March 8, 2022

Matinas BioPharma Reports Fourth Quarter and Full Year 2021 Financial Results and Operational Highlights

– Fifteen Patients Enrolled to Date in Cohort 4 of EnACT (all oral induction regimen); Topline Interim Data Expected Q3 2022 –

– Potential Pathway to NDA Submission for MAT2203 with Confirmatory Data to Come from Cohort 5 of EnACT Trial –

– Second in vivo Study of Oral LNC-remdesivir to Commence in March 2022 –

– Moving Aggressively into Nucleic Acids with Internal Discovery Programs Initiated with mRNA, DNA and Antisense Oligonucleotides (ASOs) –

– $49.6 million at Year-End 2021, Sufficient to Fund Planned Operations Through 2023 –

– Management to Host Conference Call Today, Tuesday, March 8th, at 8:30 a.m. ET –

BEDMINSTER, N.J., March 08, 2022 (GLOBE NEWSWIRE) -- Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), 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 reported financial results for the fourth quarter and full year ended December 31, 2021, along with a corporate update.

“We are proud of the significant progress we made in 2021 to advance our LNC platform technology, including delivering compelling data for MAT2203 in the first three cohorts of the EnACT trial and meeting with the U.S. Food and Drug Administration (FDA) for an End of Phase 2 meeting,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “In 2022, in addition to delivering data from Cohort 4 of the EnACT trial in the third quarter, we have moved aggressively into the formulation and delivery of nucleic acids and have initiated internal discovery programs based on the delivery of mRNA, DNA and antisense oligonucleotides. While we are very excited about our infectious disease small molecule programs, we believe that our LNC delivery technology has the potential to become a preferred and novel modality for the targeted intracellular delivery of these complex therapeutics. The unique properties of our LNC platform, including oral bioavailability, extrahepatic targeting, large payload capacity, and improved stability and safety, are supported by key preclinical data that differentiates our technology from both lipid nanoparticles and viral vectors. We believe these unique properties represent the next generation in intracellular drug delivery.”

Fourth Quarter 2021 Highlights and Recent Events

- 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 15 patients enrolled to date in Uganda. Cohort 4 is designed to study an all-oral regimen of MAT2203 during the 14-day induction period, followed by four additional weeks of oral consolidation therapy with MAT2203. Cohort 4 is comprised of 40 patients on MAT2203 and a control group of 16 patients receiving IV amphotericin B. Enrollment in this open-label cohort is expected to complete in the second quarter of 2022, with availability of topline interim data anticipated in the third quarter of 2022.

- The Company is scheduled to meet with the FDA in the second quarter of 2022 to finalize cohort design of an expansion of EnACT to include a new Cohort 5 which is planned to generate the confirmatory data of MAT2203 as step-down therapy requested by FDA to support and file a New Drug Application (NDA). This additional cohort will increase the number of clinical sites in Uganda and should commence in the second half of 2022 pending FDA feedback.

- The Company plans to submit a formal Request for Scientific Advice to the European Medicines Agency (EMA) during the second quarter of 2022 to align and plan for expanding the regulatory footprint for MAT2203 globally.

- Preclinical studies of MAT2203 in *Candida auris* and *mucormycosis* (black fungus) scheduled to begin in the second quarter of 2022 to support potential label expansion.

- The Company recently selected and reached agreement with a leading, global contract manufacturing organization to support the scale-up and commercial manufacturing for MAT2203 in anticipation of a potential NDA submission in late 2023 or early 2024.

- A single ascending dose (SAD) study of MAT2501 (oral amikacin) in healthy volunteers is ongoing, with data expected later in the second quarter of 2022.

- The Company, 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) will commence a second in vivo study of LNC-remdesivir in March of 2022 with data expected in mid-2022.

- A global process to identity and potentially secure a partner to continue development of LYPDISO™ remains ongoing. Further update is anticipated in the second quarter of 2022.

Fourth Quarter and Full Year 2021 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2021, were approximately $49.6 million, compared to $58.7 million at December 31, 2020. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

For the fourth quarter of 2021, net loss attributable to common shareholders was $6.7 million, or a net loss of $0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of $6.6 million, or a net loss of $0.03 per share (basic

and diluted), for the same period in 2020. For the full year of 2021, net loss attributable to common shareholders was $23.7 million, or a net loss of $0.11 per share (basic and diluted), compared to a net loss attributable to common shareholders of $23.2 million, or a net loss of $0.12 per share (basic and diluted), for the full year of 2020. 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, Tuesday, March 8, 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 13727084. 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 redefining 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 in route of administration (including oral), position Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

MAT2203 is an oral, LNC formulation of the highly effective, but also highly toxic, antifungal medicine amphotericin B, primarily used as a first-line treatment for invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. The DSMB unanimously approved the progression of EnACT into Cohort 4 in December of 2021. Cohort 4 commenced in January of 2022, with data expected in the second half of 2022.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic amikacin, primarily used to treat chronic and acute bacterial infections. With the support of the Cystic Fibrosis Foundation, MAT2501 is currently undergoing important preclinical studies and commenced a Phase 1 human clinical trial in the fourth quarter of 2021. MAT2501 would be the first and only oral aminoglycoside, and is being positioned with an initial indication for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis.

LYPDISO™, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, intended for the treatment of cardiovascular and metabolic conditions. This next-generation omega-3 therapy has been shown in two head-to-head studies to provide effective triglyceride-lowering and significantly higher EPA blood levels

than Vascepa®. A global process to identity and potentially secure a partner to continue development of LYPDISO remains ongoing.

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, 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.
Consolidated Balance Sheets
(Audited)

	December 31, 2021	December 31, 2020
ASSETS:		
Current assets:		

Cash and cash equivalents	$ 21,029,806	$ 12,432,481
Marketable securities	28,592,049	46,246,573
Restricted cash - security deposit	50,000	136,000
Prepaid expenses and other current assets	1,321,466	2,739,791
Total current assets	50,993,321	61,554,845
Non-current assets:		
Leasehold improvements and equipment - net	1,537,728	1,523,950
Operating lease right-of-use assets - net	4,218,890	3,276,639
Finance lease right-of-use assets - net	22,270	58,007
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	10,332,753	9,412,461
Total assets	$ 61,326,074	$ 70,967,306
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 938,270	$ 349,941
Accrued expenses	2,850,888	2,795,329
Operating lease liabilities - current	538,546	391,498
Financing lease liabilities - current	21,039	30,853
Total current liabilities	4,348,743	3,567,621
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	4,140,387	3,304,063
Financing lease liabilities - net of current portion	2,621	23,660
Total non-current liabilities	4,484,273	3,668,988
Total liabilities	8,833,016	7,236,609
Stockholders' equity:		
Series B Convertible preferred stock	-	3,797,705
Common stock	21,627	20,010
Additional paid-in capital	184,251,138	167,192,003
Accumulated deficit	(131,634,208)	(107,507,193)
Accumulated other comprehensive (loss)/income	(145,499)	228,172

Total stockholders' equity	52,493,058	63,730,697
Total liabilities and stockholders' equity	$ 61,326,074	$ 70,967,306
	-	-

Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss

	For the Three Months Ended December 31, (Unaudited)		For the Year Ended December 31, (Audited)	
	2021	**2020**	**2021**	**2020**
Revenue:				
Research and development	$ -	$ 62,500	$ 33,333	$ 158,333
Costs and expenses:				
Research and development	4,239,832	3,525,573	14,583,283	14,358,918
General and administrative	2,474,180	3,025,812	10,184,805	10,005,967
Total costs and expenses	6,714,012	6,551,385	24,768,088	24,364,885
Loss from operations	(6,714,012)	(6,488,885)	(24,734,755)	(24,206,552)
Sale of New Jersey net operating loss & tax credits	-	-	1,328,470	1,073,289
Other income, net	14,572	148,005	122,870	686,425
Net loss	$ (6,699,440)	$ (6,340,880)	$ (23,283,415)	$ (22,446,838)
Preferred stock series B accumulated dividends	-	(218,050)	(395,799)	(793,442)
Net loss attributable to common shareholders	$ (6,699,440)	(6,558,930)	$ (23,679,214)	$ (23,240,280)
Net loss available for common shareholders per share - basic and diluted	$ (0.03)	(0.03)	$ (0.11)	$ (0.12)

Weighted average common shares outstanding - basic and diluted	216,255,256	199,347,750	210,178,332	196,894,628
Other comprehensive (loss)/income, net of tax				
Unrealized (loss)/gains on securities available-for-sale	(143,905)	(129,596)	(373,671)	237,537
Reclassification to net loss	-	(5,777)	-	(8,485)
Other comprehensive (loss)/income, net of tax	(143,905)	(135,373)	(373,671)	229,052
Comprehensive loss attributable to stockholders	$ (6,843,345)	$ (6,476,253)	$ (23,657,086)	$ (22,217,786)

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Source: Matinas BioPharma Holdings, Inc.

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