MATEON THERAPEUTICS INC

FORM 8-K
(Current report filing)

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Address	701 GATEWAY BLVD. SUITE 210 SOUTH SAN FRANCISCO, CA 94080
Telephone	650-635-7000
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Sector	Healthcare
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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 7, 2017

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

Delaware		
(State or Other Jurisdiction of Incorporation)		
0-21990		**13-3679168**
(Commission File Number)		(IRS Employer Identification No.)
701 Gateway Boulevard, Suite 210, South San Francisco, CA		**94080**
(Address of Principal Executive Offices)		(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 7, 2017, Mateon Therapeutics, Inc. ("Mateon") issued a press release announcing the U.S. Food and Drug Administration's grant of Fast Track designation to Mateon's product candidate OXi4503 for the treatment of acute myeloid leukemia.

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 7, 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 7, 2017

/s/ Matthew M. Loar

By: Matthew M. Loar
Chief Financial Officer

Exhibit 99.1

Mateon Therapeutics Receives FDA Fast Track Designation for OXi4503 in Patients with Acute Myeloid Leukemia

SOUTH SAN FRANCISCO, Calif., June 7, 2017 — Mateon Therapeutics, Inc. (OTCQX:MATN), a biopharmaceutical company developing vascular disrupting agents (VDAs) for the treatment of orphan oncology indications, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the company's product candidate OXi4503 for the treatment of acute myeloid leukemia (AML).

Fast Track designation is a process designed to facilitate the development and expedite the review of drugs to treat serious or life-threatening conditions and address unmet medical need. Once an investigational agent receives Fast Track designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication allows potential issues to be resolved quickly and as they arise, often leading to earlier drug approval and access by patients.

"The receipt of Fast Track designation from the FDA represents an important milestone for our OXi4503 program and follows promising results, including three complete remissions, from the initial cohorts of our on-going OX1222 study in patients with relapsed/refractory AML," said William D. Schwieterman, M.D., President and Chief Executive Officer of Mateon. "This latest development provides further momentum for this groundbreaking study, and occurs in advance of the completion of the fifth patient cohort in OX1222 – which we expect by the end of this year."

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 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 (combretastatin A1-diphosphate or CA1P) is a dual-mechanism vascular disrupting agent. In preclinical and clinical studies, it has been observed to compromise the tumor vasculature, resulting in extensive tumor cell death and necrosis while also possibly affecting the cell shape and attachment of hematopoietic stem cells. OXi4503 is being evaluated for relapsed/refractory AML and myelodysplastic syndrome (MDS) in combination with cytarabine in OX1222, a phase 1b/2 study. In addition to Fast Track status, OXi4503 has been granted orphan drug designation for the treatment of AML in both the United States and Europe.

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 advancement of OXi4503, the results of clinical trials, the potential significance of this data and its relation to other 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 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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