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): September 13, 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) 484-8805

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 7.01 Regulation FD Disclosure.

Matinas BioPharma Holdings, Inc. (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 and incorporated herein by reference.

The information in this Item 7.01 and Exhibit 99.1 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	Corporate Presentation dated September 13, 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: September 13, 2022

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

MATINAS BIOPHARMA

Corporate Presentation

September 2022

Forward Looking Statements

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 Nanocrystal (LNC) Platform: Clinically Validated Intracellular Delivery

Next generation platform delivery beyond LNPs and viral vectors

Extra-hepatic Targeting

- Selective uptake by phagocytic cells (e.g., macrophages) and cells with externalized phosphatidylserine (e.g., injured, inflamed and infected cells and tumor cells)
- Demonstrated delivery across the blood-brain barrier (BBB)

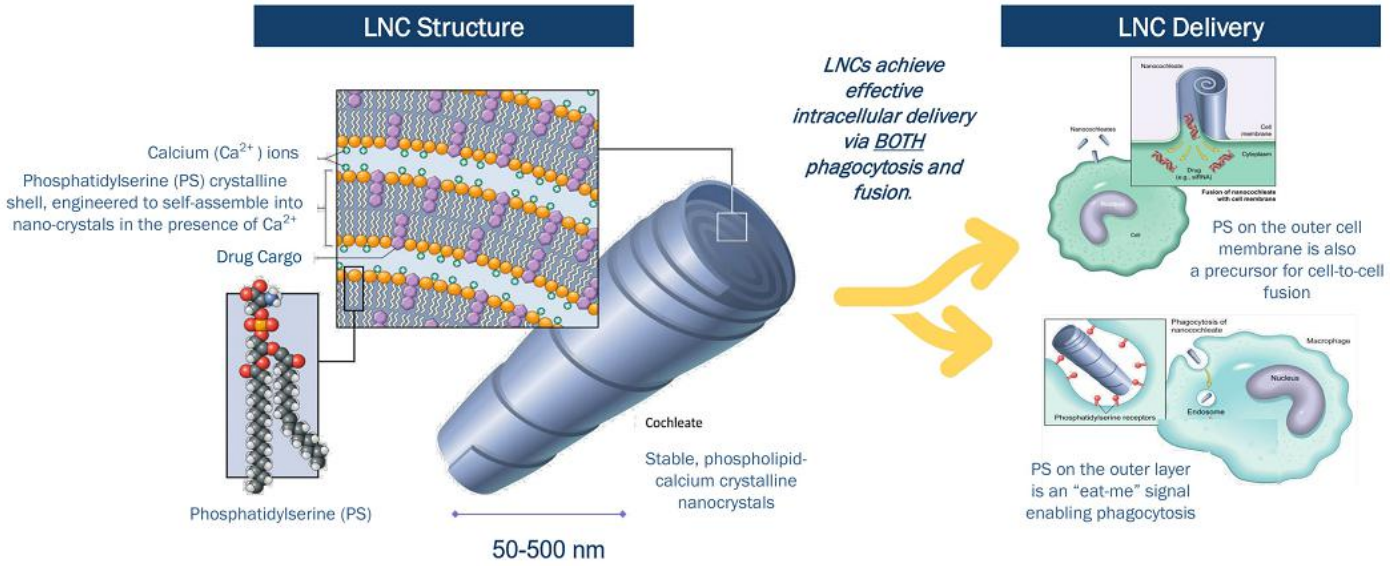
Safe

- No evidence of immunogenicity
- No cytotoxicity
- Deliver high tissue concentrations of drug with low plasma levels
- No off-target toxicity observed to date

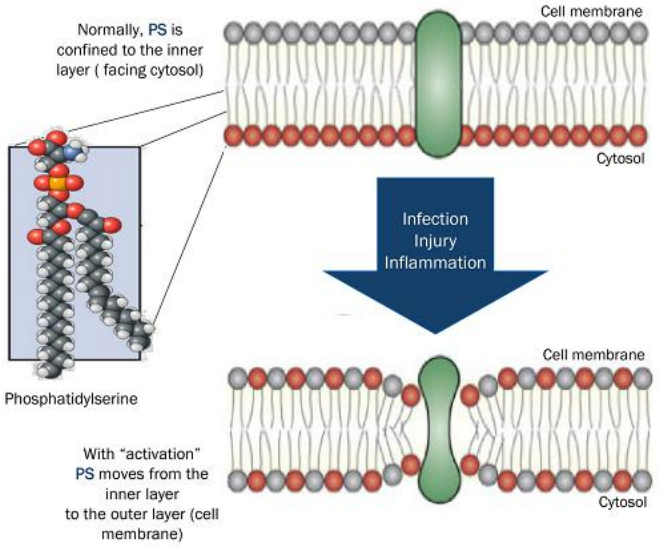
Versatile

- Delivery of small molecules, nucleic acid polymers (ASOs, DNA, mRNA, siRNA), proteins, peptides and vaccines without membrane damage
- Multiple routes of administration (including oral)
- Improved stability and shelf-life

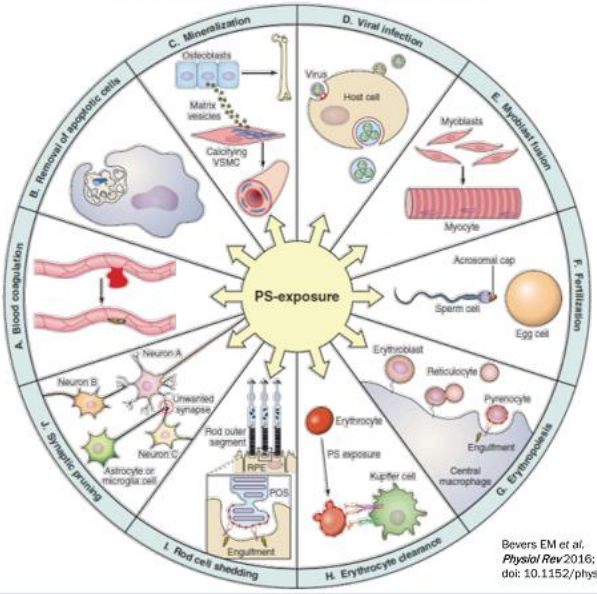
What Are Lipid Nanocrystals (LNCs) and How Do They Deliver Drugs?



Physiologic Importance of Phosphatidylserine on the Surface of Cells



Expression of PS on Multiple Cell Surfaces



Bevers EM *et al.* *Physiol Rev* 2016; 96: 605-45 doi: 10.1152/physrev.00020.215

MATINAS BIOPHARMA

Unlocking the Full Potential of the LNC Platform

Matinas is working internally and with third parties to push the boundaries of LNC delivery

Past

Oral Formulations of Anti-Infectives

- MAT2203
- MAT2501

Present

Intracellular Delivery of Nucleic Acids

- siRNA
- ASO
- mRNA
- DNA

Future

Broad Therapeutic Applications

Infection
- Anti-infectives
- Antivirals

Immune Rx
- Vaccines
- Immune tolerance

Pulmonary
- Acute/chronic respiratory diseases

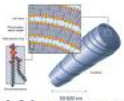
Oncology
- Hematologic & solid tumor malignancies

Inflammation
- Neuro-inflammatory diseases
- Autoimmune diseases
- Acute/chronic Inflammatory diseases

Fibrosis
- Organ fibrosis
- Wound healing

MATINAS BIOPHARMA

LNC: The Next Generation of Intracellular Nucleic Acid Delivery



	Lipid Nanocrystals (LNCs)	Adeno-Associated Virus (AAV)	Lipid Nanoparticle (LNP)
Oral Dosing	✓ 2 Proven Assets	✗ Not Orally Available	✗ Not Orally Available
Targeting	✓ Phagocytes & activated cells	✗ Local delivery to eye and CNS	✗ RES, spleen, liver uptake
Payload size	✓ > 11 kb genomes	✗ < 5 kb genomes	✓ No practical limits
Safety / Redosing	✓ Non-immunogenic platform	✗ Genome integration; limited redosing	✗ Anti-PEG allergy can limit redosing
Stability	✓ mRNA stable for 4 months at room temp.	✗ Cold chain required	✗ Cold chain with limited shelf life

Matinas' Pipeline and Discovery Programs: Internal and Collaborative

Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Collaborators
MAT2203 LNC-Amphotericin B (oral)	*Cryptococcal Meningitis*	*EnACT Cohort 4 (Top-line Results Q4 2022)*				NIH
	Invasive Fungal Infections	*In vivo studies ongoing*				
MAT2501 LNC-Amikacin (oral)	*Non-tuberculous mycobacteria (NTM)*	*Phase1 SAD Study*				Cystic Fibrosis Foundation
LNC-Remdesivir (oral)	*SARS-COVID19*					Gilead, NIH
LNC-ASO	*Undisclosed*					Genentech, A Member of the Roche Group
LNC-small molecule						
LNC-Fab fragment						
LNC-mRNA	*Vaccines*					BioNTech
Internal platform programs (LNC nucleic acids)	*Undisclosed*	*mRNA, DNA Plasmids, Oligos*				

Internal Programs *Joint Programs*

MAT2203

ORAL AMPHOTERICIN B

Phase 3 set to commence Q1 2023

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MAT2203: Unmet Medical Need in Invasive Fungal Infections

MAT2203 is a promising potential therapeutic option
for the treatment of multiple serious and life-threatening fungal infections

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MAT2203: A Novel Approach with a Proven Therapeutic Agent

MAT2203

Oral amphotericin B formulation utilizing LNCs

Initial indication in cryptococcal meningitis

Efficient **intracellular delivery** to immune cells and delivery directly to infected tissues

IMPROVED PROFILE

LNC formulation enables oral administration, bioavailability and **improved nephrotoxicity** over IV amphotericin

Demonstrated ability to **cross the blood-brain barrier (BBB)** with an oral therapy

POTENTIAL CLINICAL IMPACT

Potential to **expand the use of amphotericin B** beyond treatment of CM to other invasive infections and prophylaxis for immunocompromised (IC) patients

Orphan Drug Designation (ODD) + 4 Qualified Infectious Disease (QIDP) and Fast Track Designation

Cryptococcal Meningitis Is a Severe Fungal Infection with High Mortality

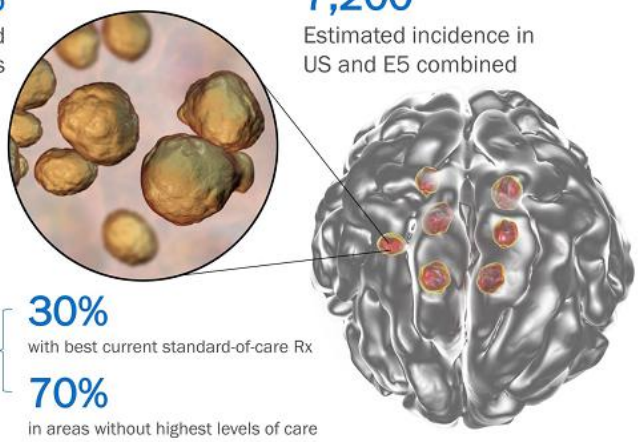
Deadly invasive fungal infection of the brain

Typically affects immunocompromised individuals

10-20%
of all HIV-related deaths

180,000
deaths per year worldwide

7,200
Estimated incidence in US and E5 combined



Mortality VERY HIGH

30%
with best current standard-of-care Rx

70%
in areas without highest levels of care

TREATMENT ALGORITHM

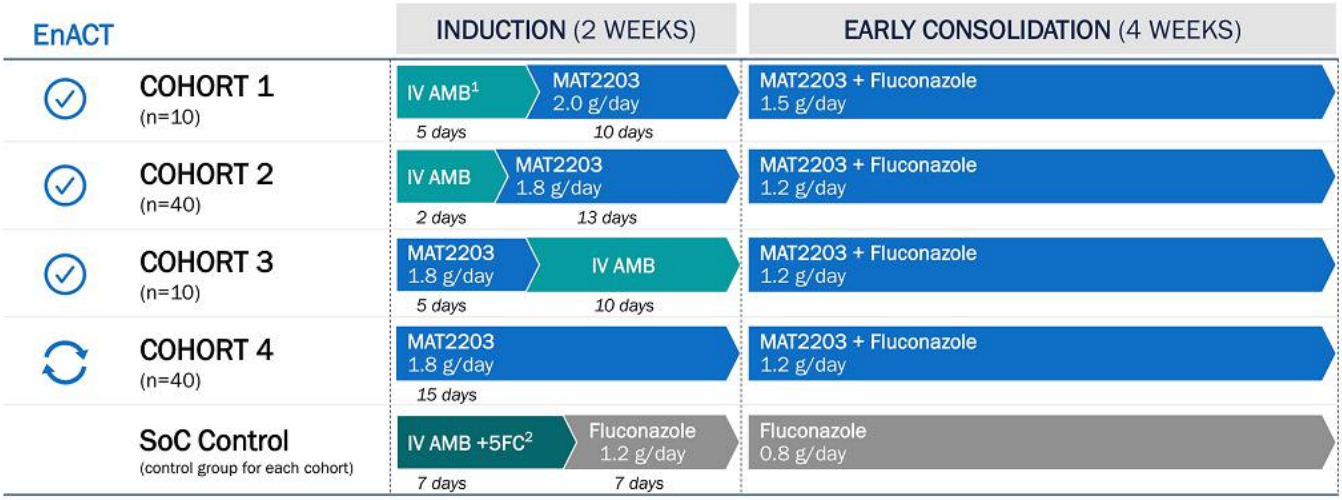
Induction:
IV amphotericin B (either liposomal Ambisome™ or Amphotericin B deoxycholate) + flucytosine (5FC) for 1-2 weeks

Consolidation:
fluconazole for 8-12 weeks

MAJOR CHALLENGES

- High mortality
- Complex, resource-intense regimens requiring daily administration of IV amphotericin B
- Treatment-associated renal toxicity limits options

MAT2203: EnACT Phase 2 Study



- 45/56 participants enrolled to date
- Topline data expected Q4 2022

PRIMARY ENDPOINT:
Early Fungicidal Activity (EFA) > 0.20

SECONDARY ENDPOINTS:
Sterilization of CSF cultures,
Prevention of relapse (no breakthroughs),
Survival at 18 weeks, and Demonstrated safety

1. IV AMB = intravenous amphotericin B
2. Flucytosine

MAT2203: EnACT Phase 2 Study Results

EnACT Clinical Data Validates the Use of the LNC Platform to Enable Oral Administration and Overcome Toxicity

Exceeded the primary endpoint threshold

- EFA for MAT2203 was 0.42 (95% CI 0.29 to 0.55)

All patients completing induction achieved CSF sterility

- 97% for patients receiving MAT2203
- 76% for patients receiving SOC

No breakthrough Infections

- Over 10 weeks, no patients showed breakthrough infections post MAT2203 treatment

"Early Survival" at Day 30

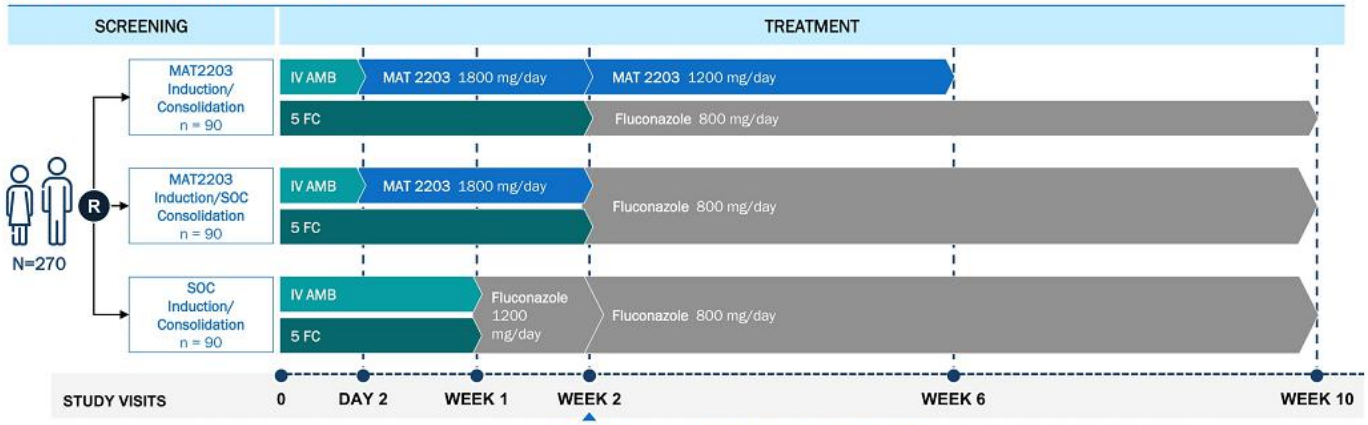
- 98% for patients receiving MAT2203
- 88% for patients receiving IV Ampho (SOC)

MAT2203 was safe and well-tolerated over 6 weeks of treatment

- Repeat dosing showed no renal toxicity or electrolyte abnormalities
- No discontinuations due to AEs nor MAT2203-related SAEs

EnACT Phase III Pivotal Study Design

Assess MAT2203 as step-down induction and consolidation therapy after 2 days of IV AMB
Validate results observed in EnACT
Randomized 1:1:1 ratio to 1 of 2 MAT2203 arms or SoC



- 270 participants
- 4 sites in Uganda
- Study Initiation Q1 2023
- NDA Filing H1 2025

PRIMARY ENDPOINT:
All-cause mortality at 2 weeks

Key Secondary Efficacy Endpoint:
Survival time through 10 weeks without *Cryptococcus* culture-positive relapse of meningitis

Other Secondary Endpoints include:
- Incidence of Grade 3-5 lab AEs
- Rate of CSF Cryptococcus clearance (EFA)
- CSF culture sterility (cumulative incidence over 10 weeks)
- 10-week survival time
- Use of rescue/additional IV AMB beyond scheduled use

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Value Proposition for MAT2203

Oral Administration
enables earlier release from hospital or avoidance of home infusion

+

Lack of Nephrotoxicity
enables longer treatment duration supported by oral administration

LIFE CYCLE MANAGEMENT

Overall Development Strategy:

CM is gateway indication, with stacking of follow-on indications including IFI and prophylaxis indications

IFI Phase 3 study start Q3 2023

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MAT2203: Addressing a $550M+ Market with Active Regional and Global Pharma

- Cryptococcal Meningitis
- Invasive fungal infections
- Prophylaxis in IC patients

Comparable Deals

CIDARA THERAPEUTICS / mundipharma — *September 2019*

Cidara licenses ex-US / ex-Japan rights of rezafungin to Mundipharma

Upfront: $30M w/ $9M equity
Milestones: Co-development funding

Total Deal Value: Potentially $568M+

SCYNEXIS / HANSOH PHARMA — *February 2022*

Scynexis licenses Greater China rights of Ibrexafungorpis to Hansoh

Upfront: $10M
Milestones: $112M in regulatory / commercial milestones, plus royalties

Total Deal Value: $122M

F2G / SHIONOGI — *May 2022*

F2G licenses Asia & Europe rights of olorofim to Shionogi

Upfront: $100M
Milestones: $380M in regulatory / commercial milestones, plus royalties and shared dev. costs

Total Deal Value: $480M

CIDARA THERAPEUTICS / melinta therapeutics — *July 2022*

Cidara licenses US rights of rezafungin to Melinta

Upfront: $30M
Milestones: $60M in regulatory, $370M in commercial, plus royalties

Total Deal Value: $480M

MAT2501
& ONGOING PARTNERSHIP PROGRAMS

MAT2501: NTM Program Overview and SAD Topline Results

- NTM organisms are a frequent cause of challenging pulmonary infections, especially in patients with pre-existing inflammatory lung diseases such as cystic fibrosis
- LNC formulation enables oral administration, bioavailability and potentially eliminates oto-& nephron-toxicity, both of which are significant risks with the current standard of care, IV amikacin

Single Ascending Dose (SAD) PK Study Topline Results

QIDP & ODD potentially provide 12+ years exclusivity upon approval

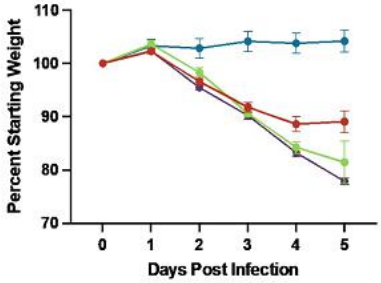
Accelerated with $4.5M Cystic Fibrosis Foundation award

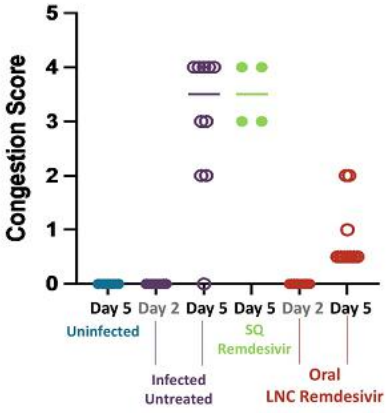
- Results confirmed earlier findings with legacy formulation at the same doses (200, 400, 800) with an additional higher dose (1000 mg; fasted/fed) tested in this study
- No SAEs or study discontinuations (only dose-related adverse event was diarrhea (mild to moderate))
- No evidence of ototoxicity or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

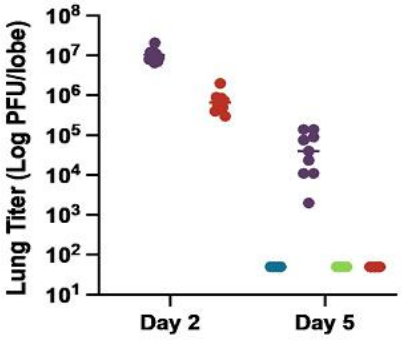
LNC-remdesivir: *In vivo* Assessment of Efficacy Against SARS-CoV-2

GILEAD

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







- Uninfected Control
- Infected, Untreated Control
- SQ Remdesivir 25 mg/kg BID
- Oral LNC-Remdesivir 30 mg/kg BID

LNC-mRNA: Exclusive Research Collaboration with BioNTech

Focused on mRNA and certain other nucleic acids

- $2.75 million upfront exclusive access fee plus research funding
- Ongoing license agreement negotiations
- 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 and enhanced stability
  - Non-immunogenic transfection
  - Able to elicit strong humoral and cellular immunity

Expanding LNC Intellectual Property Portfolio

Continuingly increasing our patent suite to increase protection and exclusivity

MAT2203 & 2501 potentially entitled to 12+ years of exclusivity (QIDP & ODD status)

Global Platform IP base protection out to 2037 with 20 patents issued in last 5 years

Strong IP & Regulatory Designations

Experienced Leadership Team

Executive Team

Jerome D. Jabbour, J.D.
Chief Executive Officer

Thomas J. Hoover, MBA
Chief Business Officer

Theresa Matkovits, Ph.D.
Chief Development Officer

James J. Ferguson, M.D.
Chief Medical Officer

Keith A. Kucinski, CPA, MBA
Chief Financial Officer

Hui Liu, Ph.D., MBA
Chief Technical Officer

Raphael J. Mannino, Ph.D.
Chief Scientific Officer

Board of Directors

Herbert Conrad
Chairman of the Board

Eric J. Ende, MD, MBA
Director

James. S. Scibetta
Director

Kathryn P. Corzo
Director

Natasha Giordano
Director

Matthew A. Wikler, MD, MBA
Director

Jerome D. Jabbour, J.D.
CEO

Matinas Has Executed on Multiple Milestones..... With More to Come

	1H 2022 Milestones & Catalysts	2H 2022 and Beyond Milestones & Catalysts
MAT2203	✓ FDA approval on Phase 3 of EnACT ✓ Initiate preclinical studies in *C. auris* and *mucormycosis* ✓ Data available from Phase 1 SAD study in healthy volunteers	✓ Feedback from EMA (ODD and Scientific Advice) ✓ PoC data from preclinical studies in *mucormycosis* ↻ Interim topline data from Cohort 4 of EnACT (all oral regimen Q4 2022 ↻ Initiate Phase 3 confirmatory study for CM induction (Q1 2023) ↻ Potential Global or Regional Commercialization partner
LNC Platform & Collaborations	✓ Initiate & receive data from 2nd *in vivo* study of oral LNC-RDV (sponsored by NIAID/Gilead ✓ *In vivo* & *in-vitro* studies with mRNA, DNA, oligonucleotides ✓ Nucleic acid research collaboration with large pharma	↻ Potential BioNTech License Agreement & expansion of established research collaboration ↻ Potential additional platform collaborations

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