

November 15, 2016



Matinas BioPharma Reports 2016 Third Quarter Financial Results and Provides Corporate Update

– Company to commence initial study in the Phase 1 program for MAT2501 and second Phase 2 study for MAT2203 in Q4 2016 –

– On track to report Phase 2 topline data for MAT2203 in the first half of 2017 –

BEDMINSTER, N.J., Nov. 15, 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 quarter ended September 30, 2016.

The Company also reviewed the progress of its lead anti-infective product in development, [MAT2203](#), an orally-administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent), 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.

“We have made notable progress this year with MAT2203 and MAT2501, specifically in the past quarter with the commencement of patient dosing in our Phase 2a study of MAT2203,” said [Roelof Rongen, Chief Executive Officer](#). “Our recent regulatory and clinical achievements have established a strong foundation on which we can build in a meaningful way in the near term. Importantly, we have taken significant steps forward in providing physicians and patients with 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; all of which we expect to unlock significant value for our shareholders.”

KEY RECENT CORPORATE HIGHLIGHTS

- Presented [preclinical data of orally administered encochleated influenza vaccine in murine model at IDWeek 2016](#);
- Received [Notice of Allowance of a U.S. patent for the Company’s proprietary methods related to the composition and the formation of cochleate lipid-crystal nano-particles containing tiny oil droplets in which very hydrophobic compounds can be dissolved](#);
- Successfully [completed private placement equity financing of \\$8.0 million](#) which positions the Company to move toward an up-listing to a national exchange;
- Presented [cryptococcal meningitis preclinical data of MAT2203 at AIDS-Associated Mycosis Meeting 2016](#); and

- Received [Issuance 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.

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 [patient dosing in NIH-Sponsored Phase 2a study for the treatment of mucocutaneous candidiasis infections](#) with MAT2203; and
- Received [Qualified Infectious Disease Product \(QIDP\) designation with Fast Track status for MAT2203 for the prophylactic treatment of invasive fungal infections due to immunosuppressive therapy](#) from U.S. Food and Drug Administration (FDA).

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

- Prepared for the initiation of Phase 1 clinical study under the open IND for the treatment of NTM.

Matinas received [FDA clearance to initiate a Phase 1 clinical study of MAT2501 under the open IND for the treatment of non-tuberculous mycobacterium infections](#). The FDA has 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, Matinas believes MAT2501 would become the first orally bioavailable aminoglycoside and represent a significant improvement over existing therapies from a treatment and health economic perspective.

EXPECTED NEAR-TERM MILESTONES

- Commence the initial study in the Phase 1 program for MAT2501 in Q4 2016;
- Commence Phase 2 study for the treatment of vulvovaginal candidiasis (VVC) in Q4 2016;
- Commence tolerability/PK study of MAT2203 in patients with a hematologic malignancy in H1 2017;
- Up-list to a National Exchange in the next two quarters;
- Report topline data from the Phase 2a clinical study of MAT2203 in the first half of 2017;
- Report topline data from Phase 2 clinical study of VVC in the first half of 2017; and
- Engage with the FDA on a MAT2203 pivotal registration-directed clinical development program and enter Phase 3 as quickly as possible.

Summary of Financial Results for Third Quarter 2016

For the nine months ended September 30, 2016, the Company reported a net loss of

approximately \$5.7 million, or a net loss share basic and diluted of \$0.11, compared to a net loss of approximately \$7.1 million, or a net loss per share basic and diluted of \$0.14, for the nine months ended September 30, 2015. The net loss for the nine months ended September 30, 2016 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 \$6.2 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. The FDA has designated MAT2203 as a Qualified Infectious Disease Product for the treatment of invasive candidiasis, aspergillosis and 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 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 under the open IND 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.

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 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.

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

	September 30, 2016 (Unaudited)	December 31, 2015 (Audited)
ASSETS		
CURRENT ASSETS		
Cash	\$ 6,219,641	\$ 3,226,997
Restricted cash	55,583	100,326
Prepaid expenses	254,005	231,797
Total current assets	6,529,229	3,559,120
Equipment - net	368,822	377,723
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Other assets, including long term security deposit	54,844	115,370
TOTAL ASSETS	\$ 11,306,760	\$ 8,406,078
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	\$ 209,463	\$ 497,842
Note payable	188,873	-
Accrued expenses	941,334	610,206
Deferred rent liability	11,226	9,225
Lease liability	9,743	11,261
Total current liabilities	1,360,639	1,128,534
LONG TERM LIABILITIES		
Deferred tax liability	1,205,141	1,205,141
Lease liability - net of current portion	19,004	-

TOTAL LIABILITIES	2,584,784	2,333,675
STOCKHOLDERS' EQUITY		
Convertible preferred stock, stated value \$5.00 per share, 1,600,000 and 0 shares issued and outstanding as of September 30, 2016 and December 31, 2015 respectively (liquidation preference – \$12,393,809 at September 30, 2016) Net of issuance costs.	6,086,350	–
Common stock par value \$0.0001 per share, 250,000,000 and 250,000,000 shares authorized at September 30, 2016 and December 31, 2015, respectively; 57,919,709 issued and outstanding as of September 30, 2016; 57,180,148 issued and outstanding as of December 31, 2015	5,793	5,719
Additional paid in capital	35,917,737	29,253,848
Accumulated deficit	(33,287,904)	(23,187,164)
Total stockholders' equity	<u>8,721,976</u>	<u>6,072,403</u>
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	<u>\$ 11,306,760</u>	<u>\$ 8,406,078</u>

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

	Three Months Ended September 30,	
	2016	2015
Revenue:		
Contract research revenue	\$ -	\$ 59,858
Costs and Expenses:		
Research and development	835,308	879,196
General and administrative	999,803	1,339,430
Total costs and expenses	<u>1,835,111</u>	<u>2,218,626</u>
Loss from operations	<u>(1,835,111)</u>	<u>(2,158,768)</u>
Other income/(expense), net	<u>(3,325)</u>	<u>4,143</u>
Net loss	\$ (1,838,436)	\$ (2,154,625)
Convertible preferred stock beneficial conversion feature accreted as a deemed dividend	<u>(4,393,809)</u>	<u>-</u>
Net loss attributable to common shareholders	\$ (6,232,245)	\$ (2,154,625)
Net loss available for common shareholders per share - basic and diluted	\$ (0.11)	\$ (0.04)
Weighted average common shares outstanding:		
Basic and diluted	<u>57,628,917</u>	<u>56,970,295</u>

	Nine Months Ended September 30	
	2016	2015
Revenue:		
Contract research revenue	\$ -	\$ 194,494
Costs and Expenses:		
Research and development	2,399,595	3,682,336
General and administrative	3,293,233	3,641,337
Total costs and expenses	<u>5,692,828</u>	<u>7,323,673</u>
Loss from operations	(5,692,828)	(7,129,179)
Other expense, net	<u>(14,103)</u>	<u>(88)</u>
Net loss	\$ (5,706,931)	\$ (7,129,267)
Convertible preferred stock beneficial conversion feature accreted as a dividend	<u>(4,393,809)</u>	<u>-</u>
Net loss attributable to common shareholders	<u>\$ (10,100,740)</u>	<u>\$ (7,129,267)</u>
Net loss available for common shareholders per share - basic and diluted	<u>\$ (0.18)</u>	<u>\$ (0.14)</u>
Weighted average common shares outstanding:		
Basic and diluted	<u>57,505,788</u>	<u>49,574,729</u>

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Source: Matinas BioPharma Holdings, Inc.