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Matinas BioPharma Reports 2017 Third Quarter Financial Results and Provides Corporate Update

BEDMINSTER, N.J., Nov. 15, 2017 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (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 September 30, 2017 and reviewed its operational progress of its lead anti-infective products in development and expected near-term milestones.

“In the third quarter, our team worked with leading key opinion leaders and our clinical and regulatory advisors to analyze in great detail a compilation of very encouraging preclinical and clinical data generated for MAT2003. Patients undergoing treatment for acute lymphoblastic leukemia (ALL), a blood-borne cancer, are at high risk for invasive fungal infections (IFIs) due to their specific chemotherapy. The profile of MAT2203 uniquely positions it to significantly reduce the occurrence of potentially lethal IFIs in these patients. We believe the compelling MAT2203 data package, combined with the proposed clinical and regulatory pathway we have established, positions us to successfully engage with the FDA to move our MAT2203 clinical development program forward to a pivotal Phase 3 registration study for the prevention of IFIs,” stated Roelof Rongen, Chief Executive Officer of Matinas. “Our team continues to work diligently to establish a clear path forward for our development programs as we complete the remainder of 2017 and work towards creating significant value-driving events throughout 2018.”

ANTIFUNGAL MAT2203 RECENT ACHIEVMENTS

- Reported topline data from Phase 2 clinical study of orally administered MAT2203 in the treatment of vulvovaginal candidiasis indicating that MAT2203 was safe and well tolerated while demonstrating signals of efficacy through a mechanism involving systemic absorption, including a dose response;

- Announced positive interim data from NIH-conducted Phase 2a clinical study of orally administered MAT2203 for the treatment of chronic refractory mucocutaneous candidiasis providing for the safe and efficacious long-term use of MAT2203 (now longer than nine months without encountering safety issues); and

- Presented positive preclinical efficacy data of MAT2203 in a mouse model of cryptococcal meningitis demonstrating dramatic improvement in treatment with MAT2203 and the ability to systemically cross the blood/brain barrier.
    - Mortality results were consistent with what has been seen in MAT2203 treated models of invasive candidiasis and invasive aspergillosis and the fluorescence

images of brain tissue further support the unique ability of cochleates to penetrate deep into infected organs.

MAT2203 NEXT STEPS

- Commence tolerability/PK study of MAT2203 in leukemia patients as a critical piece of the Phase 2 development program prior to commencing a pivotal Phase 3 registration trial in prevention of IFIs in patients with ALL. Initial data expected Q4 2018;

- Conduct Type B Meeting (face-to-face) in early Q1 2018 with FDA to review overall data package for MAT2203, the Company's plans to finalize Phase 2 with data from its tolerability/PK study in leukemia patients and to position MAT2203 with FDA toward a Phase 3 clinical program in prevention of IFIs in patients with ALL; and

- Evaluate and commence one or more studies in cryptococcal meningitis in partnership with the University of Minnesota to demonstrate patient efficacy in invasive fungal infections as a way to supplement the overall data package for MAT2203 during 2018.

ANTIBACTERIAL MAT2501 RECENT ACHIEVEMENTS

- Reported positive topline data from the Phase 1 single-ascending dose study of MAT2501 in healthy volunteers.
    - No serious adverse events were reported.
    - Oral administration of MAT2501 at all tested doses yielded blood levels that were well below the safety levels recommended for injected amikacin.
    - Data supports further development of MAT2501 for the treatment of non-tuberculous mycobacterium (NTM) infections.
    - Results from Phase 1 study demonstrating systemic absorption and accumulation in the urine were encouraging toward the potential for MAT2501 to treat more acute bacterial infections, such as gram negative urinary tract infections (cUTIs).

MAT2501 NEXT STEPS

- Commence multiple-ascending dose PK/tolerability study of MAT2501 in healthy volunteers in Q2 2018;

- Announce results of PK/tolerability study in Q4 2018; and

- Initiate Phase 2 NTM study in Q4 2018.

Q3 2017 SUMMARY OF FINANCIAL RESULTS

For the nine months ended September 30, 2017, the Company reported a net loss of approximately $11.9 million, or a net loss share basic and diluted of $0.33, compared to a net loss of approximately $5.7 million, or a net loss per share basic and diluted of $0.18, for the nine months ended September 30, 2016. The net loss for the nine months ended September 30, 2017 is primarily attributable to ongoing research and development activities related to MAT2203 and MAT2501 as well as the costs associated with operating as a public

company. The Company ended the quarter with cash and cash equivalents of approximately $9.0 million.

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. 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. 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 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 Statements of Operations
(Unaudited)

	Three Months Ended September 30,	
	2017	2016
Revenue:		
Contract research revenue	$ 44,906	$ -
Costs and Expenses:		
Research and development	2,013,063	835,308
General and administrative	1,440,141	999,803

Total costs and expenses	3,453,204	1,835,111
Loss from operations	(3,408,298)	(1,835,111)
Other income/(expense), net	13,584	(3,325)
Net loss	**$ (3,394,714)**	**$ (1,838,436)**
Dividend to preferred shareholders	(608,343)	-
Convertible preferred stock beneficial conversion feature accreted as a deemed dividend	-	(4,393,809)
Net loss attributable to common shareholders	$ (4,003,057)	$ (6,232,245)
Net loss available for common shareholders per share - basic and diluted	$ (0.04)	$ (0.11)
Weighted average common shares outstanding: Basic and diluted	92,222,601	57,628,917

	Nine Months Ended September 30,	
	2017	**2016**
Revenue:		
Contract research revenue	$ 104,781	$ -
Costs and Expenses:		
Research and development	6,711,997	2,399,595
General and administrative	5,264,609	3,293,233
Total costs and expenses	11,976,606	5,692,828
Loss from operations	(11,871,825)	(5,692,828)
Other income/(expense), net	13,354	(14,103)
Net loss	**$ (11,858,471)**	**$ (5,706,931)**
Dividend to preferred shareholders	(608,343)	-
Convertible preferred stock beneficial conversion feature accreted as a deemed dividend	-	(4,393,809)
Inducement charge from exercise of warrants	(16,741,356)	-
Net loss attributable to common shareholders	$ (29,208,170)	$ (10,100,740)
Net loss available for common shareholders per share - basic and diluted	$ (0.33)	$ (0.18)
Weighted average common shares outstanding: basic and diluted	89,468,153	57,505,788

Matinas BioPharma Holdings Inc.
Consolidated Balance Sheets
Unaudited

	September 30, 2017 (Unaudited)	December 31, 2016 (Audited)
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	**$ 9,000,674**	**$ 4,105,451**
Restricted cash	**155,404**	**155,610**
Prepaid expenses	**1,017,372**	**304,427**
Total current assets	**10,173,450**	**4,565,488**
Leasehold improvements and equipment - net	**1,460,455**	**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	**535,999**	**540,845**
TOTAL ASSETS	**$ 16,523,769**	**$ 9,816,341**
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable	**$ 341,593**	**$ 475,602**
Note payable	**297,912**	**118,046**
Accrued expenses	**753,760**	**829,724**
Deferred revenue	**74,844**	**-**
Deferred rent liability	**395,620**	**11,485**
Lease liability	**19,020**	**9,936**
Total current liabilities	**1,882,749**	**1,444,793**
LONG TERM LIABILITIES		
Deferred tax liability	**1,205,141**	**1,205,141**
Lease liability - net of current portion	**47,914**	**16,446**
Stock dividends payable - long term	**603,143**	**-**
TOTAL LIABILITIES	**3,738,947**	**2,666,380**
STOCKHOLDERS' EQUITY		
Series A Convertible preferred stock, stated value $5.00 per share, 1,600,000 shares authorized as of September 30, 2017 and December 31, 2016; 1,507,858 and 1,600,000 shares issued and outstanding as of September 30, 2017 and December 31, 2016, respectively, (liquidation preference - $8,142,433 at September 30, 2017)	**5,735,845**	**6,086,350**
Common stock par value $0.0001 per share, 250,000,000 and 250,000,000 shares authorized at September 30, 2017 and December 31, 2016, respectively; 92,950,096 issued and outstanding as of September 30, 2017; 58,159,495 issued and outstanding as of December 31, 2016	**9,294**	**5,817**

Additional paid in capital	**54,686,207**	**36,237,504**
Accumulated deficit	**(47,646,524)**	**(35,179,710)**
Total stockholders' equity	**12,784,822**	**7,149,961**
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	**$ 16,523,769**	**$ 9,816,341**

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Source: Matinas BioPharma Holdings, Inc.