

# Matinas BioPharma Reports 2017 First Quarter Financial Results and Provides Corporate Update

- Announced positive topline data from initial study in Phase 1 program for MAT2501 –
- Company on track to report interim Phase 2 data of MAT2203 for mucocutaneous candidiasis and topline data of MAT2203 Phase 2 study for vulvovaginal candidiasis in June 2017 –

BEDMINSTER, N.J., May 16, 2017 (GLOBE NEWSWIRE) -- <u>Matinas BioPharma Holdings</u>, <u>Inc.</u> (NYSE MKT:MTNB), a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today announced its financial results for the quarter ended March 31, 2017.

The Company also reviewed the progress of its lead anti-infective products in development, MAT2203, an orally administered, encochleated formulation of amphotericin B (a broad spectrum fungicidal agent), and MAT2501, an orally administered, encochleated formulation of the broad spectrum aminoglycoside antibiotic, amikacin, to treat gram-negative bacterial infections and other intercellular bacterial infections.

"We have made notable, fundamental progress in the first quarter of 2017 on the corporate and clinical fronts. With our recent commencement of trading on the NYSE MKT, the successful completion of a warrant tender offer that strengthened our balance sheet, and key appointments of Dr. Ende to our board of directors and Dominick DiPaolo as SVP of Quality and Regulatory compliance, I believe that Matinas is positioned for great advancements this year," said Roelof Rongen, Chief Executive Officer. "We remain focused on the progression of our MAT2203 and MAT2501 clinical programs, and look forward to announcing interim results and topline data in June, which we believe have the potential to provide important validation of our cochleate platform technology broadly."

### **Q1 2017 CORPORATE HIGHLIGHTS**

- Commenced trading on the NYSE MKT;
- <u>Successfully completed warrant tender</u> offer with gross proceeds of \$13.5 million from exercise of warrants:
- Bolstered board of directors with the appointment of Eric J. Ende, MD, MBA;
- Strengthened executive management team with the appointment of <u>Dominick DiPaolo</u> as Senior Vice President of Quality and Regulatory Compliance; and
- Opened a Good Laboratory Practice (GLP) lab space/Good Manufacturing Practice (GMP) commercial scale manufacturing facility.

## Q1 2017 ANTI-INFECTIVE DEVELOPMENT PROGRAM ACHIEVEMENTS

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

• Initiated <u>open-label extension to Phase 2a Study of MAT2203 in chronic</u> mucocutaneous candidiasis.

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

- Reported positive topline data from the Phase 1 single-ascending dose study of MAT2501 in healthy volunteers; and
- Reported positive preclinical efficacy results of MAT2501 in an*in vitro* Model of *Mycobacterium abscessus* infection.

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

- NIH to report interim results from the open-label, NIH-sponsored Phase 2a clinical study of MAT2203 in immunocompromised patients on June 3, 2017 at ASM Microbe 2017 in New Orleans;
- Report topline results from the ongoing Phase 2 study of MAT2203 in VVC in June 2017;
- Commence tolerability/PK study of MAT2203 in patients with a hematologic malignancy in Q3 2017 to position this lead product candidate for a pivotal study in this population; and
- Commence multiple ascending dose PK/tolerability study of MAT2501 in healthy volunteers.

#### Q1 2017 SUMMARY OF FINANCIAL RESULTS

For the three months ended March 31, 2017, the Company reported a net loss attributable to common shareholders of approximately \$21.2 million, or a net loss share basic and diluted of \$0.25, compared to a net loss attributable to common shareholders of approximately \$2.2 million, or a net loss per share basic and diluted of \$0.04, for the three months ended March 31, 2016. The net loss for the quarter ended March 31, 2017 is primarily attributable to an inducement charge from the exercise of warrants and also includes the ongoing research and development activities related to the Company's MAT2203 antifungal and MAT2501 antibacterial product candidates as well as the costs associated with operating as a public company. The Company ended the quarter with cash and cash equivalents of approximately \$15.8 million.

Based on Management's current projections, the Company believes that cash on hand is sufficient to fund operations into June 2018.

	March 31, 2017 (Unaudited)	December 31, 2016 (Audited)		
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$ 15,834,798	\$ 4,105,451		
Restricted cash	155,636	155,610		
Prepaid expenses	803,039	304,427		
Total current assets	16,793,473	4,565,488		
Equipment - net	344,158	356,143		
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	540,145	540,845		
TOTAL ASSETS	\$ 22,031,641	\$ 9,816,341		
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable Note payable Accrued expenses Unearned revenue Deferred rent liability Lease liability Total current liabilities	\$ 1,247,487 47,218 471,501 164,656 11,744 10,134 1,952,740	\$ 475,602 118,046 829,724 - 11,485 9,936 1,444,793		
LONG TERM LIABILITIES				
Deferred tax liability Lease liability - net of current portion	1,205,141 13,837	1,205,141 16,446		
TOTAL LIABILITIES	3,171,718	2,666,380		
Commitments	-	-		
STOCKHOLDERS' EQUITY				
Convertible preferred stock, stated value \$5.00 per share, 1,600,000 shares authorized at March 31, 2017 and December 31, 2016, 1,590,000 and 1,600,0000 shares issued and outstanding as of March 31, 2017 and December 31, 2016 respectively (liquidation preference – \$7,950,000 at March 31, 2017)	6,048,310	6,086,350		

Common stock par value \$0.0001 per share, 250,000,000 shares authorized at March 31, 2017 and December 31, 2016; 90,985,192 issued and outstanding as of March 31, 2017; 58,159,495 issued and outstanding as of December 31, 2016	9,098	5,817
Additional paid in capital	52,478,342	36,237,504
Accumulated deficit	(39,675,827)	(35,179,710)
Total stockholders' equity	18,859,923	7,149,961
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 22,031,641	\$ 9,816,341

The accompanying notes are an integral part of these condensed consolidated financial statements.

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

	Three Months Ended			
	March 31,			
		2017		2016
Revenue:	<u></u>		_	
Contract research revenue	\$	14,969	_	<u> -</u>
Costs and Expenses:				
Research and development		2,384,218		921,711
General and administrative		2,117,975	_	1,315,777
Total costs and expenses		4,502,193	_	2,237,488
Loss from operations		(4,487,224	)	(2,237,488 )
Other income/(expense), net		(8,893	) _	(7,122 )
Net loss	\$	(4,496,117)	)	\$ (2,244,610 )
Inducement charge from exercise of warrants		(16,741,356	)	-
Net loss attributable to common shareholders	\$	(21,237,473	) =	\$ (2,244,610)
Net loss available for common shareholders per share - basic and diluted	\$	(0.25	) <u></u>	\$ (0.04)
Weighted average common shares outstanding: basic and diluted		84,595,597	=	57,287,955

The accompanying notes are an integral part of these condensed consolidated financial statements.

#### **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 orally using our proprietary and novel oral formulation may offer a new and promising alternative for patients and doctors. Currently, there are two Phase 2 studies underway with MAT2203. The first is an open-label Phase 2a NIH/NIAID-sponsored clinical study with MAT2203 immunocompromised patients with refractory mucocutaneous candidiasis. The second is a Phase 2 study of MAT2203 in patients with vulvovaginal candidiasis (VVC). Data from both studies is expected to be announced in June of 2017. The FDA has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) for the treatment of invasive candidiasis and the treatment of aspergillosis, as well as for the 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, lipidcrystal, nanoparticle delivery technology. Amikacin is currently used to treat different types of chronic and acute bacterial infections, including non-tuberculous mycobacterium (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). 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 efficacy after oral bioavailability and targeted delivery of amikacin directly to the site of infection in murine models of both pulmonary (lung) and disseminated NTM 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 is also exploring the development of MAT2501 for the treatment of a multi-drug resistant, gram negative bacterial infections. The Company recently reported positive topline data from its Phase 1 single ascending dose study in healthy volunteers. 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.

#### **About Matinas BioPharma**

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications. 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 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 <a href="https://www.matinasbiopharma.com">www.matinasbiopharma.com</a> and connect with the Company on <a href="https://www.matinasbiopharma.com">Twitter, LinkedIn, Facebook</a>, and <a href="https://www.matinasbiopharma.com">Google+</a>.

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.

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Source: Matinas BioPharma Holdings, Inc.