### 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): January 9, 2024

#### 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.)

General Instruction A.2. below):	intended to simultaneously satisfy the	filing obligation of the registrant under any of the following provisions (see		
☐ Written communications pursuant to Rule 425 under th	e 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 C	FR 240.14d-2(b))		
☐ Pre-commencement communications pursuant to Rule	13e-4(c) under the Exchange Act (17 Cl	FR 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 emergi	ing growth company as defined in Rule	405 of the Securities Act of 1933 (17 CFR 8230 405) or Rule 12b-2 of the		
Securities Exchange Act of 1934 (17 CFR §240.12b-2).	, , , , , , , , , , , , , , , , , , ,	403 of the Securities Act of 1753 (17 CFR §250.403) of Rule 120-2 of the		
Securities Exchange Act of 1934 (17 CFR §240.12b-2).	, , , , , , , , , , , , , , , , , , ,	403 of the Securities Act of 1333 (17 CFR §230.403) of Rule 120-2 of the		
Securities Exchange Act of 1934 (17 CFR §240.12b-2).  Emerging growth company □	the registrant has elected not to use the	extended transition period for complying with any new or revised financial		
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			
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			

#### 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 January 9, 2024
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: January 9, 2024 By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour
Title: Chief Executive Officer

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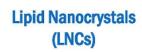
# Corporate Presentation January 2024

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





- 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 <u>inflammation</u> and <u>cancer</u>

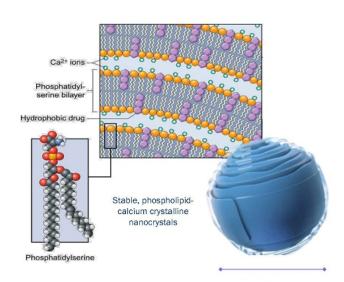
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#### Lipid Nanocrystals (LNCs): A Clinically Validated Intracellular Delivery Platform

50-500 nm



#### Delivery of small molecules and small oligonucleotides

 Successful delivery of small molecules, proteins, small oligonucleotides (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



#### Phosphatidylserine Enables Cellular Targeting and Intracellular Delivery

**Targeting** Stressed Cells Externalize PS Normally, PS With injury, is confined to PS moves from the inner the inner layer layer to the outer layer (facing cytosol) of the cell membrane Infection Injury Oncogenes PHOSPHATIDYLSERINE (PS)

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

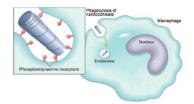
T-cells

OTHER ACTIVELY DIVIDING CELLS (including extracellular pathogens)

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

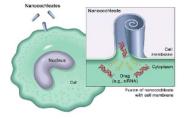
#### **PHAGOCYTOSIS**

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 cargocarrying LNCs to cells expressing PS on their outer membranes.



MATINAS

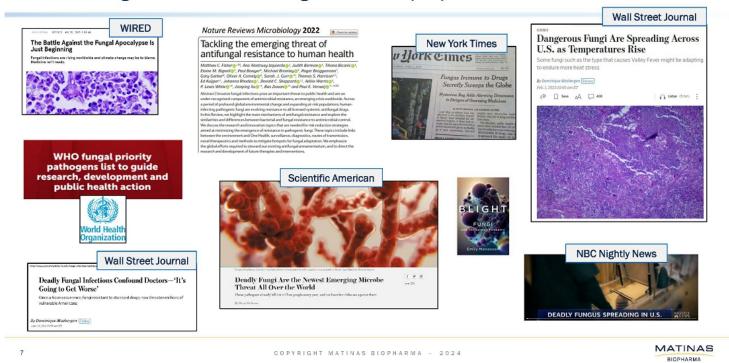
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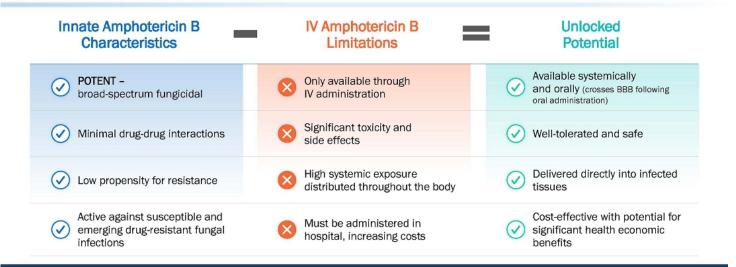
**Clinical Validation of LNC Delivery** 



#### The Growing Threat of Invasive Fungal Infections (IFIs)



#### MAT2203: Unlocking the Full Potential of Amphotericin B

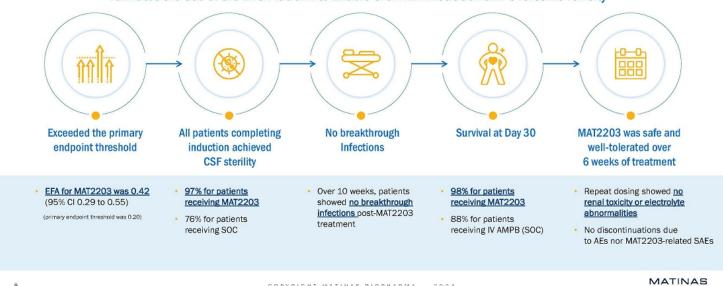


MAT2203 is a promising potential therapeutic option for the treatment of MULTIPLE serious and life-threatening fungal infections



#### 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



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

Clinical Infectious Diseases









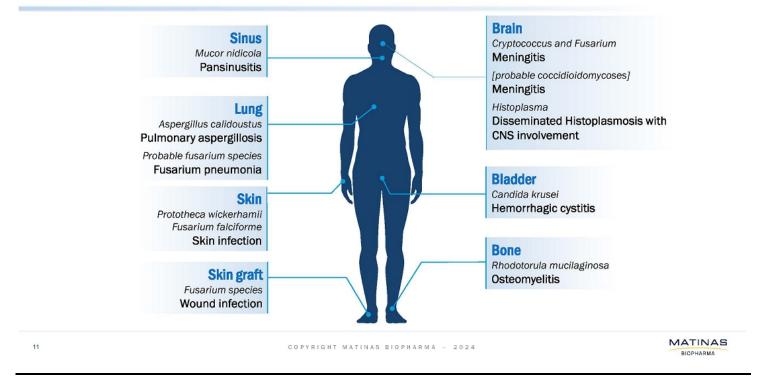
#### Oral Lipid Nanocrystal Amphotericin B for Cryptococcal Meningitis: A Randomized Clinical Trial

David R. Boulware, 1,a, Mucunguzi Atukunda, 2,a Enock Kagimu, Abdu K. Musubire, Andrew Akampurira, Lillian Tugume, Kenneth Ssebambulidde, 2,3 John Kasibante, Laura Nsangi, Timothy Mugabi, Jane Gakuru, Sarah Kimuda, Derrick Kasozi, Suzan Namombwe, Isaac Turyasingura, 2 Morris K. Rutakingirwa, Edward Mpoza, Enos Kigozi, Conrad Muzoora, Jayne Ellis, Caleb P. Skipper, Theresa Matkovits, Peter R. Williamson, Darlisha A. Williams, Ann Fieberg, Kathy H. Hullsiek, Mahsa Abassi, Biyue Dai, and David B. Meya 12

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



#### MAT2203 Expanded Access Program - Targeted Treatment of IFIs Throughout the Body



#### MAT2203 Expanded Access/Compassionate Use Program

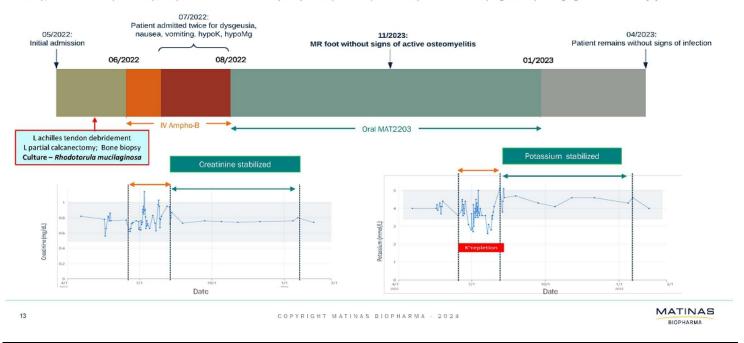
#### **Demonstrated Efficacy in Treatment of Patients with Limited Treatment Options**

- 14 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, Vanderbilt University Medical Center, Children's Hospital of Philadelphia
- Patients were not responding/resistant to, or unable to receive, azole therapy
- Patients were switched to treatment with IV Amphotericin B 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 baseline
- 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

#### Compassionate Use - Recovery from IV Amphotericin B Kidney Toxicity with MAT2203



A 38 y/o female with systemic lupus erythematosus on chronic hydroxychloroquine and prednisone presented with a progressively enlarging wound on her left foot.



#### 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 <u>critical priority</u> 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 and Development 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)
  - Potential registration through leveraging LPAD pathway
  - Other regulatory designations protected and maintained (QIDP, ODD, Fast-Track, potential for Breakthrough Therapy)
- Received written preliminary feedback from FDA on potential composite superiority endpoint and overall study design in late December 2023
  - Feedback moves Company closer to alignment with FDA
  - Meeting to discuss and finalize protocol in process of being scheduled for early Q1
- Preparations underway with global CRO in preparation for Phase 3 study implementation
- · Development and commercial partnership discussions remain ongoing

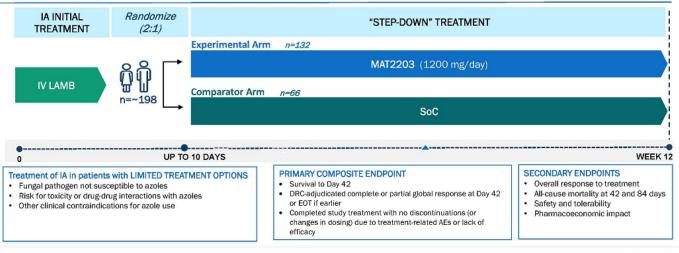
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#### Proposed Phase 3 Study Design in Invasive Aspergillosis (IA)

- > To demonstrate that initial treatment with IV LAMB followed by step-down to oral MAT2203 is <u>superior</u> to IV LAMB followed by SoC treatment in adult patients with Invasive Aspergillosis (IA) who are unable to receive treatment with a mold-active azole and have limited alternative treatment options
- Patients will be randomized 2:1 to receive either oral MAT2203 (Experimental Arm) or continued IV LAMB followed by Standard of Care (Comparator Arm)





Phase 2 Cryptococcal Meningitis (Proof of Concept) Phase 3
Invasive Aspergillosis
Oral step-down therapy
(Limited- or no-treatment Option Patients)

LCMTreatment of Other IFIsProphylaxis

**VALUE** 

#### Near-Term Development Strategy:

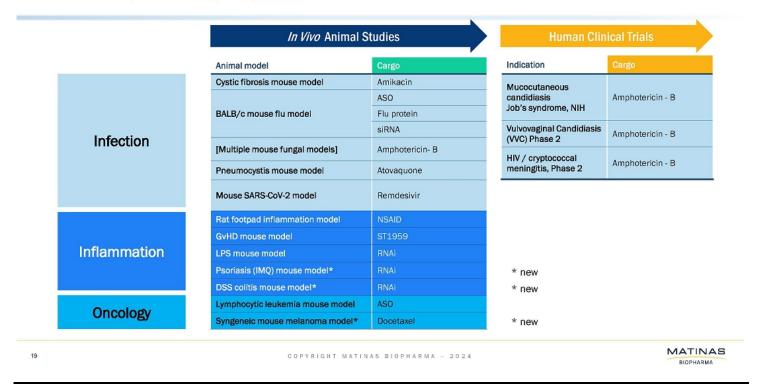
Focused strategy on Phase 3 registration trial in Invasive Aspergillosis in patients with limited or no treatment options under the Limited Population Pathway for Antifungal Drugs (LPAD)\*

\* NDA review issue

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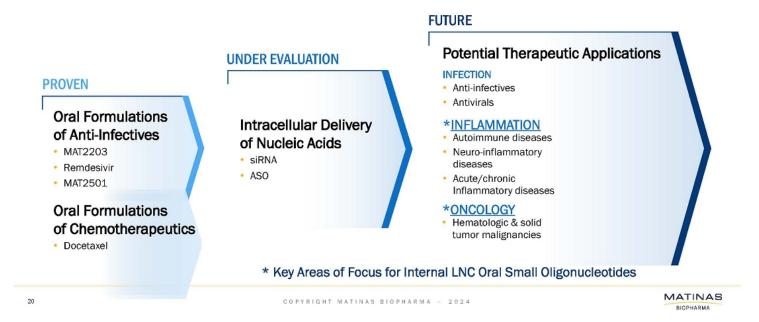


#### **LNC Therapeutic Cargo Experience to Date**



#### Unlocking the Full Potential of the LNC Platform

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

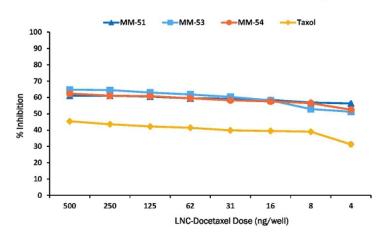


#### In vitro Tumor Cell Inhibition with LNC Docetaxel Formulations

#### 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

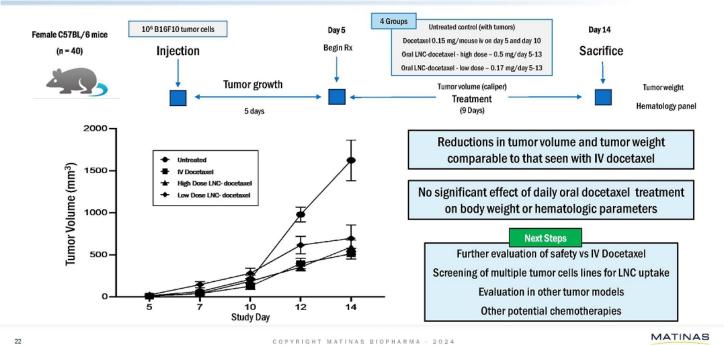


MCF7 breast cancer cells

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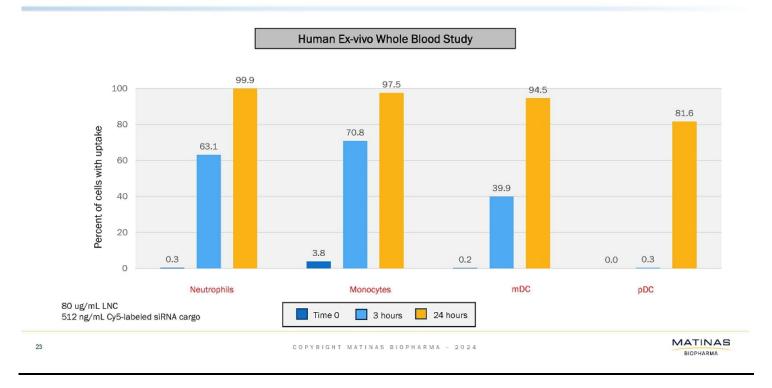
#### In vivo Therapeutic Efficacy of Oral Docetaxel LNCs in a Murine Syngeneic Melanoma Model



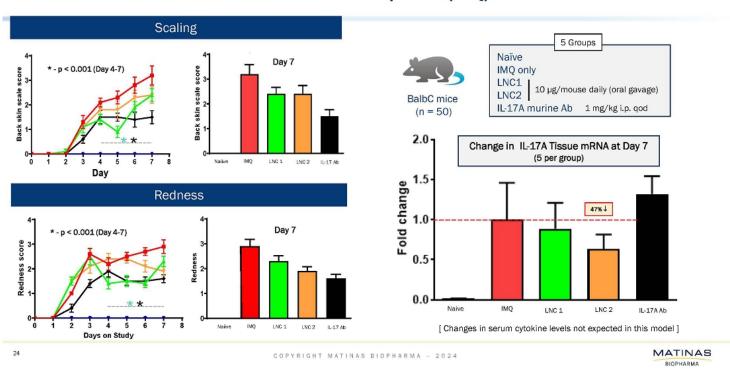
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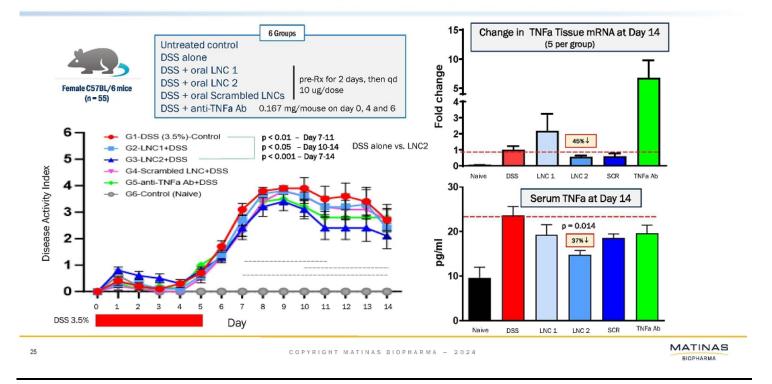
## LNC-formulated Small Oligos Show Strong Uptake in Innate Immune Cells Support Role in Treating Inflammation



#### Effect of Oral LNC IL-17A RNAi in a Murine Imiquimod (IMQ) Psoriasis Model



#### Effect of Oral LNC-TNFa RNAi in a Murine DSS Acute Colitis Model



#### **Summary of Recent Key Advances**

- Successful in vivo oral delivery of LNC-Docetaxel in a melanoma tumor model
  - · Reductions in tumor weight and volume comparable to those seen with IV docetaxel
  - · No adverse effects on body weight or hematologic parameters
- Successful in vivo oral delivery of LNC formulations of 2 different RNAi oligonucleotides targeting inflammatory cytokines
  - · Documented biological activity and therapeutic impact in two different disease models.
    - Psoriasis (IL-17A)
      - · Reduction in tissue IL-17A mRNA levels (skin)
      - · Statistically significant improvement in clinical scoring of skin lesions
    - Colitis (TNFa)
      - · Reductions in tissue TNFa mRNA levels (colon)
      - . Statistically significant reductions in serum TNFα levels
      - · Statistically significant improvement in disease activity scores

These results highlight and validate the unique capabilities of the LNC platform beyond MAT2203

- 1) Oral delivery
- Delivery of active therapeutics (small molecule and small oligo) to diseased tissues <u>outside the liver</u>
- Low blood levels of active drug, with potential for improved safety

#### **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

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MATINAS

#### **Experienced Leadership Team**





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





Thomas Hoover, MBA Chief Business Officer





Theresa Matkovits, Ph.D. Chief Development Officer



TIDS 6 NOVARTIS



James Ferguson, M.D. Chief Medical Officer





Keith Kucinski, CPA, MBA Chief Financial Officer





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

::: Allergan Alcon Segirus

#### **BOARD OF DIRECTORS**

Eric Ende, M.D., MBA Chairman of the Board

**Herbert Conrad** 

Director

MERRILL genzyme















Natasha Giordano Director











Jerome D. Jabbour, J.D.



MATINAS BIOPHARMA

#### **Matinas Investment Thesis**

#### **Financial Summary**



Runway into Q3 2024



\$18.2M1 in Cash, Cash Equivalents and Marketable Securities



Non-Dilutive **Financing Options** 

#### Near-Term Milestones – Setup for Strong Start to 2024



Q1 - FDA Meeting to Finalize P3 Protocol Following Written Preliminary Feedback Moving Company Closer to Alignment with FDA



Q1 - LNC-docetaxel Maximum Tolerated Dose Longer Term Safety Study vs. IV-docetaxel



Q1 - Additional in vivo Oral Delivery of Small Oligonucleotide Targeting Inflammation



Q1 - Potential MAT2203 Domestic/Regional/Global Partnership



Q1 - Screening of Tumor Cell Lines for LNC Uptake Including Breast, Brain, Liver & Lung



Q1 - Evaluation of LNC-docetaxel in Additional Tumor Models



Q2 - Potential New Platform Collaboration

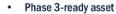


2024 - Potential BARDA Funding for MAT2203

#### Solid Value "Foundation"

#### MAT2203





Highest unmet need



#### **Substantial UPSIDE**

LNCs Facilitating ORAL Delivery of Small Oligonucleotides

And

Establishing Internal and **External Pipelines** 

> MATINAS BIOPHARMA