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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 10, 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.

Matinas BioPharma Holdings, Inc. (the "Company") intends to use a slide presentation in connection with a conference to take place on Thursday, August 10, 2017 and thereafter at various conferences and 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" 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.

All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned 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.

(d)	<u>Exhibit No.</u>	<u>Description.</u>
	99.1	Slide Presentation, dated August 10, 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: August 10, 2017

By: /s/ Roelof Rongen

\_\_\_\_\_  
Name: Roelof Rongen

Title: Chief Executive Officer

# MATINAS



Transforming the Way Potent Medicines  
for Infectious Diseases are Designed

Canaccord Genuity 37<sup>th</sup> Annual Growth Conference  
*Jerrone D. Jabbour, Co-founder and President*

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.*

## Overview

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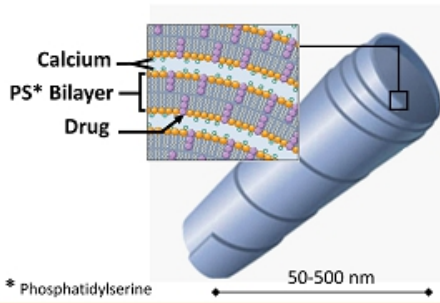
- Clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications
- Flagship product, MAT2203 – orally-administered, encochleated amphotericin B, a broad spectrum fungicidal agent preparing to enter Phase 3
  - Commencing tolerability/PK study in Q4 2017 in leukemia patients, with data expected in mid-2018
  - Engaging FDA Q4 2017 with the goal to enter Phase 3 registration trial in prevention of invasive fungal infections (IFI) in patients with Acute Lymphoblastic Leukemia (ALL) as quickly as possible
- MAT2501 – orally-administered, encochleated amikacin, a broad spectrum aminoglycoside antibiotic agent – initially targeting NTM indication
  - Phase 1 multiple ascending dose PK study to commence Q4 2017
- Strategic opportunities leveraging cochleate technology to improve therapeutic profile of drugs for potential partners

# Cochleate Technology Enables Targeted Oral Delivery of Potent Medicines

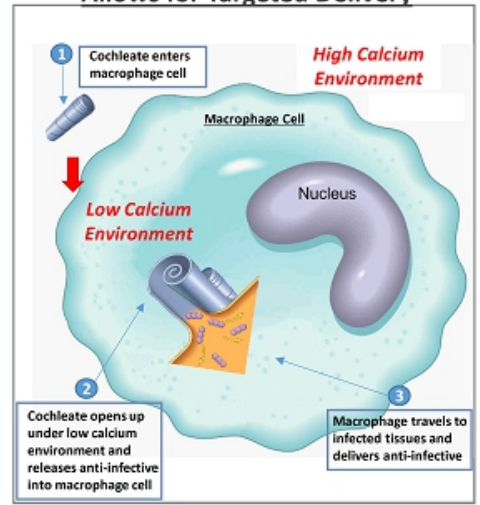


## Platform Drug Delivery Technology

- Reduces toxicity by containing drug inside particle
- Size and surface features facilitate **targeted delivery**
- Enables oral administration



## Allows for Targeted Delivery





### › Broad Spectrum Fungicidal

- Amphotericin B is perhaps the broadest spectrum antifungal agent
- Designated as **QIDP** with **Fast Track Status** for treatment of aspergillus, invasive candidiasis and prevention of invasive fungal infections

### › Few Drug–Drug Interactions

- 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 oral bioavailability, dramatic reduction in toxicity and targeted delivery



# IFI Prevention Represents a Significant Market Opportunity



## IFI Prevention:

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



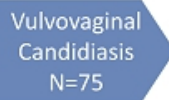


## Phase 2 Studies

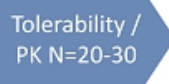


### Mucocutaneous Candidiasis, up to N=16

- ✓ Positive interim data reported
- ✓ Demonstrated safe and efficacious long-term use of MAT2203



- ✓ Study completed
- ✓ Achieved primary endpoint
- ✓ Safe and well tolerated
- ✓ Demonstrated efficacy through systemic absorption and dose response



- Tolerability/PK/other clinical factors in acute leukemia patients to commence Q1 2018

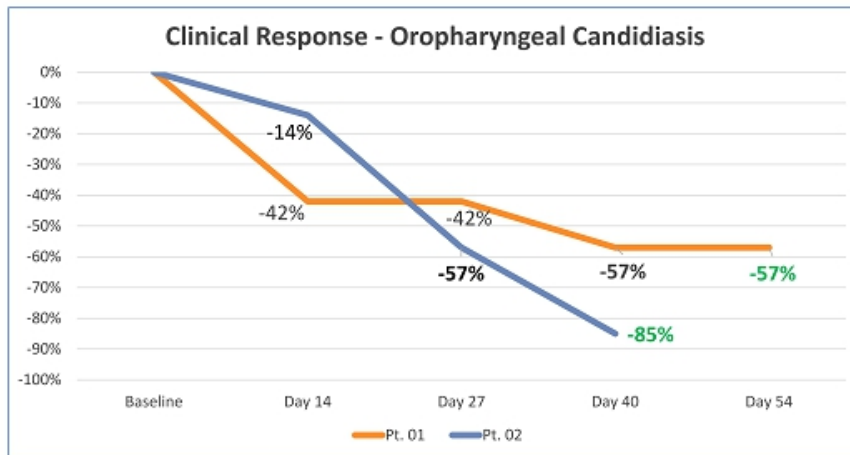
## MAT2203 – Interim Data from NIH Mucocutaneous Candidiasis Phase 2 Study

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- Two out of two patients met the primary endpoint in achieving  $\geq 50\%$  clinical response
- Patients reported meaningful Quality of Life improvements
  - Able to eat a greater variety of foods, including those that are acidic and spicy
  - Reported less pain
- 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
- IRB-approved two separate six-month extensions; first two patients elected to enroll and both have now been under treatment for more than eight months

# MAT2203 Demonstrated a Meaningful Clinical Response

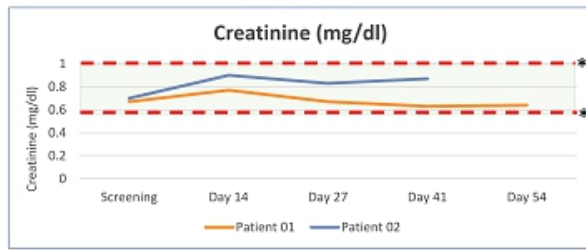


Both Patients Met Primary Endpoint ( $\geq 50$  Clinical Response)  
After 14 Days of Treatment at Efficacious Dosage

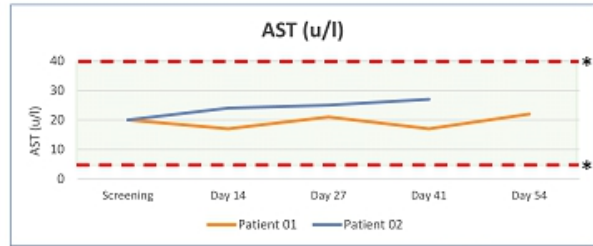
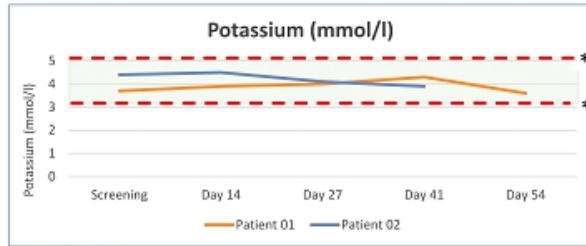
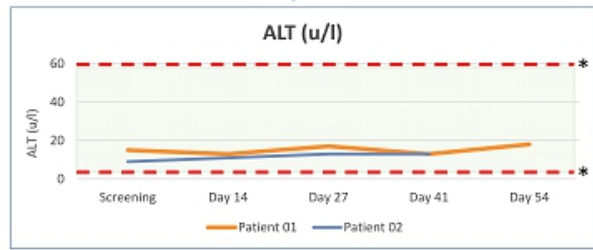
# Indicators of Renal and Hepatic Toxicity Remained Within Normal Limits Throughout Treatment Period in NIH Study



## Renal



## Hepatic



# NIH Study 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)	

## Takeaways from Vulvovaginal Candidiasis (VVC) Phase 2 Study

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- VVC study chosen to further establish the safety and tolerability profile of MAT2203 while demonstrating efficacy through a mechanism involving systemic absorption
- VVC provided increased patient exposure to expedite path toward a pivotal registration trial
- Study of MAT2203 in patients with primary VVC infections:
  - Substantial reduction of severity attributes (~ 80% reduction over 12 days)
  - Clinical cure rates >50% with dose-response observed for 400mg versus 200mg MAT2203 dose

# NIH and VVC Studies Significantly Strengthen MAT2203 Human Safety and PK Database



- **Current Database:**

	<u>Safety</u>	<u>24-hr PK in Serum</u>	<u>Other PK</u>
Single Dose	36 patients	36 patients	none
<b>Multiple Dose</b>	<b>93* patients</b>	<b>21 patients</b>	<b>70** patients</b>

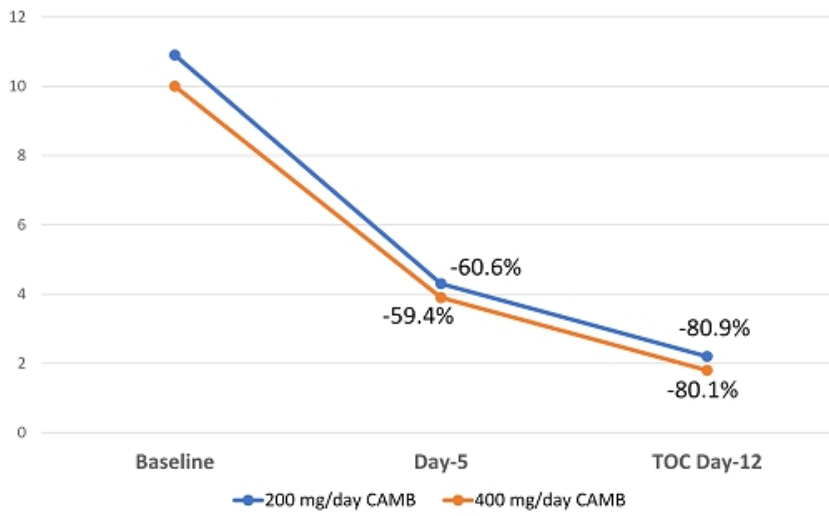
- In the VVC study, MAT2203 impact on liver and kidney function in 91 patients exposed to MAT2203
  - MAT2203 liver enzyme elevation in one patient was due to naproxen use, not an AE for MAT2203
  - One patient had a >50% increase in creatinine, however, remained within normal value range
- In the NIH-study, both patients' kidney and liver function have been within normal ranges for more than six months
  - During the study, both patients remained within normal value ranges at 800mg/day and 400mg/day dosing for 8 and 6 weeks respectively
  - Kidney and liver function have maintained well in extension study, now for more than 6 months



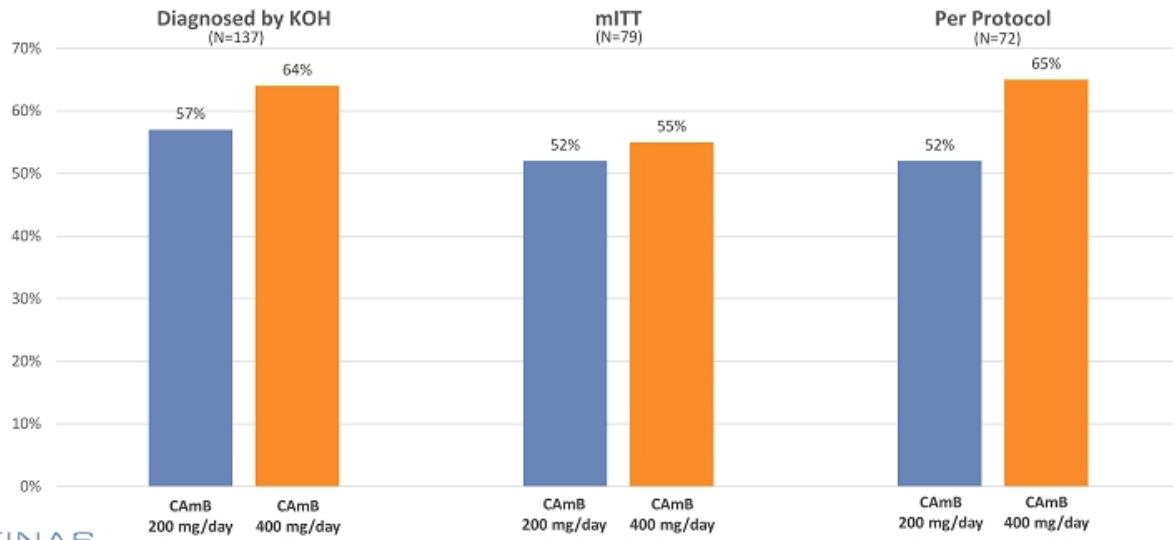
# Substantial Reductions of Mean Composite Clinical Score in Both MAT2203 Treatment Arms



Mean Composite Clinical Score Over Time in VVC Study (mITT population)



# Dose-Response Observed with MAT2203 in Phase 2 VVC Study: Clinical Cure Rates at Day 12 TOC-visit



## Final Element of Phase 2 Program Toward IFI Prevention



### Tolerability/PK in Acute Leukemia - Expected to Commence Q1 2018

- Patients: Diagnosed with ALL or AML, entering first induction treatment or subsequent chemotherapy and expected to have preexisting or chemotherapy induced neutropenia (N=30)
- Primary Objective: To establish maximum tolerable dose in patients with acute leukemia and treat for the duration of the neutropenic period (up to 90 days)
- Secondary Objectives:
  - To evaluate safety and multiple-dose PK of CAmb after oral administration
  - To evaluate absence or presence of breakthrough fungal infection or need for treatment with other systemic antifungal
  - Assess surrogate efficacy markers IFI risk
- Open-Label



## Phase 3 Studies

### IFI Prevention

Efficacy & safety in patients treated with chemotherapy for Acute Lymphoblastic Leukemia

### Pivotal Phase 3 Study

- N = 400-500 patients
- Double-blind control group
- Primary Endpoint: Incidence of IFI
- Secondary Endpoint: Safety

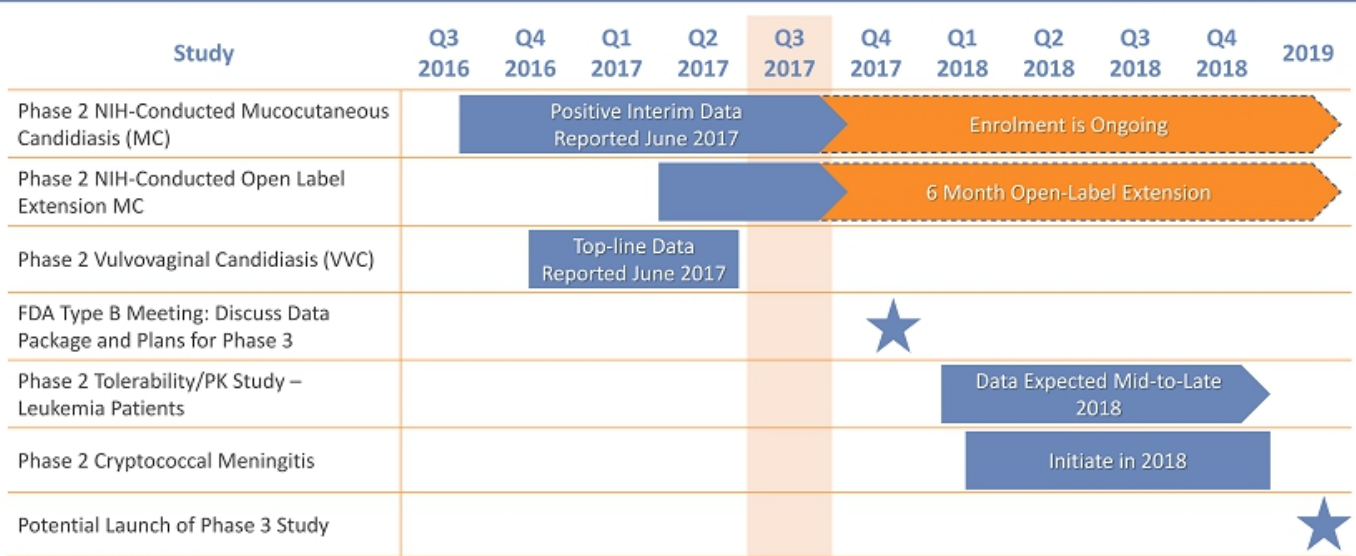
### IFI Treatment

Efficacy & safety in patients with:

- Cryptococcal Meningitis
- Candidiasis
- Aspergillosis

Phase 2 study in cryptococcal meningitis in partnership with University of Minnesota to commence H1 2018

# MAT2203 Development Roadmap





### › **Broad Spectrum Aminoglycoside**

- Designated as **QIDP** and received **Orphan Drug Designation** for treatment of non-tuberculous mycobacterium (NTM)
- Positive Phase 1 reported March 2017

### › **Potential Additional High-Need Indications**

- Cystic fibrosis associated lung infections
- Drug-resistant urinary track infections
- Pneumonia in Hospital/ICU or long-term care

### › **Cochleate Benefits**

- Potential to be first orally administered amikacin without toxicity or side effects as seen with IV

## MAT2501 Targeting NTM and Drug-Resistant Gram-Negative Bacterial Infections

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- MAT2501 formulates the broad-spectrum aminoglycoside amikacin into our lipid-crystal nano-particle cochleate technology
- Active IND for the treatment of non-tuberculous mycobacterium (NTM) infections (environmentally transmitted organisms)
  - Chronic lung infection with similar course of progression as tuberculosis
  - Approximately 50,000 to 90,000 patients in the US; 40% refractory to treatment
  - IV amikacin used as add-on therapy in refractory patients
- Demonstrated efficacy in preclinical models of disseminated NTM and pulmonary NTM infections, as well as biofilm models of NTM
- Company is exploring treatment of more acute drug-resistant gram-negative infections

## MAT2501 Positive Phase 1 Results

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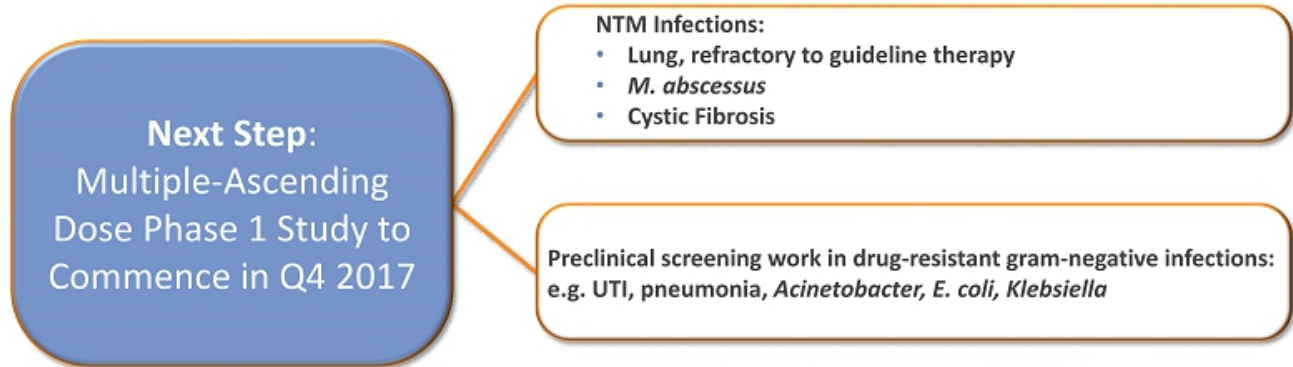
- Single-ascending dose study in healthy volunteers (200, 400, 800mg)
- Evaluated drug kinetics (blood, urine, feces), tolerability and acute safety
- Peak blood levels were an area of focus; IV amikacin is known to generate high peak levels with potential kidney- and neuro-toxic effects (hearing loss), therefore safety limits exist for IV amikacin (<10 µg/ml before redosing, peak levels not to exceed 35 µg/ml)
  - Single-dose MAT2501 amikacin peak levels did not exceed 0.1 µg/ml, leaving more than 100x safety margin; our thesis: this is supportive of meeting this parameter under multi-dosing
  - Other kinetic data indicating significant absorption and distribution: e.g. single-dose peak levels exceeding 3 µg/ml in urine (30-40x blood level), >0.2 µg/ml on Day 2 (>2x peak plasma)
- No serious adverse events (AE) reported
  - Most AEs were of mild and gastro-intestinal nature
  - These AEs were similar to those seen with MAT2203; not believed to be of antibiotic nature
- Tolerability data appear to support 400mg BID dosing; to be confirmed in multiple-ascending dose Phase 1 study (evaluate: kinetics, safety, tolerability)



# MAT2501 Has High Differentiation Potential in a Rapidly Evolving Anti-Infective Arena



## MAT2501 HAS THE POTENTIAL TO BE THE FIRST ORAL AMINOGLYCOSIDE



**Potential to bring a new class of antibiotics into the community setting, while reducing hospitalization costs**

# MAT2501 Development Roadmap



Study	Q4 2016	Q1 2017	Q2 2017	Q3 2017	Q4 2017	Q1 2018	Q2 2018	Q3 2018	Q4 2018
Phase 1 Single-Ascending Dose		Positive Topline Results May 2017							
Phase 1 Multiple-Ascending Dose PK/Tolerability						Results Expected Q2 2018			
Phase 2 Non-Tuberculous Mycobacterium								Initiate H2 2018	

# Management Team and Board of Directors



## Strong Development and Commercialization Track Record

### Management

<p><b>Roelof Rongen</b> Co-Founder, Chief Executive Officer, Director</p>	 
<p><b>Jerome D. Jabbour, JD</b> Co-Founder, President</p>	 
<p><b>Raphael J. Mannino, PhD</b> Chief Scientific Officer</p>	 
<p><b>Dominick DiPaolo</b> Senior Vice President of Quality and Regulatory Compliance</p>	 
<p><b>Douglas F. Kling</b> SVP, Clinical Development and Project Management</p>	 
<p><b>Abdel Fawzy, PhD</b> Co-Founder, EVP, Pharmaceutical &amp; Supply Chain Development</p>	 
<p><b>Gary Gaglione, CPA</b> VP, Finance, Acting-CFO</p>	 

### Board of Directors

<p><b>Herbert Conrad</b> Chairman of the Board</p>	 
<p><b>Roelof Rongen</b> Co-Founder, Chief Executive Officer, Director</p>	 
<p><b>James S. Scibetta</b> Director</p>	
<p><b>Eric J. Ende, MBA, MD</b> Director</p>	 
<p><b>Stefano Ferrari</b> Director</p>	
<p><b>Adam Stern</b> Director</p>	

# Prominent Clinical Advisors



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## J. Carl Craft, MD - Chair

- Former Chief Scientific Officer for Medicines for Malaria Venture (MMV)
- Former Venture Head at Abbott Laboratories Anti-Infective Development Group



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## Prof. Oliver Cornely, MD, FACP, FIDSA

- Head of Translational Platform, Principal Investigator, Clinical Trials Center Cologne
- President of the European Confederation of Medical Mycology



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## Dimitrios P. Kontoyiannis, M.D., M.S., Sc.D., PhD (Hon), FACP, FIDSA, FECMM

- The Texas 4000 Distinguished Endowed Professor For Cancer Research, Department of Infectious Diseases, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX
- Frances King Black Endowed Professor, Department of Infectious Diseases, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX
- Deputy Head Research, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX



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## Peter G. Pappas, MD, FACP

- Professor of Medicine in the Division of Infectious Diseases and Tinsley Harrison Clinical Scholar at the University of Alabama in Birmingham
- Principal Investigator for the Mycoses Study Group



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## David S. Perlin, PhD

- Internationally renowned expert in infectious disease, with primary expertise in fungal infections and mechanisms of antifungal drug resistance
- Executive Director of the Public Health Research Institute (PHRI)
- Professor of Microbiology, Biochemistry and Molecular Genetics at New Jersey Medical School



## Financial Profile

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NYSE MKT	MTNB
Share Price	\$1.43
Market Cap	~\$130 million
3M Avg. Daily Vol.	~620,000
Shares Outstanding	~91 million

*Current cash on hand as well as cash potentially available through Controlled Equity Offering Sales Agreement will be sufficient to meet operating obligations for at least a year and if fully utilized would finance the Company's operations through 2019*

## A Compelling Investment Opportunity

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- ✓ Data generated to date across all studies validates the delivery mechanism of action of drug delivery platform and warrants advancing MAT2203 into a Phase 3 registration study
- ✓ Company engaging with FDA in Q4 2017 with the goal of moving MAT2203 into Phase 3 as quickly as possible
- ✓ MAT2203 is poised as potentially game-changing product to become the gold standard and drug of choice to prevent and treat invasive fungal infections.
- ✓ MAT2501 is potentially first ever oral aminoglycoside with potential to be a solution for a variety of chronic and acute bacterial infections, including gram-negative bacterial infections
- ✓ The next six, 12 and 18 months will be full of value-creating milestones that we believe will have the potential to drive significant value in Matinas

# MATINAS



Transforming the Way Potent Medicines  
for Infectious Diseases are Designed

Corporate Presentation  
August 2017

NYSE MKT: MTNB

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