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

January 3, 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.)

5 West Forsyth Street **Suite 200** **Jacksonville, FL**	**32202**
(Address of principal executive offices)	(Zip Code)

(904) 516-5436
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 January 3, 2019, the Company issued a press release announcing year-end updates to its lead clinical programs**.** A copy of this 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 January 3, 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 4th day of January, 2019.

MARKER THERAPEUTICS, INC.
(Registrant)

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

Exhibit 99.1

Marker Therapeutics Provides Updates of its Lead Clinical Programs

Reports clinical data updates with MultiTAA T cells in lymphoma, multiple myeloma and acute lymphoblastic leukemia

Reports completion of enrollment for TPIV200 Phase II study in ovarian cancer

Reports interim immunogenicity findings of TPIV200 Phase II study in triple negative breast cancer

Houston, TX – January 3, 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 announced a year-end update in five clinical trials using the Company's therapeutic products, LAPP and MAPP multi-antigen targeted T cell (MultiTAA) therapies and TPIV200, its Folate Receptor Alpha (FRα) peptide cancer vaccine product candidate.

"We are pleased to provide an update on our progress in advancing clinical trials using our therapeutic platform," stated Peter L. Hoang, President & CEO of Marker Therapeutics. "With our MultiTAA cell therapies, we continue to build on the size and depth of our patient dataset. These updates now bring our total reported number of patients to 72, up from 57 in our previously reported results. I believe this represents one of the most extensive sets of clinical results in cell therapy for cancer treatment and illustrates the potential safety and clinical effects of MultiTAA T cells for patients suffering from a number of terrible cancers."

"In our vaccine program, we continue to demonstrate our commitment to excellence in our clinical execution," Mr. Hoang continued. "Last year when I joined the company, I expressed that we would work to improve our clinical efficiency, and I believe that the completion of enrollment of our FRV-004 study in ovarian cancer over six months ahead of schedule reflects our dedication to that objective. In fact, we have now completed enrollment of our last two clinical trials significantly ahead of projections, reflecting the commitment of our management and clinical team to execute multi-center studies effectively."

The Company reported clinical updates in three Baylor College of Medicine (BCM)-sponsored Phase I/II clinical trials using its MultiTAA T cell therapies, LAPP and MAPP:

Lymphoma

In the Phase I/II clinical trial in lymphoma, BCM has now treated 15 patients with active disease who have failed an average of four lines of prior therapy. Of these patients, five patients experienced transient disease stabilization followed by disease progression. Four patients have ongoing stable disease of between 9 to 24+ months following infusion of the MultiTAA-specific T cells, while the remaining six have all had complete and durable responses (4 months to 60+ months), as assessed by PET imaging.

- No relapses observed to date for any patient entering a complete response (CR).
- Patients with active disease who have ongoing complete responses after infusion of MultiTAA cells are now between 1 and 5 years in CR (ongoing).
- Several patients with stable disease show potential for durable disease stabilization, with two patients observed to have stable disease for over 9 months and 24 months, respectively.
- Responses in all six patients who entered a CR were associated with an expansion of infused T cells as well as the induction of antigen spreading.
- None of the treated patients developed cytokine release syndrome, neurotoxicity or any other infusion-related adverse events.

BCM has also treated 17 patients who had developed a CR following their last treatment (adjuvant therapy) for lymphoma, and all but two of these patients remain in remission (3-42 months post-infusion). Monitoring has continued on all patients previously reported, and none of these patients have yet relapsed with disease. Average duration of remission for patients with a continuing complete response (CCR) is over 26 months (ongoing), versus 16 months (ongoing) as of the last patient update.

Multiple Myeloma

Marker Therapeutics also provided an update to the BCM-sponsored Phase I/II clinical trial in multiple myeloma. Results were presented at an oral presentation at the American Society of Hematology (ASH) 2018 Annual Meeting.

- Ten patients with active disease were 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.

· 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.

Acute Lymphoblastic Leukemia

Marker Therapeutics also reported initial results from the BCM-sponsored Phase I clinical trial in acute lymphoblastic leukemia (ALL). In this study, patients were treated with MultiTAA T cells as a maintenance therapy for patients in CR post-allogeneic stem cell transplant. Leukemic relapse remains the major cause of treatment failure in hematopoietic stem cell transplant (HSCT) recipients.

· 10 patients have been enrolled and treated in this clinical trial, with eight patients evaluable for response. To date, all but one remains in CR, with patients ranging from 1 to 22 months in CCR (ongoing). Because of the highly refractory nature of these patients, the length of CCRs and the low rate of relapse amongst these patients, the Company believes that these early results are promising and may represent meaningful clinical benefit.

Marker Therapeutics also reported key updates from clinical studies of TPIV200, its Folate Receptor Alpha (FRα) peptide cancer vaccine product candidate.

Ovarian Cancer

Marker Therapeutics reported that it had completed enrollment in its Phase II study in ovarian cancer (Study FRV-004), using TPIV200 as a maintenance therapy for patients in their first remission after surgery and platinum-based chemotherapy. Marker has enrolled, randomized, and treated 120 patients at 17 clinical sites. The study completed enrollment six months faster than anticipated. The Company expects to reach its planned interim analysis trigger of 50 patients who have progressed by the end of the second quarter of 2019, with interim data reported by year end.

- Enrollment of this study was completed over six months ahead of schedule, reflecting ongoing management initiatives to improve and enhance clinical operations efficiency.

- Marker had previously projected the initiation of its interim analysis to begin in Q4 2018, triggered by the 50th patient to progress following treatment. Despite faster than expected enrollment of patients in this study, as of the end of December fewer than 50 patients had progressive disease. As a result, Marker now expects to reach its planned interim analysis trigger by end of the second quarter of 2019, with interim data reported by year end.

Triple Negative Breast Cancer

Marker Therapeutics also reported initial findings from its interim analysis of its dose-finding study (Study FRV-002) in patients with 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.

“These additional clinical results strongly augment our existing, previously disclosed patient dataset. In patients who were treated for active disease in lymphoma, we continue to see long-lived, ongoing complete responses that are now durable beyond five years and have yet to observe a patient who achieves a CR subsequently relapse,” said Dr. Richard Kenney, Acting Chief Medical Officer of Marker Therapeutics. “Notably, in the adjuvant lymphoma patients we have also not seen any additional relapses, with several patients now beyond four years in their continuing complete response. While the median progression-free survival has not yet been reached in any of these trials, observationally it appears that the time to progression for patients receiving MultiTAA T cell therapy may compare favorably with results reported in CD19 and BCMA-targeted CAR-T studies in lymphoma and multiple myeloma, without inducing the toxicities normally associated with gene-modified adoptive cell therapies.”

“Given the highly refractory nature of the patients with acute lymphoblastic leukemia treated, we believe the preliminary results appear to be very promising, with only one patient having relapsed to date,” continued Dr. Kenney. “These early results may indicate that MultiTAA therapy may be able to drive clinical benefit for these patients without the need for donor-lymphocyte infusions (DLIs), and the associated risk of graft versus host disease (GvHD). Finally, our clinical sites have been very supportive of our Phase II vaccine studies in ovarian and breast cancer, and their rapid enrollment is a credit to our Principal Investigators and clinical investigative sites, as well as our clinical operations team. We are pleased with the progress in building our clinical development infrastructure and believe we can leverage that experience to drive our upcoming MultiTAA T cell studies efficiently.”

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 multi-tumor antigen specific T cell therapies, including our LAPP and MAPP programs; 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 MultiTAA T cell clinical trials conducted by Baylor College of Medicine. 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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