
**UNITED STATES
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

Date of Report (Date of earliest event reported)

September 28, 2020

MATEON THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

000-21990
(Commission
File Number)

13-3679168
(IRS Employer
Identification No.)

29397 Agoura Road Suite 107
Agoura Hills, CA 91301
(Address of principal executive offices and Zip Code)

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

(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of class	Trading Symbols	Name of each exchange on which registered
N/A		

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

Entry to MOU with Windlass

On September 1, 2020 Mateon Therapeutics, Inc. (“Mateon” or the “Company”), executed the final MOU with Windlas Biotech Private Limited for the development and commercialization of Artemisinin as therapeutic pharmaceutical and herbal supplement against COVID-19. Windlas Biotech Private Limited is a 20-year-old company with a strong track record of research, development, manufacturing and distribution of pharmaceutical products in India, USA and several other emerging markets. It has four large scale manufacturing facilities employing more than 1500 employees and is the 5th largest Contract Development and Manufacturing Organization (CDMO) serving top innovator as well as generic pharma companies across the world. It has developed more than 500 different formulations (> 2Billion doses annually) of anti-viral, cardiovascular, anti-diabetic, anti-infective, CNS and dermatology products. Windlas will be performing the following activities in support of Artemisinin development in India:

- Sponsor and conduct the study in India by engaging a local CRO.
- Develop the formulation as per the applicable GMP guidelines.
- Manufacture the Clinical Trial Material (CTM) batches.
- Secure the necessary approvals from Indian government for the clinical study including regulatory documents, dossiers for Ethical Committees, manufacturing licenses etc.
- Supervise the CRO to ensure timelines and audit CRO to ensure data quality.
- Advise Mateon on all aspects of the clinical trial in the course of the study.
- Provide Mateon any data required on the GMP manufacturing process for the product.
- Provide Mateon with relevant data from the study.
- Provide Mateon with GMP manufactured product for distribution worldwide.
- Collaborate with Mateon on publishing study in reputable scientific journals.
- Work with Mateon for a joint press release upon EC approval for international publication.

To effectively combat COVID-19 we need an agent that is inexpensive and readily available for mass distribution. Artemisinin fits this profile and has been previously worked on for eradication of malaria. Therefore, if proven effective in this clinical trial- Artemisinin is more likely to become an effective agent against COVID-19 than expensive new drugs such as remdesivir which are out of reach of the general population both in pricing and availability. Once proven effective, Windlas has the ability to manufacture the billions of doses needed to combat this pandemic worldwide both as treatment and prophylactic.

ARTI-19 trial has been cleared by India regulatory authorities for initiation. The trial is now registered under CTRI and three sites have been selected, their IRB approval obtained and their staffs are being trained into the protocol/EDC. Additional sites will be added as the trial progressed.

CTRI/2020/09/028044. Phase IV study to evaluate the safety and efficacy of Artemisinin- a herbal supplement on COVID-19 subjects. Interventional. Artemisinin 500 mg capsule. <http://ctri.nic.in/Clinicaltrials/advsearch.php>

Sites: 1) Government Medical College & Government General Hospital, Srikakulam, ANDHRA PRADESH. 2) Rajarshi Chhatrapati Shahu Maharaj Government Medical college and Chhatrapati Pramila Raje Hospital, MAHARASHTRA. 3) Seven Star Hospital, MAHARASHTRA

Press releases

AGOURA HILLS, Calif., September 14, 2020 (GLOBE NEWSWIRE) — Mateon Therapeutics “Mateon” (OTC.QB: MATN), a leading developer of TGF- β therapeutics for oncology and COVID-19, announced today that ARTI-19, for Artemisinin Intervention against COVID-19, has been cleared for enrollment in India.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>	<u>Incorporation by reference</u>
10.1	Windlas Mateon MOU	Filed herewith.
99.1	9-14-2020 ARTI-19 Press Release	Filed herewith.

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: September 28, 2020

/s/ Vuong Trieu
By: Vuong Trieu
Chief Executive Officer

MEMORANDUM OF UNDERSTANDING (MOU)

Memorandum of Understanding

Between

**Windlas Biotech Private Limited
Dehradun, Uttarakhand, India**

And

Mateon Therapeutics, Inc.

Agoura Hills, California, USA

RECITALS

This Memorandum of Understanding (MOU) sets forth our mutual understanding regarding an intended co-development agreement between Mateon Therapeutics, Inc. ("Mateon"), having a place of business at 29397 Agoura Road, Suite 107, Agoura Hills, CA 91301, USA and Windlas Biotech Private Limited ("Windlas") with place of business at 705-706 Vatika Professional Point, Golf Course Extension Road, Gurgaon, HR 122001, India. (collectively "The Parties").

- Windlas Biotech Private Limited is a 20-year-old company with a strong track record of research, development, manufacturing and distribution of pharmaceutical products in India, USA and several other emerging markets. It has four large scale manufacturing facilities employing more than 1500 employees and is the 5th largest Contract Development and Manufacturing Organization (CDMO) serving top innovator as well as generic pharma companies across the world. It has developed more than 500 different formulations (> 2Billion doses annually) of anti-viral, cardiovascular, anti-diabetic, anti-infective, CNS and dermatology products. Besides large volume manufacturing it offers research capabilities in chemical synthesis, analytical methods development, process optimization and formulation development that are dedicated to accelerating the pharmaceutical development projects of its research partners.
- Mateon Therapeutics is an immuno-oncology company (OTC: MATN) dedicated to the development of first in class RNA therapeutics as well as small molecule drugs against cancer and COVID-19.

AREAS OF COLLABORATION

The said Memorandum of Understanding lists the responsibilities of each party and any sub-contractors for either. It is understood that any such agreement is subject to our mutual consensus on terms and entering into by Mateon and Windlas of a definitive agreement (DA). The subject of this collaboration is limited to Artemisinin based products (herbal supplements and or future medicinal products).

OVERVIEW

Mateon and Windlas wish to collaborate on formulation development, manufacturing, clinical research, commercialization and distribution of Artemisinin as a herbal supplement (or medicinal drug in future) for use as an anti-viral (including for COVID-19 patients) in a humanitarian effort for India. The collaboration is driven by the parties' desire to expedite the treatment and prevention of COVID-19. Mateon demonstrated potent anti-viral activity of the supplement versus SARS-CoV-2 based on in-vitro testing of medical grade Artemisinin. Windlas has the required experience in developing cGMP compliant dosage forms of herbal supplements, nutraceuticals, AYUSH products and allopathic medicines. Mateon will provide technical support Windlas to seek government approval of the herbal supplement in India with a clinical trial to demonstrate the efficacy of Artemisinin as a therapy. Mateon recognizes Windlas's formulation development, manufacturing and distribution capabilities India which will be required for getting this Ayurvedic herb to as broad a population as possible.

MATEON OBLIGATIONS AND RESPONSIBILITIES

Mateon will:

- Engage Windlas to sponsor and conduct the study in India.
 - Will pay a management & services Fee to Windlas at enclosed schedule (Exhibit A) for the work in exchange for access to the formulation development data of Windlas and the clinical trial data for the trial conducted in India.
 - Collaborate with Windlas and its CRO on final protocol submission to the Ethical Committees.
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- Review submission dossier to the EC's for completion.
- Provide scientific and operational oversight for the study.
- Provide in-vitro testing protocol to Windlas for the product.
- Work with Windlas on a joint press release upon EC approval for international publication.
- Collaborate with Windlas on publishing study in reputable scientific journals.

Windlas OBLIGATIONS AND RESPONSIBILITIES

Windlas will (at its own cost):

- Sponsor and conduct the study in India by engaging a local CRO.
- Develop the formulation as per the applicable GMP guidelines.
- Manufacture the Clinical Trial Material (CTM) batches.
- Secure the necessary approvals from Indian government for the clinical study including regulatory documents, dossiers for Ethical Committees, manufacturing licenses etc.
- Supervise the CRO to ensure timelines and audit CRO to ensure data quality.
- Advise Mateon on all aspects of the clinical trial in the course of the study.
- Provide Mateon any data required on the GMP manufacturing process for the product.
- Provide Mateon with relevant data from the study.
- Provide Mateon with GMP manufactured product for distribution worldwide.
- Collaborate with Mateon on publishing study in reputable scientific journals.
- Work with Mateon for a joint press release upon EC approval for international publication

RIGHTS and OBLIGATIONS FOR BOTH COMPANIES

- Mateon shall retain exclusive rights to market Artemisinin worldwide on its own or its sublicensees except for India wherein Windlas shall have the exclusive marketing rights.
 - Windlas shall retain exclusive right to manufacture Artemisinin product (or its future herbal or allopathic variants) at its own or subcontracted sites and supply to Mateon's (or its other marketing partners') worldwide market excluding North America and China (and its territories including Hong Kong, Macaw, and Taiwan). The pricing of supply shall be negotiated under good faith at arms-length based on CMO industry standards.
 - Both companies will collaborate on an expanded trial in India.
 - Both companies will collaborate on a humanitarian effort for distribution to address the pandemic
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CONFIDENTIALITY

Each Party undertakes to observe the confidentiality and secrecy of documents, information and other data received from, or supplied to, the other Party during the period of the implementation of this Memorandum of Understanding or any other agreements made pursuant to this Memorandum of Understanding;

Both Parties agree that the provisions of this Article shall continue to be binding between the Parties notwithstanding the termination of this Memorandum of Understanding.

SUSPENSION

Each Party reserves the right for reasons of national security, national interest, public order or public health to suspend temporarily, either in whole or in part, the implementation of this Memorandum of Understanding. The suspension shall take effect immediately after notification has been given to the other Party through written communication.

REVISION, MODIFICATION AND AMENDMENT

Either Party may request in writing a revision, modification or amendment of all or any part of this Memorandum of Understanding;

Any revision, modification or amendment agreed to by the Parties shall be in writing and shall form part of this Memorandum of Understanding.

Such revision, modification or amendment shall come into force on such date as may be determined by the Parties; and

Any revision, modification or amendment shall not prejudice the rights and obligations arising from or based on this Memorandum of Understanding prior or up to the date of such revision, modification or amendment.

ENTRY INTO FORCE, DURATION AND TERMINATION

This Memorandum of Understanding shall come into force on the date of signing and shall remain in force until the execution of a definitive agreement.

Notwithstanding anything in this Article, either Party may terminate this Memorandum of Understanding by notifying the other Party of its intention to terminate this Memorandum of Understanding by a notice in writing, at least 1 month prior to its intention to do so; and

The suspension or termination of this Memorandum of Understanding shall not affect the implementation of on-going activities and/or programmes which have been agreed upon before the date of the termination of this Memorandum of Understanding.

ARRANGEMENT BETWEEN THE PARTIES

For the avoidance of doubt, the relationship of the parties under this Memorandum is not one of legal partnership, joint venture or agency.

The parties do not intend this Memorandum to be legally binding. However, the parties may enter into such legally binding agreements which will be separately negotiated and agreed in the future by both the parties in writing.

IN WITNESS WHEREOF the undersigned, being duly authorized thereto by their respective Organisations, have signed this Memorandum of Understanding.

Mateon Therapeutics Inc.

/s/ Vuong Trieu/

Date: Sept 1, 2020

Name: Vuong Trieu

Representative

Position: Chief Executive Officer

Address: 29397 Agoura Rd Ste 107

Agoura Hills, CA, 91301-2542, USA

Telephone: +1 (858) 204-7407

E-mail: vtrieu@oncotelic.com

Website: www.mateon.com

Windlas Biotech Private Limited

/s/ Hitesh Windlass/

Date: Sep 1, 2020

Name: Hitesh Windlass

Representative

Position: Managing Director

Address: Windlas Biotech Private Limited.

705-706 Vatika Professional Point, Gurgaon, HR 122001, India

Telephone: +91 124 282 1030

E-mail: hitesh@windlasbiotech.com

Website: www.windlas.com

EXHIBIT A FEE SCHEDULE

FINANCIAL DETAILS (to be finalized in the CTA between Windlas and CRO)

Professional Fee Charges	Amount in INR
Technical and advisory services	68,31,000
Insurance costs	5,50,000
Local taxes @ 18%	13,28,580
Any incidental costs approved by both parties (to be added in relevant milestone)	
Total Amount:	87,09,850

STUDY TIMELINES AND PAYMENT MILESTONE

Sr. No.	Milestone Payment for Professional Fee	Amount in INR
1.	On Signing Contract	22,61,116
2.	After 1 st EC approval	16,12,116
3.	After 2 sites initiated for clinical trial	8,06,058
4.	50 % of Recruitment Over in Clinical trial	12,09,087
5.	100 % of Recruitment Over	8,06,058
6.	Database Lock	8,06,058
7.	Clinical Study Report + any incidental amount	12,09,087
	Total	87,09,850*

- Incidental amount if any approved by both parties to be added in relevant milestone.
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MATEON'S GLOBAL STUDY FOR ARTEMISININ INTERVENTION AGAINST COVID-19 CLEARED FOR PATIENT ENROLLMENT IN INDIA.

AGOURA HILLS, Calif., September 14, 2020 (GLOBE NEWSWIRE) -- Mateon Therapeutics "Mateon" (OTC.QB: MATN), a leading developer of TGF- β therapeutics for oncology and COVID-19, announced today that its global study based on its ARTI-19 protocol for Artemisinin Intervention against COVID-19 has been cleared for patient enrollment in India.

ARTI-19 in India is being conducted by Windlas as part of a co-development agreement between Windlas Biotech Private Limited (Windlas) and Mateon. The two companies executed an MOU on August 19, 2020 for the development and commercialization of Artemisinin as both a therapeutic pharmaceutical as well as herbal supplement against COVID-19. Windlas is a 20-year-old company with large scale manufacturing facilities in India employing more than 1500 employees and is the 5th largest Contract Development and Manufacturing Organization (CDMO) serving pharma companies across the world.

The development of Artemisinin against COVID-19 is dependent on the successful completion of the ARTI-19 clinical trial "Artemisinin Intervention trial against COVID-19", which is being initiated globally in Africa, India, and South America. Windlas is Mateon's manufacturing partner for clinical trial and commercial product roll out.

Saran Saund, Chief Business Officer and GM of AI division of Mateon commented "By collecting data from multiple clinical observational studies globally, the company expects to establish Artemisinin efficacy against COVID-19 as an affordable front-line treatment for this pandemic. The company's antisense therapeutic against COVID-19 (OT-101) is meant for hospitalized COVID-19 patients who are no longer responsive to Artemisinin."

About ARTI-19 India

ARTI-19 in India is a "A Prospective, Randomized, Multi-center, Open label, Interventional Study to Evaluate the Safety and Efficacy of Artemisinin 500 mg capsule in Treatment of Adult Subjects with COVID-19". This trial will compare the efficacy of oral doses with standard-of-care (SOC) versus SOC alone. Oral administration of Artemisinin 500 mg capsule/day for 5 days with SOC per cycle with the option to repeat as needed until disease is resolved or subject is discharged, up to a total of consecutive 3 cycles ("5 days treatment, 5 days off"). SOC is standard-of-care as per Clinical Management Protocol: COVID-19, Government of India Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division). The global goal of ARTI-19 is enrolled 3,000 patients in the trial to support the approval of Artemisinin against COVID-19. Safety is defined as: 1) Adverse events (AEs) during the study and 2) Serious adverse events (SAEs) during the study. Efficacy is defined as: 1) Relief in the sign and symptoms of COVID-19 as per WHO Clinical Progression Scale and 2) Relief in the sign and symptoms of COVID-19 per the Duration of Symptoms.

About COVID-19 in India

India's COVID-19 tally rose to 4,754,356 and the death toll surged to 78,586, as 94,372 new cases and 1,114 deaths were reported across the country in past 24 hours. This was revealed by the latest data released by the federal health ministry on Sunday, Sep 13, 2020. India's new cases detected per day are more than double the daily average of the United States and Brazil. India has emerged as the worst hit country globally in terms of new COVID-19 cases discovered every day. Over the past one week the average number of daily infections has been over 90,000. This average was around 24,000 two months ago, and 58,000 a month ago.

About Artemisinin

Artemisinin can target multiple viral threats including COVID-19 by suppressing both viral replication and clinical symptoms that arise from viral infection. Viral replication cannot occur without TGF- β . Artemisinin, purified from a plant *Artemisia annua*, is able to inhibit TGF- β activity and is able to neutralize SARS-CoV-2 (COVID-19) in vitro at an EC50 of 0.45 ug/ml (Mateon's test result at Utah State University), and a Safety Index of 140, which is better than remdesivir and chloroquine. Artemisinin antiviral activity against SARS-CoV-2 was confirmed recently by Cao R. et al. "Anti-SARS-CoV-2 Potential of Artemisinin's In Vitro". ACS Infectious Diseases 2020 6 (9), 2524-2531. The unpurified herb extract has no anti-viral activity. Artemisinin also has been reported to have antiviral activities against hepatitis B and C viruses, human herpes viruses, HIV-1, influenza virus A, and bovine viral diarrhea virus in the low micromolar range. In the clinic, Artemisinin exhibits early efficacy signals against COVID-19. To date, 25 effective cases have been reported, with an average time of negative nucleic acid conversion of 4 days, and a negative conversion rate of 10 days after nucleic acid detection reached 96%. No serious adverse reactions were seen. After treatment, the patient's chest image examination showed that the inflammation in the lungs was relieved and the symptoms were significantly improved. Because it targets a host protein- TGF- β that plays a pivotal role in ARDS pathophysiology (and not a virus-intrinsic target), Artemisinin does not promote the development of drug-resistant viral mutations.

About Mateon Therapeutics

Mateon was created by the recent reverse merger with Oncotelic which became a wholly owned subsidiary of Mateon Therapeutics Inc. (OTC.QB:MATN) creating an immuno-oncology company dedicated to the development of first in class RNA therapeutics as well as small molecule drugs against cancer and infectious diseases. OT-101, the lead immuno-oncology drug candidate of Mateon/Oncotelic, is a first-in-class anti-TGF- β RNA therapeutic that exhibited single agent activity in some relapsed/refractory cancer patients in clinical trial settings. OT-101 also has activity against COVID-19 and is being tested in clinical trial against COVID-19. Mateon/Oncotelic is seeking to leverage its deep expertise in oncology drug development to improve treatment outcomes and survival of cancer patients with a special emphasis on pediatric cancer patients. Mateon has rare pediatric designation for DIPG (CA4P) and melanoma (CA4P). For more information, please visit www.oncotelic.com and www.mateon.com.

Mateon's Cautionary Note on Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this communication regarding strategy, future operations, future financial position, prospects, plans and objectives of management are forward-looking statements. Words such as “may”, “expect”, “anticipate”, “hope”, “vision”, “optimism”, “design”, “exciting”, “promising”, “will”, “conviction”, “estimate,” “intend,” “believe”, “quest for a cure of cancer”, “innovation-driven”, “paradigm-shift”, “high scientific merit”, “impact potential” and similar expressions are intended to identify forward-looking statements. Forward-looking statements contained in this press release include, but are not limited to, statements about future plans, the progress, timing, clinical development, scope and success of future clinical trials, the reporting of clinical data for the company’s product candidates and the potential use of the company’s product candidates to treat various cancer indications. Each of these forward-looking statements involves risks and uncertainties and actual results may differ materially from these forward-looking statements. Many factors may cause differences between current expectations and actual results, including unexpected safety or efficacy data observed during preclinical or clinical studies, clinical trial site activation or enrollment rates that are lower than expected, changes in expected or existing competition, changes in the regulatory environment, failure of collaborators to support or advance collaborations or product candidates and unexpected litigation or other disputes. These risks are not exhaustive, the company faces known and unknown risks, including the risk factors described in the company’s annual report on Form 10-K filed with the SEC on April 10, 2019 and in the company’s other periodic filings. Forward-looking statements are based on expectations and assumptions as of the date of this press release. Except as required by law, the company does not assume any obligation to update forward-looking statements contained herein to reflect any change in expectations, whether as a result of new information future events, or otherwise.

Contact Information:

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