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Matinas BioPharma Provides Business Outlook and Sets Corporate Milestones for 2017

-- Several data milestones anticipated during 1H 2017

-- Recent warrant tender offer resulting in \$13.5 million in gross proceeds strengthens balance sheet and extends cash runway into 2Q 2018

-- New GLP/cGMP manufacturing facility positions Company for expected pivotal programs for MAT2203 and MAT2501

-- Up-list to a national securities exchange expected in 1Q 2017

BEDMINSTER, N.J., Jan. 26, 2017 (GLOBE NEWSWIRE) -- [Matinas BioPharma Holdings, Inc.](#) (OTCQB:MTNB), a clinical-stage biopharmaceutical company focused on developing innovative anti-infectives for orphan indications, today provided a business outlook and overview of anticipated events and near-term clinical and corporate milestones expected in 2017.

NEAR-TERM CLINICAL VALUE-DRIVING CATALYSTS

- Report top-line results from Phase 1 study with [MAT2501](#) in 1Q 2017;
- Report top-line results from NIH-sponsored Phase 2a study of [MAT2203](#) in immunocompromised patients in 1H 2017;
- Report top-line results from Phase 2 study of MAT2203 in patients with vulvovaginal candidiasis (VVC) in 1H 2017; and
- Commence tolerability/PK study of MAT2203 in patients with a hematologic malignancy in 1H 2017 to position this lead product candidate for a pivotal study in this population.

[Roelof Rongen, Chief Executive Officer](#), stated, "We believe that our operational diligence and focus during 2016 has positioned Matinas for a potential breakthrough year in 2017. We look forward to reporting Phase 2 data from the two studies ongoing with MAT2203, as well as reporting the Phase 1 topline data for MAT2501 in the first half of this year. We believe this human clinical data will provide further validation of our [proprietary cochleate platform technology](#), and following an expected meeting with the FDA in the second half of 2017, will position MAT2203 to enter a pivotal registration trial for the prevention of invasive fungal infections (IFIs) in patients on immunosuppressive therapy while receiving chemotherapy for

hematologic malignancies.”

CORPORATE MILESTONES EXPECTED TO FURTHER DRIVE VALUE AND INCREASE VISIBILITY TO THE INVESTMENT COMMUNITY

- Opening of a Good Laboratory Practice (GLP) lab space/Good Manufacturing Practice (GMP) commercial scale manufacturing facility in 1H 2017;
- Up-list to a national securities exchange in 1Q 2017; and
- Evaluating strategic opportunities to leverage cochleate technology to improve the therapeutic profile of drugs for potential partners.

[Jerome D. Jabbour, Co-founder and President](#) of Matinas, commented, “Through the strategic and highly [successful completion of our recent warrant tender](#), we strengthened our balance sheet and significantly extended our cash runway well into 2018. This key objective demonstrated the confidence and loyalty of our stockholder base and enables the Company to hopefully move quickly toward an up-listing of our common stock on a national securities exchange. We believe the up-listing of our stock in the near term should significantly increase visibility and facilitate access to large, fundamental healthcare investors.”

“Finally, as we continue to drive and create value on the clinical side of our business, we are also investing in critical growth infrastructure with confidence and evaluating appropriate strategic relationships as we advance our important products through clinical development with the goal of providing important and much-needed products for patients and physicians in this unfortunate era of multi-drug resistant infections,” added Mr. Jabbour.

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 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. 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 in 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) 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. In Q4 2016, Matinas initiated a Phase 1 clinical study of MAT2501 under the open IND for the treatment of non-tuberculous mycobacterium infections. Topline data from this Phase 1 study is expected in Q1 2017. The [FDA has already designated MAT2501 as a QIDP and an Orphan Drug for the treatment of NTM infections](#). The Company also intends develop 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 in an area of significant unmet medical need.

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 drug candidate MAT2203, currently in Phase 2, is 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, currently in Phase 1, 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.

Investor Contact

Jenene Thomas

Jenene Thomas Communications, LLC

Phone: +1 (908) 938-1475

Email: jenene@jenenethomascommunications.com



Source: Matinas BioPharma Holdings, Inc.