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): June 26, 2017

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 Identification No.)*

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) 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 7.01 Regulation FD Disclosure.

On June 26, 2017, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release to report topline data from its Phase 2 safety, tolerability and efficacy study of MAT2203 in women with moderate to severe vulvovaginal candidiasis ("VVC"). The press release is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed "filed" for the 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 it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d)

Exhibit No.	**Description.**
99.1	Press Release, dated June 26, 2017.

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: June 26, 2017

By: /s/ Roelof Rongen
Name: Roelof Rongen
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Reports Topline Data from Phase 2 Clinical Study of Orally-Administered MAT2203 for the Treatment of Vulvovaginal Candidiasis

– Management to host conference call today, June 26th at 8:30 am ET –

Bedminster, NJ (June 26, 2017) – Matinas BioPharma Holdings, Inc. **(NYSE MKT: MTNB)**, a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today reported topline data from its Phase 2 safety, tolerability and efficacy study of MAT2203 in women with moderate to severe vulvovaginal candidiasis (VVC). The Phase 2 study achieved its primary endpoint in demonstrating MAT2203 is safe and well tolerated. However, both the clinical and mycological responses for MAT2203 did not meet the Company's expectations and were below that of fluconazole, the guideline recommended therapy for the treatment of VVC.

Matinas management will host a conference call and live webcast for investors, analysts and other interested parties to review the topline data today, June 26, 2017 at 8:30 a.m. ET (details below).

"In this study, we were able to further demonstrate that oral delivery of encochleated amphotericin B is safe and well tolerated without the liver and kidney toxicities typically seen with administration of intravenous amphotericin B. In the context of our overall development program for MAT2203, this Phase 2 study was not designed or powered to support an indication for the treatment of VVC and therefore supplant fluconazole as the standard of care. Instead, our goal was, in addition to further establishing the safety and tolerability of MAT2203, to demonstrate efficacy of MAT2203 in a non-life threatening fungal infection consistent with the development of other anti-fungal therapies, as we prepared MAT2203 to enter a pivotal trial in the prevention of invasive fungal infections. In this particular study, we were not successful in demonstrating meaningful clinical or mycological response of MAT2203 as compared to fluconazole. However, upon review of the improvements over baseline of the composite clinical score of patient signs and symptoms at Day 5 and Day 12 at both the 200 mg and 400 mg arms, we were pleased to see what we believe could indicate clinical response which may provide support for the systemic delivery of MAT2203 to the site of infection," stated Roelof Rongen, Chief Executive Officer of Matinas BioPharma.

This completed proof-of-concept Phase 2 study of MAT2203 was a multi-center, randomized trial with the primary objective to evaluate the safety of two orally administered doses (200 mg and 400 mg) of MAT2203 compared to 150 mg of fluconazole in 137 women in the safety population. Secondary efficacy objectives were to assess the clinical cure rate and the mycological eradication rate of oral CAMB at the test of cure visit (Day 12) compared with fluconazole in 79 women with confirmed vulvovaginal candidiasis at baseline in the modified intent to treat population, and tertiary objectives were to assess pharmacokinetics (PK) of CAMB after 5 days of oral administration.

There were no serious adverse events reported in the study and the majority of treatment emergent adverse events (TEAEs) were mild in severity and unrelated to study drug. Drug-related TEAEs of orally-delivered encochleated amphotericin B should be evaluated in the context of the side effects of IV-administered unencochleated amphotericin B, which is well known for its severe and potentially lethal side effects. Drug-related TEAEs occurred in only 20% of 200 mg patients and 18% of 400 mg patients. The most frequently occurring drug-related TEAEs in the MAT2203 groups were gastrointestinal and mild in nature. Drug-related TEAEs occurred in 2% of patients on fluconazole.

“Importantly, we continue to believe in the potential of our unique platform technology as it relates to the development of MAT2203 for the prevention and treatment of invasive fungal infections. In looking at the data generated from this study contrasted with the data from our ongoing NIH Phase 2 study, it appears that both higher doses and longer duration of therapy, which yielded a significant clinical response in the immunocompromised patients in the NIH study, could be important factors in demonstrating efficacy in mucosal candidiasis. Accordingly, we believe that utilizing a higher dose for a longer duration in this study may have resulted in improvement in overall clinical and mycological responses. Despite the results from this single study of MAT2203 at low doses and for a short duration, we believe that the extensive existing body of preclinical and human data established to date with our cochleate technology warrants continued development of MAT2203, and we look forward to advancing MAT2203 to build an overall efficacy data package,” added Mr. Rongen.

Efficacy endpoints included evaluation of clinical and mycological response. Clinical response was evaluated using a composite scoring system that compared signs and symptoms of VVC from baseline to test of cure (Day 12). Signs and symptoms included itching, burning, irritation, erythema, edema, or excoriation. MAT2203 demonstrated a clinical cure in 52% of patients at 200 mg/day and 55% of patients at 400 mg/day, compared to 75% of patients on fluconazole. In the mycology outcome, 36% of patients in the 200 mg arm and 32% in the 400 mg arm experienced eradication, compared to 84% of patients in the fluconazole arm. In the composite clinical cure score of signs and symptoms at Day 12, MAT2203 demonstrated an 81% improvement in clinical symptoms at 200 mg/day, 80% improvement at 400 mg/day, compared to 94% improvement in clinical symptoms for the patients on fluconazole.

“We believe that with this study, we continue to generate important data about MAT2203 and the unique mechanism of action of the cochleate technology, which will be invaluable as we design additional studies in support of this development program,” stated Raphael J. Mannino, Chief Scientific Officer of the Company.

The Company will be receiving additional data from the study over the next few months and intends to continue to evaluate such data from this study as it becomes available, including data on pharmacokinetics, and will provide guidance on details and timing of additional development plans for MAT2203 during the third quarter of 2017.

Conference Call and Webcast Information

Matinas will host a conference call and live webcast for investors, analysts and other interested parties on Monday, June 26, 2017 at 8:30 am ET to provide an update and overview for the clinical development of MAT2203.

To participate in the call, please dial 877-407-5976 (domestic) or 412-902-0031 (international). The live webcast will be accessible on the Events page of the Investors section of Matinas' website, www.matinasbiopharma.com, and will be archived for 60 days. Interested parties can click here to access the webcast directly.

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 platform 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 and MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, 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 and MAT2501, 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.*

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Source: Matinas BioPharma Holdings, Inc.