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 14, 2021

MATINAS BIOPHARMA HOLDINGS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-38022**	**46-3011414**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer ID Number)**

1545 Route 206 South, Suite 302 **Bedminster, New Jersey** **(Address of principal executive offices)**	**07921** **(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") intends to use a slide presentation in connection with a conference to take place on Thursday, January 14, 2021 and thereafter at various conferences and investor meetings. The slide presentation is attached hereto as Exhibit 99.1.

In accordance with General Instruction B.2 of Form 8-K, the information in this Current Report on Form 8-K, including Exhibits 99.1, shall not be deemed "filed" for the 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 it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are being furnished with this report:

Exhibit No.	Description
99.1	Slide Presentation, dated January 14, 2021.

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 14, 2021

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.

Company Highlights

LYPDISO™ (MAT9001)
Next Generation
Rx Omega-3

- Initial indication in severe hypertriglyceridemia with potential expansion into multi-billion-dollar cardiovascular risk reduction market
- Clear differentiation from currently approved prescription omega-3 products, supported by strong barriers to entry
- **Q1 2021**: Key additional head-to-head topline data from Phase 2 ENHANCE-IT study vs. Amarin's Vascepa®
- **H2 2021**: Commence Phase 3 'AMPLIFY' study in severe hypertriglyceridemia (SHTG)

LNC PLATFORM
Lipid NanoCrystal Delivery
Technology

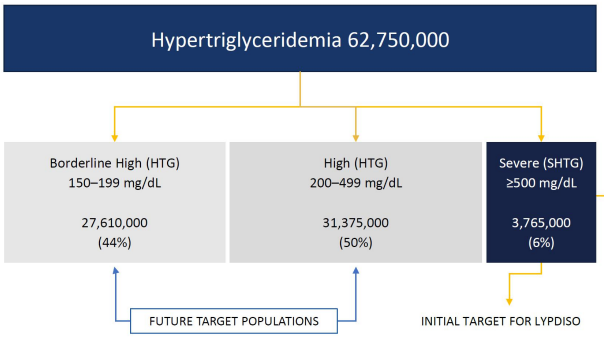
- Platform technology enabling a paradigm-shift in drug delivery pharmacokinetics: well-tolerated, targeted, intracellular delivery
- **Mid-2021**: Cohort 2 update for MAT2203 (oral amphotericin B) in the EnACT study in cryptococcal meningitis. Currently enrolling Cohort 2
- Recent $3.75M funding from Cystic Fibrosis Foundation for MAT2501 (oral amikacin) accelerates development of second LNC drug candidate
- Collaborations with NIH (oral formulation of Gilead's remdesivir), Genentech, ViiV Healthcare and others exploring LNC formulations of innovative compounds

LYPDISO™ (MAT9001) Overview

MATINAS BIOPHARMA

LYPDISO™ Targets a Significant Market Opportunity

US Adult Prevalence, Calculated*, 2020



- SHTG patients have low rates of pharmacologic intervention
- Primary treatment goal is reduction of triglycerides
- LYPDISO™ has been demonstrated to be the most potent TG-lowering omega-3 Rx
- Potential multibillion-dollar market opportunity
- LYPDISO™ has an opportunity to become the "best-in-class" product serving these populations

*Assuming 250M US adult population
Sources: DRG Dyslipidemia Disease Landscape & Forecast (2019)
Trends in Elevated Triglyceride in Adults: United States, 2001–2012, NCHS Data Brief No. 198, May 2015
Dean G. Karalis; Adv Ther (2017) 34:300–323

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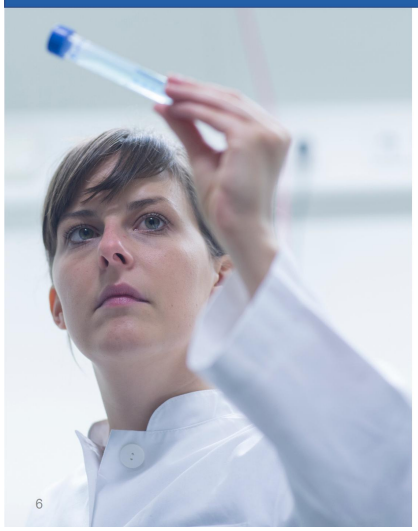
The LYPDISO™ Difference



OMEGA-3 BENEFITS

- Prescription Omega-3s offer a rare combination of potency, safety, and affordability
- Substantial benefits for both patients *AND* the US healthcare system
- Potential multi-billion-dollar market in the US (approval of Vascepa to treat patients at CV risk with TGs > 150 mg/dL)
- Well defined pathway to approval

LYPDISO™ BENEFITS

- Specifically designed to optimize treatment of dyslipidemia and severe hypertriglyceridemia
- EPA + DPA drive enhanced lipid lowering potency without raising LDL.
- EPA associated with cardio-protective benefits showing improved outcomes in a large clinical trial
- Potent omega-3 DPA combines superior TG-lowering with unique, synergistic positive impact on PCSK9, Apo-CIII and HMG-coA reductase
- Enhanced bioavailability may lead to higher EPA blood levels – linked to improved outcomes
- Free fatty-acid formulation drives superior absorption with minimal food-effect

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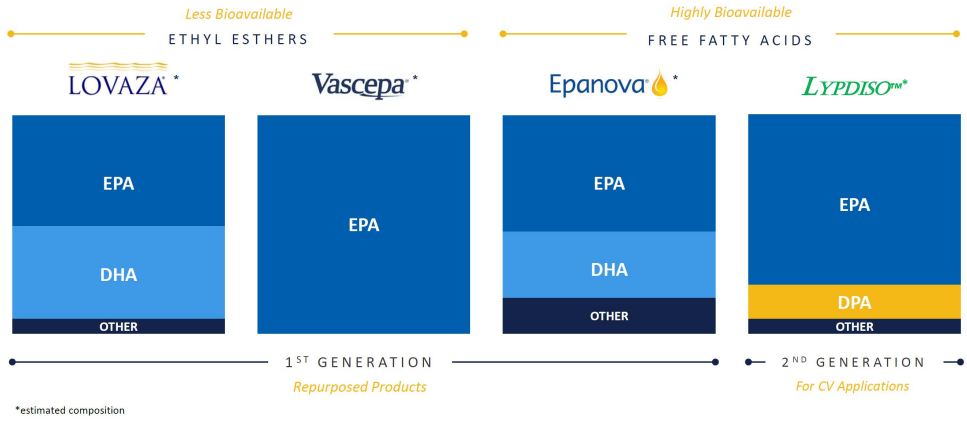
Formulated to Achieve Best-in-Class Potency



*estimated composition

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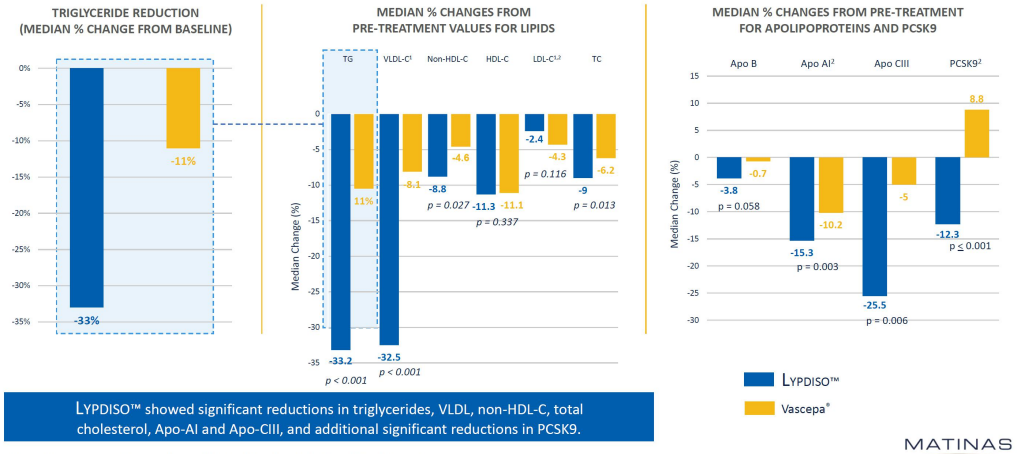
LYPDISO™ Demonstrated Superiority Head-to-Head vs. Vascepa®



LYPDISO™ showed significant reductions in triglycerides, VLDL, non-HDL-C, total cholesterol, Apo-AI and Apo-CIII, and additional significant reductions in PCSK9.

[1] Some values were not calculated because the TG concentration pre- or post-treatment was >400 mg/dL
[2] Response variable was not normally distributed (Shapiro-Wilk p<0.01), analysis was completed using ANCOVA after rank transformation for between treatment comparisons

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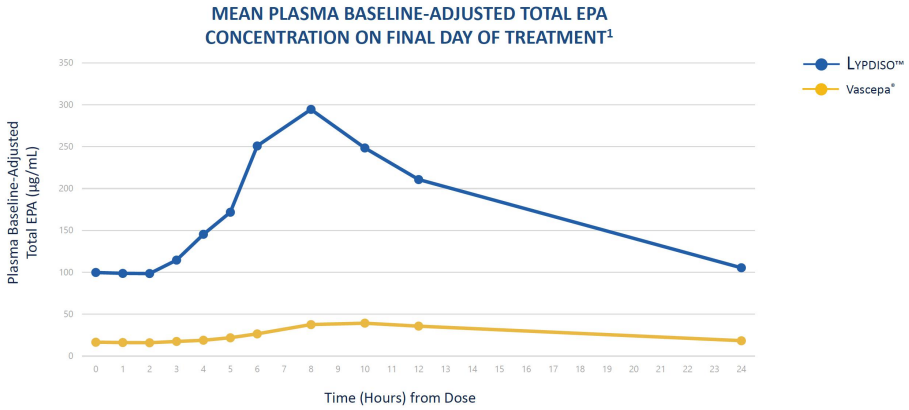
Substantially Higher EPA Blood Levels vs. Vascepa® On Low Fat Diet



1: T=0 is drug administration on final day of treatment

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Omega-3s and Outcome Benefits – A Tale of Two Levels (EPA)?

	REDUCE-IT (Vascepa®)	STRENGTH (Epanova®)
Outcome Benefit(s)	**Yes**	**No**
Trial Size	**8,179**	**13,086**
% Primary Prevention	**30%**	**50%**
% Secondary Prevention	**70%**	**50%**
Median Follow-up (years)	**4.9**	**3.3 (on drug)**
Median EPA Level	**144 (µg/mL)**	**89 (µg/mL)**
EPA	**Yes** (876 mg/capsule)	**Yes** (475 mg/capsule)
DHA	**No**	**Yes**

Bhatt DL *et al.* ***N Engl J Med*** *2019; 380: 11-22*

Nicholls SJ *et al.* ***JAMA*** *2020 (published on-line)*

Key Takeaways

- REDUCE-IT showed an outcome benefit, while STRENGTH was stopped for futility
- EPA levels were the only biomarker correlated with an outcome benefit in REDUCE-IT
- Notable differences in patient population, study duration, and EPA levels provide insight as we evaluate LYPDISO™ for clinical and commercial success

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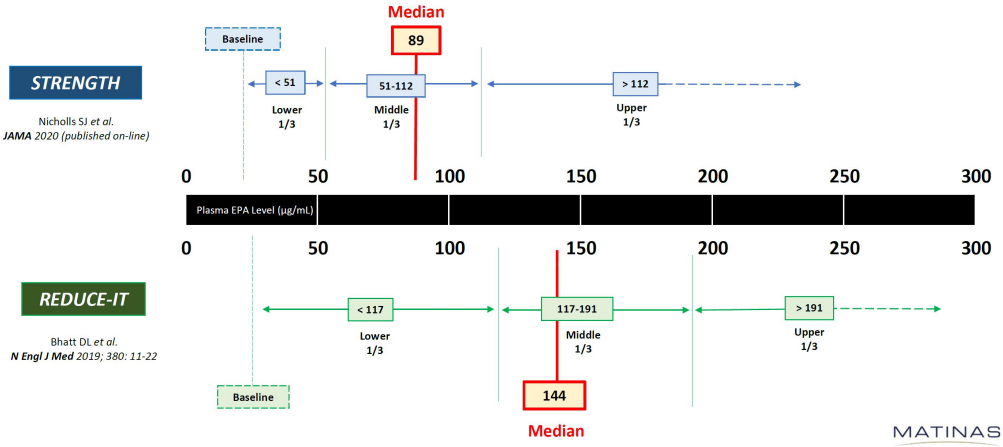
Omega-3s and Outcome Benefits – A Tale of Two Levels (EPA)?

EPA levels in STRENGTH were significantly lower than in REDUCE-IT and likely not high enough to have any therapeutic effect



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LYPDISO™ (MAT9001)
Clinical Development Plan

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The Path to Significant Market Share

REGISTRATION STUDIES

- ✓ 28-day tox study
- ✓ 90-day tox study
- ✓ Phase 1 PK vs Lovaza
  - Single dose comparative bioavailability (n=36)
- ❑ Phase 3 Pivotal in SHTG (TG 500-2000 mg/dL)
  - LYPDISO™ 4g vs placebo in SHTG patients
  - Commencing 2H 2021
  - 12-week study in ~300 patients with TG 500-2000 mg/dL (2:1 randomization)
  - Primary endpoint: % change in TG

MARKET DIFFERENTIATION STUDIES

- ✓ First head-to-head study of LYPDISO™ vs Vascepa® (n=42)
  - Patients with TGs 200-400 mg/dL
  - 14-day crossover design with 28-day washout
  - Very low-fat diet
- ❑ ENHANCE-IT head-to-head study vs Vascepa (n=100)
  - Patients with TGs 150-500 mg/dL
  - 28-day crossover design with 28-day washout
  - Dosed according to Vascepa label = twice-a-day with food (guideline recommended TLC diet)
  - Powered to show 10% absolute difference in TG reduction

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ENHANCE-IT Study: LYPDISO™ vs Vascepa®

OBJECTIVES

To assess PD effects of LYPDISO™, compared with Vascepa®, on TGs and other lipoprotein lipids, apolipoproteins, hs-CRP, and PCSK9 in men and women with elevated TGs

- Randomized, open-label, active-control crossover design (n=100)
- LYPDISO™ vs. Vascepa®, administered per Vascepa® label at 2g 2x/day with a meal each time; TLC diet
- Fasting TG 150-499 mg/dL (at least 50% with TGs ≥200-499 mg/dL)
- No other lipid-lowering Rx (stable-dose statins allowed)
- Two 28-day treatment periods, ≥ 28-day washout between treatments
- Measurement of PD parameters and omega-3 blood levels

PRIMARY ENDPOINT

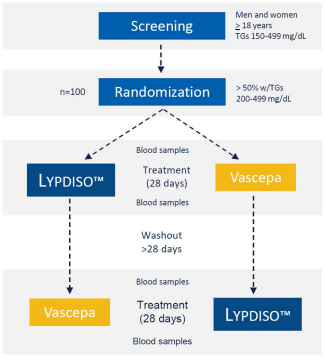
- % change from baseline to end-of-treatment in plasma TG

SECONDARY ENDPOINTS

- Total-C, LDL-C, VLDL-C, HDL-C, non-HDL-C, Apo A1, Apo B, Apo C3, PCSK9, hs-CRP
- Omega-3 fatty acids (EPA, DHA, DPA, total) in plasma

EXPLORATORY ENDPOINTS

- Plasma phospholipid levels of omega-3 fatty acids, as a % of total fatty acids
- Erythrocyte membrane levels of omega-3 fatty acids, as a % of total fatty acids (first treatment period)



Primary Endpoint: % Change from baseline in plasma TG

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Matinas and FDA Aligned on LYPDISO™ Phase 3 Program

Key Takeaways from End-of-Phase 2 Meeting

- Matinas and FDA aligned on all key aspects of Company's Phase 3 development program
- Preclinical tox program and comparative bioavailability study provided acceptable bridge to Lovaza® under 505(b)(2)
- FDA agreement to move directly into Phase 3 without additional dose-finding studies
- FDA agreement that a single 12-week study in SHTG would be sufficient demonstration of efficacy for SHTG indication
- FDA provided flexibility on additional patient safety data, providing potential for opportunity to further differentiate LYPDISO™ from existing prescription omega-3s

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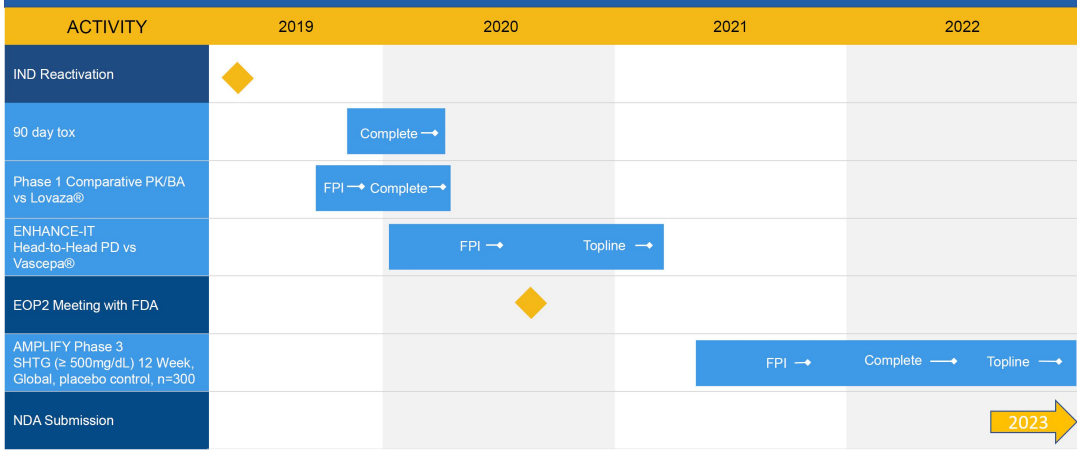
LYPDISO™ Development Timeline



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Expanding Intellectual Property Portfolio

22
PATENT APPLICATIONS

Additional IP to be developed as clinical development plan progresses

2
ORANGE BOOK-LISTABLE U.S. PATENTS ISSUED, EXTEND TO 2033

Q4 2014: US Patent No. 8,906,964
Q3 2018: US Patent No. 10,058,521
4 additional U.S. patent applications pending

NCE
EXCLUSIVITY

The active moiety of LYPDISO™ is the entire mixture of omega-3 ingredients representing a single active ingredient, which makes LYPDISO eligible for 5-year NCE exclusivity.

MATINAS BIOPHARMA

Lipid NanoCrystal Platform

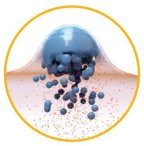
Targeted, Well-Tolerated Intracellular Delivery

LNC Platform Enables a Paradigm-Shift in Intracellular Drug Delivery

Matinas' LNC Platform comprises highly efficient, fusogenic and non-toxic drug formulations

FLEXIBLE ADMINISTRATION

- Oral
- Intramuscular
- Intravenous
- Intranasal

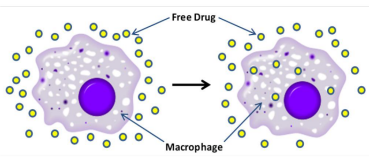


PHYSIOLOGICALLY TARGETS ACTIVATED CELLS

- No evidence of immunogenicity
- Enters cells through non-destructive membrane fusion
- Delivers high tissue concentrations of drug with low plasma levels
- Reduced toxicity of drugs
- Ability to deliver a broad range of molecules (e.g., small molecules, nucleic acid polymers, vaccines)
- Demonstrated ability to cross blood-brain barrier in animal models
- Validated in multiple clinical and pre-clinical studies

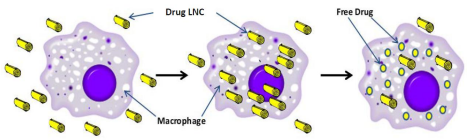
LNC Platform Also Enables a Paradigm-Shift in Drug Delivery Pharmacokinetics

Traditional Model of Drug Delivery



- Elevated drug levels in plasma generally required
- Relatively low percentage of circulating drug enters the cell
- Difficult to safely and effectively treat intracellular targets
- Elevated drug levels can often result in nonspecific toxicity

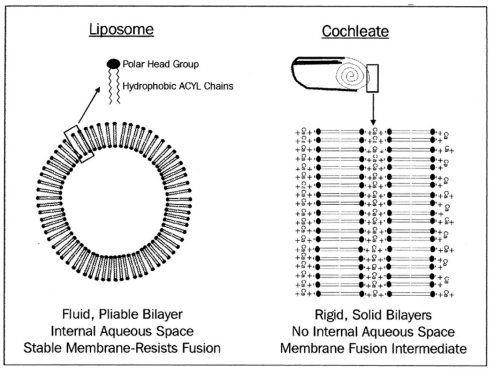
LNC Model of Drug Delivery
"Immune-Mediated Targeting"



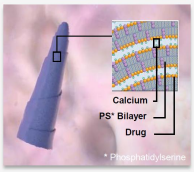
- LNCs keep active drug out of the blood, resulting in less toxicity
- LNCs are preferentially taken up by "activated" cells, i.e., macrophages, neutrophils, dendritic cells
- Low intracellular calcium concentration causes LNCs to open and release drug cargo inside cell
- Activated cells migrate to infected/inflamed tissues, allowing LNCs to 'use' the immune system to efficiently deliver drug to target, even across the blood-brain barrier – "***Trojan Horse Effect***"

Lipid NanoCrystals are *not* Liposomes or Lipid Nano-Particles

Liposomes vs. LNCs

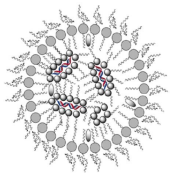


Gould-Fogerite S *et al.* ***Adv Drug Del Rev*** 1998; 32: 273-87



LNCs

+ Multiple routes of administration
+ Rigid, solid multilayered membrane
+ Non-aqueous interior
+ Resists environmental attack
+ Non-toxic
+ Generally stable at room temperature



LNPs

- No oral administration
- Fluid membrane
- Induce membrane destruction
- Can induce immunogenicity and toxicity
- Difficult to achieve room temperature stable formulations

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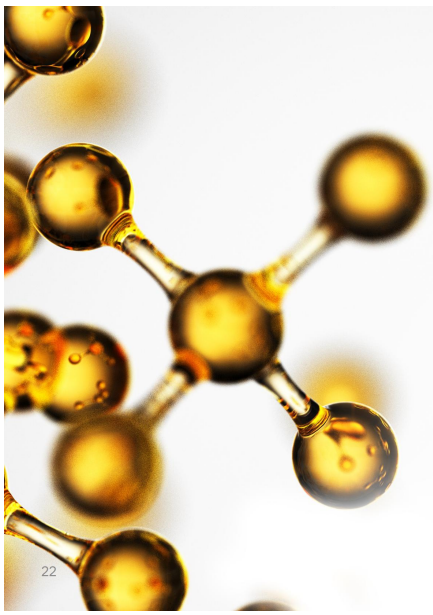

MAT2203

Oral Amphotericin B

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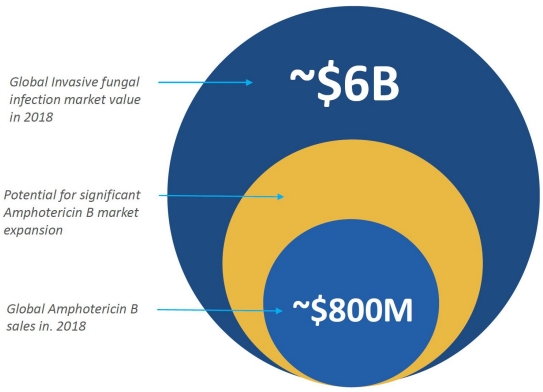
Invasive Fungal Infections Represent an Urgent Growing Global Need



- 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 and management of associated AE's accounting for up to 85% of cost of hospital stay.
- **A safer and more convenient amphotericin B would be a game-changer in the fight against invasive fungal infections.**

MATINAS BIOPHARMA

MAT2203: A Novel Approach with a Proven Therapeutic

MAT2203

- Oral amphotericin B formulation utilizing LNCs
- Being developed with support from the NIH
- Proprietary formulation with robust intellectual property protection
- Potential to expand use into larger prophylaxis and maintenance settings

IMPROVED PROFILE

- LNC formulation enables oral administration and bioavailability
- Preclinical evidence of ability to cross the blood-brain barrier with an oral therapy
- Improved Toxicity with no drug-related serious adverse events reported to date

BIG POTENTIAL

- Potential to become the preferred antifungal agent for treatment of cryptococcal meningitis and other invasive fungal infections
- Potential to cross the blood-brain barrier with an oral therapy
- Orphan Drug Designation + 4 QIDP and Fast Track Designations
- Up to 12 years marketing exclusivity, if approved

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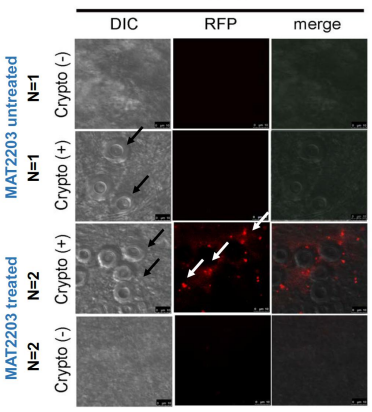
Immune-Mediated Delivery of Oral Amphotericin B Across the Blood-Brain Barrier

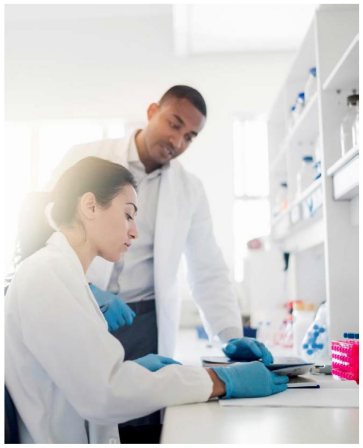
MAT2203: Preclinical Studies in a Mouse Model of Cryptococcal *Meningoencephalitis*

- MAT2203 LNCs tagged with rhodamine and dosed orally
- Crypto-positive, MAT2203 treated mice show fluorescence of LNCs at site of crypto infection
- Crypto-negative, MAT2203 treated mice show no fluorescence
- MAT2203 untreated mice show no fluorescence in both crypto-positive and negative
- **Supports immune-mediated delivery thesis that LNCs are preferentially taken up by activated cells and delivered to sites of infection/inflammation**

Brain localization of fluorescent LNC after oral dosing



EnACT Study: Encochleated Oral Amphotericin for Cryptococcal Meningitis



RATIONALE

- Traditional amphotericin B given intravenously (IV AMB) has common and substantial toxicities resulting in serious adverse events or patients having to switch medications.
- MAT2203 has demonstrated oral bioavailability, efficacy in animal models, and minimal toxicity due to targeted drug delivery to macrophages where cryptococcus yeast reside.
- An all-oral induction therapy regimen with MAT2203 would represent a **substantial** advancement in the management of invasive fungal disease and MAT2203 would also allow for transition from IV therapy in the hospital to MAT2203 in an outpatient setting.

PHASE 1 of EnACT

- Multiple ascending doses of MAT2203 to HIV infected patients without active cryptococcal meningitis to test safety and tolerability
- Completed Q1 2020
- Determined optimal tolerated dose to move into Phase 2, which commenced in July 2020.

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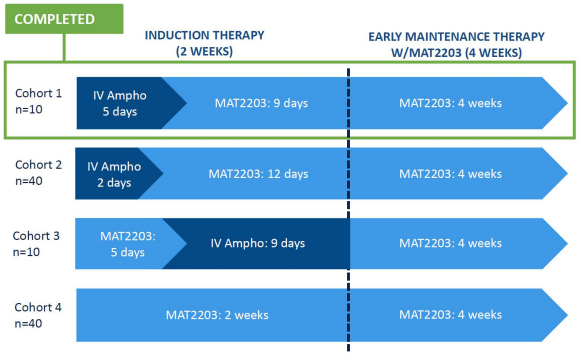
EnACT: Phase 2 in HIV Patients with Cryptococcal Meningitis



Each Cohort will have a control arm of patients of varying size receiving SOC:

IV AMB + 5-FC during induction and fluconazole during maintenance therapy

PROTOCOL DETAILS

- Open-label, sequential-cohort study assessing safety, tolerability and efficacy of MAT2203
- Assess MAT2203 as both induction and maintenance therapy
- Primary endpoint: Rate of CSF fungal clearance as measured over induction period of 2 weeks
- N=100 patients receiving MAT2203 + flucytosine (5-FC) in 4 stages of escalating durations of MAT2203 and decreasing duration of IV Amphotericin B (AMB)
- Safety and efficacy monitored throughout study by an independent Data Monitoring Committee
- All arms to receive 5-FC during induction therapy and fluconazole during maintenance therapy
- **Currently enrolling Cohort 2 following DSMB review of Cohort 1 safety and efficacy data and unanimous recommendation to proceed**

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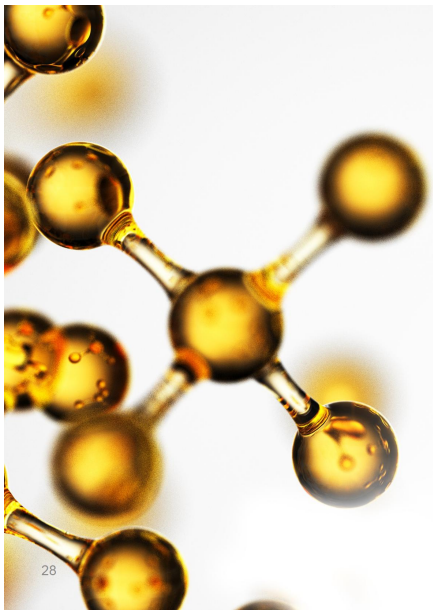


MAT2501

Oral Amikacin

MATINAS BIOPHARMA

MAT2501: A Better Amikacin

MAT2501

- Oral, LNC formulation of the broad-spectrum antibiotic Amikacin
- Initial indication in treatment of non-tuberculosis mycobacterium (NTM) infections
- Proprietary formulation with robust intellectual property protection
- Development to be accelerated with recent $3.75M Cystic Fibrosis Foundation grant

IMPROVED PROFILE

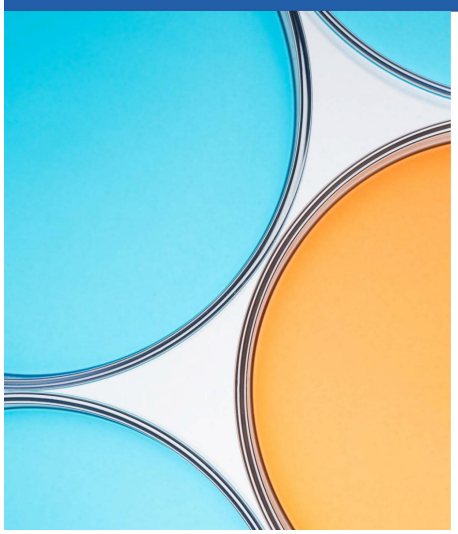
- LNC formulation enables oral administration and bioavailability
- Encouraging safety profile potentially eliminating oto- and nephro-toxicity
- Shown targeted delivery and efficacy in preclinical models of disseminated, pulmonary and biofilm NTM
- Activity against both Mycobacterium avium complex (MAC) 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) ~ $3.4B valuation

MATINAS BIOPHARMA

MAT2501: NTM Program Overview



Non-Tuberculosis Mycobacterium

- 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
- **Q4 2021** – Single Ascending Dose Phase 1
- **2022** – Begin Phase 2 Program in CF patients with NTM infections

MATINAS BIOPHARMA

Driving Opportunities for Value-Added Partnerships

We are currently working with multiple strategic and research partners to expand potential successful applications of this LNC technology.

In January 2019, we collaborated with a top global pharmaceutical company to execute our first LNC platform research evaluation of oligonucleotides. Later in 2019, we entered collaborations with ViiV Healthcare and Genentech, a member of the Roche Group, to evaluate various molecules.

In November 2020, we announced a $3.75 million award from the Cystic Fibrosis Foundation to support preclinical development of MAT2501, focused on the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis.

Finally, in December 2020, we announced a collaboration with the National Institute of Allergy & Infectious Disease (NIAID) to evaluate oral formulations of Gilead's antiviral drug remdesivir, used in the fight against COVID-19. Gilead will provide remdesivir and work with Matinas to evaluate the data from a series of planned preclinical studies with NIAID.

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Key Catalysts Supporting Investment Thesis

	Q4 2020	Q1 2021	Q2 2021	Q3 2021	Q4 2021
LYPDISO™		ENHANCE-IT - Top Line Data		Phase 3 AMPLIFY study in SHTG –2H 2021	
MAT2203	EnACT- Cohort 1 Completed		EnACT - Cohort 2 DSMB Evaluation – Mid 2021		EnACT- Enroll Cohort 3
MAT2501	$3.75M Grant from CF Foundation for MAT2501 in NTM	Preclinical PK and Tox studies			Phase 1 – Single Ascending Dose
LNC Platform	Collaboration with NIAID on Gilead's remdesivir	Collaboration Progress Updates Throughout 2021			

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