Company”) issued a press release providing business and clinical updates and an overview of highlights for 2019.

A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press release issued on March 28, 2019.

SIGNATURES

In accordance with the requirements of the Exchange Act, the registrant caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 28th day of March, 2019.

MARKER THERAPEUTICS, INC.
(Registrant)

BY: /s/ Michael Loiacono
Michael Loiacono
Chief Accounting Officer

Exhibit 99.1

Marker Therapeutics Provides Business and Clinical Update

—MultiTAA T cell therapies continue to demonstrate positive clinical data across multiple indications in investigator-sponsored trials—

—Marker plans IND submission for Company-sponsored Phase 2 AML study in the third quarter, with first patient enrolled by the end of 2019—

—First update in the solid tumor program planned for second quarter—

—Company to host business update call and webcast today at 5:00 p.m. EDT—

Houston, TX –March 28, 2019– 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 business and clinical update, as well as an overview of upcoming milestones for 2019.

"Our MultiTAA T cell therapies have continued to generate positive and compelling clinical data across various indications in several ongoing investigator-sponsored clinical trials led by Baylor College of Medicine (BCM). We plan to advance a Phase 2 Company-sponsored clinical trial in post-transplant acute myeloid leukemia (AML)—a disease area and patient population for which there are limited treatment options. We expect to finalize our clinical trial protocol in AML by the end of the second quarter of 2019 and to submit our IND in the third quarter, with the first patient enrolled by the end of the year," said Peter L. Hoang, President & CEO of Marker Therapeutics.

Continued Mr. Hoang: "While our T cell therapies remain our primary clinical focus, we are also advancing our T cell vaccine candidates, TPIV200 and TPIV100/110, for the treatment of ovarian and breast cancers. Overall, there are two Phase 2 Company-sponsored studies ongoing for TPIV200 in triple-negative breast cancer and ovarian cancer, and we anticipate reporting interim data from the ovarian cancer Phase 2 study in Q4 2019."

PROGRAM HIGHLIGHTS AND CURRENT UPDATES

Multi-Antigen Targeted (MultiTAA) T Cell Therapies

- **Acute Myeloid Leukemia Data**
  - **The Company reported a clinical update from a Phase 1 clinical trial in post-transplant AML** in oral and poster presentations at ASH in December and ASBMT and CIBMTR in February. Results from the BCM-sponsored study showed that the treatment is safe and well-tolerated and has the potential to mediate a meaningful anti-tumor effect, as well as significant *in vivo* expansion of T cells. Among the highlights from the study, 11 out of 13 patients dosed with MultiTAA T cells as a maintenance therapy after receiving allogeneic stem cell transplant remain alive, ranging from 6 weeks to 2.5 years post-infusion. Nine of these patients have never relapsed after MultiTAA therapy and continue to remain in complete remission (CR). Patients with active disease, overall survival ranged from 4 and 21 months as compared to 4.5 months in historical results after standard of care.

- **Marker will pursue post-transplant AML as the lead indication of its T cell therapy program.** Based on findings from various dose cohorts in the Phase 1 BCM-sponsored trial, Marker has made a strategic decision to focus on post-transplant AML, and plans to initiate pre-IND discussions with the U.S. FDA in the second quarter of 2019, with an IND submission for the Company-sponsored potentially pivotal Phase 2 study in the third quarter. The multicenter study will evaluate clinical efficacy of MultiTAA specific T cells in patients with AML or myelodysplastic syndromes (MDS) in both the adjuvant and active disease setting, following an allogeneic hematopoietic stem cell transplant (HSCT). The dose administered will be the maximum tolerated dose from the BCM-sponsored Phase 1 trial. In the adjuvant setting, patients will be randomized 2:1 to either MultiTAA therapy at approximately 90 days post-transplant versus standard of care observation, while the active disease patients will receive MultiTAA T cells as part of a single-arm group.

· Lymphoma Data

As reported in January, 2019:

- To date, no relapses have been observed for any patient entering a complete response (CR);
- Patients with active disease are now between 1 and 5+ years in CR after infusion of MultiTAA cells (ongoing);
- Several patients with stable disease show potential durable disease stabilization, with two patients experiencing stable disease for over 9 months and 24 months, respectively;
- Responses in all six patients who entered CR were associated with an expansion of infused T cells, as well as induction of antigen spreading.

· Acute Lymphoblastic Leukemia (ALL) Data

As reported at ASBMT and CIBMTR in February:

- Patients are now up to 28 months in continued complete remission (CCR);
- The one patient who experienced relapse displayed mixed donor/recipient chimerism after transplant, but remained in CCR for 6 months;
- Patients who remain in CCR have been durable for between 4 to 28 months, with a median of 16 months.

· Multiple Myeloma Data

As the Company reported in January, 2019, ten patients with active disease have been treated, including:

- One patient with a CR durable for approximately 29 months before relapse, was subsequently given a second treatment infusion of MultiTAA T cells, resulting in stable disease for 3 months (ongoing) after the second treatment;
- Two patients achieved partial responses (PR) of between 14 and 22 months (ongoing) as of last follow-up;
- All seven remaining patients experienced stabilization of disease following infusion of MultiTAA cells initially. Three patients developed transient disease stabilization of between 3-7 months with subsequent progression, and four patients have ongoing stable disease.
- Eight patients were treated in remission, with a median follow-up of 21 months. Only one patient has relapsed to date;
- Correlative studies show significant expansion of MultiTAA T cells, as well as significant evidence of epitope spreading with expansion of endogenous T cells specific for tumor-associated antigens that were not targeted by the MultiTAA product.

Overall, across all indications, MultiTAA therapy appears to be safe and well-tolerated, with no incidence of cytokine release syndrome, neurotoxicity or any other serious adverse events related to the therapy.

T Cell Based Vaccines

- Ovarian Cancer Data
  - As the Company reported in January, 2019, it has completed enrollment in its Phase 2 study in ovarian cancer using TPIV200 as a maintenance therapy for patients in their first remission after surgery and platinum-based chemotherapy. To date, Marker has enrolled, randomized, and treated 120 patients at 17 clinical sites. The study completed enrollment six months faster than anticipated and the Company expects to reach its planned interim analysis trigger of 55 patients who have progressed before the end of 2019.

- Triple Negative Breast Cancer Data
  - The Company also reported initial findings from its interim analysis of its dose-finding study in triple negative breast cancer, using TPIV200 as a maintenance therapy for patients in remission following first-line therapy. The four-arm study included low- and high-dose TPIV200 with or without cyclophosphamide. Of 27 patients evaluated to date for immunogenicity, 26 showed significant immune response to the vaccine treatment. Of 80 patients treated at 11 clinical sites, 11 have shown disease progression to date following treatment with TPIV200.

Marker continues to advance the development of its proprietary PolyStart™ platform, a nucleic acid-based technology with the potential to increase the potency of our vaccines by conferring a four-fold increase in expression of target-cell-specific, naturally processed antigenic epitopes on a cell's surface. This approach boosts helper and/or long-lived killer T cells, enabling their potential to effectively seek out and destroy target cells.

CASH POSITION AND GUIDANCE

Marker reported cash and cash equivalents totaling $61.7 million as of December 31, 2018. Based on current operating plans, Marker expects that current cash resources will be sufficient to meet operating requirements into Q4 of 2020.

UPCOMING NEAR-TERM POTENTIAL MILESTONES

- Pre-IND discussions for AML with the U.S. FDA in Q2;
- First update in solid tumor program in Q2 concurrently with a major medical meeting;
- IND submission for Company-sponsored Phase 2 AML study in Q3, with first patient enrolled by end of 2019;
- Interim analysis readout in the TPIV200 ovarian trial in Q4;
- Overall update on ongoing clinical trials in cell therapy at end of 2019.

Business Update Call and Webcast

Marker management will host business update conference call and webcast today at 5:00 p.m. EDT. To access the call, participants should dial 1-855-238-2333 (domestic) or 1-412-317-5215 (international) and refer to the "Marker Therapeutics, Inc. call." The webcast will be accessible in the Investors section of the Company's website at www.markertherapeutics.com. The archived webcast will be available for replay on the Marker website approximately two hours after 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. Once infused into patients, this population of T cells attacks multiple tumor targets and acts to activate the patient's immune system to produce broad spectrum anti-tumor activity. Because Marker does not genetically engineer its T cells, when compared to current engineered CAR-T and TCR-based approaches, its products (i) are significantly less expensive and easier to manufacture, (ii) appear to be markedly less toxic, and (iii) are associated with meaningful clinical benefit. As a result, Marker believes its portfolio of T cell therapies has a compelling therapeutic product profile, as compared to current gene-modified CAR-T and TCR-based therapies.

Marker is also advancing a number of innovative peptide- and gene-based immuno-therapeutics for the treatment of metastatic solid tumors, including the Folate Receptor Alpha program (TPIV200) for breast and ovarian cancers and the HER2/neu program (TPIV100/110) for breast cancer, currently in Phase II clinical trials. In parallel, we are developing a proprietary DNA expression technology named PolyStart™ that can enhance the ability of the immune system to recognize and destroy diseased cells.

For additional information, please call toll free at (904) 862-6490 or visit: markertherapeutics.com

To receive future press releases via email, please visit: https://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 and development activities relating to our non-engineered multi-tumor antigen specific T cell therapies; our TPIV200 and TPIV100/110 programs and our PolyStart™ program; 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 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. 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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