

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): September 9, 2015

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

Delaware
(State or other jurisdiction
of incorporation)

(Commission
File Number)

46-3011414
(IRS Employer
ID Number)

1545 Route 206 South, Suite 302
Bedminster, New Jersey
(Address of principal executive offices)

07921
(Zip Code)

Registrant's telephone number, including area code: (908) 443-1860

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-

Item 7.01. Regulation FD Disclosure.

Matinas BioPharma Holdings, Inc. (the “Company”) intends to use the presentation included as Exhibit 99.1 to this report in connection with an investor conference.

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.

Item 9.01. Financial Statements and Exhibits

Exhibit	Description
99.1	Corporate Presentation, dated September 9, 2015

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MATINAS BIOPHARMA HOLDINGS, INC.

Date: September 9, 2015

/s/ Roelof Rongen

Roelof Rongen, President and Chief Executive Officer



Corporate Presentation
September 2015

OTCQB: MTNB

www.matinasbiopharma.com

A banner image featuring a blue and orange background. On the left, there is a chemical structure diagram. On the right, there is a close-up of a microscope lens. The text "TRANSFORMING THE WAY POTENT MEDICINES FOR INFECTIOUS DISEASES ARE DESIGNED" is centered over the image.

TRANSFORMING THE WAY POTENT MEDICINES
FOR INFECTIOUS DISEASES ARE DESIGNED

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 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.

MTNB Overview

Clinical-stage biopharmaceutical company focused on identifying and developing safe and effective antifungal and anti-bacterial therapeutics for the treatment of serious and life-threatening infections

- Proprietary, NIH-supported, lipid-crystal nano-encapsulation technology
- Immediate focus on taking powerful, but sparingly used, anti-fungal and anti-bacterial drugs and increasing safety and potency
- MAT2203, an oral formulation of Amphotericin B with key differentiating data, for serious fungal infections, scheduled to report Phase 2a results in 2016
 - QIDP and Fast Track designations granted August 2015; positioning for Orphan Drug and Breakthrough Therapy
- MAT2501, an oral formulation of Amikacin for severe hospital-acquired bacterial infections scheduled for IND filing in 4Q 2015
- Technology has broad utility with potential in numerous Orphan Drug indications
- \$10 million financing completed Q2 2015
- Experienced management team and board with track record of building companies



Lead Therapeutic Pipeline

	Discovery	IND Preparation	Phase 2 Development	Phase 3 Development
--	-----------	-----------------	---------------------	---------------------

Anti-Infective Development Programs

MAT2203

Fungal Infections



MAT2501

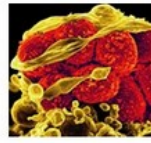
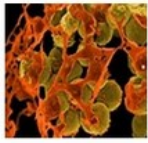
Gram-Negative Bacterial Infections



Metabolic/Cardiovascular Development Programs

Actively seeking partnering opportunities

Antimicrobial Resistance is a Global Threat



“CDC sets threat levels for drug-resistant 'superbugs'”



“Superbugs to kill 'more than cancer' by 2050”



“WHO Calls for Action on Superbugs”



“CDC sounds alarm on deadly, untreatable superbugs”

Drug-resistance threat has led to strong government incentives and specific NIH support of MTNB technology

Anti-Infective Development Incentives



- Congressional initiatives:
 - GAIN: extra 5-year exclusivity (passed)
 - ADAPT: accelerated antibiotic development pathway (pending)
 - DISARM: improved reimbursement and pricing for antibiotics (pending)
 - Additional budgetary funding of \$1.2 billion on annual basis for anti-infective development

NIH Stamp of Approval



National Institute of
Allergy and
Infectious Diseases

- NIH SBIR grants and research contracts for development of:
 - Amphotericin B
 - Gram-negative Aminoglycoside antibiotics
 - Amikacin
 - Capreomycin

Limitations of Current Anti-Infective Therapy

THE PROBLEM

- Insufficient coverage of Multidrug-resistant (MDR) fungal and bacterial infections
- Significant safety and tolerability concerns
- Lack of oral dosage forms to permit transition therapy

THE DESIRED SOLUTION

- Enormous unmet medical need for first-line treatments with the following characteristics:
 - Potency and effectiveness against broad spectrum of fungal and bacterial infections in immunocompromised patients
 - Capability of use as monotherapy in majority of hospital patients with multidrug resistant infections
 - Convenient dosing regimen
 - Favorable safety and tolerability profile
 - Availability in both IV and oral dosage forms

Cochleate Technology Offers Significant Clinical Improvement Potential

Development Work To Date

- Efficacy demonstrated in-vivo (numerous animal studies)
- Safety and tolerability demonstrated in Phase 1 human study

Protects Organs

- Cochleates act as a shield for the body from toxic drugs, significantly reducing adverse effects

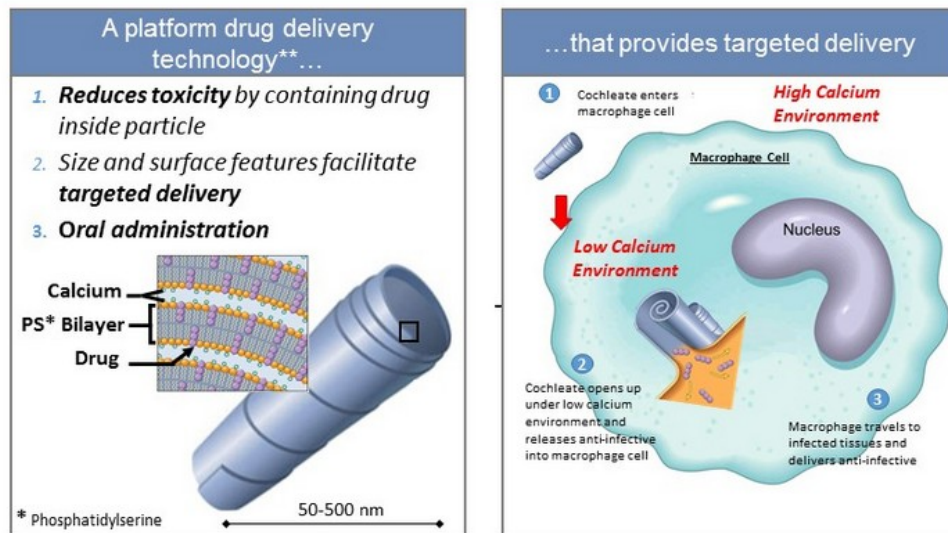
Targeted Delivery

- Cochleates are carried directly to infection sites where payload released, increasing potency

Oral Administration

- Convenience; health economic benefit vs. IV-therapy in hospital

Cochleate Cell Delivery Mitigates the Limitations of Potent IV-Administered Anti-Infectives



** Cochleate Platform patented delivery technology is under exclusive license from Rutgers University

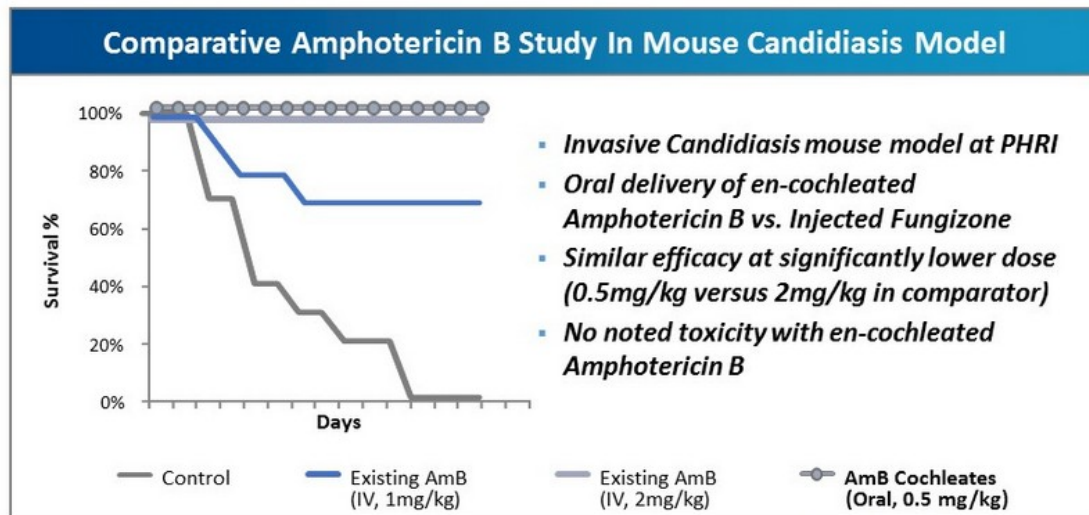
Amphotericin B Delivered in a Lipid-Crystal
Nano-Particle Cochleate Formulation

-- Broad-Spectrum Fungicidal Agent --

MAT2203 Represents Groundbreaking Advancement in Anti-Fungal Treatment

- Amphotericin B is the antifungal of choice for immunocompromised patients
- Pluses: Effective killing-agent (fungicidal), no observed clinical resistance in 50+ years of use.
- Minuses: Significant toxicity, including high risk of liver and kidney damage
- Despite limits on use, global market is ~\$700 million
- Matinas' oral formulation has significant advantages, including significantly improved tissue penetration profile, over current IV-only administration of Amphotericin B
- Demonstrated efficacy and little-to-no kidney toxicity in animal models as compared to current Amphotericin B therapy
- Differentiation supports potential to capture and expand \$700MM global Amphotericin B market
- Granted QIDP and Fast Track designations in August 2015
- Development program to focus on indications with potential for Orphan Drug and Breakthrough Therapy designations
- **MAT2203 commencing Phase 2a with NIH; data expected 2016**

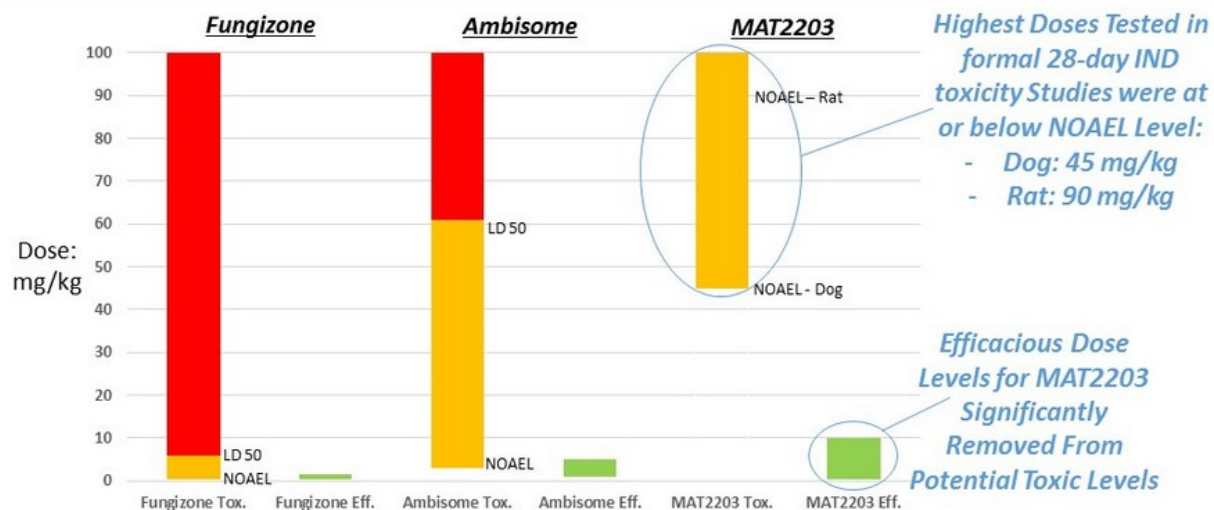
Targeted Therapy – Efficacy at a Lower Dose



Source: PHRI/Rutgers Studies in MAT2203 IND

MATINAS
BIOPHARMA

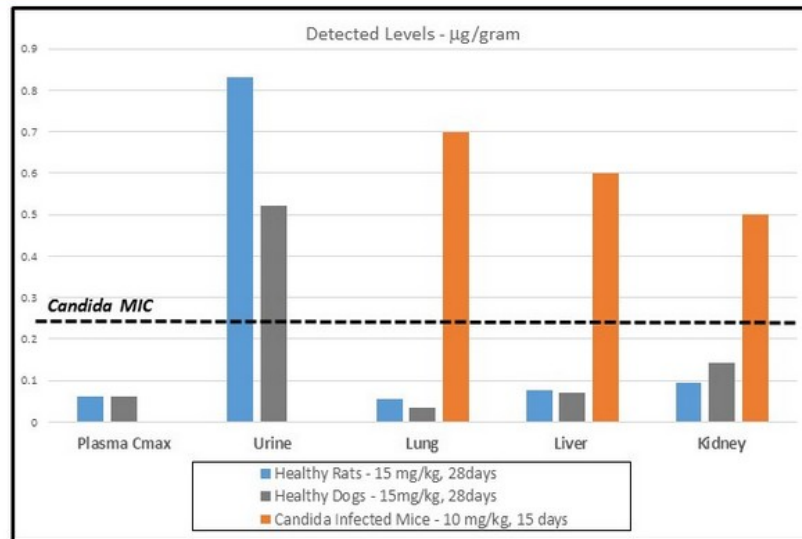
MAT2203: Significantly Lower Degree of Toxicity



Source: Monographs Fungizone and Ambisome, MAT2203 Pre-Clinical Studies

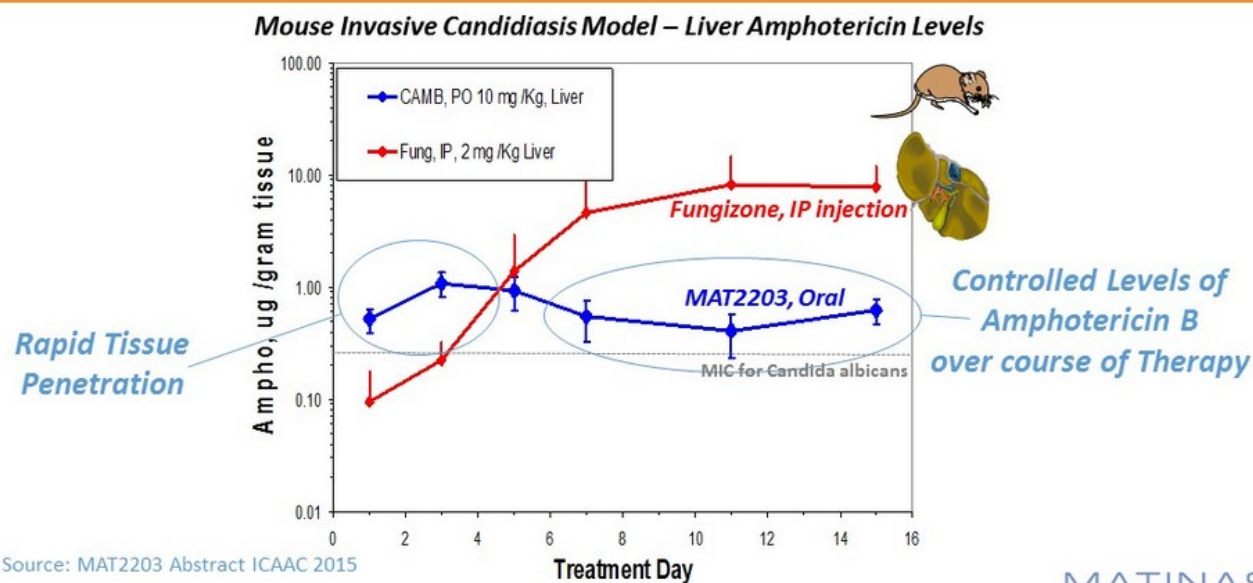
MATINAS
BIOPHARMA

Targeted Therapy: Drug Levels High in Infected Tissues



Source: MAT2203 IND pre-clinical Studies

MAT2203: Significantly Improved Tissue Penetration Profile



MAT2203 – Clinical Development Overview

	Discovery	IND Preparation	Phase 2 Development	Phase 3 Development
--	-----------	-----------------	---------------------	---------------------

MAT2203



- ✓ Successfully completed a range of efficacy animal studies at NIH with C-Amphotericin B
- ✓ Single-Dose Phase 1 study completed with favorable tolerability and no serious adverse events
- ✓ Increased production of C-Amphotericin B to ~800 doses/batch – semi-commercial scale

Next Steps:

- Phase 2a patient treatment protocol under final review in collaboration with NIH/NIAID with study commencing in Q42015 and data expected in 2016
- Engage with FDA on development program post-Phase 2a data

Amikacin Delivered in a Lipid-Crystal Nano-Particle Cochleate Formulation

-- Gram-Negative Aminoglycoside Antibiotic --

The Drug Resistant Antibiotic Market

- Widespread use of antibiotics (\$41 billion worldwide per IMS) has resulted in rapid increase in bacterial infections that are resistant to multiple antibacterial agents
- Gram-negative bacterial infections characterized as #1 unmet medical need by infectious disease specialists
- Effective first-line treatment of serious infections requires use of broad spectrum antibiotics with activity against a broad range of bacteria
- Many strains of bacteria have mutated over time, developing resistance to existing drugs
- According to 2013 CDC report, 2 million people in the U.S. each year acquire serious infections that are resistant to one or more antibiotics

MAT2501 – Development Overview

MAT2501

C-Amikacin (broad spectrum aminoglycoside)

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

Treating severe and hospital-acquired gram-negative bacterial infections

Potential High-need Indications:

- Pulmonary infections – Cystic Fibrosis and Non-Tuberculous Mycobacterium
- Hospital acquired urinary track infections
- Ventilated patients in ICU or long-term care



Cochleate Nanoparticle Delivery has Broad Utility with Potential for Orphan Drug Applications

	Collaborations	<i>In-Vitro</i>	Animal POC	IND-Prep	Human Studies
Amphotericin B	NIH / PHRI				
Amikacin	NIH				
Vaccines					
Ibuprofen					
Atovaquone	NIH				
Capreomycin	NIH				
Meropenem	NIH				
Anti-virals	NIH				
Omega-3 FA					

Intellectual Property

Cochleate Lipid Delivery Portfolio – Exclusive License from Rutgers University

- 17 issued and > 20 pending U.S. and foreign patents
 - Company controls prosecution
 - 10 patents issued within past 3 years; Patent protection currently extends through 2027
 - Pending applications can extend patent protection through 2033
- Potential for significant regulatory exclusivity (Orphan; GAIN)

Management Team

Strong development and commercialization track record

Roelof Rongen
Co-Founder, Chief Executive Officer, Director



Jerome D. Jabbour, JD
Co-Founder, Chief Business Officer & General Counsel



Raphael J. Mannino
Chief Technical Officer



George Bobotas, PhD
Co-Founder, Chief Scientific Officer



Abdel Fawzy, PhD
Co-Founder, EVP, Pharmaceutical & Supply Chain Development



Gary Gaglione, CPA
Chief Financial Officer, Vice President of Finance



Douglas F. Kling
SVP, Clinical Development and Project Management



Board of Directors

Herbert Conrad
Chairman of the Board



James Scietta
Director



Adam Stern
Director

STERNAEGIS VENTURES



Stefano Ferrari
Director



Building Prominent Scientific Advisory Board

Anti-Infectives

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

David S. Perlin, Ph.D.






- 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

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

Expecting to add additional preeminent anti-fungal/anti-bacterial KOL's in near term

Comps indicate that these new anti-infective programs should bring substantial value appreciation potential to MTNB

MTNB Programs	COMPS		
MAT2203 C-Amphotericin B <i>Fungal Infections</i> - Entering Phase 2a	 ~\$200 million [CDTX] Novel Echinocandin <i>Fungal Infections</i> - Pre-IND Stage	 ~\$1.3 billion [BSLN.SW] Isavuconazole <i>Fungal Infections</i> - NDA Approved	 ~\$3.3 billion [ANAC] Tavaborole <i>Topical Anti-Fungal</i> - Approved/Launched
MAT2501 C-Amikacin <i>Gram-Negative Bacterial Infections</i> - IND toxicology stage	 ~\$1.5 billion [INSM] Inhaled Amikacin <i>Lung Infections</i> - Phase 3	ACHAOPEN ~\$120 million [AKAO] Plazomicin <i>MDR Enterobact.</i> - Phase 3	cellceutix ~\$320 million [CTIX] Brilacidin <i>Skin Infections</i> - Phase 2 

Matinas BioPharma – Financial Snapshot

OTCQB

MTNB

Share Price

\$.94

Market Cap

~\$54 million

Shares Outstanding

~57 million

MTNB Investment Highlights

Clinical-stage biopharmaceutical company focused on identifying and developing safe and effective antifungal and anti-bacterial therapeutics for the treatment of serious and life-threatening infections

- Proprietary, NIH-supported lipid-crystal nano-encapsulation technology with true platform potential
- Initial focus on taking powerful, but sparingly used, anti-fungal and anti-bacterial drugs and increasing safety and potency
- MAT2203, an oral formulation of Amphotericin B with key differentiating data, for serious fungal infections, scheduled to report Phase 2a results in 2016
 - QIDP and Fast Track designations granted August 2015; positioning for Orphan Drug and Breakthrough Therapy
- MAT2501, an oral formulation of Amikacin for severe hospital-acquired bacterial infections scheduled for IND filing in 4Q 2015
- \$10 million financing completed Q2 2015
- Experienced management team and board with track record of building companies



Corporate Presentation
September 2015

OTCQB: MTNB

www.matinasbiopharma.com

A banner image featuring a complex chemical structure on the left and a laboratory flask on the right, set against a blue and orange background.

TRANSFORMING THE WAY POTENT MEDICINES
FOR INFECTIOUS DISEASES ARE DESIGNED
