

August 8, 2017



# Matinas BioPharma Reports 2017 Second Quarter Financial Results and Reaffirms Clinical and Regulatory Strategy to Advance MAT2203 and MAT2501

- *Second quarter marked by significant clinical progress with compelling overall Phase 2 data from two studies of flagship product candidate MAT2203*
- *Company plans to engage FDA to review overall data package generated with MAT2203 with the goal to enter Phase 3 for the prevention of invasive fungal infections as quickly as possible*
- *Company will advance MAT2501 into multiple ascending dose Phase 1 study in Q4 2017*
- *Management to host conference call / live audio webcast today at 8:30 AM ET*

BEDMINSTER, N.J., Aug. 08, 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 June 30, 2017 and reviewed the operational progress of its lead anti-infective products in development and expected near-term milestones. As previously announced, the Company will host a business update conference call with live audio webcast today, August 8<sup>th</sup> at 8:30 AM ET (details below).

Roelof Rongen, Chief Executive Officer of Matinas, stated, "The second quarter of 2017 was truly monumental for our Company, our MAT2203 product and our overall cochleate delivery platform technology. This past June we announced data from two separate clinical trials of our flagship product candidate, MAT2203, in the treatment of mucosal infections in two very different patient populations and at different dose and duration levels. Now that we have had the opportunity to review the full available data set from each of these studies and discuss them in detail with numerous key opinion leaders, as well as leading regulatory experts, we believe we have met our key objectives from these studies and are now well positioned to engage with the FDA to move our MAT2203 clinical development program into a pivotal Phase 3 registration study for the prevention of invasive fungal infections as quickly as possible."

## ANTIFUNGAL MAT2203 RECENT ACHIEVEMENTS

- 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 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 at The American Society for Microbiology's ASM Microbe 2017 Conference providing for the safe and efficacious long-term use of MAT2203; and
- Presented positive preclinical efficacy data of MAT2203 in stringent NIH mouse model of cryptococcal meningitis demonstrating dramatic improvement in treatment with MAT2203 and the ability to be systemically absorbed following oral administration and successfully cross the blood/brain barrier.

## **MAT2203 NEXT STEPS**

- Commence tolerability/PK study of MAT2203 in leukemia patients, with initial data expected in mid-to-late in 2018, as the final critical piece of the Company's Phase 2 development program prior to commencing a pivotal Phase 3 registration trial in prevention of invasive fungal infections in patients with Acute Lymphoblastic Leukemia (ALL);
- Formally request and conduct Type B Meeting (face-to-face) with FDA to review overall data package for MAT2203, review plans to finalize Phase 2 with data from the Company's tolerability/PK study in leukemia patients and to initiate discussions on the Phase 3 protocol program in prevention of invasive fungal infections by year end; 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 broaden the opportunity for MAT2203 during 2018.

## **ANTIBACTERIAL MAT2501 RECENT ACHIEVEMENTS**

In May 2017, Matinas reported positive topline data from the Phase 1 single-ascending dose study of MAT2501 in healthy volunteers in which no serious adverse events were reported and where oral administration of MAT2501 at all tested doses yielded blood levels that were well below the safety levels recommended for injected amikacin, supporting further development of MAT2501 for the treatment of non-tuberculous mycobacterium (NTM) infections. Furthermore, results from this 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 (UTIs).

## **MAT2501 NEXT STEPS**

- Commence multiple-ascending dose PK/tolerability study of MAT2501 in healthy volunteers in Q4 2017;
- Announce results of PK/tolerability study in Q2 2018; and
- Initiate Phase 2 NTM study in H2 2018.

Mr. Rongen continued, "As potentially the first ever oral aminoglycoside, we believe MAT2501 may become a solution for a variety of chronic and acute bacterial infections, including NTM as well as various gram negative bacterial infections. Following positive Phase 1 data, demonstrating evidence of systemic absorption, we plan to commence our multiple ascending dose PK study of MAT2501 in healthy volunteers before year end. We determined that moving to this second Phase 1 study is a way to build a broader foundation for MAT2501 which can then be developed for multiple indications. Following data from the multiple ascending dose study in the second quarter of 2018, we expect to be in a position to

commence a Phase 2 study for the treatment of NTM soon thereafter, driving this important product toward commercialization.”

## **Q2 2017 SUMMARY OF FINANCIAL RESULTS**

For the three months ended June 30, 2017, the Company reported a net loss attributable to common shareholders of approximately \$3.9 million, or a net loss share basic and diluted of \$0.4, compared to a net loss attributable to common shareholders of approximately \$1.6 million, or a net loss per share basic and diluted of \$0.03, for the three months ended June 30, 2016. The net loss for the quarter ended June 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 \$11.2 million.

Based on Management’s current projections, Matinas anticipates that current cash on hand at June 30, 2017 as well as cash available through the Company’s Controlled Equity Offering Sales Agreement will be sufficient to meet its operating obligations for at least a year and if fully utilized would finance the Company’s operations through 2019.

“We are extremely proud of the progress we have made so far during 2017. Our clinical development pathways are clear for MAT2203 and MAT2501, and we believe as we advance these programs, the next six, 12 and 18 months will be full of value-creating milestones that we believe will have the potential to drive significant value in Matinas,” concluded Mr. Rongen.

## **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, Tuesday, August 8, 2017 at 8:30 AM ET.

To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast will be accessible on the [Events](#) page of the [Investors](#) section of Matinas’ website, [www.matinasbiopharma.com](http://www.matinasbiopharma.com), and will be archived for 60 days.

## **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](http://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)

	<b>Three Months Ended</b>	
	<b>June 30,</b>	
	<b>2017</b>	<b>2016</b>
Revenue:		
Contract research revenue	\$ 44,906	\$ -
Costs and Expenses:		
Research and development	2,314,716	642,576
General and administrative	1,706,493	977,653
Total costs and expenses	4,021,209	1,620,229
Loss from operations	(3,976,303 )	(1,620,229 )
Other income/(expense), net	8,663	(3,656 )
<b>Net loss</b>	<b>\$ (3,967,640 )</b>	<b>\$ (1,623,885 )</b>
Net loss attributable to common shareholders	\$ (3,967,640 )	\$ (1,623,885 )
<b>Net loss available for common shareholders per share - basic and diluted</b>	<b>\$ (0.04 )</b>	<b>\$ (0.03 )</b>
<b>Weighted average common shares outstanding:</b>		
<b>Basic and diluted</b>	<b>91,611,531</b>	<b>57,593,414</b>

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2017</b>	<b>2016</b>
Revenue:		

Contract research revenue	\$ 59,875	\$ -
Costs and Expenses:		
Research and development	4,698,934	1,564,287
General and administrative	<u>3,824,468</u>	<u>2,293,430</u>
Total costs and expenses	<u>8,523,402</u>	<u>3,857,717</u>
Loss from operations	(8,463,527 )	(3,857,717 )
Other expense, net	<u>(230 )</u>	<u>(10,778 )</u>
<b>Net loss</b>	<b><u>\$ (8,463,757 )</u></b>	<b><u>\$ (3,868,495 )</u></b>
Inducement charge from exercise of warrants	<u>(16,741,356 )</u>	-
Net loss attributable to common shareholders	<u>\$ (25,205,113 )</u>	<u>\$ (3,868,495 )</u>
<b>Net loss available for common shareholders per share - basic and diluted</b>	<b><u>\$ (0.29 )</u></b>	<b><u>\$ (0.07 )</u></b>
<b>Weighted average common shares outstanding:</b>		
<b>Basic and diluted</b>	<u>88,285,929</u>	<u>57,440,685</u>

**Matinas BioPharma Holdings Inc.**  
**Condensed Consolidated Statements of Cash Flow**  
**(Unaudited)**

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2017</b>	<b>2016</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (8,463,757 )	\$ (3,868,495 )
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	24,800	26,298
Deferred rent	273	1,742
Share based compensation expense	1,687,690	793,471
Changes in operating assets and liabilities:		
Prepaid expenses	(12,828 )	163,962
Other assets	5,076	105,295
Accounts payable	(22,382 )	(21,979 )
Accrued expenses	21,696	163,050
Net cash used in operating activities	<u>(6,759,432 )</u>	<u>(2,636,656 )</u>
<b>Cash flows from investing activities:</b>		
Capital expenditures	<u>(789,705 )</u>	-
Net cash used in investing activities	<u>(789,705 )</u>	-
<b>Cash flows from financing activities:</b>		
Net proceeds from exercise of warrants	14,834,367	-
Payment of capital lease liability	(6,202 )	(12,028 )
Payment of note payable	<u>(118,046 )</u>	-

Net cash provided by (used in) financing activities	14,710,119	(12,028 )
<b>Net increase (decrease) in cash</b>	7,160,982	(2,648,684 )
<b>Cash and cash equivalents at beginning of period</b>	4,105,451	3,226,997
<b>Cash and cash equivalents at end of period</b>	<u>\$ 11,266,433</u>	<u>\$ 578,313</u>
Supplemental non-cash financing and investing activities:		
Accrued issuance cost for private placement 2016	\$ -	\$ 71,805
Preferred stock conversion	\$ 289,102	\$ -
Additional paid-in-capital for modification of warrants	\$ 16,741,356	\$ -
Equipment acquired under capital lease	\$ 49,935	\$ 31,064

Source: Matinas BioPharma Holdings, Inc.

Investor Contact  
Jenene Thomas  
Jenene Thomas Communications, LLC  
Phone: +1 (908) 938-1475  
Email: [jenene@jenenethomascommunications.com](mailto:jenene@jenenethomascommunications.com)



Source: Matinas BioPharma Holdings, Inc.