

November 2, 2022



# Matinas BioPharma Reports Third Quarter 2022 Financial Results and Highlights Recent Progress

*EnACT Phase 2 study of MAT2203 in cryptococcal meningitis met its primary endpoint with 95% two-week patient survival in the Cohort 4 all-oral regimen*

*Phase 3 pivotal trial of MAT2203 for treatment of cryptococcal meningitis to commence Q1 2023*

*The Infectious Diseases Society of America (IDSA) chose EnACT as its Outstanding Abstract and IDSA Awardee at IDWeek 2022*

*Eric J. Ende, MD, MBA appointed as Chairman of the Board effective October 1, 2022, with founding Chairman Herbert J. Conrad remaining as an Independent Director*

*\$33.1 million in cash, cash equivalents, and marketable securities at September 30, 2022, sufficient to fund planned operations through 2023*

*Management to Host Conference Call Today, Wednesday, November 2<sup>nd</sup>, at 4:30 p.m. ET*

BEDMINSTER, N.J., Nov. 02, 2022 (GLOBE NEWSWIRE) --[Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform delivery technology, today reported financial and operational results for the third quarter ended September 30, 2022, along with a corporate update.

“Since our last quarter’s reporting, the Company has achieved some very significant milestones, highlighted by our lead, Phase 3-ready asset, MAT2203, successfully completing Phase 2,” commented [Jerome D. Jabbour, Chief Executive Officer of Matinas](#). “Interim EnACT Cohort 4 survival data were recently presented at IDWeek, with results that are simply unprecedented for an oral therapy in this vulnerable patient population. Following this impressive clinical validation of our LNC platform technology, we are aggressively preparing MAT2203 for Phase 3, and remain intently focused on advancing this platform into other areas of significant need, including the intracellular delivery of nucleic acids such as mRNA and other oligonucleotides, as we look ahead to close 2022 in strong fashion.”

## Third Quarter 2022 Highlights and Recent Events

### **MAT2203**

- Interim data from Cohort 4 of the Phase 2 EnACT study *Encochleated Oral*

*Amphotericin for Cryptococcal Meningitis Trial*) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis (CM) were presented at IDWeek in October 2022. As part of IDWeek, the EnACT abstract was the recipient of the Outstanding Abstract and IDSA Awardee by the Infectious Diseases Society of America. In the EnACT trial, MAT2203 exceeded the primary endpoint threshold for early fungicidal activity (EFA) of 0.20 log<sub>10</sub> CFU/mL/day, with a mean EFA achieved of 0.30 log<sub>10</sub> CFU/mL/day with 95% confidence intervals from 0.22 – 0.38.

- Cohort 4 also yielded key secondary endpoints, including overall survival and safety. For 40 patients receiving MAT2203 treatment, interim overall survival remains at 90% through 18 weeks, while the survival rate at Week 2 was 95% (the primary endpoint for the upcoming Phase 3 registration trial in cryptococcal meningitis). Importantly, the incidence of adverse events relating to kidney function and anemia were significantly lower for MAT2203 compared to the conventional IV amphotericin B standard of care treatment across the entirety of the EnACT trial, with no evidence of kidney toxicity even with up to 6 weeks of oral MAT2203 treatment.
- The pivotal Phase 3 registration trial of MAT2203 in cryptococcal meningitis is planned to initiate early in the first quarter of 2023 and will assess MAT2203 as step-down therapy following 2 loading doses of IV amphotericin B (similar to EnACT Cohort 2). This open-label randomized trial, which will be partially financially supported by the National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS), involves a three arm non-inferiority design in approximately 270 persons living with HIV who have cryptococcal meningitis. The primary endpoint for this Phase 3 study will be 2-week all-cause mortality, with a pooled analysis across the two MAT2203 treatment arms compared with IV amphotericin as the standard of care to support either a 2-week or 6-week treatment of cryptococcal meningitis indication as supported by the data. An adaptive, de-risking design allows for the potential to add additional patients once enrollment has reached 75% to offset unforeseen patient deaths unrelated to study drug. Enrollment is expected to take approximately 18 months, with topline data expected in the second half of 2024.
- Late-breaking data demonstrating the *in vivo* efficacy of MAT2203 in treating two strains of mucormycosis (*R. delemar* and *M. circinelloides*) in immunosuppressed mice were also presented at IDWeek 2022 by Dr. Ashraf Ibrahim of the Lundquist Institute. The preclinical data with MAT2203 demonstrated a prolonged median survival time, enhanced overall survival, and reduced tissue fungal burden of target organs including lung and brain as compared to AmBisome® (IV amphotericin B), positioning MAT2203 as a potential clinical solution for this deadly invasive fungal infection.

### **External Collaborations**

- In April 2022, Matinas and BioNTech entered an exclusive research collaboration centered on the combination of Matinas' proprietary LNC platform technology and BioNTech mRNA formats. The Companies continue their collaborative formulation work on multiple nucleic acids, ultimately directed toward planned preclinical *in vitro* and *in vivo* testing. The parties remain in advanced discussions for a potential option to license the LNC platform for various nucleic acid applications.

### **Appointment of Eric Ende MD, MBA to Chairman of the Board of Directors**

In September 2022, the Company also announced the unanimous appointment of board member, Eric J. Ende, to succeed Herbert J. Conrad as Chairman of the Board, effective October 1, 2022. Mr. Conrad, the founding Chairman of Matinas, remains on the Board as an independent director of the Company. Dr. Ende joined the Company's Board of Directors in March 2017.

### **Third Quarter 2022 Financial Results**

Cash, cash equivalents and marketable securities at September 30, 2022, were approximately \$33.1 million, compared to \$49.6 million at December 31, 2021. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

For the third quarter of 2022, net loss attributable to common shareholders was \$5.5 million, or a net loss of \$0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of \$6.8 million, or a net loss of \$0.03 per share (basic and diluted), for the same period in 2021. The reduced loss resulted from the Company recording \$1.1 million in revenue from its research collaboration with BioNTech SE, along with a slight decrease in operating expenses year over year.

### **Conference Call and Webcast Details**

The Company will host a live conference call and webcast to discuss these results today, November 2, 2022, at 4:30 p.m. ET.

To participate in the call, please dial 888-609-1607 (Toll-Free) or (862) 298-0702 (Toll). The live webcast will be accessible on the [Investors](#) section of Matinas' website, [www.matinasbiopharma.com](http://www.matinasbiopharma.com), and archived for 90 days.

### **About Matinas BioPharma**

Matinas BioPharma is a biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides, and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral), positions Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

### **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 our business activities, our strategy and plans, our ongoing research collaboration with BioNTech and any potential

license of the LNC platform technology, the potential of our LNC platform delivery technology, and the future development of its product candidates, including MAT2203, MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, 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 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 Balance Sheets**

	September 30, 2022	December 31, 2021
	(Unaudited)	(Audited)
<b>ASSETS:</b>		
Current assets:		
Cash and cash equivalents	\$ 11,175,838	\$ 21,029,806
Marketable debt securities	21,875,015	28,592,049
Restricted cash - security deposit	50,000	50,000
Prepaid expenses and other current assets	3,997,798	1,321,466
Total current assets	37,098,651	50,993,321
Non-current assets:		
Leasehold improvements and equipment - net	2,144,102	1,537,728
Operating lease right-of-use assets - net	3,742,019	4,218,890
Finance lease right-of-use assets - net	7,026	22,270
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposit	200,000	200,000
Total non-current assets	10,447,012	10,332,753
Total assets	\$ 47,545,663	\$ 61,326,074

# **LIABILITIES AND STOCKHOLDERS' EQUITY:**

## **Current liabilities:**

Accounts payable	\$	656,717	\$	938,270
Accrued expenses		3,696,932		2,850,888
Operating lease liabilities - current		540,076		538,546
Financing lease liabilities - current		7,860		21,039
Total current liabilities		4,901,585		4,348,743

## **Non-current liabilities:**

Deferred tax liability		341,265		341,265
Operating lease liabilities - net of current portion		3,683,949		4,140,387
Financing lease liabilities - net of current portion		-		2,621
Total non-current liabilities		4,025,214		4,484,273
Total liabilities		8,926,799		8,833,016

## **Stockholders' equity:**

Common stock		21,685		21,627
Additional paid-in capital		188,529,404		184,251,138
Accumulated deficit		(148,996,657)		(131,634,208)
Accumulated other comprehensive loss		(935,568)		(145,499)
Total stockholders' equity		38,618,864		52,493,058
Total liabilities and stockholders' equity	\$	47,545,663	\$	61,326,074

## **Matinas BioPharma Holdings, Inc.**

### **Condensed Consolidated Statements of Operations and Comprehensive Loss**

(Unaudited)

	<b>Three Months Ended September 30,</b>		<b>Nine Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>	<b>2022</b>	<b>2021</b>
Revenue:				
Research and development	\$ 1,062,500	\$ -	\$ 2,125,000	\$ 33,333
Costs and expenses:				
Research and development	3,706,828	4,621,255	12,811,462	10,343,451
General and administrative	2,818,252	2,256,689	8,423,868	7,710,625
Total costs and expenses	6,525,080	6,877,944	21,235,330	18,054,076
Loss from operations	(5,462,580)	(6,877,944)	(19,110,330)	(18,020,743)
Sale of New Jersey net operating loss & tax credits	-	-	1,734,133	1,328,470
Other income, net	988	41,394	13,748	108,298
Net loss	\$ (5,461,592)	\$ (6,836,550)	\$ (17,362,449)	\$ (16,583,975)
Preferred stock series B accumulated dividends	-	-	-	(395,799)
Net loss attributable to common shareholders	\$ (5,461,592)	(6,836,550)	\$ (17,362,449)	\$ (16,979,774)
Net loss available for common shareholders per share - basic and diluted	\$ (0.03)	(0.03)	\$ (0.08)	\$ (0.08)
Weighted average common shares outstanding - basic and diluted	216,864,526	215,179,949	216,792,083	208,130,431
Other comprehensive loss, net of tax				
Unrealized loss on securities available-for-sale	(181,152)	(52,837)	(790,069)	(229,766)
Other comprehensive loss, net of tax	(181,152)	(52,837)	(790,069)	(229,766)
Comprehensive loss attributable to shareholders	\$ (5,642,744)	\$ (6,889,387)	\$ (18,152,518)	\$ (16,813,741)

## Investor and Media Contacts

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