

November 10, 2015



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

*- Topline data from Phase 2a clinical trial with MAT2203, oral encochleated amphotericin B, expected in 2016 -*

*- IND for MAT2501, oral encochleated amikacin, expected to be submitted in 4Q'15 -*

BEDMINSTER, N.J., Nov. 10, 2015 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on identifying and developing safe and effective therapeutics for the treatment of serious and life-threatening infections, today announced its financial results for the quarter ended September 30, 2015.

The Company also reviewed the progress of its lead drug candidate MAT2203, an orally-administered, encochleated formulation of the broad spectrum fungicidal medication amphotericin B, and the development plans for MAT2501, an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic amikacin to treat gram-negative bacterial infections and other intracellular bacterial infections.

“2015 has been a truly transformational year for Matinas BioPharma. We believe that our entry into the anti-infective space sets the stage for the company to unlock the unlimited potential of our disruptive, proprietary, lipid-crystal nano-encapsulation platform technology,” commented Roelof Rongen, President and Chief Executive Officer. “We have made substantial progress on the corporate and operational fronts by aligning the company with preeminent clinical and scientific advisors, appointing key executives, and advancing our clinical development and regulatory strategies for a milestone-driven year ahead.”

## **KEY RECENT CORPORATE ACHIEVEMENTS**

- [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;
- [Appointed Peter G. Pappas, M.D., FACP](#), an internally recognized expert and thought leader on invasive fungal infections, to the Company’s Scientific Advisory Board;
- Received [Notice of Allowance of U.S. patent for encochleated siRNA](#), providing a pathway to the development of orally administered RNA based therapies; and
- 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](#), at IDWEEK2015.

## **RECENT PROGRAM ACHIEVEMENTS**

### **MAT2203, an orally-administered, lipid-crystal nano-particle formulation of broad spectrum fungicidal agent amphotericin B**

- Received approval from the Institutional Review Board of NIH/NIAID on the protocol to conduct a [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](#);
- Granted U.S. Food and Drug Administration (FDA) designation as a [Qualified Infectious Disease Product \(QIDP\) with Fast Track status for the use of MAT2203 in the treatment of invasive candidiasis](#), a condition with increasing rates of drug resistance to established antifungal products; and
- Presented preclinical data at ICAAC/ICC 2015 demonstrating [oral encochleated amphotericin B rapidly targets and penetrates tissue infected with invasive candidiasis](#).

### **MAT2501, an orally-administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic agent amikacin for severe hospital-acquired bacterial infections**

- Preparing to file an Investigational New Drug (IND) application with the FDA;
- Presented preclinical data at ICAAC/ICC 2015 showing [significant antibacterial activity of MAT2501 against \*Mycobacterium avium\* and no noted toxicity](#);
- Formal preclinical animal toxicology studies currently ongoing at NIH; and
- Proof-of-principle animal model testing completed showing *in vivo* efficacy in *mycobacterium avium* bacterial infections.

“Over the past few months, especially as we have released key data from our development programs at prestigious infectious disease scientific meetings, we have seen keen interest from third parties that have faced challenges with either the oral delivery or overall safety of their own anti-infective medications,” stated Jerome D. Jabbour, EVP, Chief Business Officer and General Counsel. “As part of our strategy moving forward, we will evaluate opportunities which may position us to demonstrate the key attributes of our technology effectively and fulfill significant unmet medical need on a broad basis.”

## **EXPECTED NEAR-TERM MILESTONES**

- Commence patient enrollment and dosing in the MAT2203 Phase 2a study for the treatment of refractory mucocutaneous candidiasis;
- Submit the IND application to the FDA for MAT2501;
- Submit applications to the FDA for QIDP designation and Orphan Drug Designation for MAT2501;
- Report topline data from the MAT2203 Phase 2a clinical study; and
- Engage with the FDA on a MAT2203 pivotal registration-directed clinical development program.

Mr. Rongen concluded, “We expect significant momentum in the coming months with enrollment and dosing in our first Phase 2a clinical study at the NIH for MAT2203 and our IND filing for MAT2501. Based on MAT2203’s favorable Phase 1 results and its robust package of impressive preclinical data, we anticipate reporting topline data with a similar profile in 2016. We believe that orally delivered, encocleated MAT2203 and MAT2501 have the potential to transform the way potent medicines for infectious diseases are designed and administered in order to provide physicians and patients with more tolerable, safer, and effective antifungal and antibacterial treatments for multi-drug resistant infections.”

### Summary of Financial Results for Third Quarter 2015

For the nine months ended September 30, 2015, the Company reported a net loss of approximately \$7.1 million, or a net loss per diluted share of \$0.14, compared to a net loss of approximately \$7.2 million, or a net loss per diluted share of \$0.11, for the nine months ended September 30, 2014. The net loss for the quarter ended September 30, 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 quarter with approximately \$4.4 million of cash and cash equivalents.

### ***Condensed Consolidated Statement of Operations and Condensed Consolidated Balance Sheet to follow***

#### **Matinas BioPharma Holdings Inc. Condensed Consolidated Balance Sheets**

	<u>September 30, 2015 (unaudited)</u>	<u>December 31, 2014 (Audited)</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 4,362,758	\$ 2,590,713
Restricted cash - current	100,000	100,000
Grant receivables	79,810	-
Prepaid expenses	<u>342,195</u>	<u>114,425</u>
Total current assets	4,884,763	2,805,138
Equipment - net	365,542	339,995
In-process research and development	3,017,377	-

Goodwill	1,384,674	-
Other assets including long term security deposit	<u>216,555</u>	<u>216,317</u>
TOTAL ASSETS	<u><u>\$ 9,868,911</u></u>	<u><u>\$ 3,361,450</u></u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 282,097	\$ 271,155
Accrued expenses	549,985	802,746
Deferred rent obligation - current	8,232	-
Note payable - current	10,000	-
Lease liability - current	<u>22,455</u>	<u>44,362</u>
Total Current Liabilities	<u>872,769</u>	<u>1,118,263</u>
<b>LONG TERM LIABILITIES</b>		
Deferred tax liability	1,253,327	-
Contingent consideration	781,729	-
Lease liability - long term	<u>-</u>	<u>15,291</u>
TOTAL LIABILITIES	<u><u>\$ 2,907,825</u></u>	<u><u>\$ 1,133,554</u></u>
<b>STOCKHOLDERS' EQUITY</b>		
Common stock par value \$ 0.0001, 150,000,000 authorized, 57,207,335 issued and outstanding as of September 30, 2015; 32,292,650 issued and outstanding as of December 31, 2014	5,722	3,230
Additional Paid in Capital	28,136,395	16,276,430
Accumulated Deficit	<u>(21,181,031 )</u>	<u>(14,051,764 )</u>
Total Stockholders' Equity	<u>6,961,086</u>	<u>2,227,896</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u><u>\$ 9,868,911</u></u>	<u><u>\$ 3,361,450</u></u>

**Matinas BioPharma Holdings, Inc.**  
**Condensed Consolidated Statements of Operations**  
**(Unaudited)**

**Three Months Ended September 30,**  
**2015**                      **2014**

<b>Revenue:</b>		
Contract research revenue	\$ 59,858	\$ -
<b>Costs and Expenses:</b>		
Research and development	879,196	1,069,716
General and administrative	1,339,430	1,535,617
<b>Total costs and expenses</b>	<b>2,218,626</b>	<b>2,605,333</b>
<b>Loss from operations</b>	<b>(2,158,768 )</b>	<b>(2,605,333 )</b>
<b>Other income (expense), net</b>	<b>4,143</b>	<b>(6,495 )</b>
<b>Net loss</b>	<b>\$ (2,154,625 )</b>	<b>\$ (2,611,828 )</b>
<b>Net loss per share - basic and diluted</b>	<b>\$ (0.04 )</b>	<b>\$ (0.08 )</b>
<b>Weighted average common shares outstanding:</b>		
Basic and diluted	56,970,295	32,060,796

	<b>Nine Months Ended September 30,</b>	
	<b>2015</b>	<b>2014</b>
<b>Revenue:</b>		
Contract research revenue	\$ 194,494	\$ -
<b>Costs and Expenses:</b>		
Research and development	3,682,336	3,261,747
General and administrative	3,641,337	3,893,100
<b>Total costs and expenses</b>	<b>7,323,673</b>	<b>7,154,847</b>
<b>Loss from operations</b>	<b>(7,129,179 )</b>	<b>(7,154,847 )</b>
<b>Other expense, net</b>	<b>88</b>	<b>21,876</b>
<b>Net loss</b>	<b>\$ (7,129,267 )</b>	<b>\$ (7,176,723 )</b>
<b>Net loss per share - basic and diluted</b>	<b>\$ (0.14 )</b>	<b>\$ (0.22 )</b>
<b>Weighted average common shares outstanding:</b>		
Basic and diluted	49,574,729	32,020,265

## 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 also intends to file an investigational new drug application (IND) for MAT2501, which is an orally-administered, encochleated formulation of

amikacin (a broad spectrum aminoglycoside antibiotic agent) for gram-negative and intracellular 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) and Fast Track designations for MAT2203, which does not change the standards for regulatory approval or guarantee regulatory approval on an expedited basis, or at all; our ability to obtain QIDP, Fast Track and/or Orphan drug designations for MAT2501, 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.*

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