

**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 20, 2023

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38022
(Commission
File Number)

46-3011414
(IRS Employer
ID Number)

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

07921
(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 20, 2023
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 20, 2023

By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour

Title: Chief Executive Officer



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Corporate Presentation

**September/October
2023**

www.matinasbiopharma.com
NYSE American: MTNB



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. 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 Investment Thesis: LNC Delivery Unlocks Therapeutic Value

Lipid Nanocrystals (LNCs)



- Intracellular delivery
- Oral administration
- Less toxicity
- Targeting beyond the liver

MAT2203

Clinical Validation of LNC Capabilities

Pipeline Products and Opportunities

- Oral Amphotericin B - without nephrotoxicity
- Phase 3-ready (Invasive Aspergillosis in ~198 patients with limited or no treatment options)
- Provides effective longer-term fungicidal stepdown therapy for Invasive Fungal Infections
- **12** years of exclusivity* *QIDP and Orphan designations

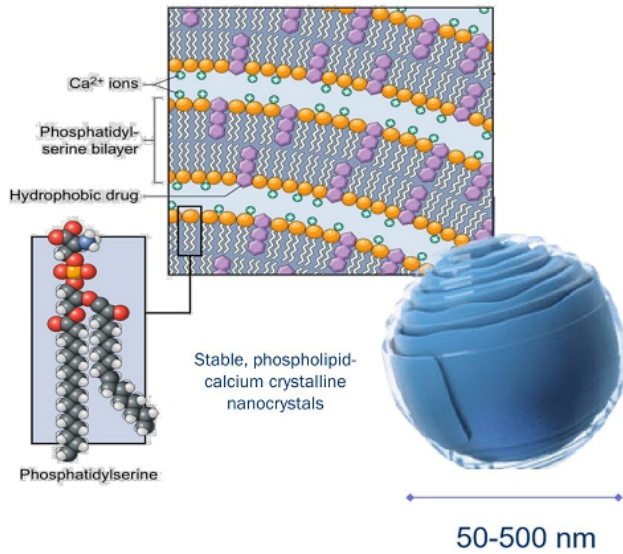
- Current efforts expanding LNC application beyond small molecules to include delivery of smaller oligonucleotides (ASOs, siRNA, RNAi)
- Expanding primary therapeutic applications from infectious disease (antifungal, antibiotic, antiviral) to inflammation and cancer
- Build upon existing external collaborations with *Genentech* and *National Resilience*

Internal and External Pipeline

Program	Indication	Discovery	Preclinical	Phase 1	Phase 2	Phase 3	Collaborators
MAT2203 LNC-Amphotericin B (oral)	Invasive Aspergillosis (LPAD)	Phase 3 Ready					NIH
LNC Internal platform programs (small oligonucleotides)	Undisclosed	RNAi (siRNA, ASOs)					Undisclosed
LNC-ASO							
LNC-small molecule	Undisclosed						Genentech <small>A Member of the Roche Group</small>
LNC-Fab fragment							
PS-NPs - mRNA and Nucleic Acids	Undisclosed						RESILIENCE

■ Internal Programs ■ Joint Programs

Lipid Nanocrystals (LNCs): A Clinically Validated Intracellular Delivery Platform



Delivery of small molecules and small oligonucleotides

- Successful delivery of small molecules, proteins, small oligos (siRNA, ASOs), and vaccines

Extra-hepatic targeting

- Selective uptake driven by phosphatidylserine enables delivery in infection, inflammation, oncology
- Validated Blood-Brain-Barrier penetration (MAT2203)

Oral delivery

- Unique structure protects cargo in GI tract, avoids first-pass hepatic metabolism

Safe & stable

- Deliver high-target tissue concentrations of drug with low plasma levels and no absorption by non-target tissues
- No evidence of immunogenicity or cytotoxicity

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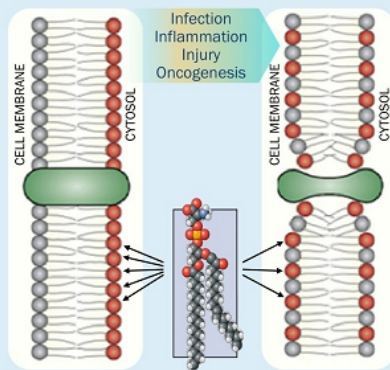
Phosphatidylserine Enables Cellular Targeting and Intracellular Delivery

Targeting

Stressed Cells Externalize PS

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

With injury, PS moves from the inner layer to the outer layer of the cell membrane



With a wide variety of potential target cells

PROFESSIONAL PHAGOCYTES

- Macrophages/monocytes
- Neutrophils
- Dendritic cells

NON-PROFESSIONAL PHAGOCYTES

- Fibroblasts, epithelial cells, endothelial cells

INJURED/STRESSED CELLS

- Infection
- Inflammation
- Other physiologic stressors

TUMOR CELLS

IMMUNE CELLS

- T-cells
- NK-cells

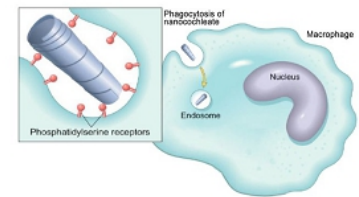
OTHER ACTIVELY DIVIDING CELLS (including extracellular pathogens)

Delivery

PS-containing LNCs deliver their cargo to the interior of cells by both phagocytosis and fusion

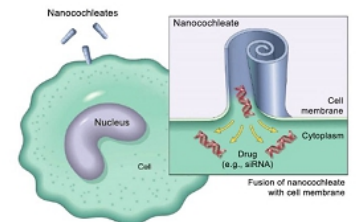
PHAGOCYTOSIS

PS on the outer layer of injured cells is an "eat-me" signal enabling recognition and uptake by professional phagocytes. Cargo-carrying LNCs can be taken up in a similar fashion, with subsequent endosomal escape of cargo.



FUSION

PS on the outer cell membrane is also a precursor for direct membrane-to-membrane fusion and more rapid direct cytosolic delivery by cargo-carrying LNCs to cells expressing PS on their outer membranes.


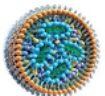






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LNCs – Differentiated from Liposomes and LNPs

	 Liposome	 LNP	 LNC
 Structure	<ul style="list-style-type: none"> Aqueous interior surrounded by bilayer Drug can be encapsulated in aqueous core or bilayer 	<ul style="list-style-type: none"> Ionizable lipid complexing with mRNA Non-aqueous interior 	<ul style="list-style-type: none"> Non-aqueous bilayer Highly stable
 Formulation Strengths	<ul style="list-style-type: none"> Enable IV administration of insoluble products 	<ul style="list-style-type: none"> Intracellular delivery (ASOs, siRNAs, mRNA) Improve stability, half-life 	<ul style="list-style-type: none"> Efficient intracellular delivery <ul style="list-style-type: none"> Large and small molecules ASOs, miRNAs, siRNAs Reduced toxicity Oral delivery
 Formulation Limitations	<ul style="list-style-type: none"> Liposomes often “leak” causing side effects IV Administration 	<ul style="list-style-type: none"> Cationic lipid toxicity not suitable for chronic use Anti-PEG allergic response Very limited shelf stability Cold-chain requirements 	<ul style="list-style-type: none"> Targeted, extra-hepatic delivery to desired cells and tissues

MAT2203 Oral Amphotericin B

Clinical Validation of LNC Delivery

The Growing Threat of Invasive Fungal Infections (IFIs)



WHO fungal priority pathogens list to guide research, development and public health action



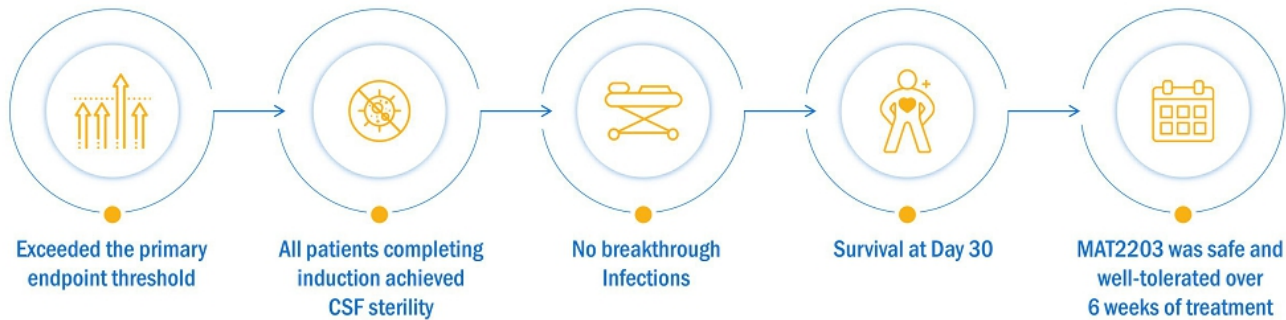
MAT2203: Unlocking the Full Potential of Amphotericin B

Innate Amphotericin B Characteristics	IV Amphotericin B Limitations	Unlocked Potential
✓ POTENT – broad-spectrum fungicidal	✗ Only available through IV administration	✓ Available systemically and orally (crosses BBB following oral administration)
✓ Minimal drug-drug interactions	✗ Significant toxicity and side effects	✓ Well-tolerated and safe
✓ Low propensity for resistance	✗ High systemic exposure distributed throughout the body	✓ Delivered directly into infected tissues
✓ Active against susceptible and emerging drug-resistant fungal infections	✗ Must be administered in hospital, increasing costs	✓ Cost-effective with potential for significant health economic benefits

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

EnACT: Phase 2 Clinical Validation of Safety and Efficacy

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



- **EFA for MAT2203 was 0.42** (95% CI 0.29 to 0.55)
(primary endpoint threshold was 0.20)
- **97% for patients receiving MAT2203**
- **76% for patients receiving SOC**
- Over 10 weeks, patients showed **no breakthrough infections** post-MAT2203 treatment
- **98% for patients receiving MAT2203**
- **88% for patients receiving IV AMPB (SOC)**
- Repeat dosing showed **no renal toxicity or electrolyte abnormalities**
- No discontinuations due to AEs nor MAT2203-related SAEs

Results of EnACT Published in Highly-Regarded Peer-Reviewed Journal

Clinical Infectious Diseases

MAJOR ARTICLE

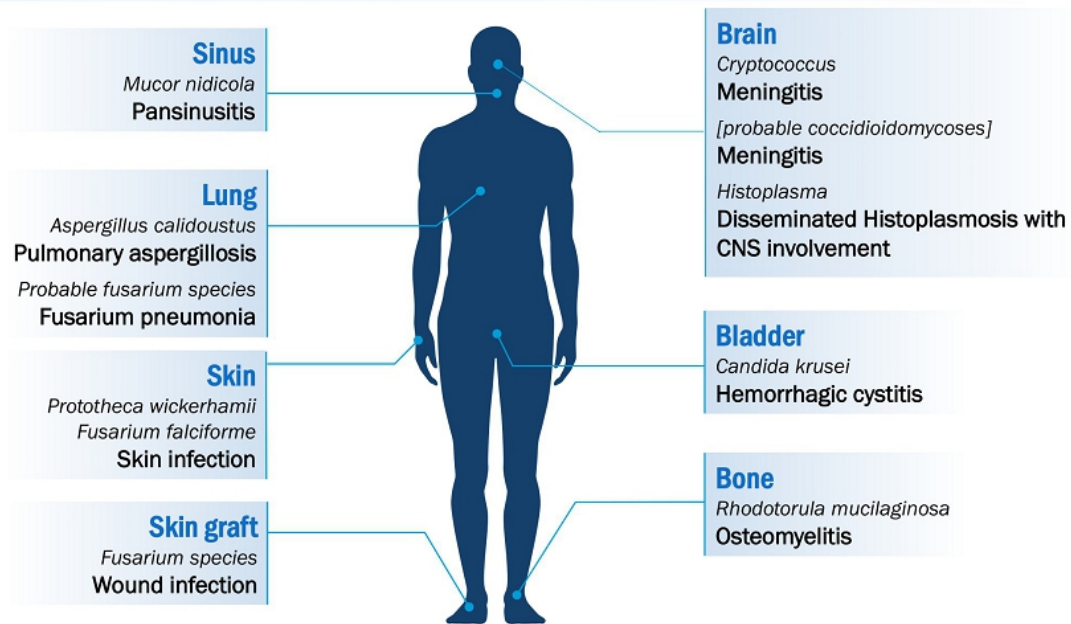


Oral Lipid Nanocrystal Amphotericin B for Cryptococcal Meningitis: A Randomized Clinical Trial

David R. Boulware,^{1,a,g} Mucunguzi Atukunda,^{2,a} Enock Kagimu,² Abdu K. Musubire,² Andrew Akampurira,² Lillian Tugume,² Kenneth Ssebambulidde,^{2,3} John Kasibante,² Laura Nsangi,² Timothy Mugabi,² Jane Gakuru,² Sarah Kimuda,² Derrick Kasozi,² Suzan Namombwe,² Isaac Turyasingura,² Morris K. Rutakingirwa,² Edward Mpoza,² Enos Kigozi,⁴ Conrad Muzoora,⁴ Jayne Ellis,² Caleb P. Skipper,¹ Theresa Matkovits,⁵ Peter R. Williamson,³ Darlisha A. Williams,¹ Ann Fieberg,⁶ Kathy H. Hullsiek,⁶ Mahsa Abassi,³ Biyue Dai,⁶ and David B. Meya^{1,2}

¹Department of Medicine, University of Minnesota, Minneapolis, Minnesota, USA; ²Infectious Diseases Institute, Makerere University, Kampala, Uganda; ³Laboratory of Clinical Immunology and Microbiology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland, USA; ⁴Department of Medicine, Mbarara University of Science and Technology, Mbarara, Uganda; ⁵Matinas Biopharma Nanotechnologies, Bedminster, New Jersey, USA; and ⁶Division of Biostatistics, School of Public Health, University of Minnesota, Minneapolis, Minnesota, USA

MAT2203 Expanded Access Program – Targeted Treatment of IFIs Throughout the Body



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MAT2203 Expanded Access/Compassionate Use Program

Demonstrated Efficacy in Treatment of Patients with Limited Treatment Options

- 11 patients with no other treatment options are currently receiving or have completed treatment with MAT2203
 - **Notable Healthcare Institutions:** NIH, University of Michigan, Johns Hopkins, City of Hope, Nationwide Children’s Hospital
- Patients were not responding/resistant to, or unable to receive, azole therapy
- Patients were switched to treatment with IV AMB with clinical response but unable to tolerate treatment due renal toxicity
 - All patients hospitalized to monitor/manage renal safety and most received IV electrolyte supplementation
- Following oral MAT2203 initiation, patients were discharged to continue treatment at home
- Renal toxicity reversed and renal function returned to normal
- All patients who received at least two weeks or more of treatment had positive clinical outcomes with significant success stories of full recovery in majority of patients

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High Unmet Medical Need in Treatment of Invasive Aspergillosis (IA)

- Invasive aspergillosis (IA) is a serious and life-threatening invasive fungal infection that occurs primarily in severely immunocompromised patients with hematological malignancies and transplant recipients
 - ~15,000 new cases per year in the U.S. alone
 - WHO, CDC, and FDA consider IA a *critical priority* and a global public health concern
- IDSA Guidelines recommend treatment with mold-active azoles as first-line treatment for 6-12 weeks
 - Azole use requires significant expertise to manage toxicities and significant drug-drug interactions that often limits duration of use
 - Resistance to azoles has been increasing globally
 - Recently, cases of breakthrough IA have been reported in patients receiving antifungal prophylaxis
 - Failures attributed to non-compliance, poor absorption, DDIs, or infection with a drug-resistant *Aspergillus* species
- Patients suffering from IA with little or no treatment options among the highest unmet medical need with approximately 3,000-5,000 cases per year (U.S. only)
 - Rare disease/orphan commercial opportunity

** Phase 3 trial dependent on securing partnership(s) or non-dilutive government funds*

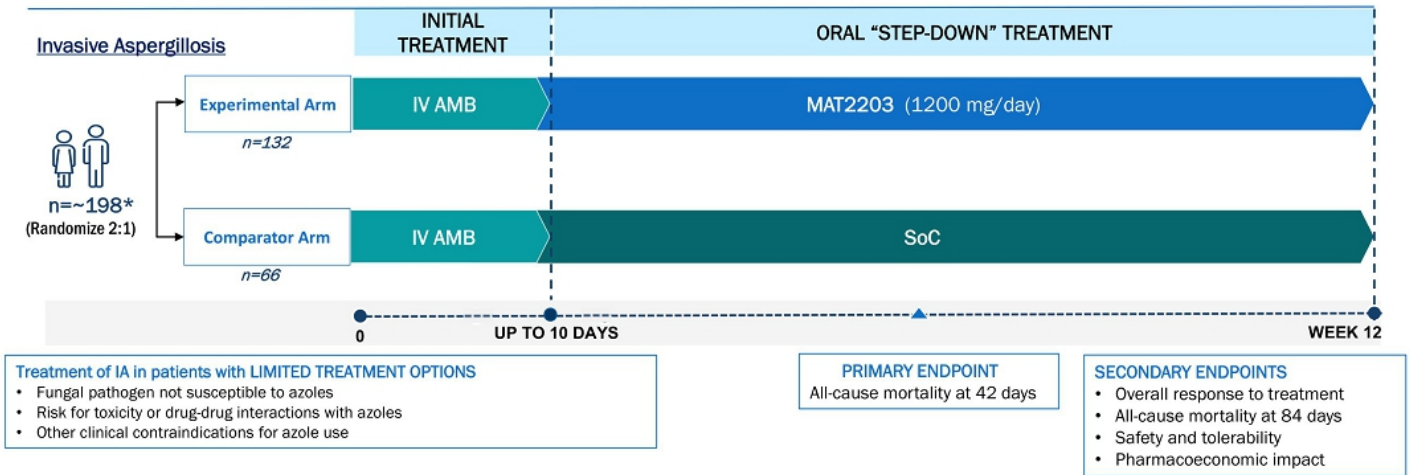
MAT2203 Regulatory Strategy

- Near-term development strategy refined to narrow initial target indication: treatment of invasive aspergillosis in patients with limited treatment options (azole-intolerant, azole-resistant, or not effectively managed with an azole)
 - Register leveraging LPAD pathway
 - Other regulatory designations protected and maintained (QIDP, ODD, Fast-Track, potential for Breakthrough Therapy)
- Restricted indication could be supported by smaller study with larger noninferiority margin (20%)
 - Regulatory precedent with Vical Program and Rezafungin approval
 - Sample size ~198 patients
 - Potential meaningful commercial opportunity in “rare disease” patient population
- FDA Type B Meeting in early Q4 to align on revised strategy and study design

Proposed Phase 3 Study Design in IA

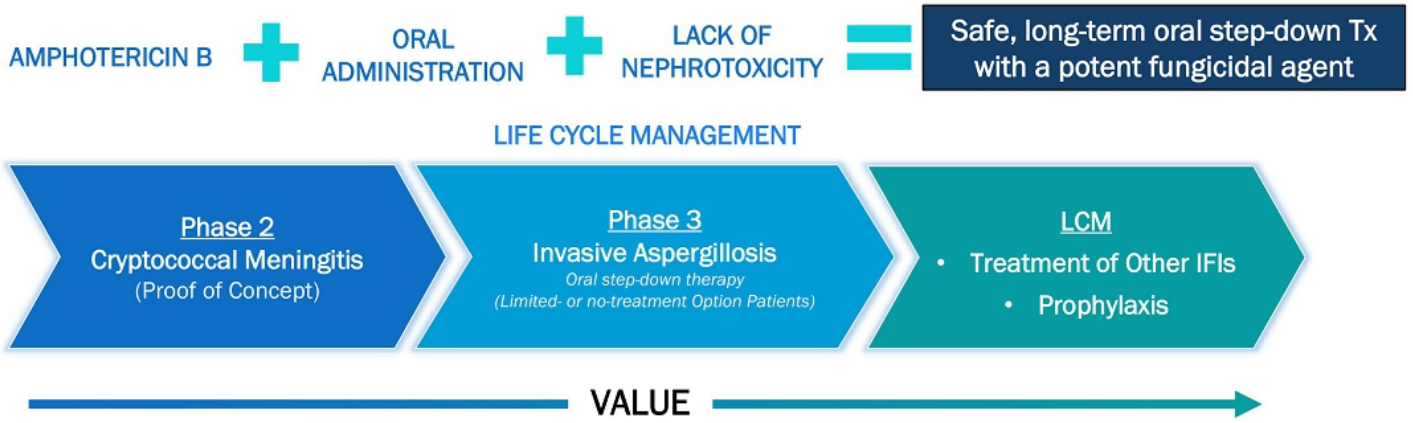
To assess the efficacy and safety of MAT2203 in patients with Invasive Aspergillosis (IA) in adults who have limited or no alternative treatment options following initial intravenous treatment

Patients will be randomized 2:1 to receive either oral MAT2203 as “step down” treatment after initial treatment with IV AMB (Experimental Arm) or Standard of Care (Comparator Arm)



17 *Sample size based on 20% NI margin, 85% power, 31% ACM rate COPYRIGHT MATINAS BIOPHARMA - 2023

MAT2203 Value Proposition



Near-Term Development Strategy:
 Focused strategy on Phase 3 registration trial in Invasive Aspergillosis in patients with limited or no treatment options under the Limited Population Pathway for Antifungal Drugs (LPAD)*
 * NDA review issue

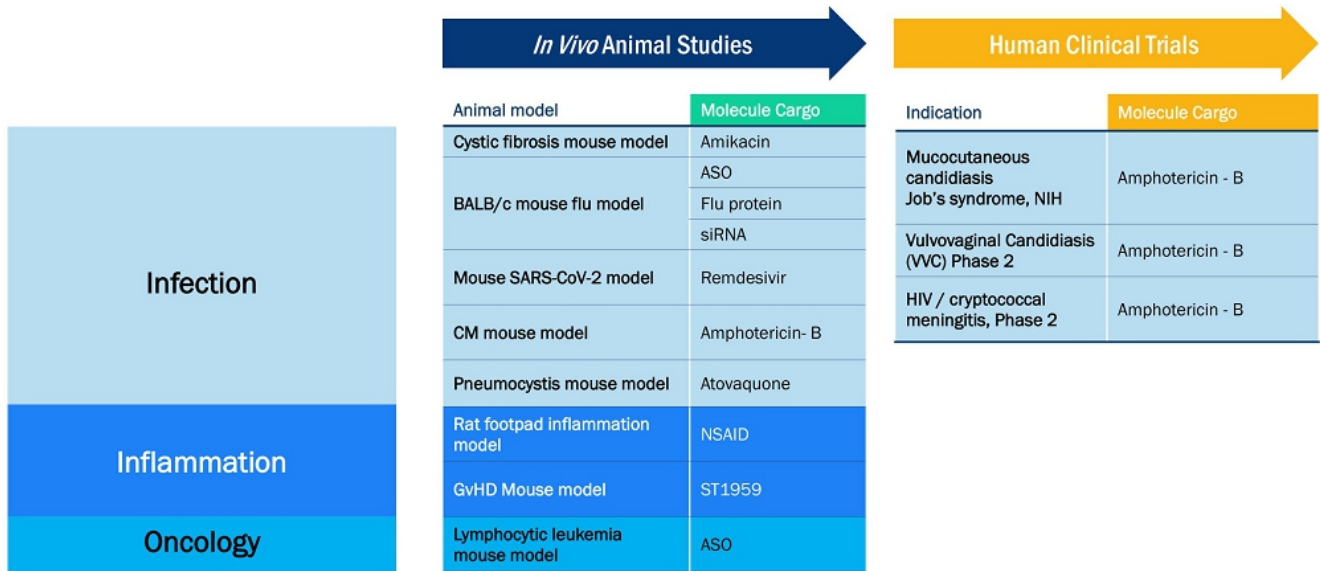
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LNCs Beyond MAT2203

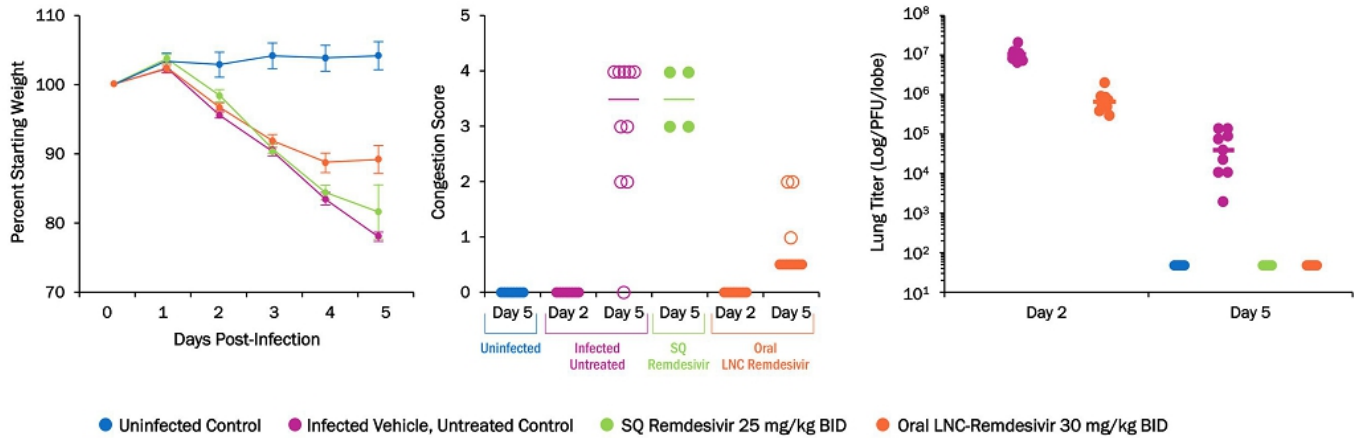
Efficient and Safe Delivery of Small Oligos



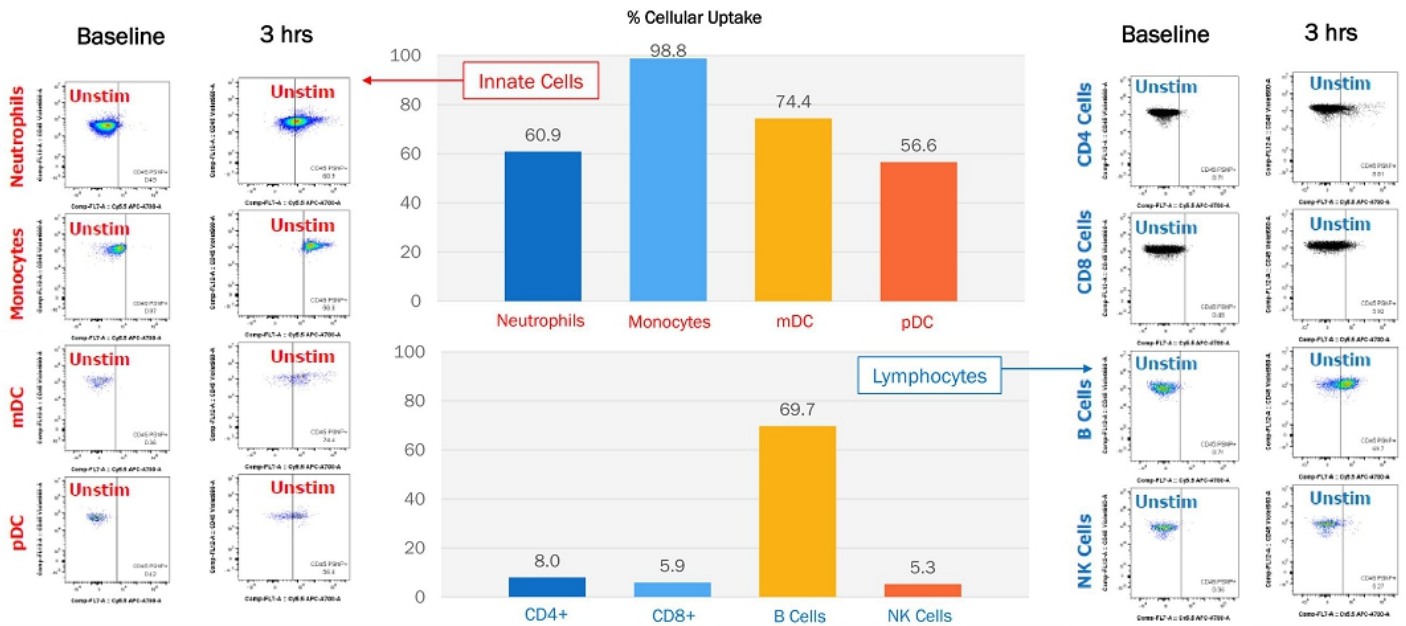
LNC Experience to Date



In Mice Infected With Sars-COV-2, Oral LNC-Remdesivir Mitigated Weight Loss, Improved Congestion Scores, and Reduced Viral Lung Titers (Beginning On Day 2)



LNCs are Taken up by Blood Cells Human Whole Blood Flow Cytometry (3 hrs incubation with labeled LNCs)

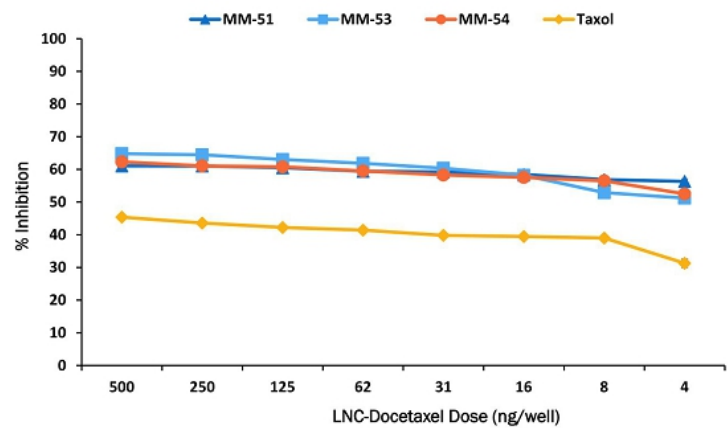


In vitro Tumor Cell Inhibition with LNC Docetaxel Formulations

RATIONALE AND NEXT STEPS

- LNC-Docetaxel program also provides insight into tumor uptake of LNCs
 - Foundation for subsequent small oligo work
- *In vitro* results demonstrate strong LNC efficacy in inhibiting tumor cell growth
- *In vivo* studies planned in multiple tumor models

3 LNC Formulations Demonstrated Significantly Better Tumor Cell Inhibition Than Unformulated Drug



MCF7 breast cancer cells

In vitro Dose-Dependent Knockdown of IL-17A in Murine T Cells

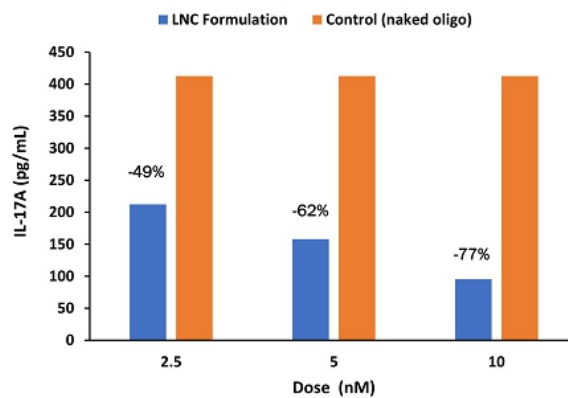
STUDY DESIGN

LNC Formulation of an RNAi

- Small oligo: 18-25 nucleotides
- EL4 cells: 200k/well
- IL-6 (0.3 ug/ml) stimulation
- Treat and evaluate @ 24 hrs
looking at IL-17 protein production

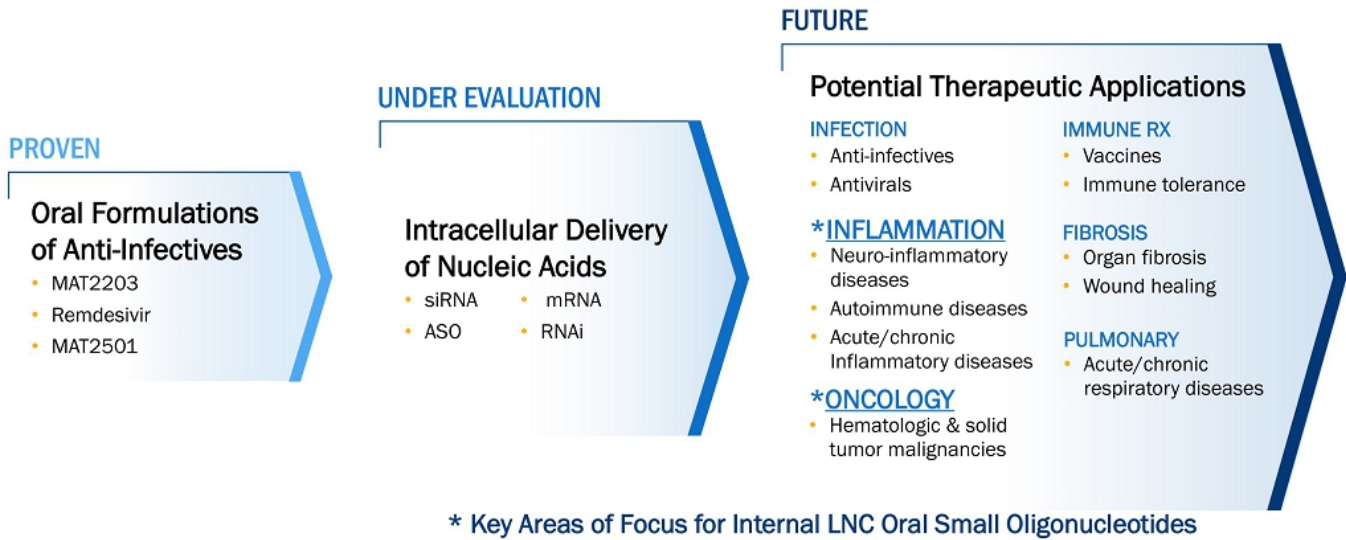
KEY RESULTS

IL-17 Knockdown



Unlocking the Full Potential of the LNC Platform

Matinas is working internally and with third parties to broaden its pipeline of LNC-based therapeutics



Rapid Evolution of Platform Sets Stage for Active Q4

	Q4 2022	Q1 2023	Q2 2023	Q3 2023	Q4 2023	
General Platform	Process enhancements (ongoing)				Oral delivery of small oligos	
Infection	EnACT presentation (ID Week)		Expend Access case presentations	EnACT publication	Pipeline Presentation and <i>Potential</i> Expanded Access Late Breaker Oral Abstract (ID week October 2023)	
		MAT2203 Expanded Access Program				
Inflammation	LNC uptake by innate immune cells <i>ex-vivo</i>	Small oligo LNCs				Biological activity of <i>orally administered</i> anti-inflammatory LNC-small oligos <i>in vitro</i> and <i>in vivo</i> (inflammation models) <i>Therapeutic</i> efficacy of <i>oral</i> anti-inflammatory LNC-small oligos <i>in vivo</i> (disease models)
		LNC uptake by T-cells <i>in vitro</i>	Biological activity of anti-inflammatory LNC-small oligo <i>in vitro</i>	Biological activity of <i>oral</i> anti-inflammatory LNC-small oligo <i>in vivo</i>		
Oncology		Small molecule LNCs	Biological activity of anti-tumor LNC-small molecule <i>in vitro</i>	Formulation optimization to prepare for <i>in vivo</i> studies	Small oligo LNCs → Small molecule LNCs Delivery and activity of oral LNC formulations <i>in vivo</i> (tumor models)	

Expanding LNC Intellectual Property Portfolio

Continuingly increasing our patent suite to increase protection and exclusivity



MAT2203 potentially entitled to **12+ years of exclusivity** (QIDP & Orphan status)



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



Recent patent applications based on **formulation work with small oligonucleotides**

Strong IP & Regulatory Designations

Experienced Leadership Team

EXECUTIVE TEAM



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



Thomas Hoover, MBA
Chief Business Officer



Theresa Matkovits, Ph.D.
Chief Development Officer



James Ferguson, M.D.
Chief Medical Officer



Keith Kucinski, CPA, MBA
Chief Financial Officer



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



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Director



Matthew Wikler, M.D., MBA
Director



Jerome D. Jabbour, J.D.
CEO



Matinas Investment Thesis

Financial Summary



Runway into Sept. 2024



\$22.5M¹ in Cash, Cash Equivalents and Marketable Securities
¹ as of 06/30/23



Non-Dilutive Financing Options

Near-Term Milestones– Setup for Strong Close to 2023

 Q4 - FDA Meeting and Feedback on MAT2203 Phase 3 Invasive Aspergillosis LPAD Study
 Q4 - ID Week MAT2203 Pipeline Presentation and Potential Compassionate Use Late Breaker Oral Abstract
 Q4 - <i>In vivo</i> Oral Delivery of a Functional Small Oligonucleotide (cytokine knockdown)
 Q4 - <i>In vivo</i> Oral Delivery with Therapeutic Impact from Internal ASO/siRNA Program
 Q4 - Oral Delivery of an Anti-Tumor LNC Small Molecule and Small Oligonucleotide
 Q4 - Potential MAT2203 Domestic/Regional/Global Partnership
 Q4 - Potential New Platform Collaboration
 2024 - Potential BARDA/ARPA-H Funding for MAT2203 and LNC Platform

Solid Value “Foundation”

MAT2203

- Clinically Validated
- Phase 3-ready asset
- Highest unmet need



Substantial UPSIDE

LNCs Facilitating ORAL Delivery of Small Oligonucleotides

And

Establishing Internal and External Pipelines