
**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): January 8, 2018

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
*(State or other jurisdiction
of incorporation)*

001-38022
*(Commission
File Number)*

46-3011414
*(IRS Employer
Identification No.)*

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))

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 January 8, 2018, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release to report that the Phase 2a clinical study of orally-administered MAT2203 for the treatment of chronic refractory mucocutaneous candidiasis, which is being conducted by the National Institutes of Health, or NIH, achieved statistical endpoint for success. Investigators from the NIH have relayed to the Company positive data from a third patient enrolled in the Phase 2a clinical study. This third patient, with long-standing azole resistant mucocutaneous candidiasis, met the primary endpoint of the Phase 2a study in achieving $\geq 50\%$ clinical response with treatment of MAT2203. MAT2203 was well tolerated with any adverse events observed being mild in severity and unrelated to study drug. With this third positive response, the study has met its statistical hurdle for success. The press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d)	<u>Exhibit No.</u>	<u>Description.</u>
	99.1	Press Release, dated January 8, 2018.

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: January 8, 2018

By: /s/ Roelof Rongen

Name: Roelof Rongen

Title: Chief Executive Officer



Matinas BioPharma Achieves Statistical Endpoint for Success in Phase 2a Clinical Study of Orally-Administered MAT2203 for the Treatment of Chronic Refractory Mucocutaneous Candidiasis

–100% (three out of three) of patients have now met the primary endpoint in achieving \geq 50% clinical response with MAT2203 –

– Study has met predetermined statistical endpoint for success –

– All patients have elected to continue treatment in open-label extension study, with two patients now receiving MAT2203 orally for 11+ months with no evidence of nephrotoxicity, while maintaining efficacy throughout –

Bedminster, NJ (January 8, 2018) – Matinas BioPharma Holdings, Inc. (NYSE MKT: MTNB), a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today announced that investigators from the National Institutes of Health (“NIH”) have relayed to the Company positive data from a third patient enrolled in the collaborative Phase 2a clinical study of Matinas’ lead anti-infective product candidate MAT2203 for the treatment of chronic refractory mucocutaneous candidiasis (“CMC”) infection. This third patient, with long-standing azole resistant mucocutaneous candidiasis, met the primary endpoint of the Phase 2a study in achieving \geq 50% clinical response with treatment of MAT2203. MAT2203 was well tolerated with any adverse events observed being mild in severity and unrelated to study drug. With this third positive response, the study has met its statistical hurdle for success.

MAT2203 is the Company’s orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B. Matinas BioPharma’s proprietary lipid-crystal nano-particle formulation of amphotericin B has a novel mechanism of absorption and distribution to infected tissues and has the potential to transform the way this potent fungicidal agent is administered and used in clinical practice.

“With the statistical success hurdle that was prospectively set at a 20% patient-response probability and now seeing a clinical response in three out of three patients, we have successfully achieved the 3 out of 16 possible clinical responders required for the study to meet its primary endpoint. This is a major milestone for this study and our platform technology more broadly,” said Roelof Rongen, Chief Executive Officer. “We continue to develop invaluable data in patients receiving MAT2203 and are exploring options with our valued collaborators at the NIH to determine next best steps for this study. In addition to impressive efficacy results in this difficult-to-treat patient population, we remain very excited about the long-term safety data of MAT2203. Whereas today amphotericin B can only be used in limited, acute settings due to its significant toxicity, we now have multiple patients who have been taking MAT2203 for almost a full year with no signs of kidney or liver toxicity.”



The third patient in this study was diagnosed with a dual *Candida albicans* and *C. glabrata* infection with azole resistance. The predominant manifestation was esophageal candidiasis, which had been refractory to treatment for a prolonged period. Patient 03 achieved a reduction in clinical symptoms at an efficacious orally administered dosage of 800 mg MAT2203 per day, meeting the response criterium of $\geq 50\%$ reduction in clinical symptoms. MAT2203 was generally well tolerated by Patient 03 and there were no signs of nephrotoxicity, hypokalemia or hepatotoxicity (measured by ALT and AST). Indicators of kidney and liver toxicity remained within normal limits throughout the treatment period. For this patient, no underlying immunocompromising condition was diagnosed. Patients 01 and 02, both with an underlying hereditary immunodeficiency called Job's Syndrome, also known as Autosomal Dominant Hyper IgE Syndrome (AD-HIES), enrolled earlier in this trial and achieved reduction in clinical symptoms of 57% (at 800mg/day) and 85% (at 400mg/day). The first two patients have enrolled in a long-term study extension and have shown no signs of kidney or liver toxicity over the approximately twelve months of being administered MAT2203. Furthermore, the clinical response to MAT2203 seen in these patients has been maintained and/or improved during the extension period in addition to patients reporting meaningful quality-of-life improvements.

“We remain extremely grateful to the patients for their ongoing participation and to the NIH for conducting this study,” commented Raphael J. Mannino, Ph.D., Matinas BioPharma's Chief Scientific Officer. “As we look forward to our upcoming meeting with the FDA, we are positioning MAT2203 to be used by and for patients who today have very few treatment or prevention options, either due to increasing drug resistance, toxicity or use-limiting drug to drug interaction with other therapies.”

The Phase 2a study is being conducted at the National Institutes of Health Clinical Center in Bethesda, MD, under the direction of Dr. Alexandra Freeman. The ongoing open-label, dose-titration study is designed to assess the efficacy, safety, tolerability and pharmacokinetics of MAT2203 in predominantly hereditary immunodeficient patients with a recurrent or chronic mucocutaneous candidiasis infection (esophageal, oropharyngeal, vaginal) who are refractory or intolerant to standard non-intravenous therapies. The study may enroll up to 16 patients, and study endpoint in the statistical analysis plan is defined as a response in three or more patients. The study includes 14-day dosing and evaluation periods. Depending on clinical response during each treatment period, investigators will have the ability to continue the effective dose for 28 total days or increase the dose of MAT2203 up to two times and extend treatment to a maximum of 54 days. To date, the Institutional Review Board of the NIAID, NIH has granted approval for two separate 6-month open-label safety extensions of this Phase 2a study to allow patients to continue to receive MAT2203.

About Mucocutaneous Candidiasis

Mucocutaneous candidiasis is a group of syndromes resulting in infections of the skin, nails and mucous membranes. These infections are caused by opportunistic candida yeast, the most common cause of fungal infections worldwide. There are more than 20 species of candida that can cause infection in humans, the most common of which is *Candida albicans*. A variety of disorders including endocrine dysfunctions, hereditary immune-system disorders, alopecia, vitiligo, malabsorption syndromes, neoplasms and other infections may also occur in patients with chronic reoccurring mucocutaneous candidiasis and autoimmune disorders. Current anti-fungal treatment management options are limited, and relapse is common following discontinuation of certain therapies. In addition, the increasing resistance of certain strains to standard antifungal treatments is a growing concern.



About MAT2203

MAT2203 is an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). Little to no clinical resistance has been reported to date with amphotericin B as compared to the rapidly emerging drug resistance seen in other antifungal therapies. Currently, IV-only administered amphotericin B is the only broad spectrum fungicidal available but its IV-delivery results in significant treatment-limiting side effects, including nephrotoxicity. The ability to provide amphotericin B orally using our proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. The FDA has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) for the treatment of invasive candidiasis and the treatment of aspergillosis, as well as for the prevention of invasive fungal infections due to immunosuppressive therapy. MAT2203 is also being explored for treatment of additional anti-fungal indications and may have the potential for Orphan Drug Designation in certain of these indications.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications. The Company's proprietary, disruptive technology utilizes lipid-crystal nano-particle cochleates to nano-encapsulate existing drugs, making them safer, more tolerable, less toxic and orally bioavailable.

The Company's lead anti-infective product candidates, MAT2203 and MAT2501, position Matinas BioPharma to become a leader in the safe and effective delivery of anti-infective therapies utilizing its proprietary lipid-crystal nano-particle cochleate formulation technology. For more information, please visit www.matinasbiopharma.com and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).



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 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 maintain and derive benefit from the Qualified Infectious Disease Product (QIDP), Orphan and/or Fast Track designations for MAT2203, which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; 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

Jenene Thomas
Jenene Thomas Communications, LLC
Phone: +1 (908) 938-1475
Email: jenene@jenenethomascommunications.com

Source: Matinas BioPharma Holdings, Inc.

###
