MATEON THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	701 GATEWAY BLVD. SUITE 210 SOUTH SAN FRANCISCO, CA 94080
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of report (Date of earliest event reported): July 31, 2017

MATEON THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Charter)

Delaware	**0-21990**	**13-3679168**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

701 Gateway Boulevard, Suite 210 **South San Francisco, CA** **(Address of Principal Executive Offices)**	**94080** **(Zip Code)**

Registrant's telephone number, including area code: (650) 635-7000

N/A
Former Name or Former Address, if Changed Since Last Report

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ 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 July 31, 2017, Mateon Therapeutics, Inc. ("Mateon") issued a press release announcing positive initial data from the fifth cohort of its phase 1b study of OXi4503 in relapsed/refractory AML.

On August 1, 2017, Mateon issued a press release announcing that it completed enrollment in the phase 2 portion of its FOCUS study of CA4P for platinum-resistant ovarian cancer.

Copies of the press releases are attached hereto as Exhibits 99.1 and 99.2, and are incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are furnished with this report:

Exhibit Number	Description
99.1	Press Release dated July 31, 2017.
99.2	Press Release dated August 1, 2017.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Mateon Therapeutics, Inc.

Date: August 1, 2017

By: /s/ Matthew M. Loar
Matthew M. Loar
Chief Financial Officer

Exhibit 99.1

Mateon Therapeutics Announces Positive Initial Data from Fifth Cohort of Phase 1b Study of OXi4503 in Relapsed/Refractory AML

- ***Two patients of four (50%) achieved a complete remission***
- ***No dose-limiting toxicities observed***

SOUTH SAN FRANCISCO, Calif. – July 31, 2017 – Mateon Therapeutics, Inc . (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today announced preliminary data from the fifth dose cohort of OX1222, a phase 1b dose-ranging study of OXi4503 in combination with cytarabine in patients with relapsed/refractory acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).

Two of four patients had morphological complete remissions after one cycle of treatment with 9.76 mg/m ^{2} of OXi4503. Both patients will receive a second cycle of treatment.

To date, five of 21 study patients in OX1222 have achieved complete remission. At lower doses of OXi4503, the complete remissions occurred following two cycles of treatment, with AML blast reductions noted following one cycle of treatment. In addition to the complete remissions, three other patients in the study experienced meaningful AML blast reductions – two in the third cohort and one in the fourth cohort.

“Every dose of OXi4503 tested in this study has shown encouraging signs of efficacy and a favorable safety profile, with the highest doses showing the earliest and best activity,” said William D. Schwieterman, M.D., President and Chief Executive Officer of Mateon. “We continue to be excited about the potential to bring a much needed new treatment option to these very ill patients.”

There were no dose-limiting toxicities observed in the fifth cohort and OXi4503 continued to have a favorable safety profile. The most common adverse events (AEs) of any grade across all cohorts include neutropenia, fever, nausea, anemia and diarrhea. Grade 3 or above AEs which were related to treatment include decreased neutrophil count (28%), decreased platelet count (28%), febrile neutropenia (22%), anemia (17%), and decreased white blood cell count (11%).

Mateon is continuing pharmaceutical partnering discussions to secure a partner or additional capital prior to initiating additional clinical studies of OXi4503 in AML.

About Acute Myeloid Leukemia

A devastating form of cancer of the blood and bone marrow, AML is the most common type of acute leukemia in adults and accounts for the greatest number of leukemia deaths in the United States. There is no standard regimen of care for patients who relapse following front-line treatment or have refractory disease. According to the NIH’s National Cancer Institute Surveillance, Epidemiology and End Results (SEER) program, there are an estimated 21,380 new cases of AML and 10,590 deaths expected in 2017 in the United States. AML arises from a clonal hematopoietic stem cell and is characterized by accumulation of malignant myeloblasts in the bone marrow and resulting in ineffective hematopoiesis. AML often responds initially to front-line treatment of conventional cytotoxic chemotherapy, but it often relapses and long-term disease-free survival is low, posing a significant challenge to treat relapsed and/or refractory disease.

About OXi4503

OXi4503 has received Fast Track designation from the U.S. Food and Drug Administration for the treatment of AML. It is a VDA that disrupts tumor vasculature residing within bone marrow while simultaneously targeting malignant myeloid cells. Preclinical data show that OXi4503 disrupts bone marrow endothelial cells which normally protect AML cells from exposure to chemotherapeutic agents. In human xenograft animal models of AML, OXi4503 has demonstrated almost complete elimination of leukemic cells. In other animal models, the combination of OXi4503 and cytarabine has shown a much greater effect against AML than either agent alone.

About Mateon

Mateon Therapeutics, Inc. is a biopharmaceutical company seeking to realize the full potential of vascular targeted therapy (VTT) in oncology. VTT includes vascular disrupting agents (VDAs) such as the investigational drugs that Mateon is developing, and anti-angiogenic agents (AAs), a number of which are FDA-approved and widely used in cancer treatment. These two approaches have distinct yet complementary mechanisms of action.

At Mateon, we believe that we can significantly improve cancer therapy by employing these two complementary approaches simultaneously. When utilized this way, VDAs obstruct existing blood vessels in the tumor leading to significant central tumor cell death while AAs prevent the formation of new tumor blood vessels.

Mateon is committed to leveraging our intellectual property and the product development expertise of our highly skilled management team to enable VTT to realize its true potential and to bring much-needed new therapies to cancer patients worldwide.

Safe Harbor Statement

Certain statements in this news release, including, but not limited to, those concerning the efficacy of OXi4503 in AML, the potential significance of this data and its relation to other clinical and pre-clinical studies are considered “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995. They can be affected by inaccurate assumptions Mateon might make or by known or unknown risks and uncertainties, including, but not limited to: the sufficiency of the Company’s cash resources to conduct and complete future clinical and pre-clinical trials; the uncertainties as to the future success of ongoing and planned clinical trials; and the unproven safety and efficacy of products under development or that may be developed in the future. Consequently, no forward-looking statement can be guaranteed, and actual results may vary materially. Additional information concerning factors that could cause actual results to materially differ from those in the forward-looking statements is contained in Mateon’s reports to the Securities and Exchange Commission, including Mateon’s reports on Forms 10-Q, 8-K and 10-K. However, Mateon undertakes no obligation to publicly update forward-looking statements, whether because of new information, future events or otherwise.

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Exhibit 99.2

Mateon Therapeutics Completes Enrollment in Phase 2 Portion of FOCUS Study of CA4P for Platinum-Resistant Ovarian Cancer

- ***Recruitment rate significantly increased following initial positive interim analysis***
- ***Interim data read-outs expected in August (40 patients), September (60 patients) and November (80 patients)***

SOUTH SAN FRANCISCO, Calif. – August 1, 2017 – Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today announced that it has completed enrollment of more than 80 patients in the phase 2 portion of its FOCUS study evaluating CA4P in combination with bevacizumab (Avastin ®) and physician's choice chemotherapy for the treatment of platinum-resistant ovarian cancer.

"Interest in this clinical trial has been significant from the oncology community. The enthusiasm of our investigators has helped us complete enrollment well in advance of our year-end 2017 goal," said William D. Schwieterman, M.D., President and Chief Executive Officer of Mateon. "We thank patients and investigators for their support, as completing enrollment in the first part of our phase 2/3 study is an important milestone. We look forward to the multiple upcoming data readouts expected over the next several months."

The next (second) interim analysis of FOCUS is anticipated in mid-August, the third in September, and the fourth and final interim analysis in November 2017. The company expects these analyses to provide preliminary information on objective response rate (ORR) for 40, 60 and all 80-plus patients, respectively, as well as provide early data on progression-free survival (PFS), the primary endpoint of the study. The study's final analysis is scheduled to occur when disease has progressed in 75% of enrolled patients.

Patients in FOCUS have ovarian cancer that has progressed within six months of treatment with a platinum-based chemotherapy. All patients are receiving the current standard of care for platinum-resistant ovarian cancer, bevacizumab (Avastin ®) and physician's choice chemotherapy, with or without CA4P.

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Mateon is committed to leveraging our intellectual property and the product development expertise of our highly skilled management team to enable VTT to realize its true potential and to bring much-needed new therapies to cancer patients worldwide.

Safe Harbor Statement

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