May 10, 2023

Matinas BioPharma Reports First Quarter 2023 Financial Results and Provides a Business Update

FDA feedback from Type B meeting reiterated the Agency's intent to work collaboratively in advancing development of MAT2203 for the treatment of invasive fungal infections (IFIs)

Phase 3 trial design is being finalized to support a broad label for IFIs under a 505(b)(2) regulatory pathway

Initial in vivo study of oral mRNA delivery did not demonstrate preclinical activity; research under the collaboration agreement with BioNTech has been concluded

Successful in vivo systemic delivery and activity of mRNA in multiple additional studies

Conference call begins at 4:30 p.m. Eastern time today

BEDMINSTER, N.J., May 10, 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 financial results for the three months ended March 31, 2023 and provides a business update.

"Feedback from our U.S. Food and Drug Administration (FDA) Type B meeting held in April was encouraging, with the Agency recognizing the significant clinical potential and medical need for an oral, well-tolerated, broad-spectrum amphotericin B product to combat the growing threat of invasive fungal infections," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "The final meeting minutes reflect the FDA's interest in continuing to work collaboratively with Matinas to benefit patients in need and provided us with valuable direction on designing a Phase 3 IFI trial. We are diligently working to finalize a protocol and accompanying statistical package that we believe will support the broadest possible label for MAT2203 for the treatment of IFIs under a streamlined 505(b)(2) regulatory pathway."

"We are pleased with the continued interest from potential partners and funding sources to advance the development of MAT2203. We plan to accelerate our ongoing business development discussions and submit our funding proposals to the Biomedical Advanced Research and Development Authority (BARDA) and through the Advanced Research Project Agency for Health (ARPA-H), a new research funding agency within the National Institutes of Health (NIH) that supports high-impact research to drive biomedical breakthroughs, during the second quarter," he added.

"Our initial *in vivo* study of oral mRNA delivery, which was based upon encouraging early *in*

vitro results, and conducted with our collaborator BioNTech, did not demonstrate preclinical activity. While disappointing, we recognize that this was an ambitious goal for a first *in vivo* study of a new, unique mRNA formulation, where, to date, no delivery technology has been successful in achieving oral delivery of mRNA. We are pleased these formulations showed activity when administered systemically in other internal studies, in addition to demonstrating prolonged stability out to 17 weeks at 4° Celsius. We continue to believe that our technology has potential to provide differentiated delivery of nucleic acids and are in the process of generating additional data in this area both through our collaboration with National Resilience which has expanded to include mRNA following the expiration of exclusivity with BioNTech, and with our internal discovery programs in the siRNA space," Mr. Jabbour concluded.

Key Program Updates and Anticipated Upcoming 2023 Milestones

MAT2203 (Oral Amphotericin B) Program

MAT2203 Phase 3 Trial Design

- The Company plans to submit a revised Phase 3 trial design in the second quarter of 2023 to assess the safety, efficacy, and tolerability of oral MAT2203 in patients with life-threatening IFIs, including patients with limited treatment options. The FDA has indicated support for a trial in aspergillosis that is designed as a non-inferiority comparison to standard-of-care IV azole antifungal treatments. The main cohort in this trial is expected to include both first- and second-line patients, and its design will likely include an early step-down to oral treatment with MAT2203 administered as monotherapy. The trial will also likely include an open-label cohort of patients with a broad range of proven or probable IFIs who otherwise have limited treatment options and are not able to step down to an oral azole. The open-label cohort is expected to support label expansion beyond aspergillosis under a 505(b)(2) regulatory pathway and will include patients with invasive mucormycosis, other rare mold infections, invasive candidiasis, candida cystitis, and endemic mycoses including coccidioidomycosis, histoplasmosis and blastomycosis.

- Based on FDA's most recent feedback, the Company is re-evaluating the specifics of the previously contemplated Phase 3 trial in cryptococcal meningitis (CM). The Company believes that a smaller, more focused trial in CM, funded by the NIH could satisfy the FDA's requirement for an additional indication for the treatment of CM.

Compassionate Use Program

- A MAT2203 compassionate use case study was presented at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) highlighting the use of MAT2203 in a patient with a rare and challenging R. mucilaginosa infection of the bone (osteomyelitis), which placed her at risk for amputation and historically has usually required long-term amphotericin B treatment. The patient was transitioned to MAT2203 under the Company's Compassionate Use Program after suffering significant electrolyte abnormalities and associated renal toxicity related to treatment with IV amphotericin B. Following the transition to oral MAT2203, the patient's renal function returned to normal, and she was able to use MAT2203 safely for six months, leading to a robust clinical response, avoidance of amputation, and a return to full mobility.

- To date seven patients with various IFIs have been treated with MAT2203 under the Company's Compassionate Use Program. Inbound requests have been received from physicians at the NIH, University of Michigan, Nationwide Children's Hospital and Johns Hopkins University on behalf of patients with no treatment alternatives. Clinical data in these limited cases have demonstrated that orally administered MAT2203 targets infected tissues, is safe and effectively eradicates IFIs in the most challenging cases. MAT2203 has successfully treated serious infections throughout the body, including bone, CNS, lung, sinus, bladder, and skin, highlighting the tissue-targeted nature of the Company's LNC platform delivery technology.

Government Grants for MAT2203 Development

- Matinas is pursuing non-dilutive funding for the development of MAT2203 in multiple IFIs from BARDA and ARPA-H. The Company believes MAT2203 is well positioned to receive funding due to its oral, well-tolerated and broad-spectrum profile, positive feedback from the FDA Type B meeting, clinical success in the Phase 2 EnACT trial in cryptococcal meningitis and results from the Compassionate Use Program. A potential BARDA and/or ARPA-H award could be sufficient to fund development of MAT2203 through to market approval for the targeted IFI indications, as well as support supply chain and commercial readiness.

Platform Collaborations

BioNTech

- In May 2023, results of an initial *in vivo* study of an oral mRNA delivery formulation, conducted in collaboration with BioNTech, did not demonstrate oral preclinical activity.
- This single study, conducted in healthy mice, involved oral administration of a unique, proprietary, non-LNC formulation of BioNTech-supplied reporter mRNA (firefly luciferase).
- This proprietary, phosphatidylserine-containing nano-formulation, distinct from traditional LNCs, was developed by Matinas to handle the physical complexity and biological fragility of mRNA and other large oligonucleotides.
- This formulation had successfully delivered mRNA *in vitro* in multiple cell lines and because of the timelines required under the BioNTech collaboration was brought forward for oral *in vivo* evaluation.
- Additional internal Matinas *in vivo* studies of similar non-LNC mRNA formulations showed activity when administered systemically (intramuscularly and intraperitoneally). In addition, these formulations have demonstrated a high degree of stability out to at least 17 weeks at 4° Celsius which compares favorably to lipid nanoparticles (LNPs).
- Matinas has filed numerous provisional patent applications based upon these novel, unique, phosphatidylserine-based formulations.
- The research collaboration between Matinas and BioNTech has been concluded.

National Resilience

- Following expiration of the exclusive agreement with BioNTech in April 2023, Matinas' collaborative research program with National Resilience was expanded to focus on *in vitro* and *in vivo* delivery of mRNA.
- Specifically, National Resilience and Matinas will collectively focus on reporter and therapeutic oligonucleotide delivery; both *in vitro* and *in vivo*, against reference LNPs. Initial data is expected in the third quarter of 2023.

LNC Internal Pipeline Development

Internal siRNA Program

- Matinas is working toward the generation of *in vitro* data from an internal program for the delivery of silencing RNA (siRNA) therapies utilizing its LNC platform technology. Initial formulation data are expected in the third quarter of 2023. This program will continue with multiple *in vivo* biodistribution and animal efficacy studies planned for the second half of 2023.

First Quarter Financial Results

Revenue for the first quarter of 2023 was $1.1 million, which was generated from research collaborations with BioNTech and Genentech. There was no revenue reported for the first quarter of 2022.

Total costs and expenses for the first quarter of 2023 were $6.7 million compared with $7.7 million for the first quarter of 2022. The decrease was primarily attributable to lower manufacturing costs of clinical trial materials, partially offset by higher headcount.

The net loss for the first quarter of 2023 was $5.5 million, or $0.03 per share, compared with a net loss for the first quarter of 2022 of $6.0 million, or $0.03 per share.

Cash, cash equivalents and marketable securities as of March 31, 2023 were $24.9 million compared with $28.8 million as of December 31, 2022. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second half of 2024.

Conference Call and Webcast

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. To participate in the call, please dial 877-484-6065 (Toll-Free) or 201-689-8846 (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 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 siRNA, 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 a preferred next-generation intracellular drug delivery platform.

In addition, Matinas has recently developed a non-LNC phosphatidylserine-based nanoparticle delivery technology that takes advantage of the same unique biological properties of phosphatidylserine that play a key role in more traditional LNCs, but with its own unique structural characteristics that allow the *in vitro* and *in vivo* delivery of larger oligonucleotides like mRNA, with several distinct potential advantages over lipid nanoparticle alternatives. For more information, please visit 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 collaboration with National Resilience, Inc., the potential of our LNC platform and PS-NP delivery technologies, 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 technologies 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.
Condensed Consolidated Balance Sheets
(in thousands, except for share data)

	March 31, 2023 (Unaudited)	December 31, 2022 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 5,739	$ 6,830
Marketable debt securities	19,118	21,933
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	3,299	5,719
Total current assets	28,206	34,532
Non-current assets:		
Leasehold improvements and equipment – net	1,998	2,091
Operating lease right-of-use assets – net	3,480	3,613
Finance lease right-of-use assets – net	25	30
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash – security deposit	200	200
Total non-current assets	10,056	10,287
Total assets	$ 38,262	$ 44,819
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 516	$ 618
Accrued expenses	791	3,099
Operating lease liabilities – current	585	562
Financing lease liabilities – current	4	7
Total current liabilities	1,896	4,286
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities – net of current portion	3,379	3,533
Financing lease liabilities – net of current portion	21	22
Total non-current liabilities	3,741	3,896
Total liabilities	5,637	8,182
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at March 31, 2023 and December 31, 2022; 217,264,526 issued and outstanding as of March 31, 2023 and December 31, 2022	22	22
Additional paid-in capital	191,342	190,070
Accumulated deficit	(158,144)	(152,631)
Accumulated other comprehensive loss	(595)	(824)
Total stockholders' equity	32,625	36,637
Total liabilities and stockholders' equity	$ 38,262	$ 44,819

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

	Three Months Ended March 31,	
	2023	**2022**
Revenue:		
Contract Revenue	$ 1,096	$ -
Costs and Expenses:		
Research and development	3,970	4,978
General and administrative	2,712	2,744
Total costs and expenses	6,682	7,722
Loss from operations	(5,586)	(7,722)
Sale of New Jersey net operating loss & tax credits	-	1,734
Other income, net	73	10
Net loss	$ (5,513)	$ (5,978)
Net loss per share – basic and diluted	$ (0.03)	$ (0.03)
Weighted average common shares outstanding:		
Basic and diluted	217,264,526	216,644,783
Other comprehensive gain/(loss), net of tax		
Unrealized gain/(loss) on securities available-for-sale	229	(484)
Other comprehensive gain/(loss), net of tax	229	(484)
Comprehensive loss	$ (5,284)	$ (6,462)

Source: Matinas BioPharma Holdings, Inc.