UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 12, 2022

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38022**	**46-3011414**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

1545 Route 206 South, Suite 302 **Bedminster, New Jersey**	**07921**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (908) 443-1860

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	MTNB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On May 12, 2022, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2022. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 7.01. Regulation FD Disclosure.

The Company updated its corporate presentation (the "Corporate Presentation") which it intends to use at various conferences and investor meetings. The Corporate Presentation is attached hereto as Exhibit 99.2 and incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated May 12, 2022.
99.2	Corporate Presentation, dated May 12, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MATINAS BIOPHARMA HOLDINGS, INC.

Dated: May 12, 2022

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

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 – 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 followed by 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

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

Peter Vozzo
ICR Westwicke
443-213-0505
peter.vozzo@westwicke.com

Source: Matinas BioPharma Holdings, Inc.

Exhibit 99.2

Forward-Looking Statement

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow 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.

Lipid Nanocrystals (LNCs) Simplify Intracellular Delivery of Nucleic Acids

	Description	Benefit
INNATELY TARGET "ACTIVATED" CELLS	▪ Macrophages/monocytes, neutrophils, dendritic cells ▪ Infected/injured cells, tumor cells	▪ Wide variety of extrahepatic targets
IMPROVED SAFETY	▪ Non-immunogenic platform ▪ Enter cells through non-destructive membrane fusion	▪ Enables repeat administration
IMPROVED STABILITY	▪ Crystal structure protects nucleic acids	▪ Avoid cold chain ▪ Flexible Administration (orally, IV, IM or via inhalation)
PAYLOAD VERSATILITY	▪ Nucleic acids (DNA, mRNA, siRNA, etc..) ▪ Proteins, peptides & small molecules	▪ Choose best therapeutic cargo regardless of size

***LNCs validated* in multiple clinical and pre-clinical studies**

MATINAS BIOPHARMA

Matinas Pipeline and Discovery Programs: Internal Clinical Stage Assets and External Collaborations

	Program	Indication	Discovery	Preclinical	Phase 1	Phase 2
MATINAS BIOPHARMA	MAT2203 LNC-Amphotericin B (oral)	Cryptococcal Meningitis	*EnACT Cohort 4 (Top-line Results Expected Q3 2022)*			
		Invasive Fungal Infections				
MATINAS BIOPHARMA / CYSTIC FIBROSIS FOUNDATION	MAT2501 LNC-Amikacin (oral)	Non-tuberculous Mycobacterial Disease (NTM)	*Phase1 SAD Study and Long Term Tox Set Stage for Phase 2 in 2023*			
GILEAD / NIH	LNC-Remdesivir (oral)	SARS-COVID19				
Genentech A Member of the Roche Group	LNC-ASO LNC-small molecule LNC-FAB	Undisclosed				
BIONTECH	LNC-mRNA	Vaccines				
MATINAS BIOPHARMA	Internal platform programs (LNC nucleic acids)	Undisclosed	*mRNA, DNA Plasmids, Oligos*			

LYPDISO™ *Partnering efforts ongoing*

Exclusive Research Collaboration with BioNTech

MATINAS BIOPHARMA BIONTECH

- Exclusive collaboration between Matinas and BioNTech focused on mRNA and certain other nucleic acids
- BioNTech's mRNA vaccine development expertise combined with Matinas' LNC delivery platform
- Builds on Matinas' extensive prior preclinical *in-vitro* vaccine work with LNC formulations of proteins, peptides and DNA plasmids
  - Oral bioavailability
  - Non-immunogenic transfection
  - Focus on eliciting strong humoral and cellular immunity
- $2.75 million upfront exclusive access fee plus research funding
- Initiated license agreement discussions

MATINAS BIOPHARMA

Exclusive Research Collaboration with BioNTech Builds on Previous Vaccine Results

Efficacy previously demonstrated w/LNCs (*in-vivo*)

- ✓ Successful oral immunization
- ✓ Substantial increases in antibody titers
  - Out to 5 months after a single oral immunization
  - Boosted with repeat administration
  - Can be even further increased with adjuvants
- ✓ Enhanced cell-mediated response (lymphocyte proliferation, cytolytic T-cell response)
- ✓ High degree of protection against viral replication
- ✓ Protective against lethal challenge
- ✓ Enhancement of a commercial vaccine

LNCs Provide Differentiation

- ✓ Can be administered SQ, IM, via inhalation, and **orally**
- ✓ Enhanced mucosal and systemic responses, humoral and cellular immunity
- ✓ High efficiency of delivery (proteins, peptides and DNA plasmids)
- ✓ Delivery mechanism itself not immunogenic
- ✓ Potential for much more stable formulations

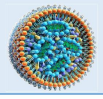
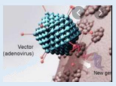
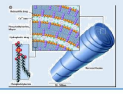
MATINAS BIOPHARMA

Lipid Nanocrystal (LNC) Platform

Targeted, Well-Tolerated Intracellular Delivery

MATINAS BIOPHARMA

LNCs Provide A Strong Alternative to LNP and AAV Delivery

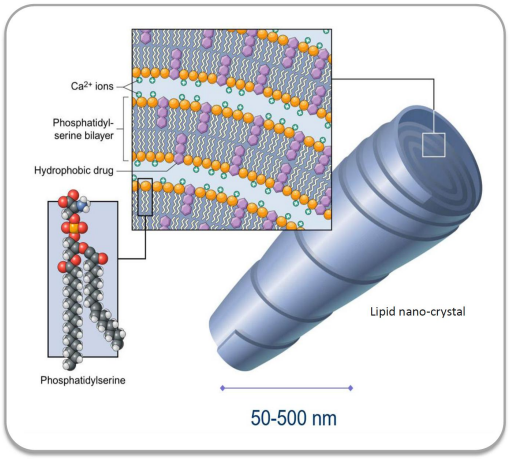
	LNP	AAV Viral Vector	LNC
			
Structure	• Ionizable lipid complexing with mRNA • Non-aqueous interior	26 nM Capsid housing	• Natural components • Non-aqueous bilayer
Targeting	• Avid uptake by RES, liver, spleen limits availability	• Limited set of targeted tissues • Local delivery to CNS, eye	• **Targeted to phagocytes and activated cells** (e.g. infected, inflamed or cancerous cells)
Payload	• Few practical limitations on size • Only 1-2% endosomal escape substantially lowers delivery efficiency	• <5 kb genome	• Demonstrated incorporation of nucleic acids (ASOs, DNA plasmids, mRNA), proteins and small molecules • Up to ***at least*** **11 kb capacity** (gene therapy, CRISPR, etc.)
Safety	• Cationic lipid toxicity not suitable for chronic use • Anti-PEG allergic response limits retreatment	• Viral genome integration concerns • Immunogenicity limits retreatment	• **Non-immunogenic platform** • No cellular toxicity due to natural PS
Stability	• Very limited shelf stability • Cold-chain requirements	• Cold chain requirements	• Solid structure allows **prolonged storage** • mRNA formulations have demonstrated 4 month stability at room temperature • Enables **oral** dosing as well as IV, inhaled & SC

LNCs can delivery large payloads in a stable delivery vehicle with no immunogenicity, novel targeting and oral delivery

MATINAS BIOPHARMA

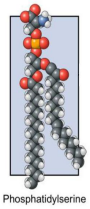
Lipid Nanocrystals (LNCs) Consist of Phosphatidylserine, Calcium and Cargo and Deliver Cargo Intracellularly

- Stable, phospholipid-calcium crystalline nanoparticles
- Calcium (Ca^{++}) – Phosphatidylserine (PS) crystalline shell
- Engineered to self-assemble into nano-crystals in the presence of Ca^{++}
- Multilayered structure with little or no internal aqueous space
- Payload can be incorporated into the layers
  - ***Hydrophobic*** molecules packaged in the interior of the bilayer
  - ***Hydrophilic*** molecules packaged between the wrapped layers
- Two routes for drug delivery
  - LNCs can fuse with target cell membranes (delivering drugs directly inside the cell)
  - LNCs can also be taken up (via phagocytosis) by target cells and deliver their contents from within endosomes to the cell interior

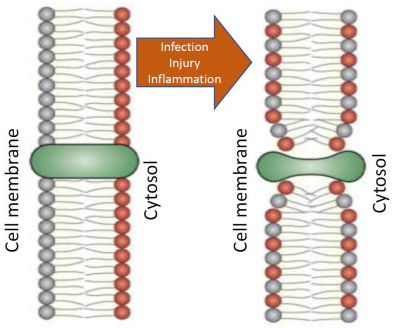


MATINAS BIOPHARMA

LNCs Work Because of PS, Which Enables Intracellular Delivery Via Two Biological Pathways



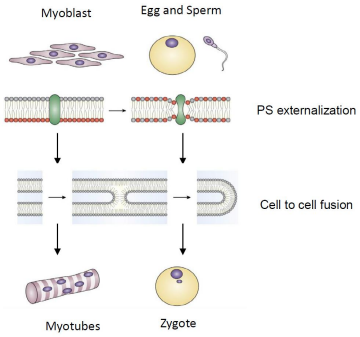
PS on the outer layer is an "eat-me" signal enabling **phagocytosis**



Normally, PS is confined to the inner layer (facing cytosol)

With "activation" PS moves from the inner layer to the outer layer (cell membrane)

PS on the outer cell membrane is also a precursor for cell-to-cell **fusion**



Whitlock JM *et al.* ***J Biol Chem*** 2021; 296: 1-16
https://doi.org/10.1016/j.jbc.2021.100411

MATINAS BIOPHARMA

LNCs Have the Potential to Target a Wide Array of Cells & Tissues

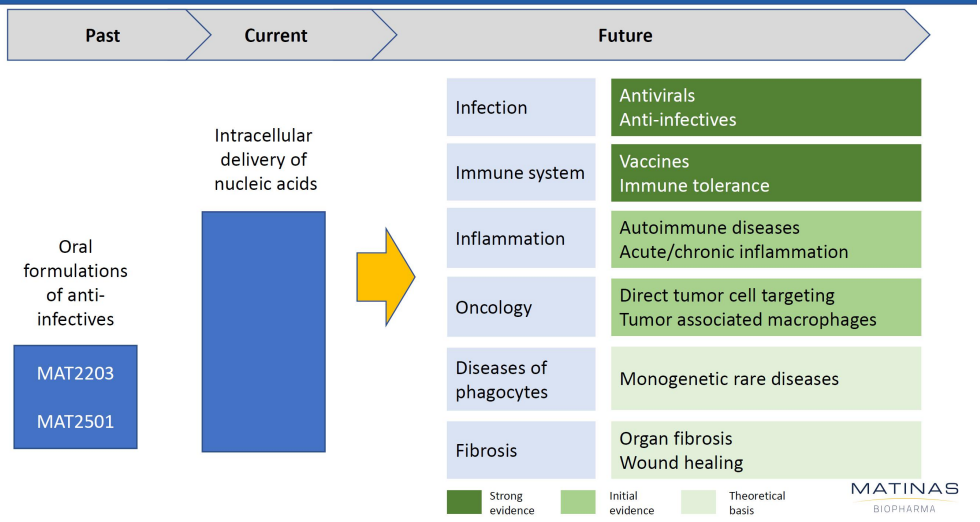
	Cells with PS Receptors or Expressing High PS Levels	Demonstrated uptake
Cells Capable of Phagocytosis	Bone marrow-derived hematopoietic cells	
	▪ Macrophages	✓
	▪ Dendritic cells	
	▪ Natural killer (NK) cells	
	Astrocytes and microglial cells (CNS macrophages)	
	Specialized epithelial cells that participate in efferocytosis	
	▪ Retinal epithelial cells	
	▪ Alveolar lung epithelial cells	
	▪ Mammary epithelial cells	
"Activated Cells" (context dependent)	Actively dividing cells	
	▪ Fibroblasts	✓
	▪ Tumor Cells	✓
	Infected Cells	✓
	Injured / Inflamed Cells	✓

LNCs are Designed to Mimic Enveloped Viruses

11

MATINAS BIOPHARMA

Multiple Potential Future Directions For LNC Platform



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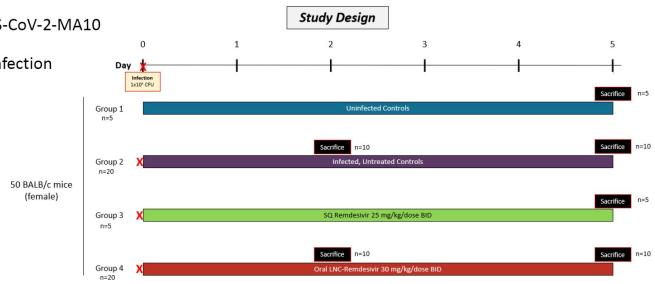
In vivo Assessment of the Efficacy of LNC-remdesivir in SARS-CoV-2 Infection

Goal: Evaluate the capacity of an orally bioavailable remdesivir formulation to block viral replication and prevent severe disease in a mouse model of SARS-CoV-2*

* Leist and Dinnon et al., ***Cell*** 2020.

- 10-week-old female BALB/c mice
- Intranasal inoculation of 10^4 PFU of SARS-CoV-2-MA10
- 4 Groups - Rx beginning 12 hours after infection
  - Uninfected controls
  - Infected, untreated controls
  - SQ RDV 25 mg/kg BID
  - Oral LNC-RDV 30 mg/kg BID
- Daily body weight
- Sacrifice at Day 2 and day 5
  - Lung titers, gross pathological congestion score (0-5) and histology.



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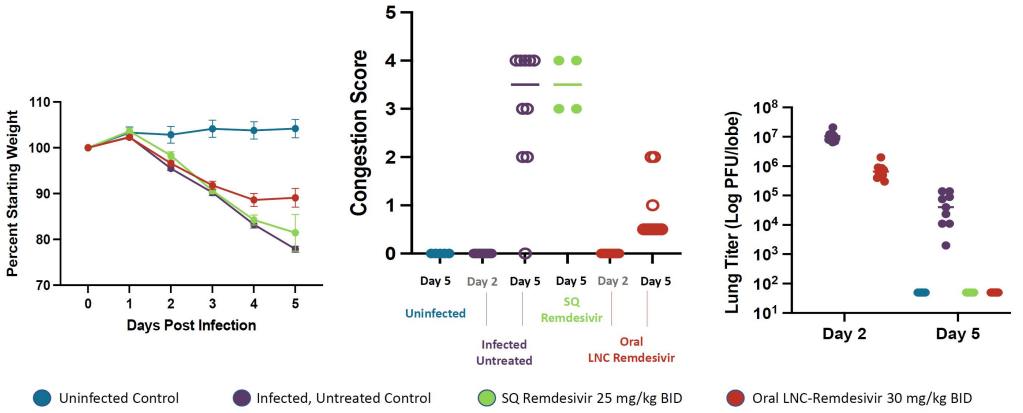
In vivo Assessment of the Efficacy of LNC-remdesivir in SARS-CoV-2 Infection



In mice infected with SARS-CoV-2, oral LNC-Remdesivir reduced viral lung titers (beginning on Day 2), improved congestion scores, and mitigated weight loss

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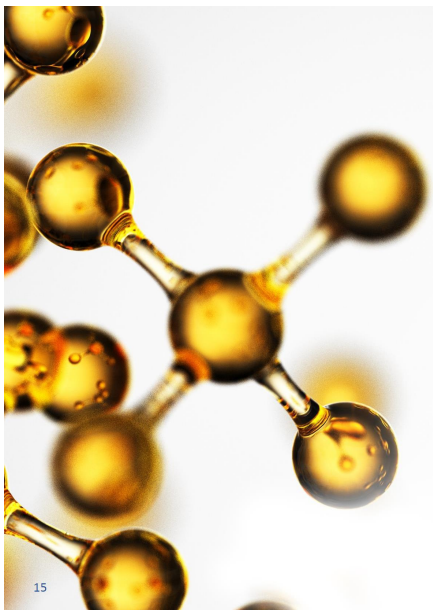

MAT2203

Oral Amphotericin B

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MAT2203: A Novel Approach with a Proven Therapeutic Agent

MAT2203

- Oral amphotericin B formulation utilizing LNCs
- Proprietary formulation with robust intellectual property protection
- Potential to expand beyond treatment of CM to treatment of other invasive infections and prophylaxis
- Program supported by the National Institutes of Health (NIH)/NIAID

IMPROVED PROFILE

- LNC formulation enables oral administration, bioavailability and improved toxicity over IV amphotericin
- Efficient intracellular delivery to immune cells with delivery directly to infected tissues
- Demonstrated ability to cross the blood-brain barrier with an oral therapy

POTENTIAL CLINICAL IMPACT

- Potential to become the preferred antifungal agent for all invasive fungal infections ($8 billion+ market)
- Orphan Drug Designation + 4 Qualified Infectious Disease (QIDP) and Fast Track Designations
- Up to *12 years marketing exclusivity*, if approved

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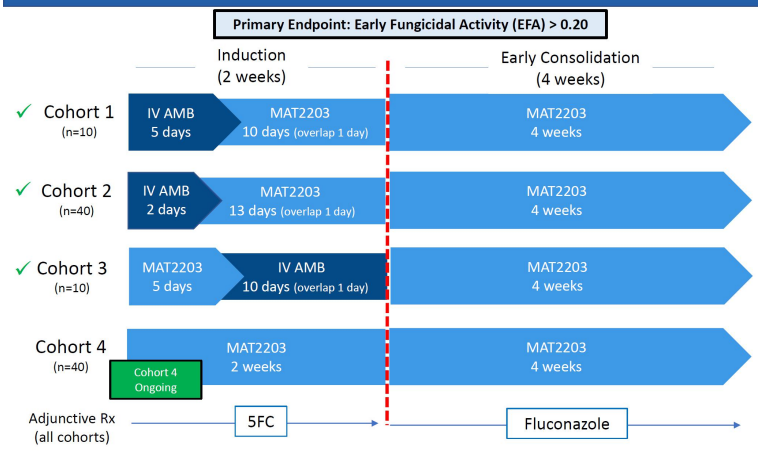
EnACT Study Design



MAT2203 TREATMENT REGIMENS:

Cohort 1
- Induction: 2.0g/day
- Consolidation: 1.5g/day

Cohort 2
- Induction: 1.8g/day
- Consolidation: 1.2g/day

- *For each Cohort, a control group receives standard of care IV AMB +5FC (7 days), followed by 1200mg Fluconazole (7 days) for Induction and then only Fluconazole (800mg) for Early Consolidation*
- *Control arm present primarily to assess patient safety*
- *EnACT **not** powered to formally test comparisons with the control arm standard of care*

*IV AMB = intravenous amphotericin B

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EnACT Cohort 2 Met Primary Endpoints – Effective at Delivering Drug ACROSS Blood Brain Barrier

EnACT Cohort 2 Endpoints

- **Primary Endpoint**: Early Fungicidal Activity (**EFA**) $\log_{10}$ CFU/mL/day at Day 14 >0.20
  - EFA > 0.20 - associated with lower mortality and improved clinical outcomes[1]
- **Secondary Endpoints**
  - Sterilization of CSF cultures
  - Prevention of relapse (no breakthroughs)
  - Survival at 18 weeks
  - Demonstrated safety

EnACT Cohort 2 Results

- ✓ EFA for MAT2203 was **0.42** (95% CI 0.29 to 0.55), exceeding the primary endpoint threshold
- ✓ All 39 MAT2203 patients completing induction achieved CSF sterility
  - (a) 97% for patients receiving MAT2203
  - (b) 76% for patients receiving SOC
- ✓ No breakthrough infections during MAT2203 treatment (10 weeks)
- ✓ "Early Survival" at Day 30
  - (a) 98% for patients receiving MAT2203
  - (b) 88% for patients receiving IV Ampho (SOC)
- ✓ MAT2203 was safe and well-tolerated over **6 weeks** of treatment
  - No renal toxicity or electrolyte abnormalities
  - No discontinuations due to AEs nor MAT2203-related SAEs

EnACT Clinical Data Validate the Use of LNCs to Overcome Delivery Challenges

1 ***Clin Infect Dis.*** 2020;71(5):e45-49 EFA is measure of antifungal activity in the CSF during induction treatment for CM

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MAT2203 EnACT Update and Lifecycle Management for Label Expansion

EnACT Cohort 4 Update

- All-oral regimen administered during induction (14 days) followed by consolidation treatment through Week 6
- Target: 40 patients on MAT2203 and 16 patients on SoC
- 50% enrolled (28 patients) through May 12th
- First DSMB review already conducted with recommendation to continue enrollment in the cohort without any changes to study design or dosing regimen
- Next DSMB review (50% enrollment) scheduled for end of May 2022
- Topline Data expected Q3 2022

Preclinical Update

- Preclinical studies in *C. Auris* and *Mucormycosis* initiated to support the label expansion of MAT2203
- Preliminary preclinical study conducted assessing effect of MAT2203 vs standard of care (SoC) liposomal amphotericin B (L-AMB) in an established murine model of *mucormycosis* caused by *Rhizopus delemar* infections
  - ➢ Data generated to date demonstrate that MAT2203 is as effective as L-AMB in protecting against *mucormycosis* due to *R. delemar*
  - ➢ Confirmatory studies in additional strains ongoing
- Preclinical evaluation of MAT2203 for *C. Auris* initiated April 2022; preliminary data expected Q3 2022.

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MAT2203 Regulatory Updates: Pathway to NDA Approval and Phase 3 Registration Trial

Follow-up Clinical Type C Meeting held April 2022

- ➢ FDA is evaluating potential registration of MAT2203 for **both** step-down induction and consolidation indications based upon the conduct of a **single** Phase 3 Trial
  - Represents a further streamlined development program, compared with the traditional requirement of two separate, "adequate and well-controlled" Phase 3 trials per indication for registration
- ➢ Pivotal study design features a non-inferiority trial with an IV amphotericin B and flucytosine (5-FC) comparator arm
- ➢ FDA recommended the following for the planned Phase 3 pivotal study:
  - Primary endpoint for induction: All-Cause Mortality at 2 Weeks
  - Non-inferiority margin of 10% (N=~250 patients; 80% power)
  - Total safety database ~300 patients (patients treated at the to-be-recommended dose and duration of treatment)
  - Key secondary endpoint for consolidation indication: meningitis culture-positive relapse-free survival time through Week 18
  - FDA meeting planned for July 2022 to reach final agreement on study design; Phase 3 to potentially commence later in 2022
  - NIH continued financial support of Phase 3 program anticipated

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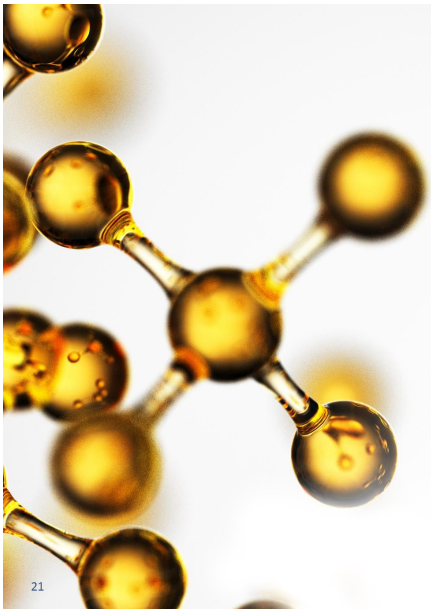

MAT2501

Oral Amikacin

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MAT2501: A Better Amikacin

MAT2501

- Oral, LNC formulation of the broad-spectrum antibiotic Amikacin
- Initial indication in treatment of non-tuberculous mycobacterial (NTM) infections
- QIDP and Orphan Designations potentially provide 12+ years of exclusivity upon approval
- Proprietary formulation with robust intellectual property protection
- Development accelerated with $4.5M Cystic Fibrosis Foundation award

IMPROVED PROFILE

- LNC formulation enables oral administration and bioavailability
- Encouraging safety profile potentially eliminates oto- and nephro-toxicity
- Shown targeted delivery and efficacy in preclinical models of disseminated, pulmonary and biofilm NTM
- Activity against both Mycobacterium avium complex (MAC) and M. abscessus complex (MABC)

SIGNIFICANT UNMET NEED

- Potential to become the first oral aminoglycoside
- 80-90K US NTM patients; 40% refractory to treatment
- Potential use in acute, gram-negative infections
- Improvement over *INSM's Arikayce® (inhaled amikacin)

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MAT2501: NTM Program Overview and SAD Topline Results

Non-Tuberculous Mycobacterial Disease

- NTM organisms, widely present in the environment, are a frequent cause of challenging pulmonary infections, especially in patients with pre-existing inflammatory lung diseases such as cystic fibrosis
- Approximately 40-60% of patients have infections that are macrolide-resistant, and cure rates in these macrolide-resistant patients can be as low as 40-60%
- IV amikacin carries significant concomitant risk of both oto- and nephro-toxicity
- Inhaled amikacin (Arikayce®) has similar side effects and presents a challenge for absorption in CF patients with excessive pulmonary mucus

Preliminary Development Timeline

- **2022** – Long Term Tox and Positioning for Phase 2 in NTM (2023); planning for other indications

Single Ascending Dose (SAD) PK Study Topline Results

- Results confirmed earlier findings with legacy formulation at the same doses (200, 400, 800) with an additional higher dose (1000 mg; fasted/fed) tested in this study
- No SAEs or study discontinuations (only dose-related adverse event was diarrhea (mild to moderate))
- No evidence of ototoxicity or renal toxicity
- Rapid absorption with oral administration (T_{max} 2 hours)
- Dose-proportional increases in exposure
  - Exposure significantly lower compared with IV administered amikacin

Expanding LNC Intellectual Property Portfolio

30
ISSUED U.S. & FOREIGN PATENTS EXTEND TO AT LEAST 2033

20 Patents Issued Within Last 5 Years

30+
PENDING PATENT APPLICATIONS ACROSS PLATFORM COULD EXTEND TO 2040

Additional IP to be developed as clinical development plan progresses.

Regulatory Exclusivity

MAT2203 and MAT2501 both have QIDP and Orphan Designations Potentially Entitling Each Product to 12+ Years of Exclusivity

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Summary and 2022 Milestones & Catalysts

	1H 2022 Milestones & Catalysts	2H 2022 Milestones & Catalysts
MAT2203	☑ FDA Feedback on Cohort 5 of EnACT ☑ Initiate preclinical studies of MAT2203 in *C. auris* and *mucormycosis*	☑ Interim Topline Data from Cohort 4 of EnACT ☑ Data from MAT2203 preclinical studies in *C. auris* and *mucormycosis* ☑ Potential MAT2203 Partnership
MAT2501	☑ Data availability from MAT2501 Phase 1 SAD study in healthy volunteers	
LNC Platform and Collaborations	☑ Initiate and receive data from 2nd *in vivo* study of oral LNC-RDV sponsored by NIAID/Gilead ☑ Conduct internal in-vitro and in-vivo studies with mRNA, DNA, oligonucleotides ☑ Potential research collaboration with large pharma in nucleic acids