

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): August 18, 2015

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

Delaware
(State or other jurisdiction
of incorporation)

(Commission
File Number)

46-3011414
(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:

- ☐ 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))
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Item 8.01 Other Events.

On August 18, 2015, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release announcing that the U.S. Food and Drug Administration designated the Company’s lead product candidate, MAT2203, as a Qualified Infectious Disease Product (QIDP) and granted MAT2203 Fast Track designation. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.**(d) Exhibits**

Exhibit No.	Description
99.1	Press Release, dated August 18, 2015.

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.

Date: August 18, 2015

/s/ Roelof Rongen

Roelof Rongen, President and Chief Executive Officer

**Matinas BioPharma's Lead Antifungal Product Candidate
MAT2203 Granted QIDP and Fast Track Designations by U.S.
FDA**

Bedminster, NJ (August 18, 2015) – Matinas BioPharma Holdings, Inc. (OTCQB: MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective antifungal and anti-bacterial therapeutics for the treatment of serious and life-threatening infections, today announced that the U.S. Food and Drug Administration (FDA) has designated the Company's lead drug candidate MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status.

MAT2203 is an orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B, a powerful, intravenously-administered antifungal agent. QIDP and Fast Track designations have been granted for the use of MAT2203 in the treatment of invasive candidiasis, a condition with increasing rates of drug resistance to established anti-fungal products.

QIDP designation, provided under the Generating Antibiotic Incentives Now Act (GAIN Act), offers certain incentives for the development of new antibacterial or antifungal drugs, including eligibility for Fast Track, priority review and, if MAT2203 is ultimately approved by the FDA, eligibility for an additional five years of marketing exclusivity. The award of Fast Track status enables more frequent interactions with the FDA to expedite the development and review process for drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical need.

"Invasive drug resistant candida fungal infections may spread to critical organs such as the brain, heart or bloodstream and are potentially life-threatening, especially when they occur in immunocompromised patients," stated Roelof Rongen, President and Chief Executive Officer of Matinas BioPharma. "While the antifungal amphotericin B has demonstrated little or no resistance in clinical practice, it currently has limited treatment use in fungal infections due to severe toxicity issues. MAT2203 is a novel, encochleated orally bioavailable formulation of amphotericin B and is designed to provide targeted delivery to the site of infection along with a significantly improved safety and tolerability profile."

Mr. Rongen added, "We believe MAT2203 has the potential to bring a much needed effective, broad-spectrum and significantly less toxic antifungal to at-risk patients with invasive and resistant fungal infections. QIDP designation for MAT2203 is a major step forward for this program, positioning us for eligibility for an additional five years of marketing exclusivity if MAT2203 is approved by the FDA, while Fast Track status should help expedite the development of MAT2203 in order to bring this important medication to patients and clinicians who need it in their battle against serious and potentially life-threatening fungal infections."

Matinas BioPharma is developing MAT2203 for the treatment of serious and life-threatening fungal infections in collaboration with the National Institutes of Health/National Institute of Allergy and Infectious Disease (NIH/NIAID). A Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis is expected to commence during the third quarter of 2015, with data expected in the first quarter of 2016, or earlier under certain circumstances.

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 anti-fungal 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 via MAT2203's proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 demonstrated a positive safety and tolerability profile with no serious or dose-related adverse events reported, including little or no nephrotoxicity as compared to placebo. A Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis is expected to commence during the third quarter of 2015. MAT2203 is also being explored for treatment of additional anti-fungal indications including cryptococcal meningoencephalitis, aspergillosis and leishmaniasis, and may have the potential for Orphan Drug Designation in certain indications.

About Invasive Candidiasis

Invasive candidiasis is an infection caused by a type of opportunistic fungus called *Candida*, the most common cause of fungal infections worldwide. Unlike *Candida* infections occurring in the mouth and throat (also called "thrush") or vaginal "yeast infections," invasive candidiasis is a serious infection that can affect the blood, heart, brain, eyes, bones, and other parts of the body. Candidemia, a bloodstream infection with *Candida*, is a common infection in hospitalized patients. Current anti-fungal treatment management options can be difficult and relapse is common following discontinuation of certain therapies resulting from increased anti-fungal resistance.

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum antifungal and anti-bacterial therapeutics for the treatment of serious and life-threatening infections. The Company's proprietary, disruptive technology utilizes lipid-crystal nano-particle cochleate to nano-encapsulate existing drugs, making them safer, more tolerable, less toxic and orally available. The Company's lead drug candidate is MAT2203, an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). The Company also intends to file an investigational new drug application (IND) for MAT2501, which is an orally-administered, encochleated formulation of Amikacin (a broad spectrum aminoglycoside antibiotic agent) for gram-negative and intracellular bacterial infections. In addition, the Company is exploring development and partnership options for MAT9001, a prescription-only omega-3 fatty acid-based composition under development for hypertriglyceridemia, which has shown superiority versus Vascepa[®] (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoproteins and PCSK9 levels.

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 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) and 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: jthomas@matinasbiopharma.com

Media Contact:

David Connolly
LaVoieHealthScience
Phone: +1 (617) 374-8800
Email: dconnolly@lavoiehealthscience.com

Source: Matinas BioPharma Holdings, Inc.

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