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): August 16, 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 August 16, 2017, Mateon Therapeutics, Inc. ("Mateon") issued a press release announcing the results of the Second Interim Analysis of its FOCUS Study in Platinum Resistant Ovarian Cancer.

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 August 16, 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 16, 2017

/s/ Matthew M. Loar

By: Matthew M. Loar
Chief Financial Officer

Exhibit 99.1

Mateon Therapeutics Announces Results from Second Interim Analysis of CA4P Phase 2/3 FOCUS Study in Platinum-resistant Ovarian Cancer

- *Primary Endpoint - Early Progression Free Survival data favors CA4P*
- *CA4P continues to be safe and well-tolerated*
- *Next interim analysis expected in September*

SOUTH SAN FRANCISCO, Calif. – August 16, 2017 – Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today announced results from its second scheduled interim analysis of the ongoing phase 2/3 FOCUS study evaluating CA4P in combination with bevacizumab (Avastin ®) and physician's choice chemotherapy in patients with platinum resistant ovarian cancer (prOC).

FOCUS is designed to evaluate whether the addition of CA4P improves progression-free survival (PFS), the primary endpoint of the study, as well as objective response rate (ORR) and other measures. All patients enrolled in the FOCUS study are receiving either CA4P or placebo plus the current standard-of-care for platinum-resistant ovarian cancer, bevacizumab (Avastin ®) and chemotherapy. The current interim analysis is based on initial results from the first 40 patients (19 with CA4P, 21 with placebo) in the study who have been treated for at least two months or discontinued from the trial. A total of 91 patients have been enrolled in the phase 2 portion of FOCUS. The next (third) interim analysis will be conducted when approximately $^{3}/_{4}$ of the enrolled patients (originally targeted at 80) have been treated for at least two months or discontinued from the study.

"We are encouraged that early data on the primary endpoint of the study continue to favor CA4P and that our investigational drug remains well tolerated," said William D. Schwieterman, M.D., President and Chief Executive Officer. "There is a large unmet medical need in the ovarian cancer market as patients with prOC have low survival rates and few treatment options. We look forward to additional and more mature data from the 3 rd interim analysis expected just over one month from now – in this upcoming analysis we will have more data on the current patients, who will have had additional time under treatment, as well as initial efficacy and safety information on approximately 25 additional patients."

Efficacy Results

PFS, the primary endpoint of the study, continues to favor the CA4P group, with a 1.68 month increase in median PFS for the patients receiving CA4P compared to control (6.64 months vs. 4.96 months; HR=0.68; p=0.456). Progression events are available from 16 of 40 (40%) patients: six patients (31.6%) in the CA4P arm and ten (47.6%) patients in the control arm progressed or died while in the study.

Partial responses were observed in 4 of 16 (25.0%) patients treated with CA4P and 6 of 19 (31.6%) patients treated with the control regimen. Stable disease was observed in 9 of 16 (56.3%) patients treated with CA4P compared to 11 of 19 (57.9%) patients treated in the control arm.

Safety Results

CA4P continues to show a favorable safety profile. Most patients receiving CA4P experienced transient increases in blood pressure (BP) compared to the control arm (57.9% vs. 9.5%, respectively). BP increases generally peaked two hours following treatment and normalized without clinical sequelae two to three hours later. Rates of grade 3 hypertension were similar between the treatment and control arms (21.1% vs. 23.8%). There was one case of grade 4 hypertensive crisis in the CA4P arm. Adverse events that occurred in >25% of patients and more frequently in the treatment arm included nausea, fatigue, cough, and hypertension, most of which were mild to moderate in severity. Rates of neutropenia, anemia, and thrombocytopenia were low and similar between treatment arms.

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, safety and efficacy of CA4P, future clinical trial results, the potential significance of the interim data and the company's need for additional funding in the near term 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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