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): April 18, 2023

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**	**07921**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (908) 484-8805

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.

On April 18, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing that Marisa H. Miceli, MD Professor of Medicine, Specializing in Fungal Infections and Transplant Diseases, Division of Infectious Diseases, Internal Medicine, at the University of Michigan and her team delivered a presentation at the 33rd European Congress of Clinical Microbiology & Infectious Diseases ("ECCMID") discussing the Company's MAT2203's product candidate's clinical impact in treating a compassionate use patient suffering from Rhodotorula mucilaginosa ("R. mucilaginosa"), a rare and opportunistic invasive fungal infection. A copy of the press release is furnished as Exhibit 99. 1 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On April 18, 2023, the Company announced that Dr. Miceli delivered an oral presentation at the ECCMID discussing MAT2203's clinical impact in treating a compassionate use patient suffering from an R. mucilaginosa infection following discontinuation of treatment with IV-amphotericin B due to electrolyte abnormalities and

associated toxicities. MAT2203 was well-tolerated and led to a robust clinical response with no renal adverse effects, allowing for six continuous months of daily treatment with regular outpatient monitoring. The patient's renal function improved and remained at baseline throughout treatment. While taking MAT2203, the patient did not experience electrolyte abnormalities evident while taking IV-amphotericin B.

The Company is in the final stages of planning a Phase 3 program for MAT2203 with the U.S. Food and Drug Administration. The Company's goal is to add to the growing body of evidence to fully evaluate the significant potential of MAT2203 in the treatment of invasive fungal infections and, if appropriate, support broader use of this investigational drug

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 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 our product candidates; the 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 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 April 18, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: April 18, 2023

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

Compassionate Use Patient Treated with Matinas BioPharma's MAT2203 and Showing Complete Clinical Resolution of Rare *R. mucilaginosa* Fungal Infection Featured in Oral Presentation at ECCMID

BEDMINSTER, N.J. (April 18, 2023) – Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, announces that Marisa H. Miceli, MD, Professor of Medicine, Specializing in Fungal Infections and Transplant Diseases, Division of Infectious Diseases, Internal Medicine, at the University of Michigan and her team delivered an oral presentation earlier today at the 33rd European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) in Copenhagen discussing MAT2203's clinical impact in treating a compassionate use patient suffering from *Rhodotorula mucilaginosa (R. mucilaginosa)*, a rare and opportunistic invasive fungal infection.

"We are extremely pleased with the positive clinical impact that MAT2203, oral amphotericin B, had on an extremely ill patient with very limited treatment options," said Dr. Miceli. "*R. mucilaginosa* infection is rare and challenging to treat, due to innate antifungal resistance requiring long-term amphotericin B treatment, which historically leads to significant nephrotoxicity. In our patient, IV-amphotericin B had to be discontinued due to electrolyte abnormalities and associated toxicities. Following transition, MAT2203 was well-tolerated, and led to a robust clinical response with no renal adverse effects, allowing for six continuous months of treatment with regular outpatient monitoring. Based on our experience, MAT2203 appears to represent a safe and well-tolerated oral treatment option that can be safely administered in the outpatient setting to patients who require long-term antifungal treatment with amphotericin B."

Key elements of Dr. Miceli's team presentation included:

- *Rhodotorula* are a genus of pigmented yeasts and represent a rare, but opportunistic and emerging threat often highly resistant to antifungal therapy. Patients can require months of consistent IV-amphotericin B therapy to clear the infection, putting them at significant risk for kidney toxicity.
- The patient was at risk of amputation of her foot where the infection was located and was generally unable to walk. The patient began treatment with liposomal IV-administered amphotericin B but developed serious kidney toxicities attributed to the use of IV-amphotericin B. As a result, treatment with IV-amphotericin B was discontinued and Dr. Miceli applied to Matinas' Compassionate Use Expanded Access Program for treatment with MAT2203.
- The patient was admitted for monitored initiation of MAT2203 with a dosing regimen of 300mg, four times a day.

- Following initiation with MAT2203, the patient's renal function improved and remained at baseline throughout treatment. While taking MAT2203, the patient experienced none of the electrolyte abnormalities evident while taking IV-amphotericin B.
- The patient received MAT2203 daily for six months and ended therapy in January 2023 following complete clinical resolution of the fungal infection while regaining the use of her foot.

"The outcomes observed in this compassionate use case are highly encouraging, although we recognize the data are limited," said Theresa Matkovits, PhD, Chief Development Officer at Matinas. "This is one of several cases with successful outcomes using MAT2203 as part of our ongoing Expanded Access Program. We are in the final stages of planning a Phase 3 program for MAT2203 with the U.S. Food & Drug Administration. Our goal is to add to the growing body of evidence to fully evaluate the significant potential of MAT2203 in the treatment of invasive fungal infections and, if appropriate, support broader use of this investigational drug."

MAT2203 is not yet licensed or approved anywhere globally.

About MAT2203

Matinas BioPharma is developing MAT2203 as a potential oral broad-spectrum treatment for invasive deadly fungal infections. Although amphotericin B is a fungicidal agent, it is currently only available through an intravenous route of administration, which is known to be associated with a number of significant safety issues such as renal toxicity and anemia due to very high circulating levels of amphotericin B. MAT2203 has the potential to overcome the significant limitations of the currently available amphotericin B products due to its targeted oral delivery, combining comparable fungicidal activity with targeted delivery resulting in a lower risk of toxicity and potentially creating the ideal antifungal agent for the treatment of invasive fungal infections.

About ECCMID

The European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) has become one of the most comprehensive and influential congresses in the field of infectious diseases and an exciting networking opportunity, bringing together more than 14,000 colleagues from all over the world. The scientific program is built by the ECCMID Programme Committee, an independent group of experts representing all disciplines related to clinical microbiology, infectious diseases, infection control and prevention, and public health.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology to maximize global clinical impact and patient access. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery for both small molecules and larger, more complex molecules such as mRNA, DNA plasmids, antisense oligonucleotides, and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral) positions Matinas' LNC technology potentially to become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors. For more information, please visit www.matinasbiopharma.com.

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 our business activities, our strategy and plans, our collaborations with National Resilience, Inc. and BioNTech SE, the potential of our LNC platform delivery technology, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing 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.

Investor Contact

LHA Investor Relations
Jody Cain
Jcain@lhai.com
310-691-7100

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