# 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): April 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**<br>**Bedminster, New Jersey**<br>**(Address of principal executive offices)** | **07921**<br>**(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 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 April 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: April 13, 2022

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


## 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.

## LNCs Simplify Intracellular Delivery of Nucleic Acids

| | Description | Benefit |
|---|---|---|
| **INNATELY TARGET "ACTIVATED" CELLS** | ▪ Macrophages/monocytes, neutrophils, dendritic cells<br>▪ Infected/injured cells, tumor cells | ▪ Wide variety of extrahepatic targets |
| **IMPROVED SAFETY** | ▪ Non-immunogenic platform<br>▪ Enter cells through non-destructive membrane fusion | ▪ Enables repeat administration |
| **IMPROVED STABILITY** | ▪ Crystal structure protects nucleic acids | ▪ Avoid cold chain<br>▪ Flexible Administration (orally, IV, IM or via inhalation) |
| **PAYLOAD VERSATILITY** | ▪ Nucleic acids (DNA, mRNA, siRNA, etc..)<br>▪ 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 and Collaborative

| | | Discovery | Preclinical | Phase 1 | Phase 2 |
|---|---|---|---|---|---|
| MATINAS BIOPHARMA | MAT2203 LNC-Amphotericin B (oral) | *Cohort 4 Commenced January 2022* | | | |
| MATINAS BIOPHARMA / CYSTIC FIBROSIS FOUNDATION | MAT2501 LNC-Amikacin (oral) | *Phase1 SAD Study results mid-2022* | | | |
| NIH / GILEAD | LNC-Remdesivir (oral) | *In vitro and in vivo SARS-CoV-2 studies* | | | |
| Genentech A Member of the Roche Group | LNC-ASO LNC-small molecule | *2 of 3 programs initiated* | | | |
| BIONTECH | LNC-mRNA | *Vaccines* | | | |
| MATINAS BIOPHARMA | Internal platform programs – LNC nucleic acids | *mRNA, DNA Plasmids, Oligos* | | | |

*LYPDISO™* *Partnering efforts ongoing*



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## 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



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## 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



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## Lipid Nanocrystal (LNC) Platform

### Targeted, Well-Tolerated Intracellular Delivery



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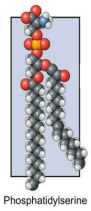
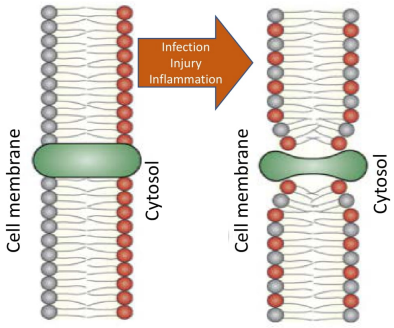
## LNCs Work Because of PS, Which Enables Intracellular Delivery Via Two Biological Pathways



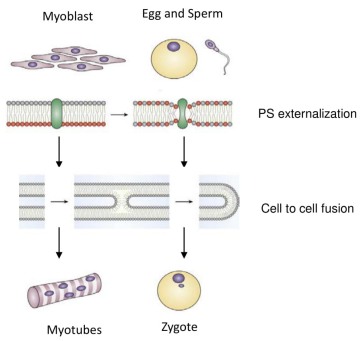

PS on the outer layer is an "eat-me" signal enabling **phagocytosis**




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



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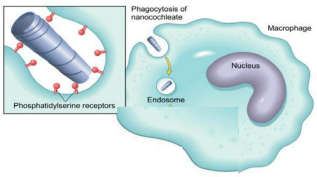
## Intracellular Uptake Via Phagocytosis and/or Fusion Enables Targeting to Phagocytes and "Activated" Cells

***Phagocytosis***
***Initiated by binding of PS to PS receptors***

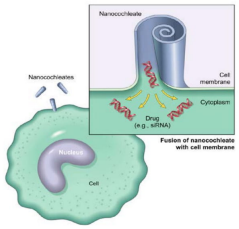



**Macrophages readily engulf LNCs and their cargo into vesicles (endosomes).**

***Intracellular delivery via phagocytosis, fusion, or BOTH***

- **Bone marrow-derived hematopoietic cells**
  **(Macrophages, dendritic cells, natural killer (NK) cells)**
- **Infected Cells**
- **Injured Cells**
- **Tumor Cells**
- **Astrocytes and microglial cells (CNS macrophages)**
- **Specialized epithelial cells that participate in efferocytosis**
  - **Retinal epithelial cells**
  - **Alveolar lung epithelial cells**
  - **Mammary epithelial cells**
- **Actively dividing cells**

***Fusion***
***Initiated by expression of PS on the surface of cells***




**LNCs can fuse with cell membranes and deliver cargo molecules directly to the cytoplasm**

***LNCs are designed to mimic enveloped viruses***



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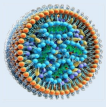
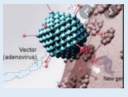
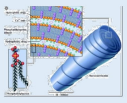
## LNCs Provide A Differentiated Alternative to LNP and AAV Delivery of Nucleic Acids

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

***LNCs have large payload capacity, no immunogenicity and novel targeting***



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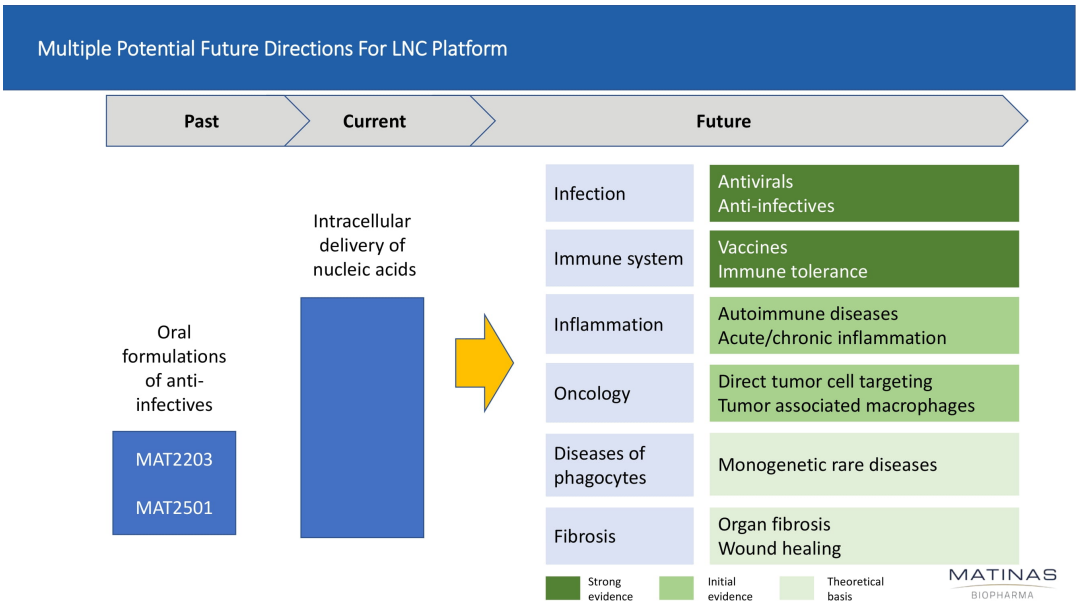
Multiple Potential Future Directions For LNC Platform
Past
Current
Future
Oral formulations of anti-infectives
MAT2203
MAT2501
Intracellular delivery of nucleic acids
Infection
Antivirals
Anti-infectives
Immune system
Vaccines
Immune tolerance
Inflammation
Autoimmune diseases
Acute/chronic inflammation
Oncology
Direct tumor cell targeting
Tumor associated macrophages
Diseases of phagocytes
Monogenetic rare diseases
Fibrosis
Organ fibrosis
Wound healing
Strong evidence
Initial evidence
Theoretical basis
MATINAS
BIOPHARMA


MAT2203
Oral Amphotericin B
MATINAS
BIOPHARMA
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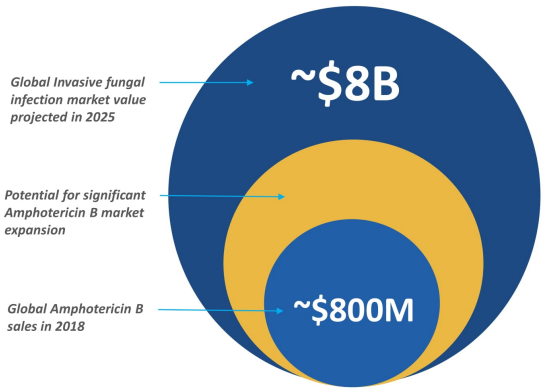
## Invasive Fungal Infections Represent an Urgent Growing Global Need




- Invasive fungal infections are an urgent and largely overlooked global problem due to increasing use of immunosuppressive therapies, and growing resistance to current anti-fungal therapies due to lack of recent innovation.
- Amphotericin B is the gold standard broad spectrum antifungal treatment but has inconvenient IV administration and significant toxicity that limit its use in prophylaxis and maintenance settings.
- Amphotericin B sales ~$800M globally despite toxicity with management of associated AE's accounting for up to 85% of cost of hospital stay.
- ***A safer and more convenient amphotericin B could be a game-changer in the fight against invasive fungal infections.***

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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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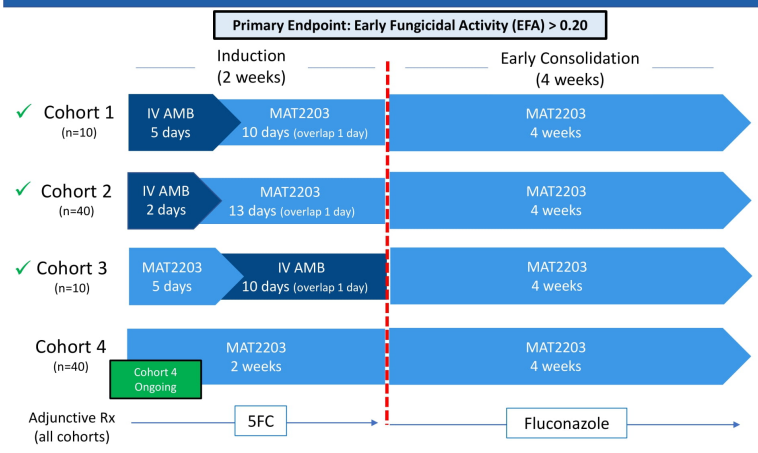
## EnACT Study Design




**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*

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*IV AMB = intravenous amphotericin B

## EnACT Cohort 2 Met Primary Endpoints

| EnACT Cohort 2 Endpoints | EnACT Cohort 2 Results |
|---|---|
| ▪ **Primary Endpoint**: Early Fungicidal Activity (**EFA**) $\log_{10}$ CFU/mL/day at Day 14 >0.20<br>▪ EFA > 0.20 - associated with lower mortality and improved clinical outcomes[1] | ✓ EFA for MAT2203 was **0.42** (95% CI 0.29 to 0.55), exceeding the primary endpoint threshold |
| ▪ **Secondary Endpoints**<br>▪ Sterilization of CSF cultures<br>▪ Prevention of relapse (no breakthroughs)<br>▪ Survival at 18 weeks<br>▪ Demonstrated safety | ✓ All 39 MAT2203 patients completing induction achieved CSF sterility<br>✓ No breakthrough infections during MAT2203 treatment (10 weeks)<br>✓ Survival rates were **>90%** in Cohort 2<br>✓ MAT2203 was safe and well-tolerated over **6 weeks** of treatment<br>• No renal toxicity or electrolyte abnormalities<br>• 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 Updates and Upcoming Milestones

### EnACT Updates

- Additional analyses of Cohort 2 Data Demonstrate:
  (1) "Early Survival" at Day 30
  (a) 98% for patients receiving MAT2203
  (b) 88% for patients receiving IV Ampho (SOC)
  (2) Achieving sterility
  (a) 97% for patients receiving MAT2203
  (b) 76% for patients receiving SOC
- Cohort 4 commenced January 2022 with 22 patients enrolled through April 11th
  - All-oral regimen during induction (14 days)
  - ~40 patients on MAT2203, ~16 patients on SOC
- Topline Interim Data expected Q3 2022

**Preclinical studies in *C. Auris* and *Mucormycosis* planned for 2022 to broaden MAT2203 Label**

### FDA Feedback and Next Steps

- End-of-Phase 2 Meeting held December 2021
- No questions raised on efficacy, safety or tolerability
- Request "Confirmatory Evidence" to support step-down indication for induction for MAT2203 from IV Amphotericin B
- No requirement for separate study or U.S. patients
- Supportive of expanding EnACT with additional, new Cohort 5, designed similarly to Cohort 2 at 5 identified clinical sites in Uganda
- Meeting to finalize Cohort 5 design with FDA in Q2 2022
- Potential NDA filing by end of 2023 (***subject to FDA feedback***)
- NIH financial support anticipated

**Request for Scientific Advice to the European Medicines Agency (EMA) planned for Q2 2022 to expand global footprint for MAT2203**



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## EnACT Cohort 2 Results Provide Important Validation of LNC Platform Capabilities

**Meaningful to MAT2203**

- Adding oral to IV delivery
- Reducing treatment-limiting toxicity
- Able to deliver therapy across the Blood-Brain Barrier

**Extendable to LNC Platform**

- True targeted intracellular delivery
- Repeated administration without signs of immunogenicity

The EnACT Cohort 2 results are an important demonstration of how Matinas' LNC platform can provide meaningful clinical impact in CM and beyond



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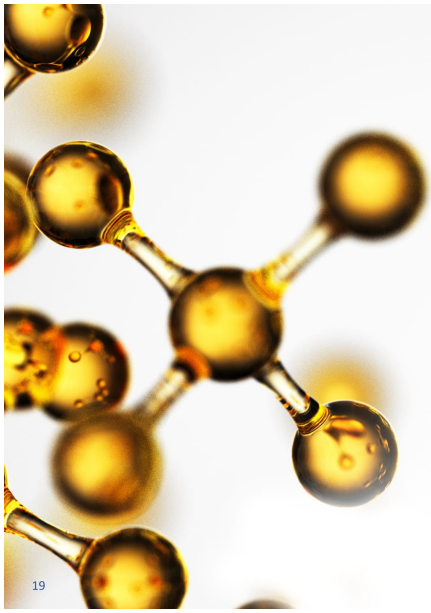

# MAT2501

## 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 to be accelerated with $4.2M 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)* *$3.7B market cap*



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## MAT2501: NTM Program Overview

### 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

- **2021** – Preclinical PK and Tox studies
- **October 2021** – Commenced Human Phase 1 SAD; Data expected 1H 2022
- 2022 – Long Term Tox and Positioning for Phase 2 in NTM; planning for other indications

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## Driving Opportunities for Value-Added Partnerships Built around the LNC Platform

Genentech
A Member of the Roche Group

- In 2019, we entered a collaboration with Genentech/Roche to evaluate LNC delivery of up to three molecules, including antisense oligonucleotides.

CYSTIC FIBROSIS FOUNDATION®

- In November 2020, announced $3.75 million award from the Cystic Fibrosis Foundation (CFF) to support preclinical development of MAT2501, focused on treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with CF. Total CFF award for MAT2501 over $ 4.5 million

GILEAD NIH

- Additional *in vivo* work on LNC oral formulation of COVID-19 antiviral drug remdesivir ongoing at UNC and supported by NIAID. Data expected in mid-2022.

BIONTECH

- Exclusive Research Collaboration announced April 2022; focused on combining BioNTech's mRNA vaccine development expertise with Matinas' novel LNC delivery platform to advance novel formulations of mRNA vaccines and other treatments. Upfront $2.75 million exclusive access fee plus research funding. Parties working toward broader license agreement for LNC Platform.

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## 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**

MATINAS BIOPHARMA



## Executive Officers and Board of Directors

### EXECUTIVE OFFICERS

| | |
|---|---|
| **Jerome D. Jabbour**<br>Co-Founder, Chief Executive Officer | Reliant |
| **Thomas Hoover, MBA**<br>Chief Business Officer | Millendo Therapeutics, sunovion, GSK GlaxoSmithKline |
| **James J. Ferguson III, M.D., FACC, FAHA**<br>Chief Medical Officer | Amgen, AstraZeneca |
| **Theresa Matkovits, Ph.D.**<br>Chief Development Officer | nps pharmaceuticals, The Medicines Company, Novartis |
| **Keith A. Kucinski, CPA, MBA**<br>Chief Financial Officer | PAR Pharmaceutical, barr |
| **Raphael J. Mannino, Ph.D.**<br>Chief Scientific Officer | Rutgers New Jersey Medical School, biodelivery sciences |
| **Hui Liu, Ph.D., MBA**<br>Chief Technology Officer | Seqirus, Allergan an AbbVie company, Alcon |

### BOARD OF DIRECTORS

| | |
|---|---|
| **Herbert Conrad**<br>Chairman of the Board | PHARMASSET, Roche |
| **Eric J. Ende, M.D., MBA**<br>Director | genzyme, Merrill Lynch |
| **James S. Scibetta**<br>Director | ImmuneID, MAVERICK THERAPEUTICS, PACIRA |
| **Kathryn Penkus Corzo**<br>Director | bit.bio, Takeda, SANOFI GENZYME |
| **Natasha Giordano**<br>Director | PLX PHARMA INC., Xanodyne pharmaceuticals, inc. |
| **Matthew A. Wikler, M.D., MBA FIDSA**<br>Director | The Medicines Company, FDA |
| **Jerome D. Jabbour**<br>Director | Reliant, MATINAS BIOPHARMA |



## Summary and 2022 Milestones & Catalysts

| | 1H 2022 Milestones & Catalysts | 2H 2022 Milestones & Catalysts |
|---|---|---|
| MAT2203 | ☑ FDA Feedback on Cohort 5 of EnACT<br>☑ Initiate preclinical studies of MAT2203 in *C. auris* and *mucormycosis* | ☑ Interim Topline Data from Cohort 4 of EnACT<br>☑ Data from MAT2203 preclinical studies in *C. auris* and *mucormycosis*<br>☑ 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<br>☑ Conduct internal in-vitro and in-vivo studies with mRNA, DNA, oligonucleotides<br>☑ Potential research collaboration with large pharma in nucleic acids | |


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Corporate Presentation
April 2022
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