

January 30, 2023



# Matinas BioPharma Provides Business Update and 2023 Strategic Outlook

*2022 Success Has Increased Confidence to Focus LNC Delivery Platform on the Future of Medicine - Delivering Genes*

*Prioritization on Building External Partnerships and an Internal Pipeline Centered on Gene Therapies and Nucleic Acids*

*Collaborations with BioNTech (mRNA Partner) and National Resilience (Nucleic Acid Platform Partner) Expected to Generate Initial In Vivo Data in 1H 2023*

*Seeking BARDA Financial Support and FDA Feedback on Phase 3 Study in Invasive Fungal Infections of MAT2203 Prior to Commencing Phase 3 Program*

*Ended 2022 with Approximately \$28.8 Million, Sufficient to Fund Planned Operations into Q2 2024*

*Conference Call and Live Audio Webcast Scheduled Today, January 30 at 4:30 p.m. ET*

BEDMINSTER, N.J., Jan. 30, 2023 (GLOBE NEWSWIRE) -- [Matinas BioPharma](#) (NYSE AMER: MTNB, Matinas), a clinical-stage biopharmaceutical company focused on redefining the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology, today is providing a business update on its ongoing programs and discussing its strategic outlook for 2023.

"In 2022 we successfully demonstrated that MAT2203, our lead asset based on our lipid nanocrystal (LNC) delivery platform, could safely and effectively deliver unprecedented survival outcomes, with an oral therapy, for patients suffering from deadly fungal infections," commented [Jerome D. Jabbour, Chief Executive Officer of Matinas](#) "Our success with smaller molecules increased our confidence in the platform and empowered us to focus on what we believe is the real future of medicine – the ability to safely and effectively deliver therapies that affect the genetic mechanisms underlying disease. We are striving to create an internal and external pipeline of product candidates in the nucleic acid and gene therapy space that take advantage of the unique and proprietary nature of our delivery technologies. Our ongoing collaborations with BioNTech and, recently, National Resilience, have aligned Matinas with two of the world's leading companies in the gene therapy space. These collaborations were designed to accelerate the overall development of our LNC platform and maximize the value we can obtain from third parties while providing us with critical data and information necessary to establish and develop an internal pipeline of nucleic acid therapies."

Jabbour added, "During these uncertain economic times, we remain cognizant of our cash

resources and have chosen to prioritize those activities which we believe will create the greatest shareholder value. Through these strategic choices, we have extended our cash runway into the second quarter of 2024, well beyond potential value-creating catalysts and near-term opportunities for non-dilutive funding from LNC partners and/or BARDA. We could not be more excited about what we are building at Matinas, and we believe that 2023 will be a great year for the Company and its shareholders.”

## Key Program Updates and Anticipated Upcoming Milestones

### LNC Platform Internal Data Generated

- During 2022 and early 2023, the Company has generated the following key data in our strategic focus areas of nucleic acids and gene therapies:
  - (a) Developed multiple flow cytometry and fluorescence cell-based assays with compelling validations of ***intracellular uptake and gene expression*** with our LNC formulations.
  - (b) ***Successful delivery of multiple larger nucleic acids*** coded with reporter genes ***across multiple cell lines*** (HeLa, HEK293, A375, etc.).
  - (c) Multiple oligonucleotide formulations that have ***demonstrated strong gene expression potency*** at nanogram per well dosage level, comparable to industry standard Lipofectamine.
  - (d) Internal mRNA formulations that have ***shown excellent stability*** and ***remain biologically active over 10 weeks at 4°C storage conditions***.
  - (e) Multiple formulations with ***little to no cytotoxicity*** during *in vitro* cell viability evaluations supporting an anticipated favorable safety profile compared with other drug delivery technologies.

### LNC Internal Pipeline Development

- Based on historical data with the LNC platform, along with recent learnings from internal work and its collaborations, the Company believes the greatest chance of early success in developing our own pipeline of nucleic acid drug candidates is with smaller oligonucleotides like antisense oligonucleotides (ASOs) and small interfering or silencing RNA (siRNAs). The properties of these molecules are particularly suited for our LNC platform, and the Company believes that its technology can facilitate oral delivery and extrahepatic targeting – currently two of the greatest challenges in this developing area.
- The Company has commenced a research program focused on ASO/siRNAs that it expects will generate *in vitro* delivery data early in the second quarter of this year, followed by multiple *in vivo* biodistribution and animal efficacy studies in the second half of 2023. If successful, the Company anticipates being in position to identify our next internal product candidate in late 2023. The Company believes success in these studies could position it to develop an entire pipeline of ASO and siRNA therapies.

## LNC Platform Collaborations

- **BioNTech** – Signed Exclusive Research Collaboration in April 2022, including \$4.25 million in funding from our partner. The parties are preparing for *in vivo* studies (biodistribution and disease) during the first quarter of 2023, with data expected in the second quarter of 2023.
- **National Resilience** – In January 2023, the parties entered into a Material Transfer and Evaluation Agreement focused on exploring the potential for oral delivery of identified nucleic acids. The parties are closely collaborating on a comprehensive research program comprising the design, formulation, optimization, and *in vitro* and *in vivo* testing of these nucleic acid formats in combination with Matinas' proprietary LNC platform, with initial data expected in the second and third quarters of 2023, respectively.
- **Genentech** – Genentech recently extended this collaboration for another year through 2023.
- **NIAID/Gilead** – While the series studies performed with LNC remdesivir were successful in demonstrating reduced viral lung titers, improved lung congestion scores and reduced COVID-associated weight loss, Gilead has informed Matinas that it has focused its development efforts on its internal oral nucleoside prodrug of remdesivir.

## MAT2203 (oral amphotericin B) Program

- In November 2022, the Biomedical Advanced Research and Development Authority (BARDA) announced an initiative seeking private sector partners developing late-stage, broad-spectrum antifungal drugs to treat high priority fungal infections, including aspergillus, mucormycosis, and certain forms of candidiasis. BARDA has solicited proposals from industry, and the Company believes MAT2203 is a strong candidate for funding based upon its oral, well-tolerated and broad-spectrum profile, along with its recent clinical success in Phase 2 with cryptococcal meningitis. The Company is scheduled to meet with BARDA during the first quarter of 2023 and has included all associated costs for full development for MAT2203 in its proposal. The Company believes pausing the start of its Phase 3 clinical trial in cryptococcal meningitis pending the outcome of BARDA's evaluation of MAT2203 is the best possible course for this life-saving drug. In 2021, BARDA funding for vaccines stood at \$36.9 billion, therapeutics at \$14.1 billion, and diagnostics at \$51 million.
- The Company is preparing to submit a formal Meeting Request to the U.S. Food and Drug Administration (FDA) to discuss plans for a second Phase 3 study to assess the efficacy, safety, and tolerability of MAT2203 in patients with serious, life-threatening invasive fungal infections with limited treatment options. The protocol synopsis currently includes the treatment of four invasive fungal infections: invasive aspergillosis, invasive candidiasis, chronic coccidioidomycosis (Valley Fever), and invasive Mucormycosis. The Company's strategy is to leverage the success and data from EnACT to limit the required size of this study. The Company currently plans to enroll approximately 100 patients in a single arm design with no head-to-head active comparator, which it believes should be acceptable given historical precedent and the challenges associated with the target patient population to be evaluated. The Company anticipates meeting with FDA in the second quarter of 2023 to discuss its proposed

design and strategy for approval. The Company believes that FDA guidance on this Phase 3 study is critical to its BARDA proposal as well as to prospective domestic and global partners currently evaluating MAT2203, based on feedback received to date.

- The success of MAT2203 in the EnACT Phase 2 clinical trial in cryptococcal meningitis has attracted the attention of clinicians and patients without viable options for the treatment of a variety of fungal infections for which amphotericin B may be suitable, except for significant concerns relating to the toxicity of the currently available intravenous formulations of amphotericin B. Currently, there are four (4) patients who have been approved by FDA to receive MAT2203 on an emergency use basis since August of 2022, including one patient suffering from both mucor and aspergillosis. Overall, these patients have responded well to treatment with MAT2203, with notable clinical improvements. The Company will continue to evaluate opportunities to provide MAT2203 on an emergency basis for patients as it believes these are opportunities to showcase the safety and efficacy of MAT2203 outside clinical trial settings which represent important additional patient data for both FDA and prospective partners to review.

## **Financial Outlook**

The Company's preliminary, unaudited estimate of cash, cash equivalents and marketable securities at December 31, 2022, is approximately \$28.8 million, subject to completion of the audit of the Company's consolidated financial statements for the year ended December 31, 2022. This compares to \$49.9 million at December 31, 2021. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations into the second quarter of 2024.

## **Conference Call and Webcast Details**

The Company will host a live conference call and webcast to discuss this corporate update and 2023 business outlook today, Monday, January 30 at 4:30 p.m. ET. To participate in the call, please dial (877) 407-5976 or (412)-902-0031. The live webcast will be accessible on the Investors section of Matinas BioPharma's 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.

For more information, please visit [www.matinasbiopharma.com](http://www.matinasbiopharma.com).

## **Matinas 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 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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