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): March 28, 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.)

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))				
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).				
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. \Box				

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 Prese	

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Corporate Presentation dated March 28, 2024

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: March 28, 2024 By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour Title: Chief Executive Officer

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Corporate Presentation April 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

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
 - **ORALTO** Treatment of Invasive Aspergillosis in ~216 patients with limited or no treatment options
- Provides effective longer-term fungicidal stepdown therapy for Invasive Fungal Infections
- 12 years of exclusivity*

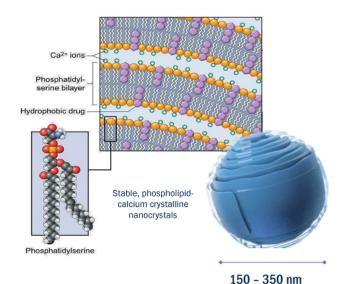
*QIDP and Orphan designations

- · Expand LNC cargo capabilities:
 - · small molecule chemotherapeutics
 - oral delivery of small oligonucleotides ASOs, siRNA, RNAi
- Future focus on <u>inflammation</u> and <u>oncology</u>

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



Delivery of small molecules and small oligonucleotides

 Successful oral delivery of therapeutics in infectious disease, inflammation, and oncology

Extra-hepatic targeting

- Selective delivery to targeted tissues facilitated by phosphatidylserine
- Validated Blood-Brain-Barrier penetration with MAT2203 in cryptococcal meningitis

Oral delivery

- Unique structure protects cargo in GI tract
- Particle size obviates 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

Stressed Cells Externalize PS

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

Infection Inflammation Injury Oncogenesis

PHOSPHATIDYLSERINE (PS)

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

With a wide variety of potential target cells

e variety of PS-containing

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

Delivery

PROFESSIONAL PHAGOCYTES

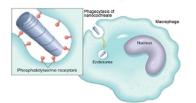
- · Macrophages/monocytes
- Neutrophils
- Dendritic cells

NON-PROFESSIONAL PHAGOCYTES

 Fibroblasts, epithelial cells, endothelial cells

PHAGOCYTOSIS

PS on the outer layer of injured cells is an "eat-me" signal enabling recognition and uptake by professional phagocytes



INJURED/STRESSED CELLS

- Infection
- Inflammation
- · Other physiologic stressors

TUMOR CELLS

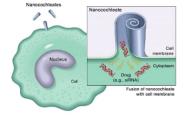
OTHER IMMUNE CELLS

T-cells

EXTRACELLUAR PATHOGENS

FUSION

PS on the outer cell membrane facilitates direct LNC-to-membrane fusion and rapid direct cytosolic delivery



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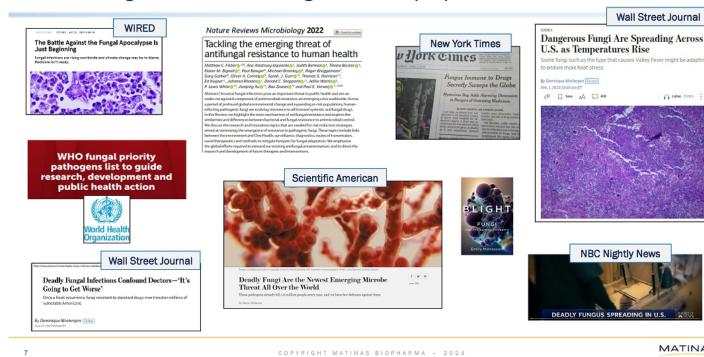
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MAT2203 Oral Amphotericin B

Clinical Validation of LNC Delivery



The Growing Threat of Invasive Fungal Infections (IFIs)



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MAT2203: Unlocking the Full Potential of Amphotericin B

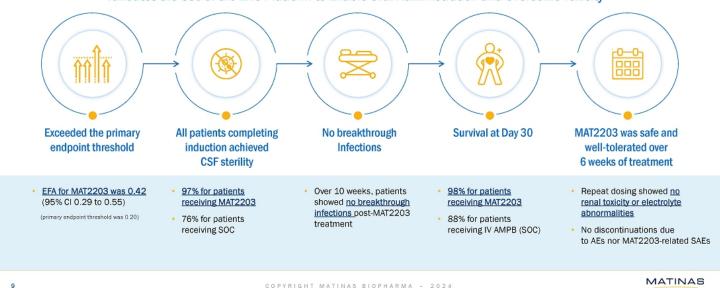
Innate Amphotericin B Characteristics	IV Amphotericin B Limitations	Unlocked Potential
POTENT - broad-spectrum fungicidal	Only available through IV administration	Available systemically and orally (crosses BBB following oral administration)
Minimal drug-drug interactions	Significant toxicity and side 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

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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



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

Clinical Infectious Diseases







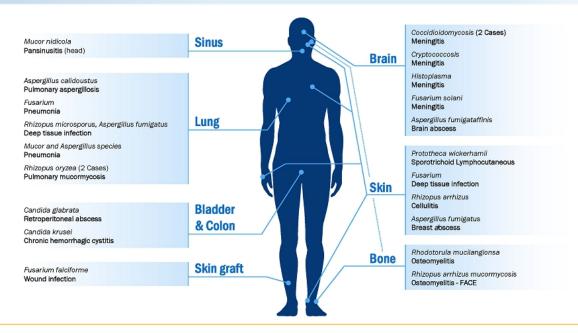


Oral Lipid Nanocrystal Amphotericin B for Cryptococcal Meningitis: A Randomized Clinical Trial

David R. Boulware, 1.a. Mucunguzi Atukunda, 2.a Enock Kagimu, 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, 5 Kathy H. Hullsiek, 6 Mahsa Abassi, 1 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; ⁵Laboratory of Clinical Immunology and Microbiology, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland, USA; ⁵Department 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, ISA

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



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MAT2203 Expanded Access/Compassionate Use Program

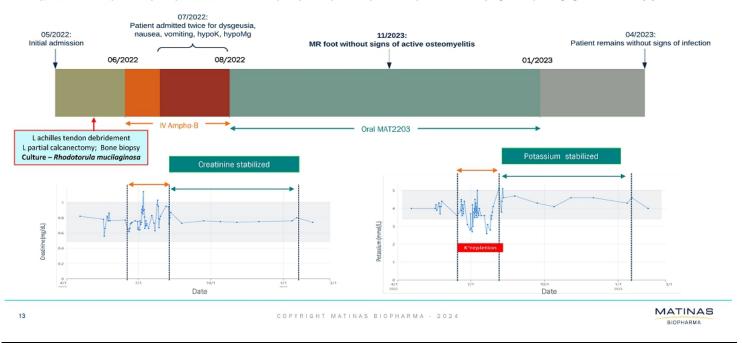
Demonstrated Efficacy in Treatment of Patients with Limited Treatment Options

- 20 patients with no other treatment options have enrolled to receive 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, Memorial Sloan Kettering, University of California, San Diego School of
 Medicine, 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 to 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 after switching to MAT2203
- 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 Invasive Aspergillosis (IA) with Limited Treatment Options

- IA is a serious, life-threatening fungal infection that occurs primarily in severely immunocompromised patients with hematologic malignancies and transplant recipients
 - ~15,000 new cases per year in the U.S.
 - WHO, CDC, and FDA all consider it 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 fungal expertise to manage toxicities and significant DDIs that can limit duration of use
 - Resistance to azoles is increasing globally
 - Breakthrough IA now being reported in patients receiving antifungal prophylaxis (azoles)
 - Failures attributed to non-compliance, poor absorption, DDIs, or infection with drug-resistant Aspergillus species
- Unmet medical need highest in IA patients who cannot take azoles
 - ~3,000-5,000 cases per year in the U.S.
 - Include patients with resistance, intolerance, DDIs, breakthrough infections
 - · No other good long-term oral options
 - Rare disease/orphan commercial opportunity



Bazaz R et al.

Pharmaceutical Journal 2019

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)
- In February 2024, reached agreement with FDA on a single Phase 3 Registration Trial in support of an NDA for the treatment of invasive aspergillosis in patients with limited treatment options (the "ORALTO" Trial)
- Preparations underway with global CRO in preparation for Phase 3 study implementation
- Development and commercial partnership discussions ongoing

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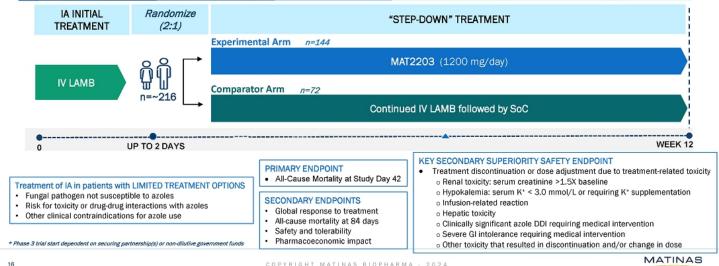
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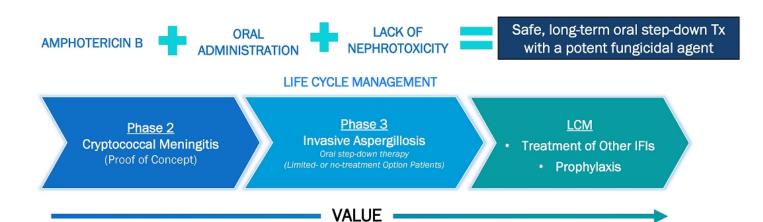


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FDA-Agreed Phase 3 Study Design in Invasive Aspergillosis (IA) (the "ORALTO" Trial)

- > To demonstrate that initial treatment with IV LAMB followed by step-down to oral MAT2203 is comparable to (noninferior) 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)





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)*

* Evaluated at time of NDA filing

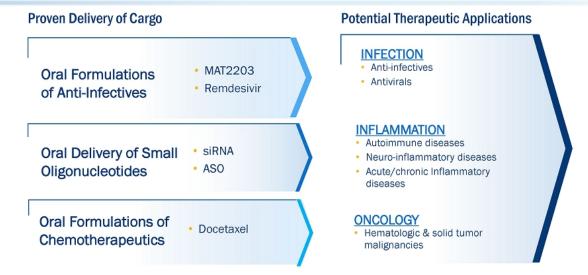
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Unlocking the Full Potential of the LNC Platform



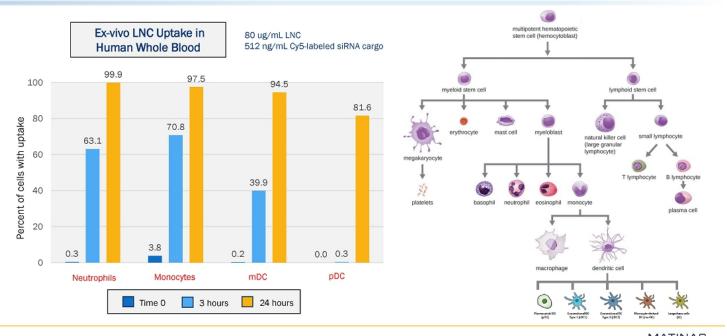
Matinas is working internally and with third parties to broaden its portfolio of LNC-based therapeutics

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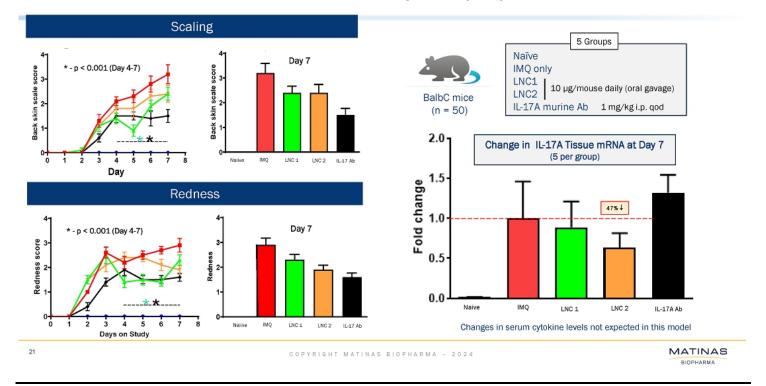
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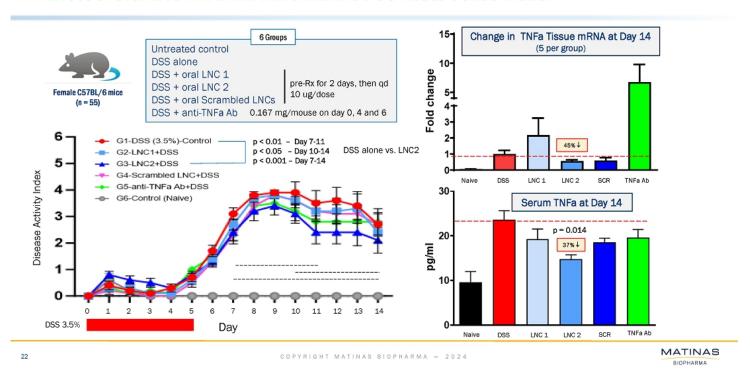
LNCs are Avidly Taken up by Innate Immune Cells - Multiple Opportunities in Inflammation



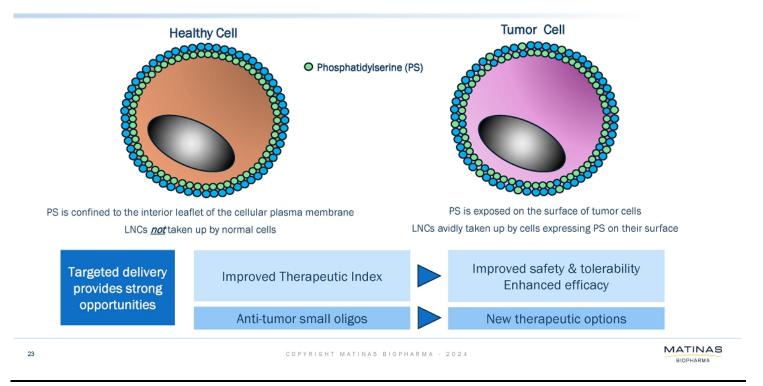
Effect of Oral LNC IL-17A RNAi in a Murine Imiquimod (IMQ) Psoriasis Model



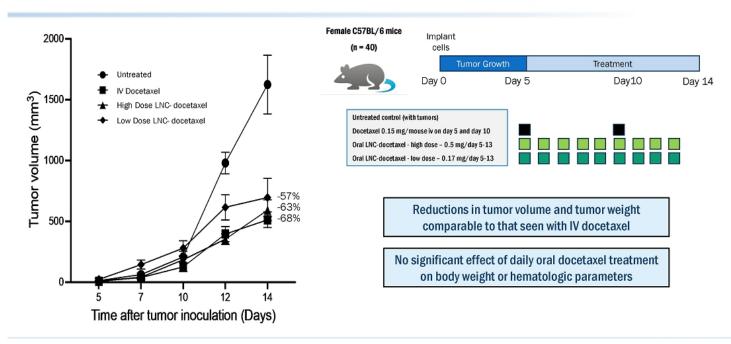
Effect of Oral LNC-TNFa RNAi in a Murine DSS Acute Colitis Model



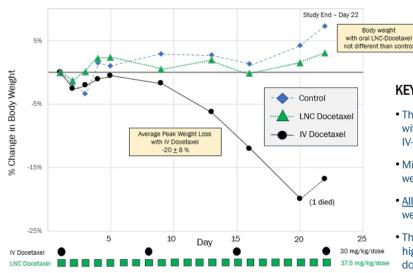
LNCs Target PS on Tumor Cells - Multiple Opportunities in Oncology



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



Oral LNC Docetaxel Markedly Reduces Toxicity





Healthy C57BL/6 mice (n = 24)

Oral saline (control)

Docetaxel 0.6 mg/mouse iv q week x 3

Oral LNC-docetaxel 0.75 mg/mouse daily through day 22

KEY TAKEAWAYS

- Through Day 22, the total amount of docetaxel administered with oral LNC-docetaxel was more than <u>8x</u> greater than with IV-docetaxel.
- Mice treated with oral LNC-docetaxel maintained their body weight; statistically no different than controls.
- <u>All</u> mice treated with IV-docetaxel lost a significant amount of weight (toxicity)—an average peak loss of 20%.
- The daily administered oral LNC-docetaxel dose was 50% higher (total administered drug 3.5x greater) than the LNCdocetaxel dose administered in the previous melanoma study.

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Recent Key Advances Highlight Broader Applicability of LNC Platform Capabilities

Oncology

- Successful in vivo oral delivery of LNC-docetaxel in a melanoma tumor model
 - · Reductions in tumor weight and volume comparable to IV docetaxel
 - No adverse effects on body weight or hematologic parameters
- Corroboration of safety in an additional in vivo study with higher dose/longer docetaxel Rx in healthy mice
 - · Daily oral dose 50% higher than prior study
 - · Total drug administered 3.5x higher than prior study
 - No weight loss compared with 20% peak weight loss with IV docetaxel

Inflammation

- Successful in vivo oral LNC delivery of 2 different RNAi oligonucleotides targeting inflammatory cytokines
- Documented biological activity <u>and</u> 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
- · Reductions in tissue TNFa mRNA levels (colon)

Colitis (TNFa)

- Statistically significant reductions in serum TNF α levels
- Statistically significant improvement in disease activity scores

Key LNC Capabilities

- Oral delivery
- Delivery of active therapeutics to diseased tissues <u>outside the liver</u>
- Low blood levels of active drug, with potential for improved safety

Expanding LNC Intellectual Property Portfolio

Increasing Patent Portfolio to Increase Protection and Exclusivity



MAT2203 potentially entitled to 12+ years of marketing exclusivity (QIDP & Orphan designations)



Owned and Licensed Global Platform IP with potential protection out to 2044



Recent patent applications based on formulation work with small oligonucleotides and in oncology

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





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

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Director







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Director







Natasha Giordano





Matthew Wikler, M.D., MBA





Jerome D. Jabbour, J.D. CEO



MATINAS BIOPHARMA

Investment Thesis

Financial Summary



Runway through Q3 2024



\$13.8M1 in Cash, Cash Equivalents and Marketable Securities

1 as of 012/31/23

Non-Dilutive



Financing Options Highest unmet need

Near-Term Milestones - Setup for Strong Start to 2024



· . .

- Q1 Successful Agreement with FDA for a Single Phase 3 Registration Trial to Support an NDA for MAT2203 for the Treatment of Invasive Aspergillosis (the "ORALTO" Trial)
- Q1 LNC-docetaxel Maximum Tolerated Dose Longer Term Safety Study vs. IV-docetaxel
- Q2 Potential MAT2203 Domestic/Regional/Global Partnership
 - Q2 Additional in vivo Oral Delivery of Small Oligonucleotides Targeting Inflammation
- Q2 In vivo Evaluation of Additional Chemo-toxic Agents Delivered with LNCs
 - Q2 Evaluation of LNC-docetaxel in Additional Tumor Models
 - Commencement and First Patient Enrolled in ORALTO Phase 3 Trial

Solid Value "Foundation"

MAT2203 (Infection)

- Clinically Validated
- Clear Registration Pathway



Substantial UPSIDE

LNC ORAL Delivery of Small Oligonucleotides in Inflammation

LNCs to Improve Therapeutic Index of Chemotherapeutic Agents in Oncology

Toward

Establishing Internal and External Pipelines