
**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): June 2, 2020

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) 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))

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class
Common Stock

Trading Symbol
MTNB

Name of Each Exchange on Which Registered
NYSE American

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 Tuesday, June 2, 2020 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Slide Presentation, dated June 2, 2020.</u>

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: June 2, 2020

By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour

Title: Chief Executive Officer



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Jefferies Virtual
Healthcare Conference
June 2, 2020



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.



MAT9001

Potential Best-in-Class Omega-3 Drug

- Potential best-in-class drug focused on severe hypertriglyceridemia with potential expansion into multi-billion dollar market
- Head-to-head data demonstrating superior triglyceride lowering and EPA levels against leading drug, Vascepa®
- Key additional head to head data from ENHANCE-IT study vs. Vascepa®
- Clear differentiation from currently approved prescription omega-3 products

LNC PLATFORM

Lipid Nano-Crystal Delivery System

- Safe, oral, targeted intracellular delivery of potent medicines
- MAT2203: Oral Amphotericin B, a broad-spectrum antifungal agent. Program financially supported by the National Institutes of Health
- EnACT study for MAT2203 in cryptococcal meningitis represents gateway opportunity for the treatment of invasive fungal infections. Expected cohort updates during 2020.
- Feasibility evaluations with three Big Pharma companies across multiple compounds

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MAT9001

Potential Best-in-Class Omega-3 Drug

- **June 2020:** Resume head-to-head ENHANCE-IT study
- **Q3 2020:** End-of-Phase 2 meetings with FDA
- **Q1 2021:** Top-line data from ENHANCE-IT study
- **H1 2021:** Commence Phase 3 in severe hypertriglyceridemia

LNC PLATFORM

Lipid Nano-Crystal Delivery System

- **Q2 2020:** Resume Phase 2 portion of EnACT study
- **EnACT** updates periodically throughout 2020/2021
- **H2 2020:** MAT2501 grant decision from CF foundation
- **LNC platform** collaboration updates
- **H2 2021:** Top Line data from EnACT study

Recently closed \$50M+ equity financing extends cash runway to early 2023, through multiple data read-outs and class catalysts.

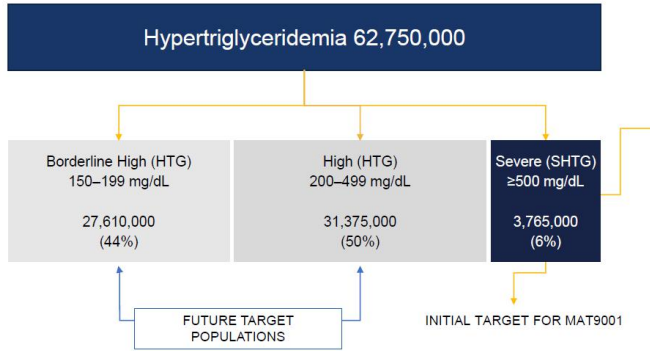


MAT9001 OVERVIEW

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US Adult Prevalence, Calculated*, 2020



- SHTG patients have low rates of pharmacologic intervention
- Primary treatment goal is reduction of triglycerides
- MAT9001 designed to be most potent TG-lowering Omega-3
- Multibillion-dollar market opportunity
- MAT9001 has an opportunity to serve this high unmet need

*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

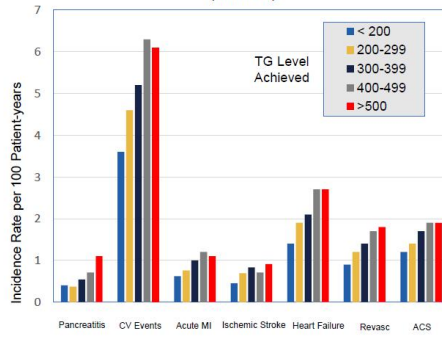
Approximately 3.5 to 4 million adults in the United States have severe hypertriglyceridemia (SHTG, ≥ 500 mg/dL).

Risk factors associated with severe hypertriglyceridemia include:

- genetic disorders
- lifestyle factors (excess alcohol intake, cigarette smoking, physical inactivity, and high carbohydrate diets)
- certain drugs (hormone therapy)
- other diseases (type 2 diabetes, chronic renal failure, and metabolic syndrome)

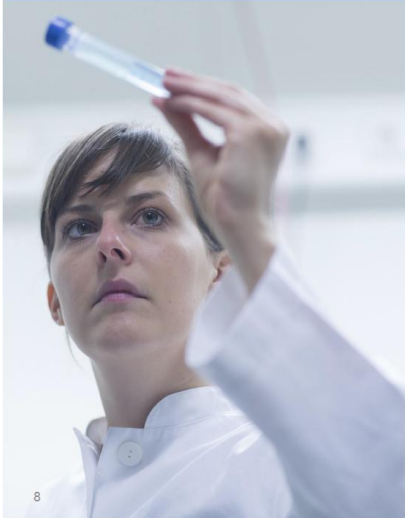
SHTG is associated with a high risk of acute pancreatitis, premature coronary heart disease, and CV mortality. These risks can be reduced in direct proportion to the degree of TG lowering.

Incidence of clinical events in SHTG Patients by level of TG achieved (n=41,210)



Christian JB et al. Am J Med 2014; 127: 36-44 <http://dx.doi.org/10.1016/j.amjmed.2013.09.018>

Trends in Elevated Triglyceride in Adults: United States, 2001–2012, NCHS Data Brief No. 198, May 2015
 Karalis DG Adv Ther 2017; 34:300–323



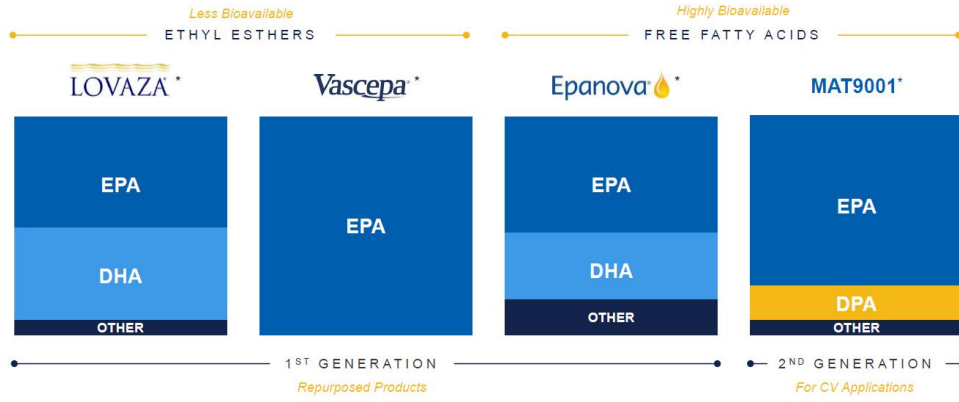
OMEGA-3 BENEFITS

- 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

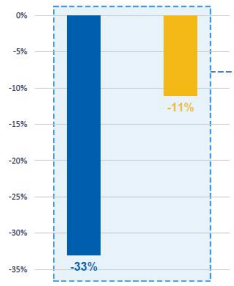
MAT9001 BENEFITS

- 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 and has shown improved outcomes in two large trials
- Addition of DPA provides improved TG lowering and unique synergistic positive impact on PCSK9, Apo-CIII and HMG-coA reductase
- Enhanced bioavailability leads to higher EPA blood levels – linked to improved outcomes
- Free fatty-acid formulation drives superior absorption and minimal food-effect
- Proprietary capsule technology limits GI side-effects

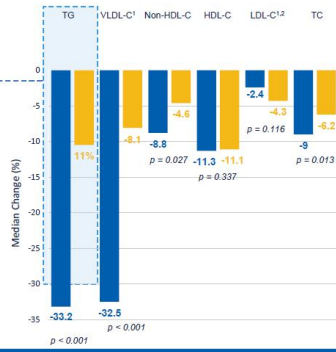
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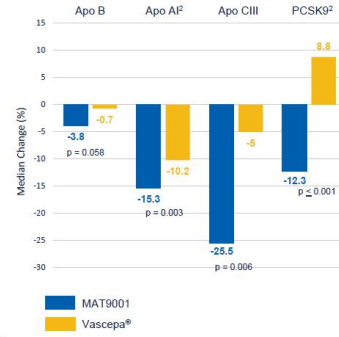
TRIGLYCERIDE REDUCTION
(MEDIAN % CHANGE FROM BASELINE)



MEDIAN % CHANGES FROM PRE-TREATMENT VALUES FOR LIPIDS

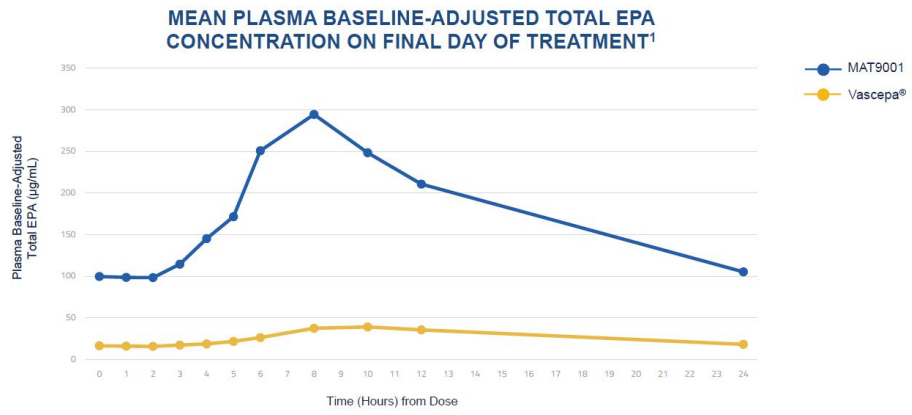


MEDIAN % CHANGES FROM PRE-TREATMENT FOR APOLIPOPROTEINS AND PCSK9



MAT9001 showed significant reductions in triglycerides, VLDL, non-HDL-C, total cholesterol, ApoAI and ApoCIII, and additional significant reductions in PCSK9.

10 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



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



MAT9001 CLINICAL DEVELOPMENT PLAN

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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)
 - MAT9001 (2g and 4g) vs placebo in SHTG patients
 - Dosing in early 2021
 - 12-week study in 390 patients with TG 500-2000 mg/dL (130 per group)
 - Primary endpoint: % change in TG



MARKET DIFFERENTIATION STUDIES

- ✓ Head-to-head study of MAT9001 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

OBJECTIVES

To assess PD effects of MAT9001, 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)
- MAT9001 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

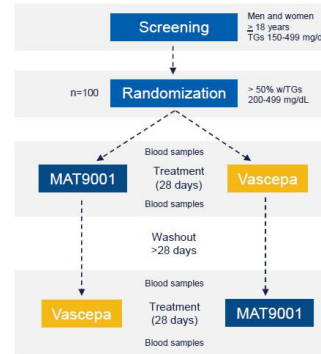
- % change from baseline to end-of-treatment in plasma TG

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

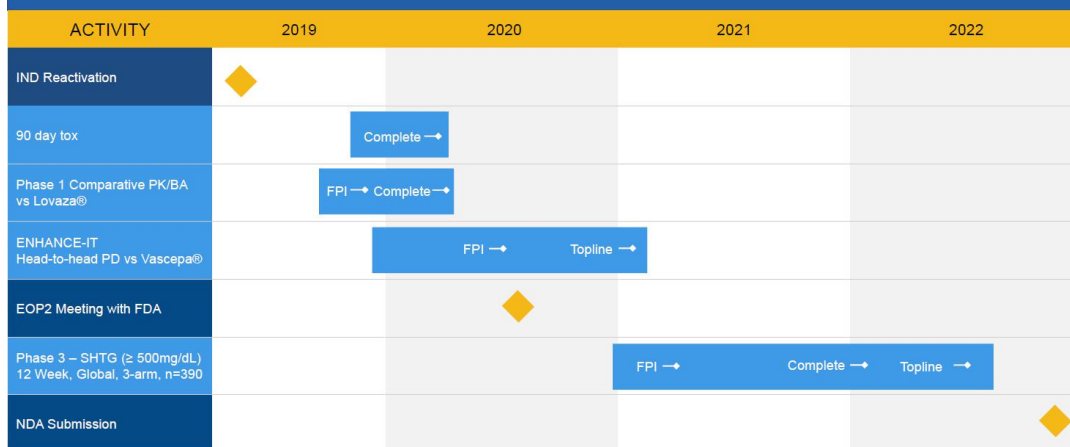
- Plasma phospholipid levels of omega-3 fatty acids, as a % of total fatty acids
- Erythrocyte membrane levels of omega-3 fatty acids, as a % of total fatty acids (first treatment period)



1^o Endpoint: % Δ from baseline in plasma TG

MAT9001 Development Timeline

MTNB





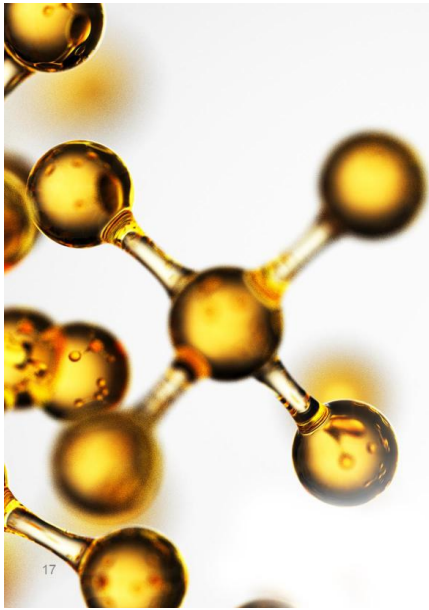
Additional IP to be developed as clinical development plan progresses.



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

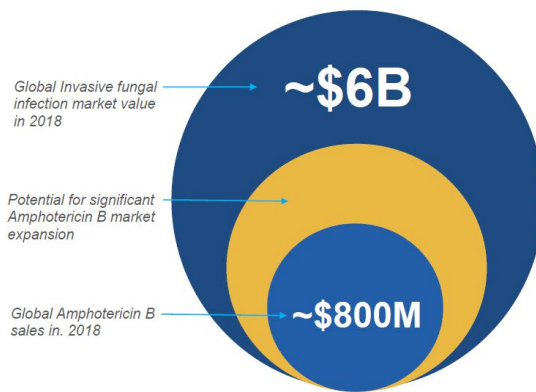


The active moiety of MAT9001 is the entire mixture of omega-3 ingredients representing a single active ingredient, which makes MAT9001 eligible for 5-year NCE exclusivity.



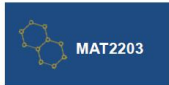
MAT2203 OVERVIEW

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- The COVID-19 pandemic has shifted the spotlight onto infectious disease drug development pipeline candidates.
- 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.**

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



- Orally administered
- Completed two Phase 2 studies
- No drug-related serious adverse events reported in either Phase 2 clinical study



- Oral bioavailability
- Reduction in toxicity
- Targeted delivery



- Potential to become the preferred antifungal agent for treatment of cryptococcal meningitis
- 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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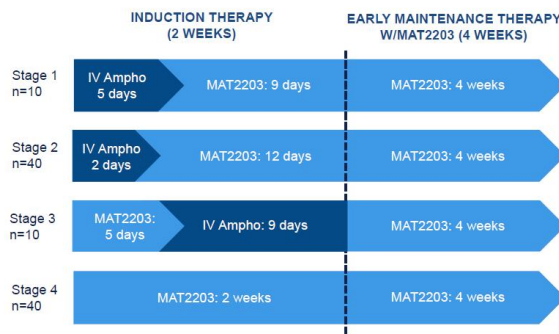
RATIONALE

- Traditional Amphotericin B deoxycholate given intravenously (IV AMB) has common and substantial toxicities that force switching.
- A novel oral formulation of amphotericin has 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 would represent a substantial advancement in the management of fungal diseases as would an oral alternative to allow for transition from IV therapy to similar oral therapy.

PHASE 1

- Completed Q1 2020
- Determine maximum tolerated dose in otherwise healthy HIV patients to move into Phase 2.
- Doses tested: 1.0, 1.5, 2.0 g/day
- All doses well tolerated
- Moved into phase 2 with top dose of 2.0 g/day

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Each stage will have a control arm of patients 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 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 independent Data Monitoring Committee
- All arms to receive 5-FC during induction therapy and fluconazole during maintenance therapy
- Maintenance with Fluconazole will continue through Week 10

LIPID NANOCRYSTAL (LNC) PLATFORM

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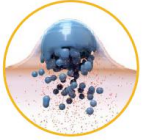
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Matinas' LNC Platform utilizes a highly efficient, physiologic and non-toxic drug formulation:



FLEXIBLE ADMINISTRATION

- Oral
- Intravenous
- Intramuscular
- Intranasal



PHYSIOLOGICALLY TARGETS ACTIVATED CELLS

- No evidence of immunogenicity
- Reduced toxicity of drugs
- Ability to deliver a broad range of molecules
- Enters cells through non-destructive membrane fusion
- Demonstrated ability to cross blood-brain barrier in animal models
- Validated in multiple clinical and pre-clinical studies



- Oral, encochleated Amikacin
- Initial target indication in non-tuberculosis mycobacterium (NTM) infections
- Proprietary formulation with robust intellectual property protection
- Development contingent on continued support from the CF Foundation



- Orally administered
- Positive single ascending dose phase 1 study
- Demonstrated efficacy in preclinical models of disseminated, pulmonary and biofilm NTM



- Oral bioavailability
- Reduction in toxicity
- Targeted delivery



- Potential to become the first oral aminoglycoside
- Bringing a new class of antibiotic into the community setting, while reducing hospitalization spend
- 80-90K US NTM patients; 40% refractory to treatment
- Potential use in acute gram-negative infections

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

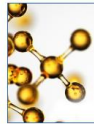
In early 2019, we collaborated with a top global pharmaceutical company to sign our first LNC platform research evaluation of oligonucleotide. Later in the year, we entered into a feasibility collaboration with Genentech, a member of the Roche Group, to evaluate various Genentech molecules.

We have also signed research collaborations with both the National Institutes of Health and ViiV Healthcare to further explore the potential of our LNC technology and evaluate the formulation of antiviral drug candidates.



MAT9001

- Resume head-to-head ENHANCE-IT study
- End-of-Phase 2 meeting with FDA
- Top-line data from ENHANCE-IT study
- Commence Phase 3 study in severe hypertriglyceridemia



MAT2203

- Resume Phase 2 portion of EnACT study
- EnACT cohort progression updates
- Top-line data from EnACT study



LNC PLATFORM

- Partnership development updates
- MAT2501 grant decision from CF Foundation

EXECUTIVE OFFICERS

Jerome D. Jabbour
Co-Founder, Chief Executive Officer



Keith A. Kucinski, CPA, MBA
Chief Financial Officer



Raphael J. Mannino, Ph.D.
Chief Scientific Officer



James J. Ferguson III, M.D., FACC, FAHA
Chief Medical Officer



Theresa Matkovits, Ph.D.
Chief Development Officer



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