

March 31, 2016



## Matinas BioPharma Reports 2015 Financial Results and Provides Business Update

- *2015 transformative year with focus on developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections*
- *2016 expected to produce confirmatory data for cochleate technology platform*
- *Topline data from Phase 2a clinical trial with MAT2203 (oral encochleated amphotericin B) expected in 2016*
- *Phase 1 clinical trial for MAT2501 (oral encochleated amikacin) expected to commence in 2016*

BEDMINSTER, N.J., March 31, 2016 (GLOBE NEWSWIRE) --[Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections, today announced its financial results for the year ended December 31, 2015.

The Company also provided a corporate overview, including recent clinical and regulatory progress and 2016 development plans related to lead anti-fungal product candidate [MAT2203](#) (orally-administered encochleated amphotericin B) and investigational drug [MAT2501](#) (orally-administered encochleated amikacin) for chronic and acute bacterial infections, including non-tuberculous mycobacteria (NTM) and multidrug-resistant gram negative bacterial infections.

“2015 represented a transformational year for Matinas BioPharma, with the acquisition Aquarius and focus on the advancement of our proprietary, disruptive cochleate lipid-crystal nano-particle delivery technology platform,” said Roelof Rongen, Chief Executive Officer. “The recent regulatory and clinical advancements for our lead programs MAT2203 and MAT2501 bring us another important step closer to providing physicians and patients orally-delivered encochleated drug formulations of two very powerful anti-infective medicines to address a significant unmet medical need with the potential to transform the way potent medicines are delivered and administered.”

### **2015 AND RECENT CORPORATE HIGHLIGHTS**

- Received [Notice of Allowance of a U.S. patent for the Company's novel lipid-crystal nano-particle cochleate formulation technology](#) covering composition, methods, formulation and use of the proprietary and transformational bio-delivery platform, as well as pharmaceutical use claims for MAT2203 and MAT2501;
- Received [Notice of Allowance for a U.S. patent for encochleated siRNA](#) providing a

- pathway to the development of orally administered RNA based therapies;
- Presented key [data on efficacy of orally administered amikacin in a murine lung-biofilm model of \*M. avium\*](#), the most prevalent organism in the causes of NTM;
- Presented key data on the [pharmacokinetics and efficacy of encochleated atovaquone in a murine model of pneumocystis, providing additional evidence for significant tissue penetration with oral administration](#);
- [Appointed Peter G. Pappas, M.D., FACP](#), an internationally recognized expert and thought leader on invasive fungal infections, to the Company's Scientific Advisory Board; and
- [Appointed Raphael J. Mannino, Ph.D.](#), an internationally recognized expert on lipid-based structures and the pioneer of cochleate technology for the formulation and delivery of biologicals and pharmaceuticals, as Senior Vice President and Chief Technology Officer of the Company.

## **ANTI-INFECTIVE DEVELOPMENT PROGRAM ACHIEVEMENTS**

*MAT2203: orally-administered, encochleated amphotericin B, a broad spectrum fungicidal agent, currently in Phase 2a clinical studies for the treatment of refractory mucocutaneous candidiasis*

- Commenced [enrollment in the National Institutes of Health \(NIH\) sponsored Phase 2a open-label, dose-titration study to assess the efficacy, safety, tolerability and pharmacokinetics of MAT2203 in hereditary immuno-deficient patients with a recurrent or chronic mucocutaneous candidiasis infection](#);
- Received Qualified Infectious Disease Product (QIDP) designation with Fast Track status for MAT2203 for both the [treatment of aspergillus](#) and the [treatment of invasive candidiasis](#) from U.S. Food and Drug Administration (FDA); and
- Presented [preclinical data demonstrating orally administered MAT2203 rapidly targets and penetrates tissue infected with invasive candidiasis](#) as compared to the original IV formulation of amphotericin B.

*MAT2501: orally-administered, encochleated amikacin, a broad spectrum aminoglycoside antibiotic agent, with a lead chronic indication for treatment of non-tuberculous mycobacterium (NTM) infections*

- Granted [Orphan Drug designation by the U.S. Food and Drug Administration \(FDA\) for MAT2501](#) for the treatment of non-tuberculous mycobacteria (NTM) infections
- Received FDA clearance to initiate the first [Phase 1 clinical study of MAT2501](#);
- Received [Qualified Infectious Disease Product \(QIDP\) designation from the FDA for MAT2501 for treatment of non-tuberculous mycobacterium \(NTM\) infections](#); and
- Presented [preclinical data showing significant antibacterial activity of orally administered MAT2501 against \*Mycobacterium avium\* and no noted toxicity](#).

"We have made great strides in advancing our anti-infective development programs over the course of 2015 and early 2016," stated Jerome D. Jabbour, President. "Looking ahead we expect the Company to be positioned for continued success in 2016, as we anticipate a data readout for MAT2203 and the launch of an important Phase 1 study to evaluate the pharmacokinetics and safety of MAT2501 in healthy volunteers. We also look forward to identifying and potentially finalizing strategic collaborations with pharmaceutical partners through which we can utilize our innovative delivery platform to improve the clinical profile of

drugs that either may have encountered problems in their own development program or, although approved, could benefit from the improved safety and/or targeted delivery that our platform has been designed to provide.”

### **EXPECTED NEAR-TERM MILESTONES**

- Initiate patient dosing in the MAT2203 Phase 2a study;
- Report topline data from the Phase 2a clinical study of MAT2203 in 2016;
- Engage with the FDA on the clinical development program for MAT2203 and requirements for registration; and
- Commence the initial study in the Phase 1 program for MAT2501 in 2016.

### **Summary of Financial Results for 2015**

For the twelve months ended December 31, 2015, the Company reported a net loss of approximately \$9.1 million, or a net loss share basic and diluted of \$0.18, compared to a net loss of approximately \$10.2 million, or a net loss per share basic and diluted of \$0.32, for the twelve months ended December 31, 2014. The net loss for the year ended December 31, 2015 is attributable to additional expenses related to the acquisition of Aquarius Biotechnologies, the ongoing research and development activities related to the Company's MAT2203 antifungal and MAT2501 antibacterial product candidates, and the clinical development expenses related to the human trials for MAT9001, as well as the costs associated with operating as a public company. The Company ended the year with approximately \$3.2 million of cash and cash equivalents.

### **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 via MAT2203's proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. In a clinical Phase 1a single-dose, double-blind, dose-escalating, pharmacokinetic study of 48 healthy volunteers, oral MAT2203 demonstrated a positive safety and tolerability profile with no serious adverse events reported, including little or no nephrotoxicity as compared to placebo. Enrollment is currently underway for the Phase 2a NIH/NIAID-funded clinical study with MAT2203 in patients with refractory mucocutaneous candidiasis, with results expected during 2016. 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 MAT2501**

MAT2501 is an orally-administered, encochleated formulation of the broad spectrum IV-only aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary, lipid-crystal, nanoparticle delivery technology. Amikacin is currently used to treat different types of chronic and acute bacterial infections, including NTM infections and various multidrug-resistant gram negative bacterial infections. IV-administered amikacin is associated with

major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use. MAT2501 is specifically designed to provide targeted delivery of the potent antibiotic amikacin while providing a significantly improved safety and tolerability profile. In preclinical studies [MAT2501 demonstrated oral bioavailability and targeted delivery of amikacin directly to the site of infection](#) in both pulmonary (lung) and disseminated NTM infections. Matinas recently received [FDA clearance to initiate a Phase 1 clinical study of MAT2501 for the treatment of non-tuberculous mycobacterium infections](#). The [FDA has also designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections](#). The Company intends to initially develop MAT2501 for the treatment of NTM infections and will also explore the development of MAT2501 for the treatment of a variety of multi-drug resistant, gram negative bacterial infections. If approved, we believe MAT2501 would become the first orally bioavailable aminoglycoside and represent a significant improvement over existing therapies from a treatment and health economic perspective.

## **About Matinas BioPharma**

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective broad spectrum therapeutics for the treatment of serious and life-threatening infections. 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 drug candidate is MAT2203, an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent). The Company has an open Investigational New Drug (IND) application for MAT2501, which is an orally-administered, encochleated formulation of amikacin (a broad spectrum aminoglycoside antibiotic agent) for acute bacterial infections, including non-tuberculous mycobacterium (NTM) and multi-drug resistant gram negative bacterial infections. In addition, the Company is exploring development and partnership options for MAT9001, a prescription-only omega-3 fatty acid-based composition under development for hypertriglyceridemia, which has shown superiority versus Vascepa<sup>®</sup> (icosapent ethyl) in reducing serum triglycerides, Total- and Non-HDL-Cholesterol, apolipoproteins and PCSK9 levels.

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

Jenene Thomas

Jenene Thomas Communications, LLC

Phone: +1 (908) 938-1475

Email: [jenene@jenenethomascommunications.com](mailto:jenene@jenenethomascommunications.com)



Source: Matinas BioPharma Holdings, Inc.