

March 15, 2023



# Matinas BioPharma Reports 2022 Financial Results and Provides a Business Update

*Near-term data readouts from internal and collaborative programs expected to support advancement of the LNC platform for delivery of nucleic acids*

*FDA feedback from MAT2203 Type B meeting expected to impact partnership discussions and facilitate potential non-dilutive BARDA and/or NIH funding*

*Conference call and webcast begin at 4:30 p.m. Eastern time today*

BEDMINSTER, N.J., March 15, 2023 (GLOBE NEWSWIRE) -- [Matinas BioPharma](#) (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, reports 2022 financial results and provides a business update.

"We are developing our LNC delivery platform with the goal of providing safe, extrahepatic delivery of nucleic acids and small molecules," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "Phase 2 MAT2203 clinical trial results demonstrated the ability of our platform to efficaciously deliver a safe, well-tolerated oral form of amphotericin B with dramatic survival results. Success to-date with MAT2203 bolsters our confidence in moving forward into the delivery of nucleic acids, and we are encouraged by our progress in this area.

"Among upcoming milestones, we expect data readouts from our internal programs with smaller oligonucleotides, as well as data relating to the delivery of larger oligonucleotides like mRNA through collaborations with BioNTech and National Resilience, two of the world's leading mRNA companies," he added. "Importantly, these programs will provide critical information in maximizing the potential applications for our technology, thereby advancing our strategy of developing robust internal and external product pipelines.

"We are also preparing to meet with the U.S. Food and Drug Administration (FDA) to seek guidance on a Phase 3 study with MAT2203 for the treatment of invasive fungal infections (IFIs). Feedback from this meeting will be instrumental in guiding our efforts to secure non-dilutive funding from the Biomedical Advanced Research and Development Authority (BARDA) and/or the National Institutes of Health (NIH), as well as in advancing ongoing discussions with potential partners for further development of this promising oral therapy for treating life-threatening fungal infections," Mr. Jabbour concluded.

## **Anticipated Second Quarter 2023 Milestones**

*BioNTech Collaboration*

- Generation of *in vivo* data arising from the combination of Matinas' LNC platform technology and BioNTech's mRNA formats resulting from our ongoing exclusive research collaboration. This collaboration has provided financial support, generated compelling *in vitro* results and provided a potential pathway for the ultimate oral delivery of mRNA, which, if successful, would represent a major breakthrough. Testing will continue with collaborative formulation work on multiple nucleic acids with *in vivo* data expected during the second quarter of 2023.

#### *National Resilience Collaboration*

- Results from *in vitro* testing under a Material Transfer and Evaluation Agreement with National Resilience, which was announced in January 2023. The parties are collaborating on a comprehensive research program including design, formulation, and optimization to explore the potential for oral delivery of certain nucleic acids with the LNC platform. The collaboration will continue with potential *in vivo* results expected in the second half of 2023.

#### *Internal ASO/siRNA Program*

- Generation of *in vitro* data from an internal program for the delivery of antisense oligonucleotides (ASO) and silencing RNA (siRNA) therapies. This program will continue with multiple *in vivo* biodistribution and animal efficacy studies in the second half of 2023. If successful, the Company anticipates being able to identify the next internal product candidate in late 2023. Study success could position Matinas to develop a pipeline of ASO and siRNA therapies.

#### *MAT2203 (Oral Amphotericin B) Program*

- Planned meeting with the FDA to discuss a Phase 3 trial to assess the safety, efficacy, and tolerability of oral MAT2203 in patients with serious, life-threatening IFIs and limited treatment options. The discussion is expected to cover the proposed trial design and strategy for potentially obtaining MAT2203 marketing approval under a streamlined 505(b)(2) regulatory pathway.

### **Anticipated Second Half 2023 Milestones**

In addition to the milestones mentioned above, the Company anticipates the following milestones in the second half of 2023:

#### *BARDA Grant for MAT2203 Development*

- Potential award of BARDA funds for the continued development of MAT2203 in multiple IFIs. The Company believes MAT2203 is well positioned to receive funding due to its oral, well-tolerated and broad-spectrum profile, and its clinical success already demonstrated in the Phase 2 EnACT trial in cryptococcal meningitis, each of which aligns well with the criteria set forth by BARDA in awarding grants for promising antifungal treatments. A potential BARDA and/or NIH award could be sufficient to complete development of MAT2203 through market approval for the targeted IFI indications, as well as support supply chain and commercial readiness.

#### *MAT2203 Domestic/Global Partnership*

- Potential for a pharmaceutical partnership for the continued development and commercialization of MAT2203 based on its success in the EnACT Phase 2 trial in cryptococcal meningitis and feedback from the FDA for the treatment of multiple serious IFIs.

## **2022 Financial Results**

Revenue for the year ended December 31, 2022 was \$3.2 million, which was generated from the research collaboration with BioNTech SE. This compares with revenue for the year ended December 31, 2021 of \$33,000, which was generated from the feasibility study agreement with Genentech Inc.

Total costs and expenses for 2022 were \$27.8 million compared with \$24.8 million for 2021. The increase was due primarily to higher research and development expenses reflecting the later stage of the Company's clinical development programs. Income from selling unused New Jersey net operating losses (NOLs) and research and development tax credits was \$3.5 million and \$1.3 million for 2022 and 2021, respectively.

The net loss attributable to common shareholders for 2022 was \$21.0 million, or \$0.10 per share, compared with a net loss attributable to common shareholders for 2021 of \$23.7 million, or \$0.11 per share.

Cash, cash equivalents and marketable securities as of December 31, 2022 were \$28.8 million compared with \$49.6 million as of December 31, 2021. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second quarter of 2024.

## **Conference Call and Webcast Details**

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. 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 the company's website and archived for 90 days.

## **About Matinas BioPharma**

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology to maximize global clinical impact and patient access. 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 studies 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 potentially to become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors. For more information, please visit [www.matinasbiopharma.com](http://www.matinasbiopharma.com).

## **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 collaborations with National Resilience, Inc. and BioNTech SE, the potential of our LNC platform delivery technology, and the future development of its product candidates, the Company's ability to identify and pursue development, licensing 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.

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Financial Tables to Follow

**Matinas BioPharma Holdings, Inc.**  
**Consolidated Balance Sheets**  
(in thousands, except for share data)

December 31,	
2022	2021

**ASSETS:**

## Current assets:

Cash and cash equivalents	\$ 6,830	\$ 21,030
Marketable debt securities	21,933	28,592
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	5,719	1,321
Total current assets	34,532	50,993

## Non-current assets:

Leasehold improvements and equipment - net	2,091	1,538
Operating lease right-of-use assets - net	3,613	4,219
Finance lease right-of-use assets - net	30	23
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash - security deposit	200	200
Total non-current assets	10,287	10,333
Total assets	\$ 44,819	\$ 61,326

**LIABILITIES AND STOCKHOLDERS' EQUITY:**

## Current liabilities:

Accounts payable	\$ 618	\$ 937
	3,099	2,851
Accrued expenses and other liabilities		
Operating lease liabilities - current	562	539
Financing lease liabilities - current	7	21
Total current liabilities	4,286	4,348

## Non-current liabilities:

Deferred tax liability	341	341
Operating lease liabilities - net of current portion	3,533	4,140
Financing lease liabilities - net of current portion	22	3
Total non-current liabilities	3,896	4,484
Total liabilities	8,182	8,832

## Stockholders' equity:

Common stock par value \$0.0001 per share, 500,000,000 shares authorized at December 31, 2022 and 2021, respectively; 217,264,526 and 216,269,450 issued and outstanding as of December 31, 2022 and 2021, respectively	22	22
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Additional paid-in capital	190,070	184,251
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Accumulated deficit	(152,631)	(131,634)
Accumulated other comprehensive loss	(824)	(145)
Total stockholders' equity	<u>36,637</u>	<u>52,494</u>
Total liabilities and stockholders' equity	<u>\$ 44,819</u>	<u>\$ 61,326</u>

**Matinas BioPharma Holdings, Inc.**  
**Consolidated Statements of Operations and Comprehensive Loss**  
(in thousands, except share and per share data)

	<b>For the Year Ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
Revenue:		
Research and development	\$ 3,188	\$ 33
Costs and Expenses:		
Research and development	16,678	14,583
General and administrative	<u>11,100</u>	<u>10,185</u>
Total costs and expenses	<u>27,778</u>	<u>24,768</u>
Loss from operations	(24,590)	(24,735)
Sale of New Jersey net operating loss & tax credits	3,491	1,328
Other income, net	<u>102</u>	<u>124</u>
Net loss	\$ (20,997)	\$ (23,283)
Preferred stock series B accumulated dividends	<u>-</u>	<u>(396)</u>
Net loss attributable to common shareholders	\$ (20,997)	\$ (23,679)
Net loss attributable to common shareholders per share – basic and diluted	\$ (0.10)	\$ (0.11)
Weighted average common shares outstanding:		
Basic and diluted	216,811,439	210,178,332
Other comprehensive loss, net of tax		
Net unrealized loss on securities available-for-sale	<u>(679)</u>	<u>(374)</u>
Other comprehensive loss, net of tax	<u>(679)</u>	<u>(374)</u>
Comprehensive loss attributable to shareholders	<u>\$ (21,676)</u>	<u>\$ (23,657)</u>



Source: Matinas BioPharma Holdings, Inc.