

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 3, 2017

**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.

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**Item 7.01 Regulation FD Disclosure.**

On June 3, 2017, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release to report interim results from 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. The press release is attached hereto as Exhibit 99.1.

The Company intends to use the presentation included as Exhibit 99.2 to this report in connection with its investor conference call on June 5, 2017.

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 Exhibits 99.1 and 99.2, 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)	<u>Exhibit No.</u>	<u>Description.</u>
	99.1	Press Release, dated June 3, 2017.
	99.2	Presentation, dated June 5, 2017.

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**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 5, 2017

By: /s/ Roelof Rongen

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Name: Roelof Rongen

Title: Chief Executive Officer

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## Matinas BioPharma Announces Interim Data from NIH-Conducted Phase 2a Clinical Study of Orally-Administered MAT2203 for the Treatment of Chronic Refractory Mucocutaneous Candidiasis

- NIH investigators present collaborative interim data of MAT2203 study at The American Society for Microbiology's ASM Microbe 2017 Conference –
- Two out of two patients met the primary endpoint in achieving  $\geq 50\%$  clinical response with MAT2203 –
  - MAT2203 was well tolerated with no serious adverse events reported –
- Both patients elected to continue treatment in open-label extension study –
- Management to host conference call Monday, June 5<sup>th</sup> at 8:30 am ET –

**Bedminster, NJ (June 3, 2017)** – 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”) presented interim data from two patients 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, at The American Society for Microbiology’s ASM Microbe 2017 Conference being held June 1–5 in New Orleans, LA. Two out of the two patients with long-standing azole resistant mucocutaneous candidiasis met the primary endpoint of the Phase 2a study, achieving  $\geq 50\%$  clinical response with treatment of MAT2203. MAT2203 was well tolerated with majority of adverse events observed being mild in severity and unrelated to study drug.

Matinas management will host a conference call and live webcast for investors, analysts and other interested parties to review the interim data on Monday, June 5, 2017 at 8:30 a.m. ET (details below).

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.

The abstract entitled, “*Oral Encochleated Amphotericin B (CAMB) in the Treatment of Chronic Azole Resistant Mucocutaneous Candidiasis*,” was presented today in poster session focused on new antifungal agents, by Alexandra Freeman, M.D., of the National Institute of Allergy and Infectious Diseases (NIAID) Laboratory of Clinical Infectious Diseases, Principal Investigator of the Phase 2a study sponsored by Matinas BioPharma. To access the poster, click here.

“We are incredibly pleased with the interim safety and efficacy results of this Phase 2a study of MAT2203. While we understand the results are representative of just two patients, these patients are difficult to treat because of their severe underlying immunocompromising condition. With the statistical success hurdle that was prospectively set at a 20% patient-response probability, seeing a clinical response in two out of two patients brings us very close to the 3 out of 16 clinical responders required for the study to meet its primary endpoint, “ said Roelof Rongen, Chief Executive Officer

“We believe that with these interim results, we have made a significant step toward establishing proof-of-concept for treating fungal infections in immunocompromised patients, and importantly have begun to demonstrate in a clinical setting the depth and breadth of our cochleate technology to deliver amphotericin B orally as a chronic treatment. We are encouraged by these initial results and believe they have the potential to be predictive of the completed study outcome, and look forward to continuing the study to further understand the potential of MAT2203. We are extremely grateful to the patients for their participation and to the NIH for conducting this study,” commented Raphael J. Mannino, Ph.D., Matinas BioPharma’s Chief Scientific Officer.

The interim data presented showed that the first two patients in this study, both with Job’s Syndrome and long-standing azole resistant mucocutaneous candidiasis for >20 years, achieved  $\geq 50\%$  clinical response after 14 days of treatment at an efficacious orally administered dosage of MAT2203, thus meeting the primary endpoint. Job’s Syndrome, also known as Autosomal dominant Hyper IgE Syndrome (AD-HIES), is a hereditary condition rendering the patients severely immunocompromised and exposes them to chronic infections, including CMC, often involving the oral, esophageal and vaginal mucosas and nails. Both patients suffered from chronic azole resistant oral CMC (or oral thrush) as their primary infection and had an inadequate response to current oral antifungal therapy. Clinical efficacy criteria were met at 400mg and 200mg of MAT2203 oral suspension twice daily in patient 01 and patient 02, respectively, with improvement upon exam in clinical symptoms and semi-quantitative fungal cultures of the oral thrush condition. The clinical severity score for oral thrush (composed of oral pain, burning, dysphagia, odynophagia, and presence of plaques) decreased by 57% for patient 01 and by 85% for patient 02, with corresponding reduction in fungal culture counts. Both patients reported meaningful quality-of-life improvements.

MAT2203 was generally well tolerated 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 a 6-8 week treatment period.

As expected, oral thrush promptly returned after stopping treatment with MAT2203. Therefore, Matinas' preliminary clinical data indicate that MAT2203 is promising as an oral systemically-absorbed broad-based antifungal without the toxicity of parenteral amphotericin B.

Both of the patients have elected to enroll in the open-label extension study.

"These results are very encouraging. I have patients like these individuals in my practice and they are very difficult to treat because they are immunocompromised and often resistant to azoles. There is a need for new drugs that can overcome resistance and be administered safely for extended periods. Seeing the data from the first two patients, I am optimistic that MAT2203 can be administered safely for long-periods and can treat resistant mucosal disease. Moving forward, I would like to see MAT2203 studied for the treatment and prevention of invasive fungal disease," commented Peter G. Pappas, MD, FACP, William E. Dismukes Professor of Medicine in the Division of Infectious Diseases in the Department of Medicine at the University of Alabama at Birmingham and the Principal Investigator for the Mycoses Study Group Education and Research Consortium.

The Phase 2a study is being conducted at the National Institutes of Health Clinical Center in Bethesda, MD, under the direction of Dr. 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 will 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. In March 2017, the Company announced that the Institutional Review Board of the NIAID, NIH granted approval for a 6-month open-label safety extension of the Phase 2a study.

The U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for the treatment of invasive candidiasis, aspergillus, and prophylaxis (prevention) of invasive fungal infections in patients of immunosuppressive therapy. MAT2203 is also being explored for treatment of additional infections including cryptococcal meningoencephalitis, and is being developed to be eligible for Orphan Drug designations in various indications.

## **Conference Call and Webcast Information**

Matinas will host a conference call and live webcast for investors, analysts and other interested parties on Monday, June 5, 2017 at 8:30 am ET to provide an update and overview for the clinical development of MAT2203. Joining Matinas management on the call will be Dr. Edmund C. Tramont, MD, National Institute of Health, Allergy and Infectious Diseases, Associate Director for Special Projects, Former Director, Division of AIDS and Co-Investigator of the study.

The conference call and live webcast will be accompanied by presentation slides. To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast and accompanying slides will be accessible on the Events page of the Investors section of Matinas' website, [www.matinasbiopharma.com](http://www.matinasbiopharma.com), and will be archived for 60 days.

## **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. Currently, there are two Phase 2 studies underway with MAT2203. The first is an open-label Phase 2a NIH/NIAID-sponsored clinical study with MAT2203 in immunocompromised patients with refractory mucocutaneous candidiasis. The second is a Phase 2 study of MAT2203 in patients with vulvovaginal candidiasis (VVC). Data from both studies is expected to be announced in June of 2017. 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](http://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.*

### **Investor Contact**

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Source: Matinas BioPharma Holdings, Inc.

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# MATINAS

  
BIOPHARMA

Transforming the Way Potent Medicines  
for Infectious Diseases are Designed

*MAT2203 - Interim Data from NIH  
Mucocutaneous Candidiasis Phase 2 Study*

NYSE MKT: MTNB

[www.matinasbiopharma.com](http://www.matinasbiopharma.com)

# Forward Looking Statement

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*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 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 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.*

# Highlights

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- Interim data from first two patients in National Institutes of Health (NIH) conducted Phase 2a study of MAT2203 for the treatment of refractory mucocutaneous candidiasis infection
- Two out of two patients met the primary endpoint in achieving  $\geq 50\%$  clinical response
- Patients reported meaningful Quality of Life improvements
- Objective evidence of effect were also observed, decreased severity of lesions, decreased quantitative fungal cultures.
- No serious adverse events reported to date during the course of the study
- MAT2203 was well tolerated with majority of adverse events observed to date being mild in severity and unrelated to MAT2203
- Both patients elected to enroll in the long-term extension study

## Background

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- MAT2203: Novel encochleated formulation of a proven molecule, amphotericin B, a broad spectrum fungicidal agent
  - Novel oral delivery through nanoparticle formulation
  - Ability to convert an IV-only administered drug into an oral formulation
  - Early evidence of better tolerability with lower toxicity
- Product profile fits well with difficult to evaluate and treat patient populations seen at the NIH
  - Patients require long term therapy due to chronic drug resistant fungal infections
  - MAT2203 offers convenient oral dosing of amphotericin B with the favorable safety profile needed for chronic therapy
- Interim data from first two patients in NIH-conducted Phase 2a study of MAT2203 for the treatment of refractory mucocutaneous candidiasis infection
- Establishes POC in nonlethal fungal infections in immunocompromised patients

## Collaboration with NIH

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- Collaboration with NIH began with IND enabling studies
- NIH is conducting the study
- Advanced Phase 2a study with enrollment and dosing of first two patients
- Study subjects chosen because of inherent impaired immuno-compensation, long term fungal infection of over 20 years and anti-fungal drug resistance except for amphotericin B
- Edmund C. Tramont, MD, MACP, FIDSA
  - Co-Investigator of the study
  - National Institutes of Health, National Institute Allergy and Infectious Diseases
  - Associate Director for Special Projects, DCR/NIAID/NIH
  - Former Director, Division of AIDS, NIAID/NIH, Consultant to the Surgeon General in Infectious Diseases

## Key Unmet Need Drivers

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1. Increasing resistance to presently available antifungal therapies
2. Increasing numbers of immunocompromised hosts/patients

# Amphotericin B

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## Value/Strengths of Amphotericin B

- Amphotericin B is the most broad spectrum fungicidal agent
- Gold standard of therapy for the treatment of all fungal infections
- Little to no clinical resistance has developed in over 60 years of use

## Limitations of Amphotericin B

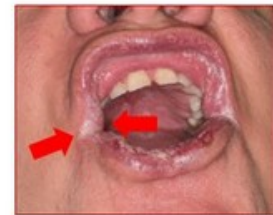
- IV dosing
- Toxicity (renal, hypokalemia) is observed at the same dose level required for efficacy and increases with therapy over 1-2 weeks



# Refractory Mucocutaneous Candidiasis Infection in Hereditary Immunocompromised Patients



- **Autosomal Dominant Hyper IgE Syndrome (HIES or Job's Syndrome)**
  - HIES is a hereditary condition resulting in a weak immune system, involving STAT3 gene and resulting in IL-17 and IL-18 signaling deficiencies
  - **Typical features:** eczema, high serum IgE levels and characteristic facial and skeletal abnormalities
  - **Highly susceptible to micro-organisms that colonize human bodies but seldom cause disease in healthy people, *Candida* (mucocutaneous candidiasis), recurrent *Staphylococcus aureus* and *Pseudomonas* infections**
- **Refractory Mucocutaneous Candidiasis Infection**
  - Persistent superficial infections of the skin, mucous membranes, and nails with *Candida* organisms
  - Limited treatment options due to resistance and toxicity associated with prolonged use of currently approved anti-fungal therapies
  - Inadequate response to standard amphotericin B "swish-and-swallow"



*Because of the very weak immune system, the anti-infective medication has to do almost the entire job on its own, with little help from the patient's immune system*



## Patients in Study Demonstrated Significant Resistance, Except to Amphotericin B



**Antifungal Agent Susceptibilities: Source Mouth**

Antifungal	Patient 01		Patient 02	
	MIC (mcg/mL)	Interpretation	MIC (mcg/mL)	Interpretation
Amphotericin B	1	D1	1	D1
Anidulafungin	0.5	I	<=0.015	S
Caspofungin	2	R	0.03	S
Fluconazole	128	R	32	R
Flucytosine	2	D1	0.06	D1
Itraconazole	NA	NA	1	D1
Micafungin	0.5	I	0.015	S
Posaconazole	2	D1	2	D1
Voriconazole	2	R	1	R

S=susceptible; I=intermediate; R=resistant; D1=there are no standardized susceptibility testing breakpoints for this drug

# MAT2203 Phase 2a Study Protocol



- Open-label, dose-titration trial of MAT2203 (oral cochleate amphotericin B)
- Evaluate up to 16 patients to determine the efficacy, safety, tolerability and pharmacokinetics of MAT2203 in treating recurring or refractory mucocutaneous candidiasis infections
- **Subjects:** hereditary immuno-deficiency patients with refractory candida mucocutaneous infections – most patients will be infected with azole resistant candida

## • Study Design:



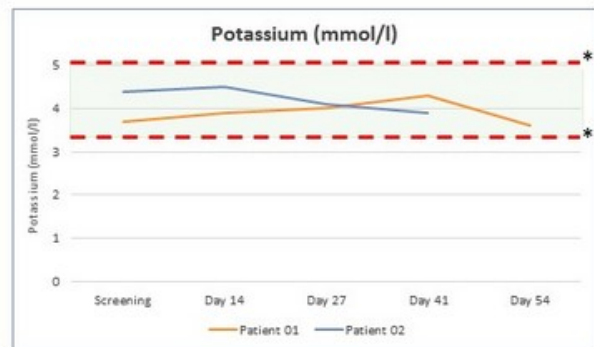
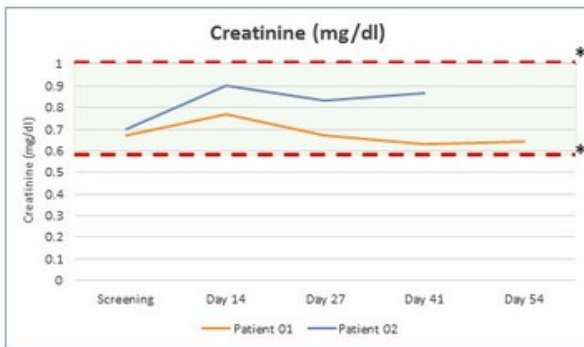
## Interim Data - Safety Highlights

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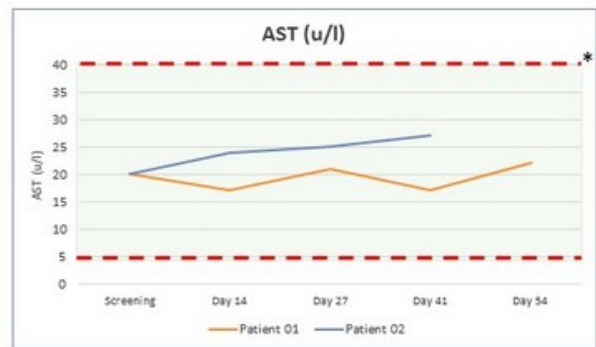
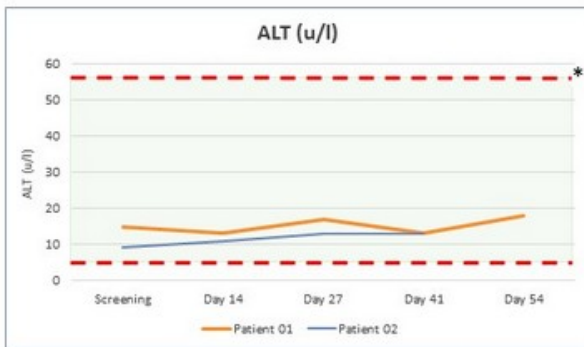
- Oral treatment with MAT2203 for up to 54 days was well tolerated
- No serious adverse events reported
- Reported adverse events were mostly mild in severity and unrelated to MAT2203
- No signs of nephrotoxicity, hypokalemia or hepatotoxicity (measured by ALT and AST)

# Renal Safety Laboratory Parameters Over 8 Weeks



Indicators of Kidney Toxicity Remained Within Normal Limits Throughout 6-8 Week Treatment Period

# Hepatic Safety Laboratory Parameters Over 8 Weeks



Indicators of Liver Toxicity Remained Within Normal Limits Throughout 6-8 Week Treatment Period

# Safety Summary - No Serious Adverse Events Reported



Incidence of Possible, Probably, or Definitely Related Treatment-Emergent Adverse Events by System Organ Class and Preferred Term				
System Organ Class	MedDRA PT	Relationship	Grade	CAMB
				N (%)
Any subject with an AE	Any			2 (100)
Metabolism/nutrition disorders	Any			2 (100)
	Decreased appetite	Possible	1	1 (50)
	Hyponatremia	Possible	1	1 (50)
Investigations	Any			2 (100)
	Blood bicarbonate abnormal	Possible	1	1 (50)
Gastrointestinal disorders	Any			1 (50)
	Nausea	Possible	2	1 (50)
	Vomiting	Possible	2	1 (50)
Nervous system disorders	Any			1 (50)
	Dizziness	Possible	1	1 (50)
Skin and subcutaneous disorders	Any			1 (50)
	Hyperhidrosis	Possible	1	1 (50)

Overall Incidence of Treatment-Emergent Adverse Events	
	CAMB N (%)
Any TEAE	2 (100)
Grade 1	2 (100)
Grade 2	2 (100)
Grade 3	1 (50)*
Grade 4	0 (0)
Grade 5	0 (0)
Common Terminology Criteria for Adverse Events	
Grade 1 = mild	
Grade 2 = moderate	
Grade 3 = severe or medically significant	
Grade 4 = life threatening	
Grade 5 = death related to AE	
*left axilla abscess (unrelated)	

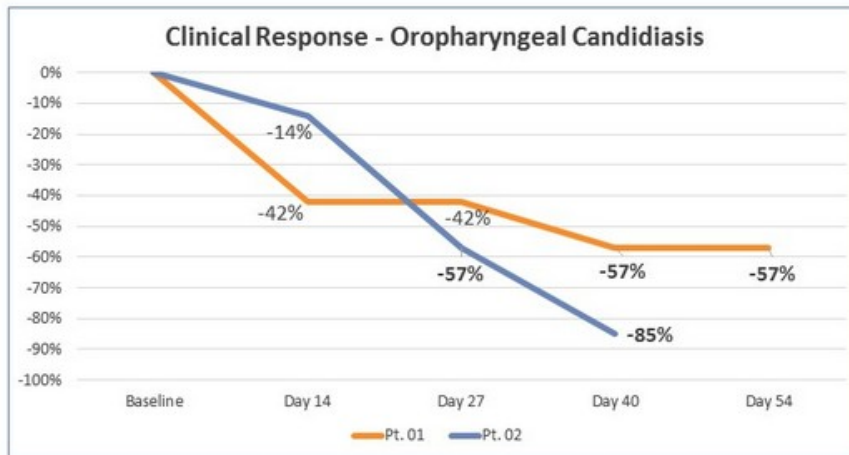
## Interim Data - Efficacy Highlights

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- Two out of two patients achieved  $\geq 50\%$  subjective and objective clinical response
  - Both patients reported improved quality of life, e.g. able to eat a greater variety of foods, including those that are acidic and spicy
- Two out of two patients achieved objective responses, verifying the subjective responses
  - Both patients experienced improvements in fungal culture response
  - Both patients mucocutaneous lesions improved: less inflammation, less pain on scrapping of the lesions for culture

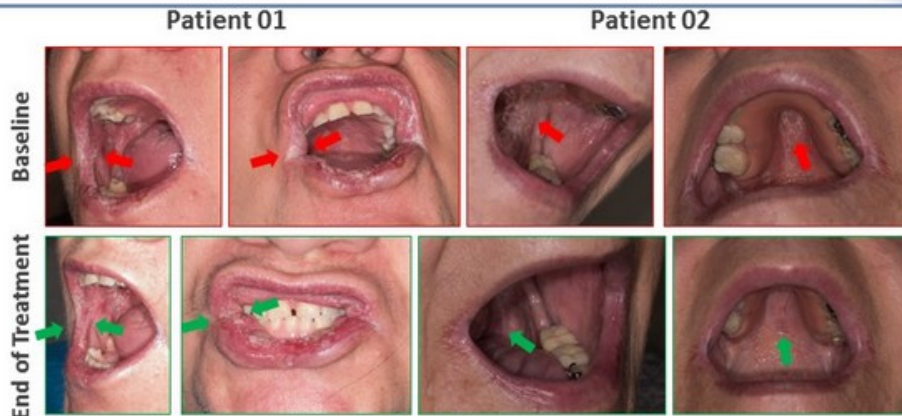
# Demonstrated a Meaningful Clinical Response



**Both Patients Met Primary Endpoint ( $\geq 50$  Clinical Response) After 14 Days of Treatment at Efficacious Dosage**

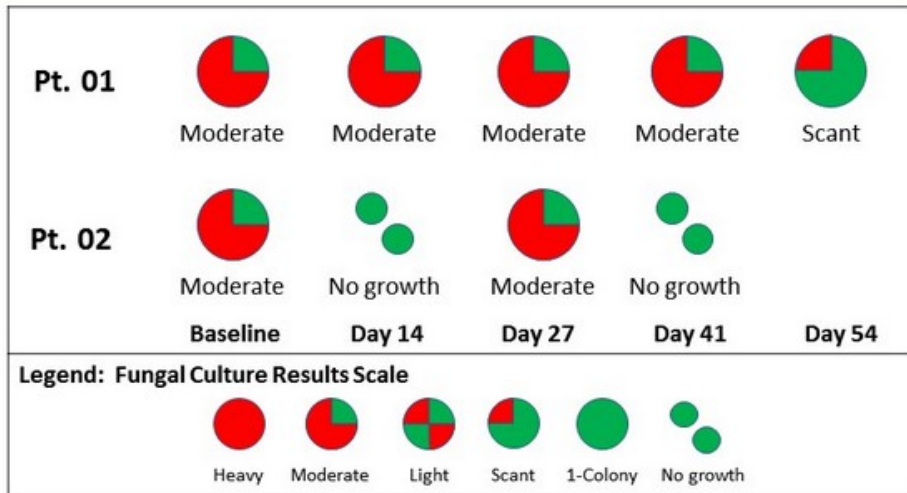


## Patient Exam / Patient Quality of Life



- Patients reported improved quality of life, e.g. as able to eat a greater variety of foods, including those that are acidic and spicy
- Both patients reported less pain

# Fungal Culture Response



## Interim Data Study Conclusion

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- Two patients with AD-HIES or Job's Syndrome with long-standing azole resistant mucocutaneous candidiasis responded clinically to oral treatment with MAT2203
- Oral treatment with MAT2203 for up to 54 days was well tolerated
  - Reported adverse events were mostly mild in severity and unrelated to MAT2203
  - There were no serious adverse events reported
- There were no signs of nephrotoxicity, hypokalemia or hepatotoxicity after oral dosing for 54 days in Patient 01 and 40 days in Patient 02
- Both patients elected to enroll in the long-term extension study

## Clinical Unmet Needs

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- Increasing resistance to presently available antifungal therapies
- Increasing number of patients being rendered immunocompromised by advancements in medicine
  - NIH is in the vanguard of studying immunocompromised patients, the number of which is expected to increase due to the growing use of immuno-compromising drugs for transplants, cancer chemotherapies, and autoimmune diseases
- Since antifungal therapy usually requires prolonged administration, there is a need for an oral, safe and effective antifungal therapy, that can be dosed conveniently over time
- An effective and non-toxic oral amphotericin B could address these unmet needs

# MAT2203 Development Program and Next Steps

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- Company takeaways
  - Response results likely predictive of study outcome
  - Safe long-term use supports development strategy towards preventative treatment
- Second Phase 2 – next data readout: vulvovaginal candidiasis (VVC) – key objectives
  - With oral delivery, demonstrate safety and efficacy comparable to fluconazole (gold standard for the treatment of primary/uncomplicated VVC)
  - Expecting data from VVC before end of June
- Interim results from this study are significant steps toward:
  - Establishing POC for the MAT2203 product
  - Providing validation of technology platform
  - Strengthening our position to also evaluate range of fungal infections, e.g. aspergillosis, coccidiomycosis, cryptococcosis, histoplasmosis, blastomycosis, molds
  - Strengthening our position to impact and change treatment paradigms

# Prevention of Invasive Fungal Infections (IFI) Represents a Significant Market Opportunity



## IFI Prophylaxis:

US Prevalence of Hematologic Malignancies is Approximately:

**340,000**

(111,000 acute forms of leukemia) + ~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

Significant savings in cost of treatment of IFI in high cost ICU or similar hospital environment, justifying economics of prevention



## IFI Treatment:

Limited population annually in US:

**46,000 candidiasis + 5,000 aspergillosis cases**  
(>90% of IFI)

Treatment period limited:

typically  
**1-3 WEEKS**  
depending on patient condition and improvement

**40-90%** mortality risk

Significant morbidity and mortality rate in patients with IFI; mortality risk 40%-90%, depending on fungal species

Significant cost of treatment for IFI, adding **~\$50,000** per IFI case in 2016 dollars



## MAT2203: IFI Prevention is a Significant Value Driver

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- QIPD and Fast Track designations granted by FDA for MAT2203 - “Prevention of invasive fungal infections (IFI) due to immunosuppressive therapy”
- Represents significant unmet clinical need - very few antifungals are approved for the preventative use in patients on immunosuppressive therapy
- Amphotericin B (currently only available for IV infusion) is not liver-metabolized and has very few drug-drug interactions with cancer/transplant therapies
- Encochleated amphotericin B (MAT2203) is designed to significantly reduce toxicities associated with the amphotericin B molecule, while making the compound absorbable in the body by convenient oral administration



# MATINAS



## BIOPHARMA

Transforming the Way Potent Medicines  
for Infectious Diseases are Designed

*MAT2203 - Interim Data from NIH  
Mucocutaneous Candidiasis Phase 2 Study*

NYSE MKT: MTNB

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