UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): September 13, 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	**07921**
(Address of principal executive offices)	**(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") issued a press release announcing positive efficacy and safety data from the first two cohorts of patients in the ongoing Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial ("EnACT") of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis. A copy of the press release is furnished as Exhibit 99. 1 hereto and incorporated herein by reference.

The Company created a presentation which includes the data from EnACT trial (the "Presentation") which it intends to use during a planned conference call on September 13, 2021 and then at various conferences and investor meetings. The Presentation is attached hereto as Exhibit 99.2.

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 99.3.

The information in this Item 7.01 and Exhibits 99.1, 99.2 and 99.3 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 8.01. Other Events.

On September 13, 2021, the Company announced positive efficacy and safety data from the first two cohorts of patients in the ongoing Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial (EnACT) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis, which is being sponsored by the National Institute of Allergy and Infectious Diseases ("NIAID").

The EnACT independent Data and Safety Monitoring Board ("DSMB") recently completed a pre-specified review of available safety and efficacy data from Cohort 2 (stepdown to MAT2203 after two days of IV amphotericin) and unanimously recommended progression to the second half of the study. Enrollment in Cohort 3 of EnACT (the safety lead-in for Cohort 4, which will be an all-oral MAT2203 treatment regimen) has commenced and is expected to complete by the end of 2021.

Topline Results from Cohort 2 of EnACT

Key topline results from Cohort 2 of EnACT include eradication of the fungal infection, survival, and safety, including longer term use of MAT2203 beyond the 2-week induction period.

Potent Early Fungicidal Activity (EFA), Cerebrospinal Fluid (CSF) Sterilization, with No Evidence of Breakthrough Infections During Treatment with MAT2203

- The primary endpoint in EnACT is EFA, a measurement of cerebrospinal fluid fungal clearance. EFA is a well-validated quantitative measure of the efficacy of antifungal agents and is a key surrogate marker for survival. EFAs of less than 0.20 log10 Cryptococcus colony forming units (CFUs) per mL CSF per day are associated with significantly higher mortality and worse clinical outcomes[1]. EFA measured above this threshold is clinically meaningful and represents robust fungal clearance. In the second cohort of EnACT, the mean EFA achieved with patients treated with MAT2203 was 0.38 log10 CFU/mL/day, with 95% confidence intervals (0.30 to 0.46) significantly higher than the prespecified primary endpoint threshold of >0.20.

[1] *Clin Infect Dis. 2020;71(5):e45-49

- All patients treated with MAT2203 who completed the induction phase achieved sterile CSF cultures during treatment (either during induction or early consolidation phases).

- There was no evidence of breakthrough or relapsed cryptococcal infections observed in any of the patients during treatment with MAT2203 through 10 weeks.

Survival

- In Cohort 2, overall survival was 95% in 40 patients randomized to receiving MAT2203.

Safety

- In both Cohorts 1 and 2, MAT2203 showed no evidence of renal toxicity or electrolyte abnormalities attributable to MAT2203, no major safety signals, and no use-limiting tolerability issues, even with longer-term treatment with MAT2203 extended beyond induction into the consolidation phase, from week 2 to week 6.

The Company is preparing to engage with the U.S. Food and Drug Administration ("FDA") to review these data as supportive of a potential early approval of MAT2203 as step-down therapy. These data may also set the stage for potential longer-term treatment options, including prophylaxis, for patients dealing with, or at risk for, deadly invasive fungal infections without the toxicities usually associated with IV amphotericin.

The EnAct trial demonstrated that two days of intravenous amphotericin B followed by rapid transition to oral LNC amphotericin B therapy was well tolerated, resulted in excellent CSF clearance of the Cryptococcus yeast, and had a 95% survival to date.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the results of the EnECT study, the LNC platform delivery technology, the Company's strategic focus and the future development of its product candidates, including MAT2203, MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval 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 may be identified by the use of forward-looking expressions, including, but not limited to, "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; the Company's ability to successfully complete research and further development and commercialization of its product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the 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 hereof. 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. The Company's product candidates are all in a development stage and are not available for sale or use.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated September 13, 2021.
99.2	Slide Presentation, dated September 13, 2021.
99.3	Corporate Presentation, dated September 13, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

MATINAS BIOPHARMA HOLDINGS, INC.

Dated: September 13, 2021

By: */s/ Jerome D. Jabbour*

Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Announces Positive Data in the Ongoing EnACT Trial of MAT2203 (Oral Amphotericin B) for the Treatment of Cryptococcal Meningitis, Exceeding the Prespecified Primary Endpoint Threshold

– Step-down therapy with MAT2203 achieved effective clearance of fungal organisms; Mean Early Fungicidal Activity (EFA) was 0.38, exceeding the prespecified primary endpoint threshold target of >0.20 –

– Overall survival was >95% in 40 patients receiving MAT2203 in Cohort 2 –

– All 39 patients completing induction with MAT2203 achieved sterility, with no evidence of breakthrough or recurrent infections during the first 10 weeks of antifungal treatment –

– Patients received MAT2203 for up to 6 weeks without kidney toxicity or electrolyte abnormalities attributable to MAT2203 –

– DSMB unanimously recommends progression to Cohort 3; Enrollment has commenced –

– Preparing to engage with FDA to review EnACT data as supportive of potential early approval of MAT2203 as step-down therapy –

– Management to host conference call today, Monday, September 13th, at 8:00 a.m. ET –

BEDMINSTER, N.J., September 13, 2021 – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) platform delivery technology, today announced positive efficacy and safety data from the first two cohorts of patients in the ongoing Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial (EnACT) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis, which is being sponsored by the National Institute of Allergy and Infectious Diseases (NIAID).

The EnACT independent Data and Safety Monitoring Board (DSMB) recently completed a pre-specified review of available safety and efficacy data from Cohort 2 (stepdown to MAT2203 after two days of IV amphotericin) and unanimously recommended progression to the second half of the study. Enrollment in Cohort 3 of EnACT (the safety lead-in for Cohort 4, which will be an all-oral MAT2203 treatment regimen) has commenced and is expected to complete by the end of 2021.

"These results are a major milestone for Matinas, MAT2203 and our LNC platform delivery technology," stated Jerome D. Jabbour, Chief Executive Officer of Matinas. "These data are a clear demonstration of how our LNC platform can have a meaningful clinical impact in a deadly disease, and a validation of how this technology can be used to overcome significant drug delivery challenges, including oral delivery of highly toxic drugs across the blood-brain barrier. The global invasive fungal infection market is projected to be more than $8 billion by 2025, and we believe an oral and well tolerated amphotericin B, which preserves the well-established efficacy of this potent drug, if approved, could be poised to capture a meaningful portion of this growing market, and fill a currently large unmet medical need. Finally, we believe these data are supportive of the enormous potential for our LNC platform delivery technology and a key for potential partners and collaborators who are currently evaluating MAT2203 and broader applications of the LNC platform to antivirals, vaccines, and nucleic acid polymers, such as mRNA."

Topline Results from Cohort 2 of EnACT

Key topline results from Cohort 2 of EnACT include eradication of the fungal infection, survival, and safety, including longer term use of MAT2203 beyond the 2-week induction period.

Potent Early Fungicidal Activity (EFA), Cerebrospinal Fluid (CSF) Sterilization, with No Evidence of Breakthrough Infections During Treatment with MAT2203

- The primary endpoint in EnACT is EFA, a measurement of cerebrospinal fluid fungal clearance. EFA is a well-validated quantitative measure of the efficacy of antifungal agents and is a key surrogate marker for survival. EFAs of less than 0.20 $\log_{10}$ Cryptococcus colony forming units (CFUs) per mL CSF per day are associated with significantly higher mortality and worse clinical outcomes[1]. EFA measured above this threshold is clinically meaningful and represents robust fungal clearance. In the second cohort of EnACT, the mean EFA achieved with patients treated with MAT2203 was 0.38 $\log_{10}$ CFU/mL/day, with 95% confidence intervals (0.30 to 0.46) significantly higher than the prespecified primary endpoint threshold of >0.20.
- All patients treated with MAT2203 who completed the induction phase achieved sterile CSF cultures during treatment (either during induction or early consolidation phases).
- There was no evidence of breakthrough or relapsed cryptococcal infections observed in any of the patients during treatment with MAT2203 through 10 weeks.

Survival

- In Cohort 2, overall survival was 95% in 40 patients randomized to receiving MAT2203.

[1] * ***Clin Infect Dis.*** 2020;71(5):e45-49

Safety

- In both Cohorts 1 and 2, MAT2203 showed no evidence of renal toxicity or electrolyte abnormalities attributable to MAT2203, no major safety signals, and no use-limiting tolerability issues, even with longer-term treatment with MAT2203 extended beyond induction into the consolidation phase, from week 2 to week 6.

"We believe that the positive data from the first half of the EnACT study represent a groundbreaking achievement in the early step-down treatment of cryptococcal meningitis with the use of an oral formulation of amphotericin and we are preparing to engage with the U.S. Food and Drug Administration (FDA) to review these data as supportive of a

potential early approval of MAT2203 as step-down therapy," commented Dr. Theresa Matkovits, Chief Development Officer of Matinas. "When viewed against historical measures of survival and eradication of fungal burden and from the standpoint of safety, MAT2203 exceeded expectations. These data also set the stage for potential longer-term treatment options, including prophylaxis, for patients dealing with, or at risk for, deadly invasive fungal infections without the toxicities usually associated with IV amphotericin. We are pleased to move forward to the next part of the EnACT trial and remain grateful to the patients, the principal investigators, and the dedicated study team at the University of Minnesota and in Uganda for their commitment to this important clinical trial."

"Overall, using only two days of intravenous amphotericin B followed by rapid transition to oral LNC amphotericin B therapy was well tolerated, resulted in excellent CSF clearance of the Cryptococcus yeast, and had a 95% survival to date, which exceeds our expectations," said David R. Boulware, M.D., MPH, Professor of Medicine, University of Minnesota Medical School, and co-principal investigator of the EnACT trial. "We are excited to continue to the next stage of the EnACT trial, testing if oral therapy alone is efficacious."

About the EnACT Study

EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 100 HIV-infected patients with cryptococcal meningitis (CM). MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B.

The EnACT trial includes a total of four cohorts of patients, with the first two cohorts testing MAT2203 as early stepdown therapy following initial treatment with IV amphotericin B during the induction period, and the second two cohorts testing MAT2203 as potential monotherapy. The induction period for all patients in each cohort (active or control) is 14 days, followed by an additional four weeks of treatment (active or control) during a consolidation/maintenance period.

All patients in the induction period of EnACT (both control and MAT2203 arms) receive background therapy of flucytosine, also known as 5-FC, which is specifically recommended to be used with amphotericin B as standard-of-care treatment during induction in patients with CM. During the consolidation/maintenance period, all patients (both control and MAT2203 arms) receive 800 mg/day of fluconazole. An independent DSMB oversees the safety of the study and reviews all available data from each cohort for both safety and efficacy and makes a recommendation on whether to proceed to the next cohort of patients.

In the MAT2203 arm of Cohort 1, 10 patients received IV amphotericin B (with 5-FC) for the first five days of induction, followed by ten days (overlapped on day 5) of oral MAT2203 (with 5-FC). In the MAT2203 arm of Cohort 2, 40 patients first received IV amphotericin B (with 5-FC) for two days, followed by thirteen days (overlapped on Day 2) of oral MAT2203 (with 5-FC). In both Cohorts 1 and 2, treatment with MAT2203 was continued after induction during the next four weeks of consolidation/maintenance treatment, administered with 800 mg/day of fluconazole.

In the MAT2203 arm of Cohort 3, 10 patients will receive 5 days of oral MAT2203 (with 5-FC), followed by 10 days (overlapped on Day 5) of IV amphotericin (with 5-FC). In the MAT2203 arm of Cohort 4, 40 patients will receive MAT2203 (with 5-FC) for the entire 14-day induction period. In both Cohorts 3 and 4, treatment with MAT2203 will continue after induction during the next four weeks of consolidation/maintenance treatment, administered alongside 800 mg/day of fluconazole.

The primary efficacy endpoint for EnACT is the quantitative microbiologic clearance rate of Cryptococcus yeasts from CSF, termed Early Fungicidal Activity (EFA). This is a quantitative measurement of the efficacy of antifungal agents as well as a key surrogate marker for survival. The primary EFA endpoint is measured from the first CSF culture with 3-4 repeated cultures obtained over the first two weeks of treatment. The prespecified endpoint threshold was achieving EFA >0.20 $\log_{10}$ CFU/mL/day, recognizing that EFAs of less than 0.20 are strongly associated with significantly higher mortality and worse clinical outcomes.

Standard of care active control HIV patients with cryptococcal meningitis (a total of 40 across all 4 cohorts) are included in EnACT, primarily to assess patient safety. The control arms for Cohorts 1 and 2 included 4 and 17 patients, respectively, and we expect that the control arms for Cohorts 3 and 4 will include 4 patients and 16 patients, respectively. In the control arms, patients receive IV amphotericin (with 5-FC) for 7 days, followed by a high dose of oral fluconazole for 7 days (to complete the 14-day induction period), and then transition to 800 mg/day of fluconazole for the 4-week consolidation phase. Either amphotericin B deoxycholate or liposomal amphotericin B (Ambisome®) can be used in the control arm. EnACT was not powered to formally test comparisons with the control arm standard of care.

The FDA has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for four indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, and the treatment of invasive candidiasis, invasive aspergillus and cryptococcal meningitis. In addition, the FDA has granted orphan drug designation to MAT2203 for the treatment of cryptococcosis.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Monday, September 13, 2021, at 8:00 a.m. ET. Presentation slides will be available on the Investors section of Matinas' website, www.matinasbiopharma.com. A question-and-answer session with the Matinas management team will follow the Company's remarks.

To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13722251. The live webcast will be accessible on the Investors section of Matinas' website, www.matinasbiopharma.com, and archived for 90 days.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) delivery platform. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop new formulations that take full advantage of the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the complex challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides and vaccines. The combination of a unique mechanism of action and flexibility in both the formulation and route of administration (including oral), position Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle and an important improvement over both lipid nanoparticles and viral vectors.

MAT2203 is an oral, LNC formulation of the highly effective, but also highly toxic, antifungal medicine amphotericin B, primarily used as a first-line treatment for invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT has completed the first two patient cohorts. Enrollment in Cohort 3 has commenced following unanimous DSMB approval, with enrollment completion for Cohort 3 expected by the end of 2021.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic amikacin, primarily used to treat chronic and acute bacterial infections. With the support of the Cystic Fibrosis Foundation, MAT2501 is currently undergoing important preclinical studies and expects to enter a Phase 1 human clinical trial later in 2021. MAT2501 would be the first and only oral aminoglycoside and is being positioned with an initial indication for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

LYPDISO™, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, intended for the treatment of cardiovascular and metabolic conditions. This next-generation omega-3 therapy has been shown in two head-to-head studies to provide effective triglyceride-lowering and significantly higher EPA blood levels than Vascepa®. The Company has initiated a process to identity and potentially secure a partner to continue development of LYPDISO.

Forward Looking Statements

This release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the LNC platform delivery technology, the Company's strategic focus and the future development of its product candidates, including MAT2203, MAT2501, the anticipated timing of regulatory submissions, the anticipated timing of clinical studies, the anticipated timing of regulatory interactions, the Company's ability to identify and pursue development and partnership opportunities for its products or platform delivery technology on favorable terms, if at all, and the ability to obtain required regulatory approval 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.

Investor and Media Contacts

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443-213-0505
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Source: Matinas BioPharma Holdings, Inc.

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, 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.

Agenda

Opening Remarks
- *Jerome D. Jabbour, Chief Executive Officer*

Review of Results
- *Theresa Matkovits, PhD, Chief Development Officer*

Principal Investigator/KOL Perspective
- *David Boulware, MD, MPH, FIDSA*

LNC Platform Implications
- James J. Ferguson, MD, Chief Medical Officer

Question & Answer Session

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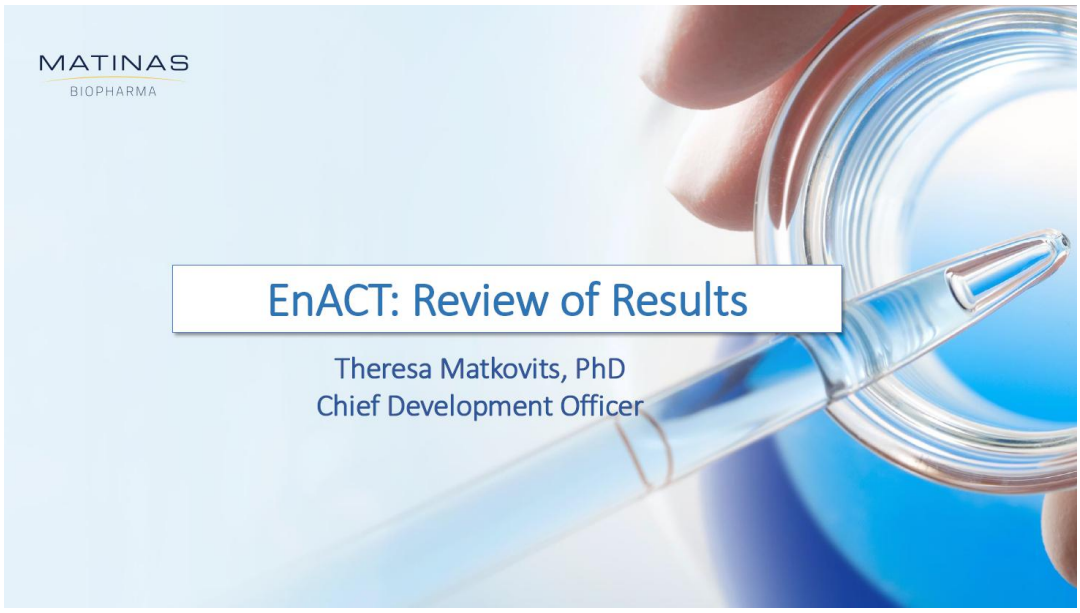


EnACT: Review of Results

Theresa Matkovits, PhD
Chief Development Officer

Disease Overview and Treatment

Cryptococcal Meningitis (CM)
- Difficult-to-treat invasive fungal infection impacting the brain and central nervous system
- Associated with high mortality

Early Treatment Phases (Standard of Care)
- Induction (1-2 weeks): IV amphotericin with oral flucytosine (5-FC), followed by fluconazole
- Consolidation/Maintenance (at least 8 weeks): Fluconazole

Amphotericin B
- Gold standard for the treatment of invasive fungal infections
- Currently only available as an intravenous (IV) formulation (Fungizone or liposomal Ambisome®)
- Significant, use-limiting side-effect profile (renal toxicity, anemia, and infusion-related reactions)
- Resource-intensive hospitalization required

MATINAS BIOPHARMA

MAT2203: A Novel Approach with a Proven Therapeutic Agent

MAT2203

- Oral amphotericin B formulation utilizing Matinas' proprietary lipid nanocrystal (LNC) delivery platform
- Proprietary formulation with robust intellectual property protection
- Initial gateway indication to treat CM with plans to expand use into treatment of other invasive fungal infections and prophylaxis
- Being developed with support from the National Institutes of Health (NIH)/NIAID

IMPROVED PROFILE

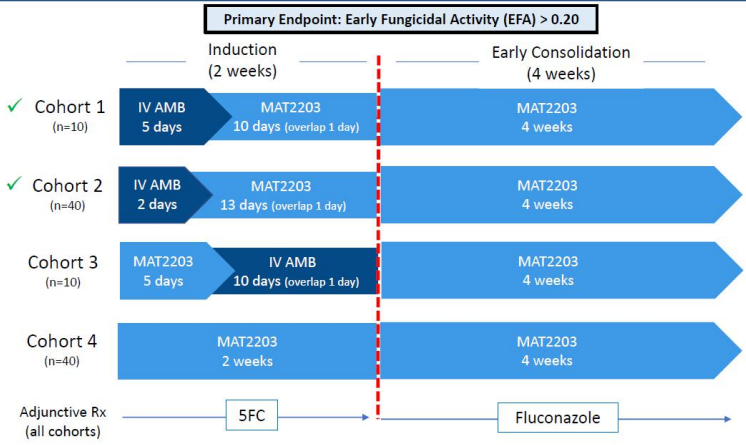
- LNC formulation enables oral administration, bioavailability and improved toxicity over IV amphotericin
- Efficient intracellular delivery to immune cells with delivery directly to infected tissues
- Demonstrated ability to cross the blood-brain barrier with an oral therapy

POTENTIAL CLINICAL IMPACT

- Potential to become the preferred antifungal agent for all invasive fungal infections ($8 billion+ market)
- Orphan Drug Designation + 4 Qualified Infectious Disease (QIDP) and Fast Track Designations
- Up to *12 years marketing exclusivity*, if approved

MATINAS BIOPHARMA

EnACT Study Design



MAT2203 TREATMENT REGIMENS:

Cohort 1
- Induction: 2.0g/day
- Consolidation: 1.5g/day

Cohort 2
- Induction: 1.8g/day
- Consolidation: 1.2g/day

- *For each Cohort, a control group receives standard of care IV AMB +5FC (7 days), followed by 1200mg Fluconazole (7 days) for Induction and then only Fluconazole (800mg) for Early Consolidation*
- *Control arm present primarily to assess patient safety*
- *EnACT **not** powered to formally test comparisons with the control arm standard of care*

*IV AMB = intravenous amphotericin B

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Key Elements of EnACT and Potential Indications

- Sequential cohort, gradually extending use of oral MAT2203, to assess safety and efficacy
- Strategic design, providing data to support up to **three potential indications**
- Rigorous safety monitoring; DSMB review after each cohort

1. **Step-down induction treatment** following initial administration of IV amphotericin
   - Shorter, simpler induction treatment
   - Opportunity for earlier patient discharge
   - Lower risk of toxicity

   Cohorts 1,2

2. **Consolidation treatment** after induction, out to 6 weeks with MAT2203
   - Amphotericin currently cannot be used for extended periods due to toxicity
   - Current SoC treatment with fluconazole has significant associated resistance and relapse

   Cohorts 1-4

3. **All-oral regimen for induction treatment**
   - Avoids all IV amphotericin-associated toxicity
   - Avoids complex treatment pathway, prolonged hospitalization

   Cohort 4

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EnACT – Baseline and Demography Summary

- 71 total patients were randomized in Cohorts 1 and 2
  - Cohort 1 (MAT2203): 10 patients
  - Cohort 2 (MAT2203): 40 patients
  - SOC (combined): 21 patients
- Demographic and baseline characteristics were comparable across the treatment groups
  - First episode of CM for the majority of patients in the study
  - Quantitative Cerebral Spinal Fluid (CSF) cultures were similar at baseline

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EnACT – Efficacy Endpoints and Analyses

- **Primary Endpoint**: **EFA** (log_{10} CFU/mL/day) at Day 14
  - Rate of CSF fungal clearance (log reduction)
  - Quantitative measure of antifungal activity of an induction treatment for CM
  - Early surrogate marker that predicts survival
- **Primary Endpoint Objective**: Demonstrate EFA for MAT2203 treated patients > 0.20
  - EFA > 0.20 - associated with lower mortality and improved clinical outcomes*
  - Achievements above this threshold are clinically meaningful, representing strong fungal clearance
- **Secondary Endpoints**
  - Sterilization of CSF cultures
  - Prevention of relapse (no breakthroughs)
  - Survival at 18 weeks

*_Clin Infect Dis._ 2020;71(5):e45-49

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EnACT – Efficacy Results for Cohort 2

Primary endpoint ACHIEVED: EFA for MAT2203 treated patients > 0.20

Key primary and secondary endpoints:

1)	**EFA:**	**0.38 log_{10} CFU/mL/day** 95% confidence intervals (0.30 to 0.46)
2)	**Patients achieving sterile culture while on MAT2203**	**100%**
3)	**Patients with relapse or breakthrough infections**	**None**
4)	**Patient survival***	**95%**
5)	**Patients with MAT2203-related renal toxicity**	**None**

* As of Sept 13th, 18-week survival data; no deaths were attributed to lack of effect of MAT2203

MATINAS BIOPHARMA

EnACT Cohort 2 – Summary of Overall Safety and Efficacy

Safety

- MAT2203 was safe and well-tolerated over **6 weeks** of treatment
  - No renal toxicity or electrolyte abnormalities
  - No other major safety signals
  - No treatment-limiting tolerability issues
- Majority of SAEs and AEs were events expected in this patient population
  - No discontinuations due to AEs
  - No MAT2203-related SAEs

Efficacy

- EFA for MAT2203 was **0.38** (95% CI 0.30 to 0.46), meeting the primary endpoint for the study
- Also met major clinical endpoints of interest:
  - All 39 MAT2203 patients completing induction achieved CSF sterility
  - Survival rates were **95%** in Cohort 2
- No breakthrough infections during MAT2203 treatment (10 weeks)

- ***EnACT Cohort 2 results highlight MAT2203's potential as early step-down oral regimen in CM treatment***
- ***No renal toxicity with longer-term treatment out to 6 weeks***
- ***First and only oral formulation of amphotericin B capable of delivering active drug across blood-brain barrier to a CNS site of infection***
- ***Sets stage for multiple, and potentially longer-term, treatment options and prophylaxis of invasive fungal infections (>$8 billion in 2025)***

MATINAS BIOPHARMA

EnACT – Principal Investigator/KOL Remarks

David Boulware, MD, MPH

Dr. Boulware is an infectious disease physician-scientist and Professor of Medicine, Division of Infectious Diseases and International Medicine at The University of Minnesota Medical School. His primary research interests are in meningitis in resource-limited areas including diagnosis, prevention, treatment, and quality improvement initiatives incorporating cost-effectiveness analyses in order to translate knowledge into improved care. Dr. Boulware's current research is focused on improving the clinical outcomes of HIV-infected persons with cryptococcal meningitis and TB meningitis. Dr. Boulware has active research collaborations in Uganda, South Africa, and Ethiopia leading a multidisciplinary, international research team. He serves on US and WHO panels for cryptococcal meningitis and WHO panels for advanced HIV disease.

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LNC Platform Implications

James J. Ferguson, MD, FACC, FAHA
Chief Medical Officer

MATINAS BIOPHARMA

Question & Answer Session

Forward-Looking Statement

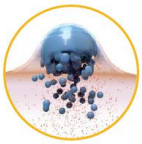
This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including those relating to the Company's product development, clinical and regulatory timelines, market opportunity, cash flow and other statements that are predictive 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.

Matinas is a True Platform Drug Delivery Company – Lipid Nanocrystals (LNCs)

LNCs Enable a Paradigm Shift in Intracellular Drug Delivery

FLEXIBLE ADMINISTRATION

- Oral
- Intramuscular
- Intravenous
- Inhalation



PHYSIOLOGICALLY TARGETS ACTIVATED CELLS

- Comprised of ***phosphatidylserine (PS) and calcium*** (critical components of natural cellular fusion)
- ***Targets "activated cells"***, including macrophages, dendritic cells, tumor cells, injured/infected cells and apoptotic cells
- Enters activated cells through ***non-destructive*** membrane fusion, phagocytosis or endocytosis facilitated by PS receptors
- ***No immunogenicity*** or adverse immune response
- ***Reduced toxicity*** associated with delivery of drugs/molecules
- ***Flexibility*** to deliver a broad range of molecules (e.g., small molecules, nucleic acids (e.g., mRNA,siRNA, DNA), proteins) and vaccines
- Demonstrated ability to ***cross blood-brain barrier*** in animal models and in patients (EnACT study of MAT2203)
- ***Validated*** in multiple clinical and pre-clinical studies

MATINAS BIOPHARMA

LNC Program Highlights

MAT2203 (oral amphotericin B)

1

- Lead LNC program in Phase 2 for treatment of Cryptococcal Meningitis (CM), a deadly invasive fungal infection
- **ACHIEVED all** primary and key secondary endpoints through Cohort 2 of EnACT
- Unanimous DSMB approval to proceed to Cohort 3; enrollment underway
- Positioned for FDA meeting to review data supportive of potential early approval as step-down therapy

MAT2501 (oral amikacin)

2

- First oral aminoglycoside used to treat chronic and acute bacterial infections
- Pursuing initial indication in treatment of Non-Tuberculous Mycobacterial Disease
- Program supported with $3.75M grant from the Cystic Fibrosis Foundation
- Schedule to commence Phase 1 single ascending dose (SAD) safety study in healthy volunteers in October 2021

LNC Platform Collaborations

3

- Genentech – 3 compounds, including antisense oligonucleotides (ASOs)
- NIH/Gilead – oral Remdesivir
- In discussions for potential delivery of vaccines, mRNA, gene therapy

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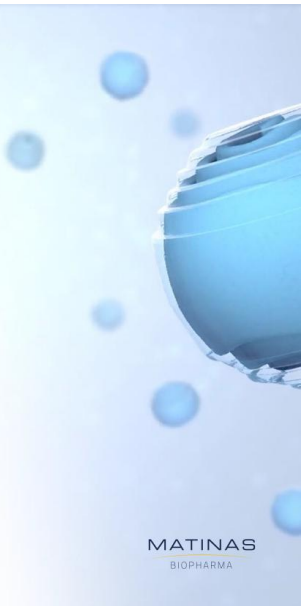
Lipid Nanocrystal (LNC) Platform

Targeted, Well-Tolerated Intracellular Delivery



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The Current Landscape of Intracellular Drug Delivery

Contents to be delivered		Targets	Therapeutic areas
Small molecules: ▪ Antibiotic ▪ Antifungal ▪ Antiviral ▪ Anti-tumor ▪ Anti-inflammatory	Gene therapy: ▪ Oligonucleotides ▪ DNA ▪ mRNA ▪ siRNA ▪ CRISPR/Cas-9	▪ Infected cells ▪ Macrophages ▪ Injured cells ▪ Tumor cells ▪ Bone marrow cells ▪ Monocytes ▪ Dendritic cells	▪ Infectious disease ▪ Anti-inflammatory Rx ▪ Oncology ▪ Vaccines ▪ Gene therapy

Current Options

- Liposomes
- LNPs
- Viral vectors

Future Needs

- Growing complexity of drugs to be delivered
- Need to deliver much larger molecules (mRNA-protein complexes, CRISPR)
- Need improved delivery efficiency (LNPs with only 1-2% endosomal escape)
- Need to improve toxicity/immunogenicity of AAV and LNPs
- Need more stable formulations (avoid -80°C storage)
- Emerging importance of cell-mediated immunity (vaccines, immune enhancers)
- Need improved delivery to active sites of infection (lung, brain)

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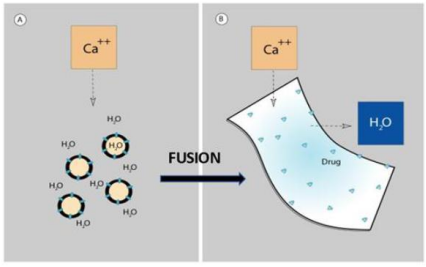
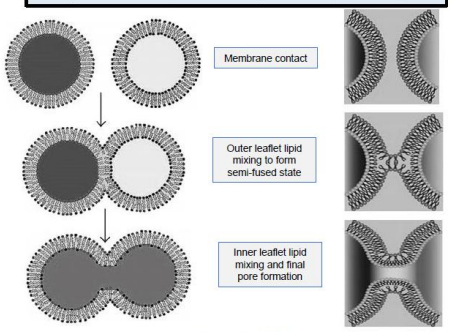
LNCs Fuse Together with Phosphatidylserine (PS) and Calcium and Then Fuse Directly with Cell Membranes

LNCs are *made* by calcium-induced fusion of PS liposomes into lipid bilayer sheets and exposing them to Ca^{++}



LNCs are, in essence, intermediates in membrane fusion

Fusion of Cell Membranes
(endosomes, exosomes, vesicles, viruses)



Roy SM *et al.* ***Journal of Lipids*** 2011
doi:10.1155/2011/528784

Bilayer lipid composition, tethering proteins and Ca^{++} are all important in initiating and propagating fusion

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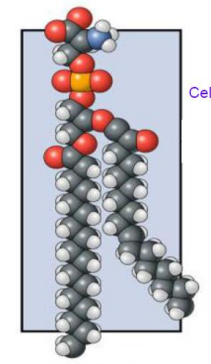
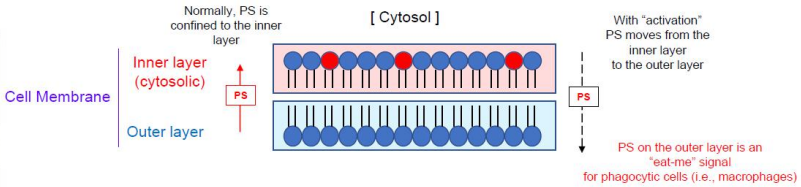
LNCs Work Because of PS – A Key Component of LNCs AND Cell Membranes



Phosphatidylserine



- PS is an integral part of cell membranes, normally localized to the inner part of the bilayer by active cellular processes
- When cells become "activated", those normal processes keeping PS on the inner layer no longer work, and PS moves to the outer layer
- PS on the outer layer is how activated cells are identified (apoptosis)

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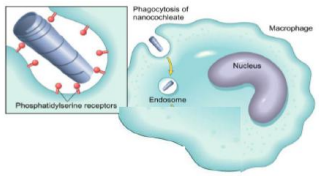
Role of PS and PS Receptors in the Uptake of LNCs into Cells

Phagocytosis
Initiated by binding of PS to PS receptors

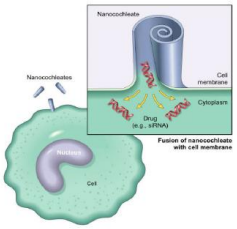


Macrophages readily engulf LNCs and their cargo into vesicles (endosomes).

Intracellular delivery via phagocytosis, fusion, or BOTH

- Bone marrow-derived hematopoietic cells
  (Macrophages, dendritic cells, natural killer (NK) cells)
- Infected Cells
- Injured Cells
- Tumor Cells
- Astrocytes and microglial cells (CNS macrophages)
- Specialized epithelial cells that participate in efferocytosis
  - Retinal epithelial cells
  - Alveolar lung epithelial cells
  - Mammary epithelial cells
- Actively dividing cells

Fusion
Initiated by expression of PS on the surface of cells



LNCs can fuse with cell membranes and deliver cargo molecules directly to the cytoplasm

❖ LNCs achieve effective intracellular delivery through **BOTH** phagocytosis and fusion.
❖ ***LNCs are designed to mimic enveloped viruses***
❖ ***LNCs exponentially increase the chances for cellular uptake, without adverse immune responses***

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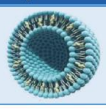
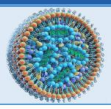
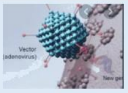
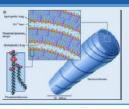
LNCs Are Differentiated from Liposomes, LNPs and Viral Vectors

	Liposome	LNP	AAV (Viral Vector)	LNC
				
Structure	• Aqueous interior surrounded by bilayer • Drug can be encapsulated in aqueous core or bilayer	• Ionizable lipid complexing with mRNA • Non-aqueous interior	• 26 nM Capsid housing <5 kb genome	• Natural components • Non-aqueous bilayer • Highly stable • Much longer shelf life
Formulation goal	• Reduce Toxicity • Improve Bioavailability • Prolong half-life	• Intracellular delivery (ASOs, siRNAs, mRNA)	• Mostly target liver • Minimize empty vectors	• Encapsulate water-soluble drugs • Control particle size • Further expand gene delivery • Significantly extend stability, shelf-life
Potential applications	• Hydrophilic and Lipophilic drugs	• mRNA, ASOs, siRNAs	• Gene therapy	• Large and small molecules • ASOs, mRNAs, siRNAs • Large nucleotides (up to 11 kB)
Challenges	• Leakage of encapsulated drug • Fusion • Limited shelf life	• Cationic lipid toxicity not suitable for chronic use • Anti-PEG allergic response • Very limited shelf stability • Cold-chain requirements	• Very high production cost • Viral genome integration • Package size < 4k BP • Re-treatment problematic • Immunogenicity	• Limited clinical experience to date

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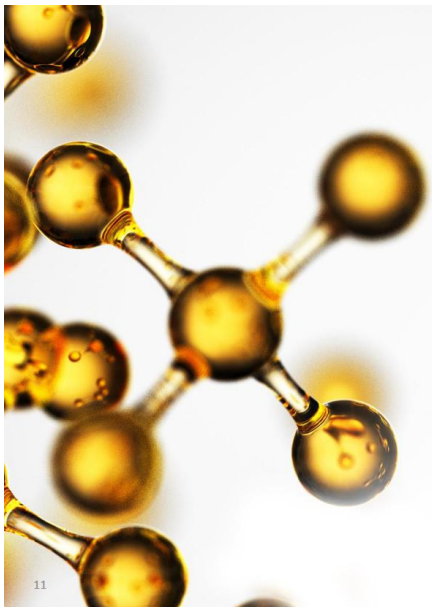

MAT2203

Oral Amphotericin B

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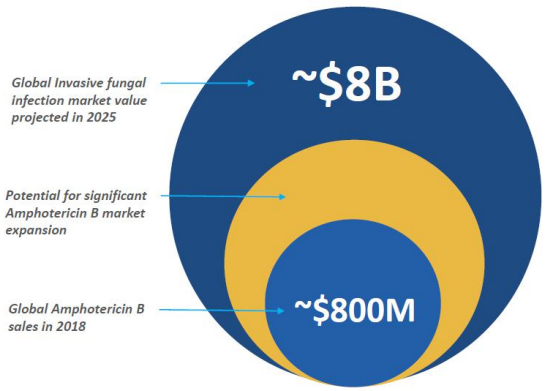
Invasive Fungal Infections Represent an Urgent Growing Global Need



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

MATINAS BIOPHARMA

MAT2203: A Novel Approach with a Proven Therapeutic Agent

MAT2203

- Oral amphotericin B formulation utilizing LNCs
- Proprietary formulation with robust intellectual property protection
- Potential to expand beyond treatment of CM to treatment of other invasive infections and prophylaxis
- Program supported by the National Institutes of Health (NIH)/NIAID

IMPROVED PROFILE

- LNC formulation enables oral administration, bioavailability and improved toxicity over IV amphotericin
- Efficient intracellular delivery to immune cells with delivery directly to infected tissues
- Demonstrated ability to cross the blood-brain barrier with an oral therapy

POTENTIAL CLINICAL IMPACT

- Potential to become the preferred antifungal agent for all invasive fungal infections ($8 billion+ market)
- Orphan Drug Designation + 4 Qualified Infectious Disease (QIDP) and Fast Track Designations
- Up to *12 years marketing exclusivity*, if approved

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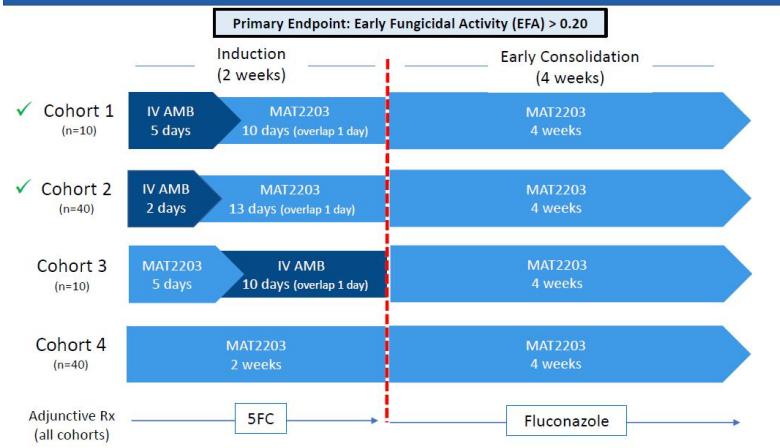
EnACT Study Design



MAT2203 TREATMENT REGIMENS:

Cohort 1
- Induction: 2.0g/day
- Consolidation: 1.5g/day

Cohort 2
- Induction: 1.8g/day
- Consolidation: 1.2g/day

- *For each Cohort, a control group receives standard of care IV AMB +5FC (7 days), followed by 1200mg Fluconazole (7 days) for Induction and then only Fluconazole (800mg) for Early Consolidation*
- *Control arm present primarily to assess patient safety*
- *EnACT **not** powered to formally test comparisons with the control arm standard of care*

*IV AMB = intravenous amphotericin B

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Key Elements of EnACT and Potential Indications

- Sequential cohort, gradually extending use of oral MAT2203, to assess safety and efficacy
- Strategic design, providing data to support up to **three potential indications**
- Rigorous safety monitoring; DSMB review after each cohort

1. **Step-down induction treatment** following initial administration of IV amphotericin
   - Shorter, simpler induction treatment
   - Opportunity for earlier patient discharge
   - Lower risk of toxicity

   Cohorts 1,2

2. **Consolidation treatment** after induction, out to 6 weeks with MAT2203
   - Amphotericin currently cannot be used for extended periods due to toxicity
   - Current SoC treatment with fluconazole has significant associated resistance and relapse

   Cohorts 1-4

3. **All-oral regimen for induction treatment**
   - Avoids all IV amphotericin-associated toxicity
   - Avoids complex treatment pathway, prolonged hospitalization

   Cohort 4

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EnACT – Baseline and Demography Summary

- 71 total patients were randomized in Cohorts 1 and 2
  - Cohort 1 (MAT2203): 10 patients
  - Cohort 2 (MAT2203): 40 patients
  - SOC (combined): 21 patients

- Demographic and baseline characteristics were comparable across the treatment groups
  - First episode of CM for the majority of patients in the study
  - Quantitative Cerebral Spinal Fluid (CSF) cultures were similar at baseline

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EnACT – Efficacy Endpoints and Analyses

- **Primary Endpoint**: **EFA** (log_{10} CFU/mL/day) at Day 14
  - Rate of CSF fungal clearance (log reduction)
  - Quantitative measure of antifungal activity of an induction treatment for CM
  - Early surrogate marker that predicts survival
- **Primary Endpoint Objective**: Demonstrate EFA for MAT2203 treated patients > 0.20
  - EFA > 0.20 - associated with lower mortality and improved clinical outcomes*
  - Achievements above this threshold are clinically meaningful, representing strong fungal clearance
- **Secondary Endpoints**
  - Sterilization of CSF cultures
  - Prevention of relapse (no breakthroughs)
  - Survival at 18 weeks

*_Clin Infect Dis._ 2020;71(5):e45-49

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EnACT Cohort 2 Results Provide Important Validation of LNC Platform Capabilities

- The EnACT Cohort 2 results are an important demonstration of how Matinas' LNC platform can provide meaningful clinical impact in a deadly disease
- They validate the use of the platform to overcome significant delivery challenges
  - Adding oral to IV delivery
  - Reducing treatment-limiting toxicity
  - True targeted intracellular delivery
  - Able to deliver therapy across the Blood-Brain Barrier
- These results illustrate how the use of LNC technology can potentially favorably impact established treatment paradigms for life-threatening diseases
- They provide tangible proof of the substantial capabilities of LNC platform delivery technology, and its enormous potential for broader application

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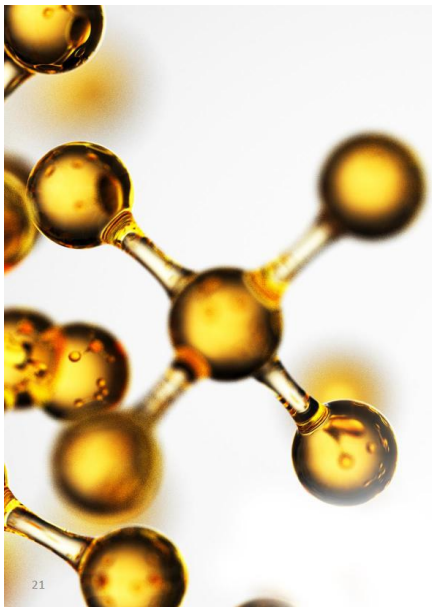

MAT2501

Oral Amikacin

MATINAS BIOPHARMA

MAT2501: A Better Amikacin

MAT2501

- Oral, LNC formulation of the broad-spectrum antibiotic Amikacin
- Initial indication in treatment of non-tuberculous mycobacterial (NTM) infections
- QIDP and Orphan Designations potentially provide 12+ years of exclusivity upon approval
- Proprietary formulation with robust intellectual property protection
- Development to be accelerated with $3.75M Cystic Fibrosis Foundation grant

IMPROVED PROFILE

- LNC formulation enables oral administration and bioavailability
- Encouraging safety profile potentially eliminates 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)

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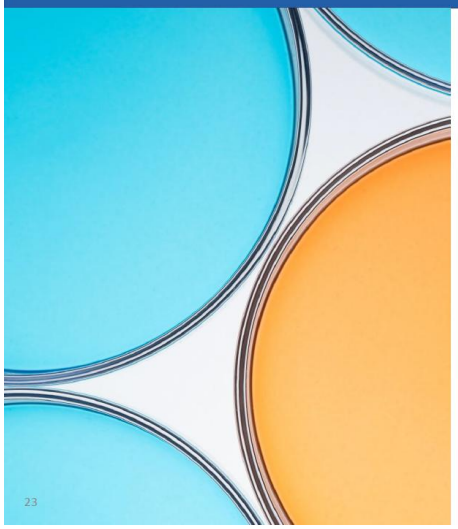
MAT2501: NTM Program Overview



Non-Tuberculous Mycobacterial Disease

- 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
- **October 2021** – Commence Human Single Ascending Dose Phase 1
- **Late 2022** – Begin Phase 2 Program in CF patients with NTM infections

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Potential Opportunities for Further Exploration

The LNC Platform has already demonstrated significant potential to move well beyond the current capabilities of LNPs and viral vectors in the following areas:

- Oligonucleotides - Efficient, non-toxic delivery
- mRNA - Enhanced stability (even at room temperature) and oral bioavailability
- siRNA – Enhanced efficacy of inhaled and IV LNCs
- Gene Therapy - High efficiency transfection, no toxicity, in-vivo expression
- Anti-viral Rx – Enhanced immune response to LNC-delivered proteins and ability to penetrate macrophages to where virus is hiding

MATINAS BIOPHARMA

Driving Opportunities for Value-Added Partnerships Built around the LNC Platform

Genentech
A Member of the Roche Group

NIH

GILEAD

CYSTIC FIBROSIS FOUNDATION®

Working with multiple strategic and research partners to expand potential successful applications of our LNC technology.

In 2019, we entered into a collaboration with Genentech/Roche to evaluate LNC delivery of up to three molecules, including antisense oligonucleotides.

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

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.

- ***In vitro studies of lipid nanocrystal (LNC) formulations of Gilead Sciences' remdesivir demonstrate meaningful efficacy compared to free remdesivir, with a favorable toxicity profile; National Institute of Allergy and Infectious Diseases (NIAID) preparing to initiate an in vivo efficacy study of LNC-remdesivir in Q3 2021.***

MATINAS BIOPHARMA

Expanding LNC Intellectual Property Portfolio

16 Patents Issued Within Last 4 Years

Additional IP to be developed as clinical development plan progresses.

MAT2203 and MAT2501 both have QIDP and Orphan Designations Potentially Entitling Each Product to 12+ Years of Exclusivity

MATINAS BIOPHARMA

LYPDISO™ - Representing the Next Generation in RX Omega-3

Product Profile

- Proprietary formulation of omega-3 fatty acids comprising primarily EPA and DPA in a free fatty acid molecular form to optimize bioavailability
- Specifically designed to optimize treatment of dyslipidemia and severe hypertriglyceridemia with enhanced bioavailability driving omega-3 levels
- EPA + DPA drive enhanced lipid lowering potency without raising LDL
- EPA levels are directly associated with cardio protective benefits showing improved outcomes in REDUCE-IT trial
- Clear differentiation from currently approved prescription omega-3 products, supported by strong barriers to entry
- **Process underway to identify a partner for further development and commercialization**

ENHANCE-IT Results (Head-to-Head Crossover study vs. Vascepa®)

- Plasma EPA concentrations were significantly higher with LYPDISO™, (46% relative percent increase change from baseline EPA level vs. Vascepa®)
- Levels of EPA have been directly correlated with improvements in cardiovascular outcomes (Vascepa® in REDUCE-IT)
- The ENHANCE-IT data indicate potential for superior cardioprotection with LYPDISO™ vs. Vascepa®
- Analysis of the Per Protocol (PP) Population demonstrated statistically significant improvement and superiority vs. Vascepa® in TGs, Total Cholesterol, and VLDL
- There were also significant reductions in hs-CRP with LYPDISO™ compared with Vascepa®, suggesting potential superior anti-inflammatory impact of LYPDISO™ (with additional potential cardiovascular and anti-inflammatory implications)
- The ENHANCE-IT data support the pursuit of a cardiovascular outcomes indication for LYPDISO™
- There were no serious adverse events reported and no dropouts related to study drug adverse events

MATINAS BIOPHARMA

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