MATEON THERAPEUTICS INC

FORM 8-K
(Current report filing)

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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): June 12, 2017

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

Delaware **(State or Other Jurisdiction of Incorporation)**	
0-21990 **(Commission File Number)**	**13-3679168** **(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 June 12, 2017, Mateon Therapeutics, Inc. ("Mateon") issued a press release announcing status updates for Mateon's clinical trials.

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.

The following exhibit is furnished with this report:

Exhibit Number	Description
99.1	Press Release dated June 12, 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: June 12, 2017

/s/ Matthew M. Loar

By: Matthew M. Loar
Chief Financial Officer

Exhibit 99.1

Mateon Therapeutics Provides Update on its
Clinical Trial Programs and Milestones

- *Interim Analyses for Key FOCUS Study Expected in August 2017 and September 2017*
- *Investigator-Sponsor Pauses Enrollment in PAZOFOS Study in U.K.*

SOUTH SAN FRANCISCO, Calif., June 12, 2017 — Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today provided an update regarding the current status of all clinical trials of its investigational drugs.

Company-sponsored studies:

FOCUS for platinum-resistant ovarian cancer

FOCUS is a phase 2/3 study in patients with platinum-resistant ovarian cancer, evaluating whether the addition of CA4P to the current standard-of-care (bevacizumab plus chemotherapy) improves progression-free survival. As of June 9, 2017, FOCUS has enrolled 57 patients in the United States, Germany and Belgium, with enrollment on-going at 37 sites. The second interim analysis, which will occur after the first 40 patients have been treated for at least two months or withdrawn from the study, remains on track to be completed in August 2017. Based on the number of patients enrolled and projected enrollment trends, the company expects the third interim analysis, representing 60 patients, to be completed in late September 2017.

OX1222 for acute myeloid leukemia

OX1222 is a dose-ascending phase 1b/2 clinical trial evaluating OXi4503 in combination with cytarabine in patients with recurrent/relapsed acute myeloid leukemia (AML). Mateon recently completed enrollment and treatment for the fourth cohort of 7.81 mg/m ^{2} of OXi4503, and no dose limiting toxicities or significant safety issues were identified among the three patients. One patient treated in the fourth cohort experienced a significant AML blast reduction, with blast counts going from 89% upon enrollment to 7% following the first cycle of treatment. However, the patient subsequently experienced an unrelated adverse event and withdrew from the study approximately two weeks after the last dose of OXi4503 in the second cycle of treatment, prior to an additional blast measurement and accordingly did not meet the criteria for a complete remission. Three complete remissions were observed in the first three cohorts (19% overall in the clinical trial to date), each of which occurred after two cycles of treatment, and two complete remissions remain on-going at 12+ and 3+ months. Enrollment is on-going in the fifth cohort of 9.76 mg/m2 of OXi4503.

Investigator-sponsored studies:

PAZOFOS for recurrent ovarian cancer

The PAZOFOS study is a phase 1b/2 investigator-sponsored study being conducted in the U.K., evaluating the combination of CA4P and the TKI-inhibitor pazopanib for patients with advanced recurrent ovarian cancer. To date, the study has enrolled and treated 20 patients with CA4P and pazopanib in the phase 1b and phase 2 portions of the trial. The study sponsor, The Christie NHS Trust, has temporarily suspended enrollment in the trial in order to collect and review additional information on two recent serious adverse events – one patient in the study experienced hypertension and myocardial ischemia, and a second patient experienced chest pain. In both cases, the events were of short duration and the clinical symptoms resolved.

The label for pazopanib, which is not approved for the treatment of ovarian cancer in the U.S., contains warnings for cardiac dysfunction, arterial thrombotic events and hypertension. CA4P has been observed in most patients to cause an acute and transient increase in blood pressure following administration.

Following review of the data available for the patients in PAZOFOS, the company does not believe any changes or adjustments to Mateon's FOCUS study are warranted. FOCUS has restrictive enrollment criteria for patients with pre-existing cardiovascular risk factors and specific algorithms for treatment of patients that experience blood pressure increases.

Neuroendocrine tumors

The Markey Cancer Center at the University of Kentucky recently began a phase 1 study evaluating the combination of CA4P and everolimus for the treatment of neuroendocrine tumors. In the first part of the study, patients are being treated with two different dosing regimens of CA4P in combination with everolimus to evaluate the safety of the drug combination and establish appropriate CA4P dosing levels.

“We are pleased that studies in both our core programs, the FOCUS study of CA4P for platinum-resistant ovarian cancer and Study OX1222 of OXi4503 for AML, are enrolling well and showing a good safety profile, as well as initial indications of efficacy,” stated William D. Schwieterman, M.D., President and Chief Executive Officer of Mateon. “We are looking forward to data read outs from each of these studies later this summer.”

“The investigator-sponsored PAZOFOS study, which uses CA4P with a different combination of drugs for recurrent ovarian cancer, also holds significant potential for patients and we’re hopeful that enrollment will resume soon,” Dr. Schwieterman added.

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 results and completion of clinical trials, the timing for these, the safety of CA4P and OXi4503, and the potential significance of this data 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 uncertainties as to the future success of ongoing and planned clinical trials; the unproven safety and efficacy of products under development or that may be developed in the future; and the sufficiency of the Company’s cash resources to conduct and complete its clinical and pre-clinical trials. 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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