

# Matinas BioPharma Reports 2016 Financial Results and Provides Corporate Update

- 2016 marked by significant corporate and clinical advancements –
- Recently announced positive topline data from initial study in Phase 1 program for MAT2501 –
- On track to report interim Phase 2 data of MAT2203 and topline data of MAT2203 VVC study in June 2017 –
  - Conference call and live audio webcast today at 8:30 a.m. ET -

BEDMINSTER, N.J., April 03, 2017 (GLOBE NEWSWIRE) -- <u>Matinas BioPharma Holdings</u>, <u>Inc.</u> (NYSE MKT:MTNB), clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today announced its financial results for the year ended December 31, 2016. As previously announced, Matinas management will host an update conference call and live audio webcast for investors, analysts and other interested parties today, Monday, April 3, 2017 at 8:30 a.m. ET (details below).

"In 2016 we achieved several noteworthy clinical milestones which prepared the Company for potential key data readouts this year that we believe will provide validation of our technology platform. We also achieved several important corporate goals, including the completion of a warrant tender to strengthen our balance sheet and the recent commencement of trading on the NYSE MKT," said Roelof Rongen, Chief Executive Officer. "We believe that with the clinical, regulatory and corporate foundation we have established over the last year, we are well positioned to build momentum over the course of 2017. We continue to work diligently in advancing our clinical programs aimed at providing physicians and patients with orally-delivered encochleated drug formulations of two powerful anti-infective medicines to address significant unmet medical need with the potential to transform the way potent medicines are delivered and administered."

## **KEY RECENT CORPORATE HIGHLIGHTS**

- Bolstered board of directors with the appoint of Eric J. Ende, MBA, MD;
- Commenced trading on the NYSE MKT;
- Successfully completed warrant tender offer with gross proceeds of \$13.5 million from exercise of warrants;
- Opened a Good Laboratory Practice (GLP) lab space/Good Manufacturing Practice (GMP) commercial scale manufacturing facility; and
- Received <u>contract award from Cystic Fibrosis Foundation Therapeutics</u> to study MAT2501 for the treatment of NTM-infection in pre-clinical models of CF.

# **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)

- Commenced <u>patient dosing in NIH-sponsored Phase 2a study for the treatment of</u> mucocutaneous candidiasis infections with MAT2203;
- Initiated enrollment and commenced patient dosing in Phase 2 study for the treatment of VVC; and
- Initiated open-label extension to Phase 2a Study of MAT2203 in chronic mucocutaneous candidiasis.

The U.S. Food and Drug Administration (FDA) has designated MAT2203 as a QIDP with Fast Track status for the treatment of <u>invasive candidiasis</u>, <u>aspergillus</u> and <u>prophylaxis</u> (<u>prevention</u>) <u>of invasive fungal infections</u> in patients on immunosuppressive therapy. MAT2203 is also being explored for treatment of additional infections including cryptococcal meningoencephalitis, and is being developed to be eligible for Orphan Drug designations in various indications.

**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 anin vitro Model of *Mycobacterium abscessus* infection.

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 tolerability/PK study of MAT2203 in patients with a hematologic malignancy in Q2 2017 to position this lead product candidate for a pivotal study in this population;
- 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; and
- Commence multiple ascending dose PK/tolerability study of MAT2501 in healthy volunteers.

# **SUMMARY OF FINANCIAL RESULTS FOR 2016**

For the twelve months ended December 31, 2016, the Company reported a net loss of approximately \$7.6 million, or a net loss share basic and diluted of \$0.21, compared to a net loss of approximately \$9.1 million, or a net loss per share basic and diluted of \$0.18, for the twelve months ended December 31, 2015. The net loss for the year ended December 31, 2016 is attributable to 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 year with cash and cash equivalents of approximately \$4.1 million.

Based on Management's current projections and with the approximate \$12.7 million raised with the close of the Company's warrant tender offer on January 13, 2017, the Company believes that cash on hand is sufficient to fund operations through the second quarter of 2018.

### CONFERENCE CALL AND WEBCAST INFORMATION

As previously announced, Matinas will host an update conference call and webcast for investors, analysts and other interested parties today, Monday, April 3, 2017 at 8:30 a.m. ET.

The conference call and <u>live webcast</u> will be accompanied by presentation slides. To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast and accompanying slides will be accessible on the <u>Investors</u> section of Matinas' website, <u>www.matinasbiopharma.com</u>, and will be archived for 60 days.

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

	December 31, 2016		 December 31, 2015	
ASSETS				
CURRENT ASSETS				
Cash and cash equivalents	\$	4,105,451	\$ 3,226,997	
Restricted cash		155,610	100,326	
Prepaid expenses		304,427	 231,797	
Total current assets		4,565,488	3,559,120	
Equipment - net		356,143	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	 540,845	 115,370
TOTAL ASSETS	\$ 9,816,341	\$ 8,406,078
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable Note payable Accrued expenses Deferred rent liability Lease liability Total current liabilities	\$ 475,602 118,046 829,724 11,485 9,936 1,444,793	\$ 497,842 - 610,206 9,225 11,261 1,128,534
LONG TERM LIABILITIES		
Deferred tax liability Lease liability - net of current portion	 1,205,141 16,446	 1,205,141 <u>-</u>
TOTAL LIABILITIES	2,666,380	2,333,675
STOCKHOLDERS' EQUITY		
Convertible preferred stock, stated value \$5.00 per share, Authorized amount issued and outstanding 1,600,000 and 0 shares as of December 31, 2016 and December 31, 2015, respectively (liquidation preference – \$8,000,000 at December 31, 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 December 31, 2016 and December 31, 2015, respectively; 58,159,495 issued and outstanding as of December 31, 2016; 57,180,148 issued and outstanding as of December 31, 2015	5,817	5,719
Additional paid in capital	36,237,504	29,253,848
Accumulated deficit	 (35,179,710 )	 23,187,164 )
Total stockholders' equity	 7,149,961	 6,072,403
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 9,816,341	\$ 8,406,078

# Matinas BioPharma Holdings, Inc. Consolidated Statements of Operations

	For the \	For the Year Ended			
	Decer	December 31,			
	2016	2015			
Revenue:					
Contract research revenue	<u>\$ -</u>	\$ 194,494			
Costs and Expenses: Research and development	3,947,644	5,292,193			
recours and development	0,047,044	0,202,100			

General and administrative	4,309,489	4,813,800
Total costs and expenses	8,257,133	10,105,993
Loss from operations	(8,257,133 )	(9,911,499 )
Sale of New Jersey net operating loss	674,901	756,472
Other income/(expense), net	(16,505)	19,627
Net loss	\$ (7,598,737)	\$ (9,135,400 )
Convertible preferred stock beneficial conversion feature accreted as a deemed dividend	(4,393,809)	
Net loss attributable to common shareholders	\$ (11,992,546)	\$ (9,135,400)
Net loss available for common shareholders per share - basic and diluted	\$ (0.21)	\$ (0.18)
Weighted average common shares outstanding: Basic and diluted	57,654,830	51,481,002

#### **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 NIH/NIAID-sponsored clinical with open-label Phase 2a studv 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 the first half 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, lipid-crystal, 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="www.matinasbiopharma.com">www.matinasbiopharma.com</a> and connect with the Company on <a href="Twitter">Twitter</a>, <a href="LinkedIn">LinkedIn</a>, <a href="Facebook">Facebook</a>, and <a href="Google+">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.

Investor Contact
Jenene Thomas

Jenene Thomas Communications, LLC

Phone: +1 (908) 938-1475

Email: jenene@jenenethomascommunications.com



Source: Matinas BioPharma Holdings, Inc.