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 6, 2016

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of incorporation)

(Commission File Number)

1545 Route 206 South, Suite 302 Bedminster, New Jersey (Address of principal executive offices) 46-3011414 (IRS Employer ID Number)

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))

Item 7.01 Regulation FD Disclosure.

Matinas BioPharma Holdings, Inc. (the "Company") intends to use a slide presentation in connection with an investor update call to take place on Thursday, October 6, 2016 and thereafter at various investor meetings. The slide presentation is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibits 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.

This Current Report on Form 8-K, including exhibit 99.1, contains "forward-looking statements" made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow 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 successfully complete research and further development and commercialization of our product candidates; 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 for 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. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. Matinas does not undertake any obligation to release publicly any revisions to such forward-looking statement 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 currently available for sale or use.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautions not to place undue reliance on any forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

Item 9.01. Financial Statements and Exhibits

ExhibitDescription99.1Slide Presentation

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: October 6, 2016

/s/ Roelof Rongen Roelof Rongen, Chief Executive Officer

Exhibit 99.1



MAT2203 CLINICAL DEVELOPMENT UPDATE CALL OCTOBER 6, 2016



Forward Looking Statement

This presentation 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 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 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 presentation. 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.







Risk of IFI in Patients with Hematologic Malignancy is Increasing and Mortality Rates are High

- Increased risk is attributed to host defense impairment due to intensive cytotoxic chemotherapies, HSCT, ablative radiation therapy, use of corticosteroids, cyclosporine, and new immunosuppressive agents.
- In a cohort of 11,802 Italian patients with hematologic malignancy there were 538 (4.6%) proven or probably IFI. Sixty-nine percent occurred in patients with AML.
- · IFI-attributable mortality rate was 39%



MATINAS

BIOPHARMA



Structure of Nanocochleate Formulations

Cargo Molecules Intercalate into the Phospholipid Bilayer Interior

Cochleate-Mediated Delivery into Activated Cells

- Cochleates are actively taken up by activated cells such as infected macrophages and virus infected cells, resulting in delivery of cargo molecules directly into the interior of the cell
- The normal low concentration of calcium within the cytoplasm of cells causes cochleates to unroll and release their contents
- The presence of calcium outside the macrophage prevents the cochleate from opening
- Once inside the macrophage, the low level of calcium, (1,000 – 10,000 times lower) causes the cochleate to open, releasing the drug. The drug tends to stay within the cell, and defuses out slowly

Cochleates Can Change the Pharmacokinetics and Biodistribution of Drugs

The Hyphen of the Alternaria Fungus Contain Rhodamine-Labeled Cochleates Within 30-minutes After Exposure

"Trojan-Horse" Phenomenon

Confocal images of interference contrast and red fluorescence to show 1% rhodamine-labeled nanocochleates (arrows) within fungal hyphae of Alternaria

> Fungicidal; Broad Spectrum

· Amphotericin B is perhaps the broadest spectrum antifungal agent

> Few Drug – Drug Interactions

 Amphotericin is not metabolized through typical liver pathways and does not experience the drug-drug interactions typically seen with many triazole antifungal agents; Allows for broader use with complicated oncology regimens

Cochleate Benefits

 Cochleates are designed to provide <u>oral bioavailability</u>, dramatic <u>reduction in toxicity</u> and <u>targeted delivery</u>

BIOPHARMA

US Regulatory Environment Provides Solid Market Exclusivity Opportunity Through GAIN and Orphan-Drug Acts

Combined 12-Year Exclusivity

MATINAS

BIOPHARMA

MAT2203 - IFI Prophylaxis is a Significant Value Driver

- On September 7, 2016, MTNB announced FDA grant of QIPD and Fast Track designations for MAT2203 for: "Prevention
 of invasive fungal infections (IFI) due to immunosuppressive therapy"
- Due to significant drug-drug interaction and lack of oral delivery forms, very few antifungals are approved for the prophylactic use in patients on immunosuppressive therapy – <u>a significant unmet clinical need remains</u>
- Amphotericin B (currently only available for intravenous infusion), the antifungal compound in MAT2203, has very few drug-drug interactions with cancer/transplant therapies
- The lipid-crystal nano-particle delivery system for MAT9001 significantly reduces toxicities associated with amphotericin B, while making the compound absorbable in the body by convenient oral administration

IFI Prophylaxis: Broad population: US prevalence of leukemia is approximately 340,000 (111,000 acute forms of leukemia) plus ~51,000 transplants annually (20,000 stem cell + 31,000 organ transplants) Treatment period extended over the entire high-risk episode: typically 6-14 weeks, depending on patient type Significant reduction of morbidity and mortality in target patient population	 <u>IFI Treatment:</u> Limited population: annually 46,000 Candidiasis + 5,000 Aspergillosis cases in US (>90% of IFI) Treatment period limited: typically 1-3 weeks, depending on patient condition and improvement Significant morbidity and mortality rate in patients with IFI; mortality risk 40%-90%, depending on fungal species
Significant savings in cost of treatment of IFI in high cost ICU or similar hospital environment, justifying economics of prevention	 Significant cost of treatment for IFI, adding ~\$50,000 per IFI case in 2016 dollars

MATINAS

BIOPHARMA

MAT2203 - Development Foundation in Orphan Drug Territory

Target Use:	Declinics	olulo olulo	Shase 2	Contenties
Candidiasis	 Image: A second s	 Image: A start of the start of	✓**	Invasive Candidiasis in US: ~46,000 cases/year
Aspergillosis	\checkmark	 Image: A start of the start of		Invasive Aspergillosis in US: ~6,000 cases/year
IFI Prophylaxis	✓*	 Image: A start of the start of	√ ***	Stem cell: ~20,000; SOT: ~31,000 procedures/year Acute Leukemia patients: ~111,000 in US
Cryptococcal Meningitis	\checkmark			Cryptococcal Meningitis in US: ~3,000 cases/year

NIH phase 2 study and committed VVC study, both forms of mucocutaneous candidiasis Planned Phase 1/2 bridging study in hematological malignancy patients **

MATINAS BIOPHARMA

MAT2203 is Ideal Product for Prevention of Invasive Fungal Infections in Patients Receiving Chemotherapy for Hematologic Malignancy

Feature	Ideal Antifungal Agent for the Prevention of IFI	Target Profile MAT2203
Safe/Well Tolerated	\checkmark	✓
Broad Spectrum Fungicidal Activity	\checkmark	✓
Convenient Oral Administration	\checkmark	✓
Few Drug-Drug Interactions	\checkmark	\checkmark
Little Drug Resistance	\checkmark	\checkmark

Phase 2 Program to Support Phase 3 Development

Phase 2 Studies

Efficacy, long term treatment of immunocompromised patients; dosing commenced

Mucocutaneous Candidiasis, up to N=16

Vulvovaginal Candidiasis N=75 Efficacy versus active control in larger patient population; Start Q4 2016

Tolerability PK & Other N=16-20 Tolerability/other clinical factors in immunocompromised patients; H1 2017 Phase 2 program provide valuable milestones:

- Proof-of-concept for the cochleate lipid-crystal nano-particle technology platform
- Proof-of-concept for the MAT2203 as an antifungal agent in treatment of active fungal infections
- Clinical experience with MAT2203 in key target populations prior to phase 3 development
- Basis for engagement with FDA on pivotal Phase 3 program

- · Goal: Evaluate antifungal efficacy and safety with orally administered CAMB
- <u>Patients</u>: Patients with diagnosis of persistent oropharyngeal (OPC), esophageal (EC), or vulvovaginal candidiasis (VVC) who are refractory or intolerant to standard non-intravenous therapies (N=16)
- <u>Primary Objective</u>: To assess the clinical response to treatment of mucocutaneous candidiasis (OPC, EC, VVC) infections after treatment for 14-days with the highest titrated dosage (Target Dosage) of CAMB per patient.
- · Secondary Objectives:
 - To assess the plasma, urine, and salivary PK of AMB after a single dose and after multiple doses (14 days)
 - · To assess the safety and tolerability
 - To assess mycological response

Clinicaltrials.gov: NCT02629419

Phase 2 Trial in Vulvovaginal Candidiasis (VVC)

- · Goal: Evaluate antifungal safety and efficacy with orally administered CAMB
- Patients: Women with diagnosis of moderate to severe VVC (N=75)
- Primary Objective: To evaluate the safety of oral CAMB 200 mg/day for 4 days
- Secondary Objectives:
 - Clinical cure rate
 - Mycology eradication
 - Responder outcome (clinical + mycology)
- Tertiary Objective: Multiple dose PK in CAMB arm
- Control Arm: Fluconazole 150 mg (single-dose)

Phase 2 Tolerability/PK in Hematologic Malignancy

- <u>Goal</u>: Evaluate the multiple-dose tolerability and PK in patients with hematologic malignancy
- <u>Patients</u>: Diagnosed with hematologic malignancy, entering first induction treatment or subsequent chemotherapy and expected to have preexisting or chemotherapy induced neutropenia (N=15)
- <u>Primary Objective</u>: To evaluate the safety & tolerability of oral CAMB for at least 14-days
- Secondary Objective:
 - To evaluate absence or presence of breakthrough fungal infection or need for treatment with other systemic antifungal
 - To evaluate multiple-dose PK of AMB after oral administration
- Open-label

Phase 3 Development Plans

- Phase 3 study for the prevention of IFI in patients diagnosed with hematologic malignancy, entering first induction treatment or subsequent chemotherapy and expected to have preexisting or chemotherapy induced neutropenia
 - N = 400-500 patients
 - Double-blind control group
 - Primary endpoint: Incidence of IFI
 - Secondary endpoint: Safety

Phase 3 Program to Provide Support of NDA Approval

MAT2203 CLINICAL DEVELOPMENT UPDATE CALL OCTOBER 6, 2016

