May 12, 2022

Matinas BioPharma Reports First Quarter 2022 Financial Results and Operational Highlights

– Announced an exclusive research collaboration with BioNTech focused on the combination of mRNA and Matinas' proprietary LNC platform technology –

– 50% of Patients Enrolled to Date in Cohort 4 of EnACT (MAT2203 in Cryptococcal Meningitis); Topline Data Expected Q3 2022 –

– Feedback from Clinical Type C Meeting with the FDA Provides Potential Pathway to NDA Submission for MAT2203 with a Single Confirmatory Trial for Both Induction and Consolidation Indications –

– Successful Second In Vivo Efficacy Study of Oral LNC-Remdesivir –

–$43.9 million at March 31, 2022, Sufficient to Fund Planned Operations Through 2023 –

– Management to Host Conference Call Today, Thursday, May 12th, at 8:30 a.m. ET –

BEDMINSTER, N.J., May 12, 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 technology, today reported financial results for the first quarter ended March 31, 2022, along with a corporate update.

"We have made substantial progress in continuing to validate our LNC platform delivery technology by delivering consistent and compelling clinical and preclinical data through advancing our internal pipeline over the past few months," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "Our recently announced collaboration with BioNTech provides clear external validation for our LNC platform from a global pharmaceutical leader and creates the opportunity for oral administration of mRNA vaccines and other cutting-edge therapeutics, which could potentially benefit hundreds of millions of patients. Our own internal discovery programs built around preclinical data validating the LNC delivery of nucleic acids and antisense oligonucleotides, combined with our ongoing projects with Genentech and Gilead, provide momentum as we seek to capitalize upon the significant potential for our proprietary, next generation delivery technology. We could not be more pleased with our progress in 2022, and believe that we are well-positioned, with numerous value-creating milestones on the horizon."

First Quarter 2022 Highlights and Recent Events

External Collaborations

- In April 2022, Matinas and BioNTech entered an exclusive research collaboration to evaluate the combination of mRNA formats and Matinas' proprietary LNC platform technology. The Companies have initiated collaborative formulation, development, and optimization work toward planned preclinical efficacy testing. BioNTech and Matinas have also commenced formal license agreement discussions for Matinas' LNC delivery platform technology.

- Data from a second *in vivo* study of oral LNC-remdesivir in mice infected with SARS-CoV-2 demonstrated that oral LNC remdesivir reduced viral lung titers (as early as Day 2), improved lung congestion scores, and reduced COVID-associated weight loss. The study was performed in collaboration with the National Institute of Allergy & Infectious Diseases (NIAID) and the Department of Epidemiology at the University of North Carolina at Chapel Hill (UNC).

- The Company expanded its collaboration with Genentech, a member of the Roche Group, to include a third compound, which is a type of antibody fragment. Matinas will be focusing on creating an optimized oral formulation applying the LNC platform for preclinical testing, with potential results anticipated later in 2022.

Internal Pipeline Progress

MAT2203

- Enrollment continues in Cohort 4 of the ongoing EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis, with 28 patients (out of a total of 56) enrolled to date in Uganda. Cohort 4 is testing an all-oral regimen of MAT2203 during the 14-day induction period, followed by four additional weeks of oral consolidation therapy with MAT2203. The Company continues to anticipate reporting topline data from Cohort 4 in the third quarter of 2022.

- Matinas recently held a productive follow-up clinical Type C meeting with the FDA and has received written feedback concerning the confirmatory data required to support the submission of a New Drug Application (NDA) for MAT2203. As reflected in the official minutes of the meeting, FDA is now considering the potential registration of MAT2203 for both a step-down induction indication as well as a consolidation treatment indication based upon a single Phase 3 confirmatory trial. This pivotal registration trial will feature a non-inferiority trial design comparing MAT2203 (administered with 5FC) with a control arm of IV amphotericin (also administered with 5-FC), randomized 2:1 in favor of MAT2203, as induction and then consolidation therapy in HIV patients with cryptococcal meningitis. Critical elements of the pivotal registration trial will likely include:
    - Primary endpoint of 2-week all-cause mortality for induction indication
    - Non-inferiority margin of 10%, translating into a total trial size of approximately 250 patients (with 80% power)
    - A key secondary endpoint may include meningitis culture-positive relapse free

survival time through 18 weeks to evaluate consolidation treatment in support of a single NDA filing for both induction and consolidation treatment with MAT2203 in patients with cryptococcal meningitis

This streamlined development pathway represents a meaningful improvement from customary requirements for an NDA submission, which traditionally requires two adequate and well-controlled Phase 3 trials for registration. The Company plans to meet with FDA in the third quarter of 2022 to finalize the trial design and anticipates that the pivotal Phase 3 registration trial will commence later in 2022, with the anticipated financial support of the National Institutes of Health.

- The Company has recently submitted a formal Request for Scientific Advice to the European Medicines Agency (EMA) to facilitate a development and registration program in support of expanding the regulatory footprint for MAT2203 globally. Concurrent with the EMA process, the Company remains in discussions with key third parties interested in obtaining rights to MAT2203 on a global and regional basis.

- Preclinical studies of MAT2203 in *Candida auris* and *mucormycosis* have been initiated to support potential label expansion for MAT2203 into the treatment of other invasive fungal infections. Preliminary data generated to date demonstrate that MAT2203 is as effective as liposomal amphotericin B in protecting against *mucormycosis*, a deadly invasive fungal infection. Additional confirmatory studies in different strains of *mucormycosis* are ongoing. Preclinical evaluation of MAT2203 against *Candida auris* was initiated in April 2022 and preliminary data is expected in the third quarter of 2022.

- In the first quarter of 2022, the Company selected and reached agreement with Thermo Fisher Scientific to support scale-up and manufacturing for MAT2203 in anticipation of a potential NDA submission. Thermo Fisher Scientific, with more than 65 locations around the world, provides integrated, end-to-end capabilities across all phases of development, including APIs, biologics, viral vectors, cGMP plasmids, formulation, clinical trials solutions, logistics services and commercial manufacturing and packaging.

MAT2501

- Results from a single ascending dose (SAD) study of MAT2501 (oral amikacin) in healthy volunteers demonstrated rapid absorption of MAT2501 following oral administration with a time to maximal concentration of approximately 2 hours. Circulating plasma levels of LNC-delivered amikacin were significantly lower than IV-administered amikacin, which is expected to translate into a significantly improved safety profile for MAT2501. There were no serious adverse events and no evidence of any renal or ototoxicity observed, two of the most common toxicities seen with IV-administered amikacin.

First Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2022, were approximately

$43.9 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 first quarter of 2022, net loss attributable to common shareholders was $6.0 million, or a net loss of $0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of $5.2 million, or a net loss of $0.03 per share (basic and diluted), for the same period in 2021. The increase was due primarily to an increase in research and development expenses.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Thursday, May 12, 2022, at 8:30 a.m. ET.

To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13727955. The live webcast will be accessible on the Investors section of Matinas' website, 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.

The Company is focused on developing an internal and external pipeline of drugs candidates based on the LNC platform. Internally, the Company has two clinical stage assets. MAT2203 is an oral, LNC formulation of the highly potent antifungal medicine amphotericin B, currently in Phase 2 clinical trials; MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside, amikacin, primarily used to treat chronic and acute bacterial infections, and currently in Phase 1. Externally, the Company has established a broad set of relationships with multiple global pharmaceutical collaborators, including BioNTech (mRNA), the National Institutes of Health and Gilead Sciences (antivirals), and Genentech, a member of the Roche Group (small molecules, antisense oligonucleotides, and antibody fragments).

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 BioNTech, 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

	March 31, 2022 (Unaudited)	December 31, 2021 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 19,328,135	$ 21,029,806
Marketable securities	24,541,834	28,592,049
Restricted cash - security deposit	50,000	50,000
Prepaid expenses and other current assets	1,199,111	1,321,466
Total current assets	45,119,080	50,993,321
Non-current assets:		
Leasehold improvements and equipment - net	2,013,322	1,537,728
Operating lease right-of-use assets - net	4,082,763	4,218,890

Finance lease right-of-use assets - net	15,835	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	10,665,785	10,332,753
Total assets	$ 55,784,865	$ 61,326,074
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 1,351,905	$ 938,270
Accrued expenses	1,840,748	2,850,888
Operating lease liabilities - current	558,702	538,546
Financing lease liabilities - current	17,134	21,039
Total current liabilities	3,768,489	4,348,743
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,993,396	4,140,387
Financing lease liabilities - net of current portion	-	2,621
Total non-current liabilities	4,334,661	4,484,273
Total liabilities	8,103,150	8,833,016
Stockholders' equity:		
Common stock	21,685	21,627
Additional paid-in capital	185,901,685	184,251,138
Accumulated deficit	(137,612,481)	(131,634,208)
Accumulated other comprehensive loss	(629,174)	(145,499)
Total stockholders' equity	47,681,715	52,493,058
Total liabilities and stockholders' equity	$ 55,784,865	$ 61,326,074

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended March 31,	
	2022	**2021**
Revenue:		
Contract research revenue	$ -	$ 33,333

Costs and expenses:		
Research and development	4,978,105	3,241,432
General and administrative	2,744,195	3,145,010
Total costs and expenses	7,722,300	6,386,442
Loss from operations	(7,722,300)	(6,353,109)
Sale of New Jersey net operating loss & tax credits	1,734,133	1,328,470
Other income, net	9,894	68,319
Net loss	$ (5,978,273)	$ (4,956,320)
Preferred stock series B accumulated dividends	-	(210,900)
Net loss attributable to common shareholders	$ (5,978,273)	$ (5,167,220)
Net loss available for common shareholders per share - basic and diluted	$ (0.03)	$ (0.03)
Weighted average common shares outstanding - basic and diluted	216,644,783	203,871,820
Other comprehensive loss, net of tax		
Unrealized loss on securities available-for-sale	(483,675)	(91,766)
Other comprehensive loss, net of tax	(483,675)	(91,766)
Comprehensive loss attributable to shareholders	$ (6,461,948)	$ (5,048,086)

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.

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