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): October 19, 2020

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38022**	**46-3011414**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

1545 Route 206 South, Suite 302 **Bedminster, New Jersey** **(Address of principal executive offices)**	**07921** **(Zip Code)**

Registrant's telephone number, including area code: (908) 443-1860

Not Applicable
(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 Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	MTNB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01 Regulation FD Disclosure.

Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing that the independent Data and Safety Monitoring Board ("DSMB") of the EnACT study (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) has completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort of patients. A copy of the press release is furnished as Exhibit 99.01 hereto and incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 attached hereto shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On October 19, 2020, the Company announced that the independent DSMB of the EnACT study (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) has completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort of patients. Enrollment in this next randomized EnACT cohort, with 40 active-treatment patients, is expected to begin shortly, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis. MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B.

The induction period for all patients in each cohort of EnACT is 14 days, followed by an additional 4 weeks of treatment with MAT2203 for all patients during a maintenance period. In total, the trial includes four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The first cohort received IV amphotericin B for the first five days of the induction period, followed by nine days of oral administration of MAT2203. The second cohort of 40 actively treated patients will receive IV amphotericin B for the first two days of the induction period, followed by twelve days of oral administration of MAT2203. The primary efficacy endpoint will be measured at Day 14, the last day of the induction period, and will include a measure of reduction in fungal count in the cerebral spinal fluid. A control arm, which includes standard of care IV amphotericin B, is included with each cohort. An independent DSMB oversees the safety of the study and reviews all data from each cohort for safety and efficacy and makes a recommendation to proceed to the next cohort of patients.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT2203, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, the Company's ability to obtain additional capital to meet its liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of its product candidates; the ability to successfully complete research and further development and commercialization of its product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in the Company's filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date hereof. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. The Company's product candidates are all in a development stage and are not available for sale or use.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated October 19, 2020.

SIGNATURES

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.

MATINAS BIOPHARMA HOLDINGS, INC.

Dated: October 19, 2020

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Announces Unanimous DSMB Approval to Progress into Second Cohort of Patients in the EnACT Study of MAT2203 (Oral Amphotericin B) for the Treatment of Cryptococcal Meningitis

– DSMB evaluated both safety and efficacy data in recommending cohort progression –

– Enrollment in second cohort of patients expected to commence imminently with next DSMB evaluation anticipated mid-2021 –

BEDMINSTER, N.J. (October 19, 2020) – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced that the independent Data and Safety Monitoring Board (DSMB) of the EnACT study (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) has completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort of patients. Enrollment in this next randomized EnACT cohort, with 40 active-treatment patients, is expected to begin shortly, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

"Cohort progression in the EnACT study is an important milestone for the development of MAT2203," commented Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma. "The unanimous DSMB recommendation is very encouraging and supports our views of the overall safety and efficacy profile of MAT2203. We look forward to promptly commencing enrollment in the next cohort of EnACT, which will provide more robust evidence about the efficacy and safety of MAT2203."

"Cryptococcal meningitis is a deadly fungal disease which results in severe, invasive infections of the brain and imposes a major burden and high mortality in vulnerable immunocompromised patients around the world," continued Dr. Matkovits. "We believe that an oral amphotericin B formulation, with targeted drug delivery directly to infected tissues throughout the body, substantially reduces the risk of toxicity without sacrificing efficacy. Based on this profile, MAT2203 has the potential to provide an invaluable solution for physicians and patients and ultimately advance the standard of care for the treatment of severe, invasive fungal infections."

"Overall, we are pleased with the safety and performance of MAT2203 following 5 days of initial intravenous (IV) amphotericin B. In the next stage of the trial, we will continue to test MAT2203 following only 2 days of initial IV amphotericin B, and we would be very pleased to see similar performance," commented David Boulware, M.D., M.P.H, Professor of Medicine at the University of Minnesota and Principal Investigator for the trial.

"Cohort progression in EnACT is also another step forward in further validating the potential of our LNC platform delivery technology," commented Raphael J. Mannino, Ph.D., Chief Scientific Officer of Matinas BioPharma. "DSMB approval to proceed to the second patient cohort is a promising signal that MAT2203 is orally bioavailable and successfully crosses the blood brain barrier. Continued success in EnACT will further demonstrate that oral, LNC delivery of therapeutic agents to the brain is possible, and we remain optimistic that our LNC platform could become an important alternative to other traditional, but problematic, delivery vehicles such as lipid nanoparticles or viral vectors, across a wide variety of therapeutic applications."

EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis. MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B.

The induction period for all patients in each cohort of EnACT is 14 days, followed by an additional 4 weeks of treatment with MAT2203 for all patients during a maintenance period. In total, the trial includes four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The first cohort received IV amphotericin B for the first five days of the induction period, followed by nine days of oral administration of MAT2203. The second cohort of 40 actively treated patients will receive IV amphotericin B for the first two days of the induction period, followed by twelve days of oral administration of MAT2203. The primary efficacy endpoint will be measured at Day 14, the last day of the induction period, and will include a measure of reduction in fungal count in the cerebral spinal fluid. A control arm, which includes standard of care IV amphotericin B, is included with each cohort. An independent DSMB oversees the safety of the study and reviews all data from each cohort for safety and efficacy and makes a recommendation to proceed to the next cohort of patients.

As previously reported, the U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for four indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, and the treatment of invasive candidiasis, invasive aspergillus and cryptococcal meningitis. In addition, the FDA has granted orphan drug designation to MAT2203 for the treatment of cryptococcosis.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

MAT9001, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia. MAT9001 is currently in a second head-to-head comparative study against Vascepa ® (ENHANCE-IT), with topline data expected in the first quarter of 2021.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nano-crystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them more targeted, less toxic and orally bioavailable.

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT will promptly begin enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

Forward-Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT2203, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval and other statements that are predictive in nature, that depend upon or refer to future events or conditions. All statements other than statements of historical fact are statements that could be forward-looking statements. Forward-looking statements include words such as "expects," "anticipates," "intends," "plans," "could," "believes," "estimates" and similar expressions. These statements involve known and unknown risks, uncertainties and other factors which may cause actual results to be materially different from any future results expressed or implied by the forward-looking statements. Forward-looking statements are subject to a number of risks and uncertainties, including, but not limited to, our ability to obtain additional capital to meet our liquidity needs on acceptable terms, or at all, including the additional capital which will be necessary to complete the clinical trials of our product candidates; our ability to successfully complete research and further development and commercialization of our product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; our ability to protect the Company's intellectual property; the loss of any executive officers or key personnel or consultants; competition; changes in the regulatory landscape or the imposition of regulations that affect the Company's products; and the other factors listed under "Risk Factors" in our filings with the SEC, including Forms 10-K, 10-Q and 8-K. Investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this release. Except as may be required by law, the Company does not undertake any obligation to release publicly any revisions to such forward-looking statements to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's product candidates are all in a development stage and are not available for sale or use.

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