
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): November 2, 2022

MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38022
(Commission
File Number)

46-3011414
(IRS Employer
ID Number)

1545 Route 206 South, Suite 302
Bedminster, New Jersey
(Address of principal executive offices)

07921
(Zip Code)

Registrant's telephone number, including area code: (908) 484-8805

Not Applicable
(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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 2.02. Results of Operations and Financial Condition.

On November 2, 2022, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2022. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

Item 7.01. Regulation FD Disclosure.

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 99.2 and incorporated herein by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that Section, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 2, 2022
99.2	Corporate Presentation, November 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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: November 2, 2022

By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour

Title: Chief Executive Officer

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Matinas BioPharma Reports Third Quarter 2022 Financial Results and Highlights Recent Progress

EnACT Phase 2 study of MAT2203 in cryptococcal meningitis met its primary endpoint with 95% two-week patient survival in the Cohort 4 all-oral regimen

Phase 3 pivotal trial of MAT2203 for treatment of cryptococcal meningitis to commence Q1 2023

The Infectious Diseases Society of America (IDSA) chose EnACT as its Outstanding Abstract and IDSA Awardee at IDWeek 2022

Eric J. Ende, MD, MBA appointed as Chairman of the Board effective October 1, 2022, with founding Chairman Herbert J. Conrad remaining as an Independent Director

\$33.1 million in cash, cash equivalents, and marketable securities at September 30, 2022, sufficient to fund planned operations through 2023

Management to Host Conference Call Today, Wednesday, November 2nd, at 4:30 p.m. ET

BEDMINSTER, N.J., November 2, 2022 – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform delivery technology, today reported financial and operational results for the third quarter ended September 30, 2022, along with a corporate update.

“Since our last quarter’s reporting, the Company has achieved some very significant milestones, highlighted by our lead, Phase 3-ready asset, MAT2203, successfully completing Phase 2,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas, “Interim EnACT Cohort 4 survival data were recently presented at IDWeek, with results that are simply unprecedented for an oral therapy in this vulnerable patient population. Following this impressive clinical validation of our LNC platform technology, we are aggressively preparing MAT2203 for Phase 3, and remain intently focused on advancing this platform into other areas of significant need, including the intracellular delivery of nucleic acids such as mRNA and other oligonucleotides, as we look ahead to close 2022 in strong fashion.”

Third Quarter 2022 Highlights and Recent Events

MAT2203

- Interim data from Cohort 4 of the Phase 2 EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis (CM) were presented at IDWeek in October 2022. As part of IDWeek, the EnACT abstract was the recipient of the Outstanding Abstract and IDSA Awardee by the Infectious Diseases Society of America. In the EnACT trial, MAT2203 exceeded the primary endpoint threshold for early fungicidal activity (EFA) of 0.20 log₁₀ CFU/mL/day, with a mean EFA achieved of 0.30 log₁₀ CFU/mL/day with 95% confidence intervals from 0.22 – 0.38.



- Cohort 4 also yielded key secondary endpoints, including overall survival and safety. For 40 patients receiving MAT2203 treatment, interim overall survival remains at 90% through 18 weeks, while the survival rate at Week 2 was 95% (the primary endpoint for the upcoming Phase 3 registration trial in cryptococcal meningitis). Importantly, the incidence of adverse events relating to kidney function and anemia were significantly lower for MAT2203 compared to the conventional IV amphotericin B standard of care treatment across the entirety of the EnACT trial, with no evidence of kidney toxicity even with up to 6 weeks of oral MAT2203 treatment.
- The pivotal Phase 3 registration trial of MAT2203 in cryptococcal meningitis is planned to initiate early in the first quarter of 2023 and will assess MAT2203 as step-down therapy following 2 loading doses of IV amphotericin B (similar to EnACT Cohort 2). This open-label randomized trial, which will be partially financially supported by the National Institutes of Health (NIH) National Institute of Neurological Disorders and Stroke (NINDS), involves a three arm non-inferiority design in approximately 270 persons living with HIV who have cryptococcal meningitis. The primary endpoint for this Phase 3 study will be 2-week all-cause mortality, with a pooled analysis across the two MAT2203 treatment arms compared with IV amphotericin as the standard of care to support either a 2-week or 6-week treatment of cryptococcal meningitis indication as supported by the data. An adaptive, de-risking design allows for the potential to add additional patients once enrollment has reached 75% to offset unforeseen patient deaths unrelated to study drug. Enrollment is expected to take approximately 18 months, with topline data expected in the second half of 2024.
- Late-breaking data demonstrating the *in vivo* efficacy of MAT2203 in treating two strains of mucormycosis (*R. delemar* and *M. circinelloides*) in immunosuppressed mice were also presented at IDWeek 2022 by Dr. Ashraf Ibrahim of the Lundquist Institute. The preclinical data with MAT2203 demonstrated a prolonged median survival time, enhanced overall survival, and reduced tissue fungal burden of target organs including lung and brain as compared to AmBisome® (IV amphotericin B), positioning MAT2203 as a potential clinical solution for this deadly invasive fungal infection.

External Collaborations

- In April 2022, Matinas and BioNTech entered an exclusive research collaboration centered on the combination of Matinas’ proprietary LNC platform technology and BioNTech mRNA formats. The Companies continue their collaborative formulation work on multiple nucleic acids, ultimately directed toward planned preclinical *in vitro* and *in vivo* testing. The parties remain in advanced discussions for a potential option to license the LNC platform for various nucleic acid applications.

Appointment of Eric Ende MD, MBA to Chairman of the Board of Directors

In September 2022, the Company also announced the unanimous appointment of board member, Eric J. Ende, to succeed Herbert J. Conrad as Chairman of the Board, effective October 1, 2022. Mr. Conrad, the founding Chairman of Matinas, remains on the Board as an independent director of the Company. Dr. Ende joined the Company's Board of Directors in March 2017.

Third Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities at September 30, 2022, were approximately \$33.1 million, compared to \$49.6 million at December 31, 2021. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

For the third quarter of 2022, net loss attributable to common shareholders was \$5.5 million, or a net loss of \$0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of \$6.8 million, or a net loss of \$0.03 per share (basic and diluted), for the same period in 2021. The reduced loss resulted from the Company recording \$1.1 million in revenue from its research collaboration with BioNTech SE, along with a slight decrease in operating expenses year over year.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, November 2, 2022, at 4:30 p.m. ET.

To participate in the call, please dial 888-609-1607 (Toll-Free) or (862) 298-0702 (Toll). 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 nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the 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 with formulation and route of administration (including oral), positions Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

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 our business activities, our strategy and plans, our ongoing research collaboration with BioNTech and any potential license of the LNC platform technology, the potential of our LNC platform delivery technology, 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.

Matinas BioPharma Holdings Inc. Condensed Consolidated Balance Sheets

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
	<u>(Unaudited)</u>	<u>(Audited)</u>
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 11,175,838	\$ 21,029,806
Marketable debt securities	21,875,015	28,592,049

Restricted cash - security deposit	50,000	50,000
Prepaid expenses and other current assets	3,997,798	1,321,466
Total current assets	37,098,651	50,993,321
Non-current assets:		
Leasehold improvements and equipment - net	2,144,102	1,537,728
Operating lease right-of-use assets - net	3,742,019	4,218,890
Finance lease right-of-use assets - net	7,026	22,270
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposit	200,000	200,000
Total non-current assets	10,447,012	10,332,753
Total assets	\$ 47,545,663	\$ 61,326,074

LIABILITIES AND STOCKHOLDERS' EQUITY:

Current liabilities:		
Accounts payable	\$ 656,717	\$ 938,270
Accrued expenses	3,696,932	2,850,888
Operating lease liabilities - current	540,076	538,546
Financing lease liabilities - current	7,860	21,039
Total current liabilities	4,901,585	4,348,743
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,683,949	4,140,387
Financing lease liabilities - net of current portion	-	2,621
Total non-current liabilities	4,025,214	4,484,273
Total liabilities	8,926,799	8,833,016
Stockholders' equity:		
Common stock	21,685	21,627
Additional paid-in capital	188,529,404	184,251,138
Accumulated deficit	(148,996,657)	(131,634,208)
Accumulated other comprehensive loss	(935,568)	(145,499)
Total stockholders' equity	38,618,864	52,493,058
Total liabilities and stockholders' equity	\$ 47,545,663	\$ 61,326,074



Matinas BioPharma Holdings, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue:				
Research and development	\$ 1,062,500	\$ -	\$ 2,125,000	\$ 33,333
Costs and expenses:				
Research and development	3,706,828	4,621,255	12,811,462	10,343,451
General and administrative	2,818,252	2,256,689	8,423,868	7,710,625
Total costs and expenses	6,525,080	6,877,944	21,235,330	18,054,076
Loss from operations	(5,462,580)	(6,877,944)	(19,110,330)	(18,020,743)
Sale of New Jersey net operating loss & tax credits	-	-	1,734,133	1,328,470
Other income, net	988	41,394	13,748	108,298
Net loss	\$ (5,461,592)	\$ (6,836,550)	\$ (17,362,449)	\$ (16,583,975)
Preferred stock series B accumulated dividends	-	-	-	(395,799)
Net loss attributable to common shareholders	\$ (5,461,592)	\$ (6,836,550)	\$ (17,362,449)	\$ (16,979,774)
Net loss available for common shareholders per share - basic and diluted	\$ (0.03)	\$ (0.03)	\$ (0.08)	\$ (0.08)
Weighted average common shares outstanding - basic and diluted	216,864,526	215,179,949	216,792,083	208,130,431
Other comprehensive loss, net of tax				
Unrealized loss on securities available-for-sale	(181,152)	(52,837)	(790,069)	(229,766)

Other comprehensive loss, net of tax	(181,152)	(52,837)	(790,069)	(229,766)
Comprehensive loss attributable to shareholders	<u>\$ (5,642,744)</u>	<u>\$ (6,889,387)</u>	<u>\$ (18,152,518)</u>	<u>\$ (16,813,741)</u>

Investor and Media Contacts

Ankit Bhargava, MD
Allele Communications, LLC
815.721.4912
matinas@allelecomms.com

Source: Matinas BioPharma Holdings, Inc.

The logo for MATINAS BIOPHARMA is centered on the left side of the slide. It features the word "MATINAS" in a large, dark blue, sans-serif font. Below it is a thin, curved yellow line. Underneath the line is the word "BIOPHARMA" in a smaller, dark blue, sans-serif font. The entire logo is enclosed within a large, light blue, stylized circular frame that has a textured, layered appearance.

MATINAS

BIOPHARMA

Q3 2022 Results Call Presentation

November 2, 2022
















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

Matinas Has Executed on Multiple Milestones..... With More to Come

	1H 2022 Milestones & Catalysts	2H 2022 and Beyond Milestones & Catalysts
MAT2203	<ul style="list-style-type: none">  FDA approval on Phase 3 of EnACT  Initiate preclinical studies in <i>C. auris</i> and <i>mucormycosis</i>  Data available from Phase 1 SAD study in healthy volunteers 	<ul style="list-style-type: none">  Feedback from EMA (ODD and Scientific Advice)  PoC data from preclinical studies in <i>mucormycosis</i>  Interim topline data from Cohort 4 of EnACT (all oral regimen) October 2022  Initiate Phase 3 confirmatory study for treatment of CM (Q1 2023)  Potential Global or Regional Commercialization partner
LNC Platform & Collaborations	<ul style="list-style-type: none">  Initiate & receive data from 2nd <i>in vivo</i> study of oral LNC-RDV (sponsored by NIAID/Gilead)  <i>In vivo</i> & <i>in-vitro</i> studies with mRNA, DNA, oligonucleotides  Nucleic acid research collaboration with large pharma 	<ul style="list-style-type: none">  Potential BioNTech License Agreement & expansion of established research collaboration  Potential additional platform collaborations



MAT2203

ORAL AMPHOTERICIN B

Phase 3 to Commence Q1 2023

MAT2203: Unmet Medical Need in Invasive Fungal Infections

In October 2022, The World Health Organization (WHO) released its first fungal priority pathogens list to guide research and development¹

Matinas is leveraging the safety and efficacy of MAT2203 to meet the needs of both critical and high priority groups:



Critical Priority per WHO:



Cryptococcal meningitis: Phase 2 success and QIDP



Aspergillosis: Preclinical data and QIDP

High Priority per WHO:



Mucormycosis: Preclinical data



¹<https://www.who.int/publications/i/item/9789240060241>

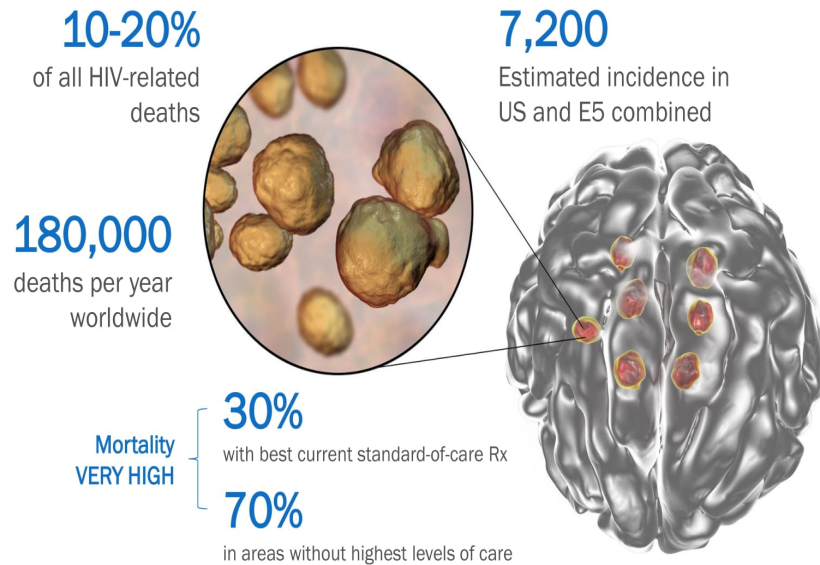
MAT2203: Unmet Medical Need in Invasive Fungal Infections



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

Cryptococcal Meningitis Is a Severe Fungal Infection with High Mortality

Deadly invasive fungal infection of the brain Typically affects immunocompromised individuals



TREATMENT ALGORITHM

Induction:

IV amphotericin B (either liposomal Ambisome™ or Amphotericin B deoxycholate) + flucytosine (5FC) for 1-2 weeks

Consolidation:

fluconazole for 8-12 weeks

MAJOR CHALLENGES

- High mortality
- Complex, resource-intensive regimens requiring daily administration of IV amphotericin B
- Treatment-associated renal toxicity limits options

MAT2203: EnACT, a Successful Phase 2 Study

EnACT		INDUCTION (2 WEEKS)	EARLY CONSOLIDATION (4 WEEKS)
✓	COHORT 1 (n=10)	<div> <div>IV AMB¹</div> <div>MAT2203 2.0 g/day</div> <div>5 days10 days</div> </div>	MAT2203 + Fluconazole 1.5 g/day
✓	COHORT 2 (n=40)	<div> <div>IV AMB</div> <div>MAT2203 1.8 g/day</div> <div>2 days13 days</div> </div>	MAT2203 + Fluconazole 1.2 g/day
✓	COHORT 3 (n=10)	<div> <div>MAT2203 1.8 g/day</div> <div>IV AMB</div> <div>5 days10 days</div> </div>	MAT2203 + Fluconazole 1.2 g/day
✓	COHORT 4 (n=40)	<div> <div>MAT2203 1.8 g/day</div> <div>15 days</div> </div>	MAT2203 + Fluconazole 1.2 g/day
✓	SoC Control (control group for each cohort)	<div> <div>IV AMB +5FC²</div> <div>Fluconazole 1.2 g/day</div> <div>7 days7 days</div> </div>	Fluconazole 0.8 g/day

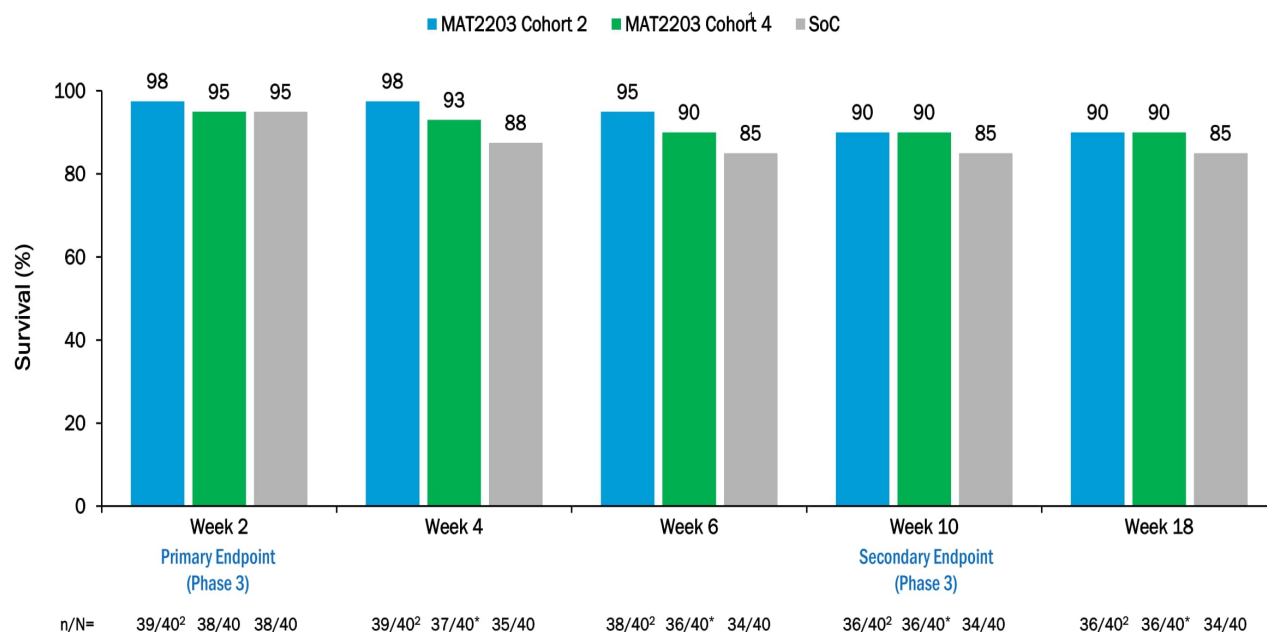
• Enrollment **COMPLETE**
56/56 patients; follow-up ongoing

1. IV AMB = intravenous amphotericin B
2. Flucytosine

PRIMARY ENDPOINT:
Early Fungicidal Activity (EFA) > 0.20

KEY SECONDARY ENDPOINTS:
Sterilization of CSF cultures,
Prevention of relapse (no breakthroughs),
Survival at 18 weeks, and Demonstrated safety

Cohort 2 and Cohort 4 Key Secondary Efficacy Endpoint: Survival



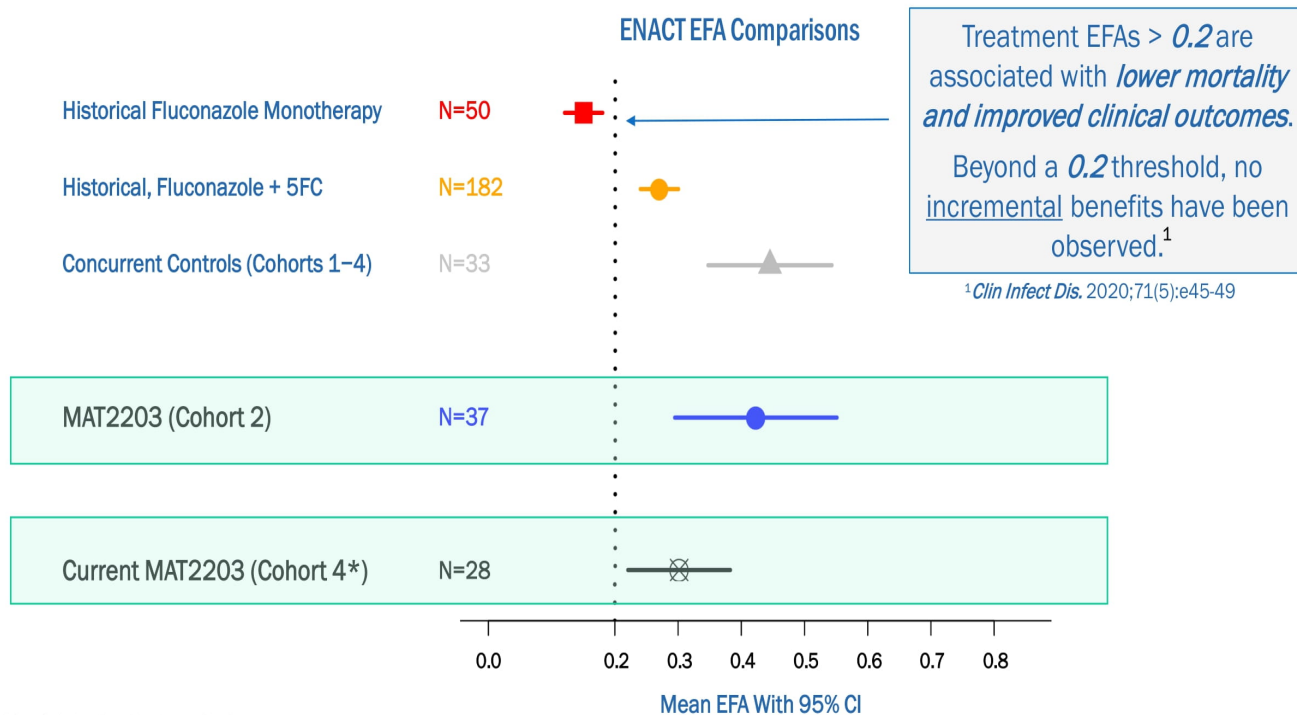
1. Combined SoC Cohorts 1 through 4.

2. Patient 110554 died on Day 2 while on IV AMB and did not receive a full daily dose on MAT2203.

* Interim data, clinical data collection ongoing

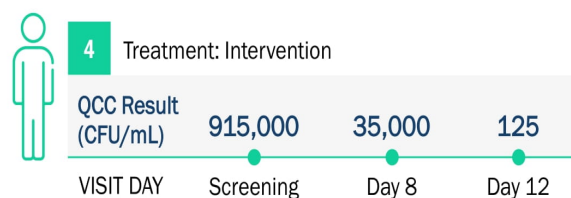
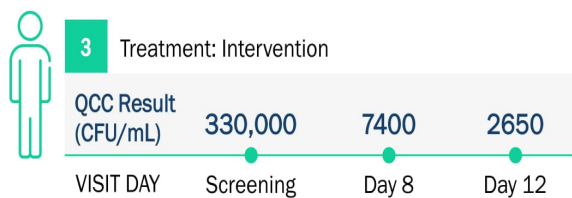
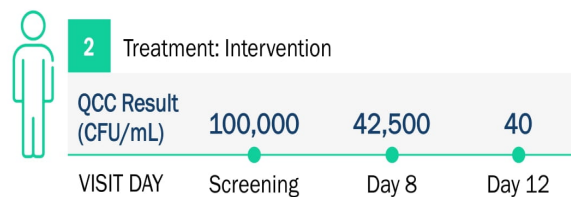
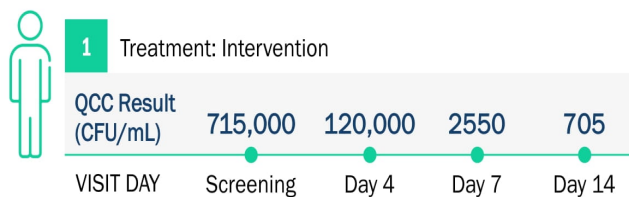
Abbreviations: SoC=standard of care.

MAT2203 Met the Primary Endpoint (EFA) in Both Cohort 2 (step down) and 4 (all oral)



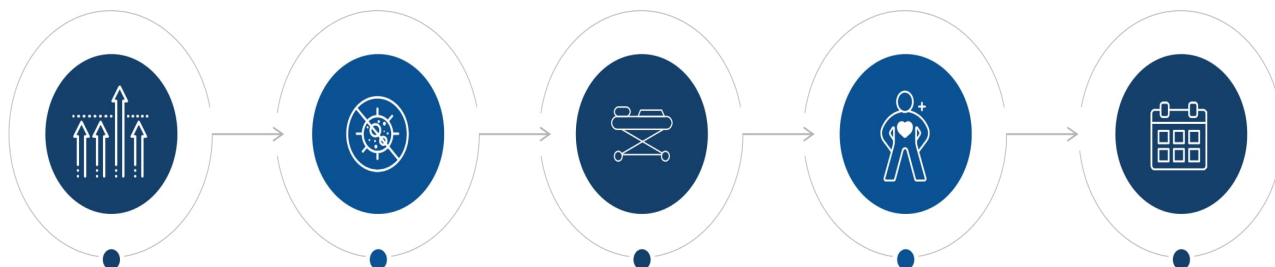
MAT2203 Cohort 4 Antifungal Activity

Examples of Noteworthy Antifungal Activity in Patients with High Baseline Counts



EnACT : Cohort 2 Results (Phase 3 Design Replicates Cohort 2)

EnACT Clinical Data Validates the Use of the LNC Platform to Enable Oral Administration and Overcome Toxicity



Exceeded the primary endpoint threshold

- EFA for MAT2203 was 0.42 (95% CI 0.29 to 0.55)

All patients completing induction achieved CSF sterility

- 97% for patients receiving MAT2203
- 76% for patients receiving SOC

No breakthrough Infections

- Over 10 weeks, no patients showed breakthrough infections post MAT2203 treatment

"Early Survival" at Day 30

- 98% for patients receiving MAT2203
- 88% for patients receiving IV Ampho (SOC)

MAT2203 was safe and well-tolerated over 6 weeks of treatment

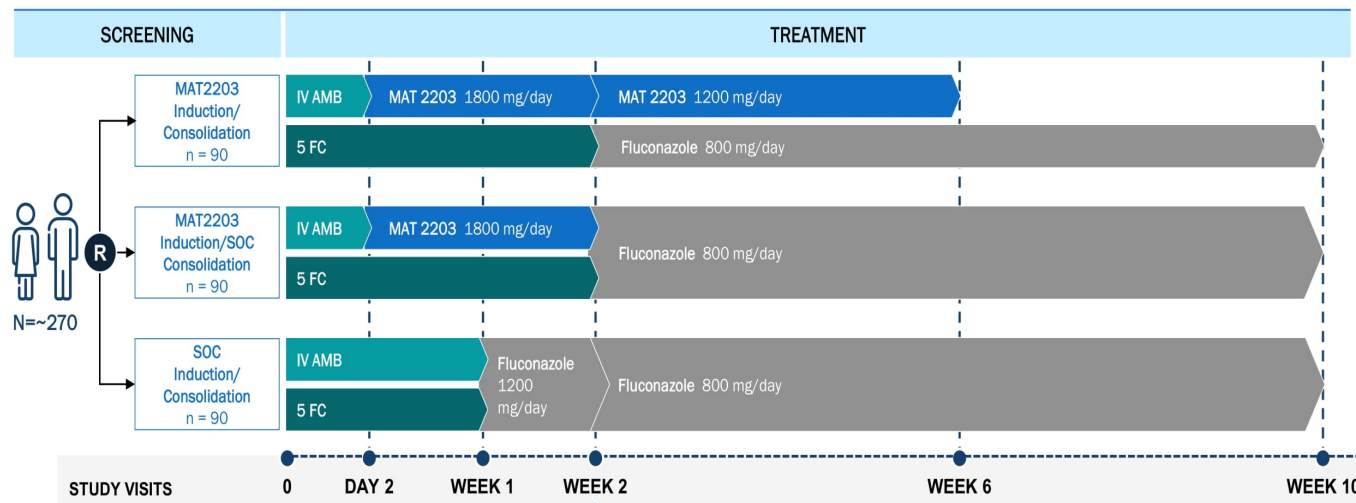
- Repeat dosing showed no renal toxicity or electrolyte abnormalities
- No discontinuations due to AEs nor MAT2203-related SAEs

Phase III Pivotal Study Design – To Initiate Q1 2023 (Replicates Cohort 2 of EnACT)

Assess MAT2203 as step-down therapy after 2 days of IV AMB for the Treatment of Cryptococcal Meningitis

Validate results observed in EnACT

Randomized 1:1:1 ratio to 1 of 2 MAT2203 arms or SoC



- ~270 participants
- 4 sites in Uganda
- Study Initiation Q1 2023
- NDA Filing H1 2025

PRIMARY ENDPOINT:
All-cause mortality at 2 weeks

Key Secondary Efficacy Endpoint:
Survival time through 10 weeks without *Cryptococcus* culture-positive relapse of meningitis

Other Secondary Endpoints include:

- Incidence of Grade 3-5 lab AEs
- Rate of CSF *Cryptococcus* clearance (EFA)
- CSF culture sterility (cumulative incidence over 10 weeks)
- 10-week survival time
- Use of rescue/additional IV AMB beyond scheduled use

Value Proposition for MAT2203

Oral Administration

enables earlier release
from hospital or avoidance
of home infusion



Lack of Nephrotoxicity

enables longer treatment duration
supported by oral
administration

LIFE CYCLE MANAGEMENT



Overall Development Strategy:

Cryptococcal meningitis is a gateway indication, with plans to secure multiple orphan indications including IFI and prophylaxis

IFI Phase 3 study start projected for 2H 2023



MAT2203: Potential for Treating Mucormycosis

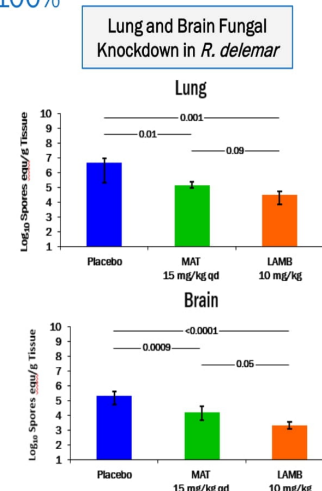
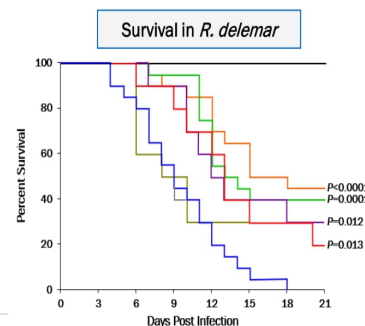
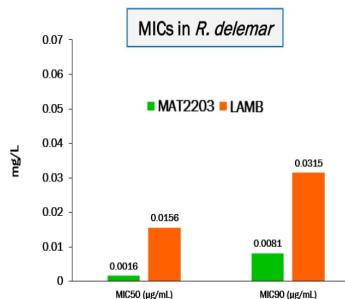
Mucormycosis (Black Fungus)

A life-threatening infection commonly caused by *Rhizopus* species, seen in immunocompromised patients, with mortality rates >50% to 100%

Current Approved Rx

- IV Amphotericin B
- Isavuconazole

- MAT2203 demonstrated *in vitro* killing activity **5-10-fold higher than AmBisome®** against two clinical isolates of *R. delemar* and *M. circinelloides* activity
- MAT2203 demonstrated *in vivo* efficacy in treating *R. delemar* or *M. circinelloides* pulmonary infection in immunosuppressed mice
 - Prolonged median survival time
 - Enhanced overall survival
 - Reduced tissue fungal burden of target organs
- *In vivo* efficacy of MAT2203 was equivalent to the efficacy shown by the current standard of care (AmBisome®)



MAT2203: Addressing a \$550M+ Market with Active Regional and Global Pharma



Cryptococcal Meningitis

Invasive fungal infections

Prophylaxis in IC patients

Comparable Deals



September 2019



Cidara licenses ex-US / ex-Japan rights of rezafungin to Mundipharma

Upfront: \$30M w/ \$9M equity
Milestones: Co-development funding

Total Deal Value: Potentially \$568M+



May 2022

F2G licenses Asia & Europe rights of olorofim to Shionogi

Upfront: \$100M
Milestones: \$380M in regulatory / commercial milestones, plus royalties and shared dev. costs

Total Deal Value: \$480M



February 2022

Scynexis licenses Greater China rights of Ibrexafungon to Hansoh

Upfront: \$10M
Milestones: \$112M in regulatory / commercial milestones, plus royalties

Total Deal Value: \$122M



July 2022

Cidara licenses US rights of rezafungin to Melinta

Upfront: \$30M
Milestones: \$60M in regulatory, \$370M in commercial, plus royalties

Total Deal Value: \$480M

The LNC Platform



Lipid Nanocrystal (LNC) Platform: Clinically Validated Intracellular Delivery

Next generation delivery - beyond LNPs and viral vectors



Extra-hepatic Targeting

- Primary component (phosphatidylserine) facilitates preferential cellular uptake
- Demonstrated uptake by phagocytes and cells with externalized PS
- Enables targeted extra-hepatic delivery in infection, inflammation and oncology
- Demonstrated delivery across the BBB



Safe

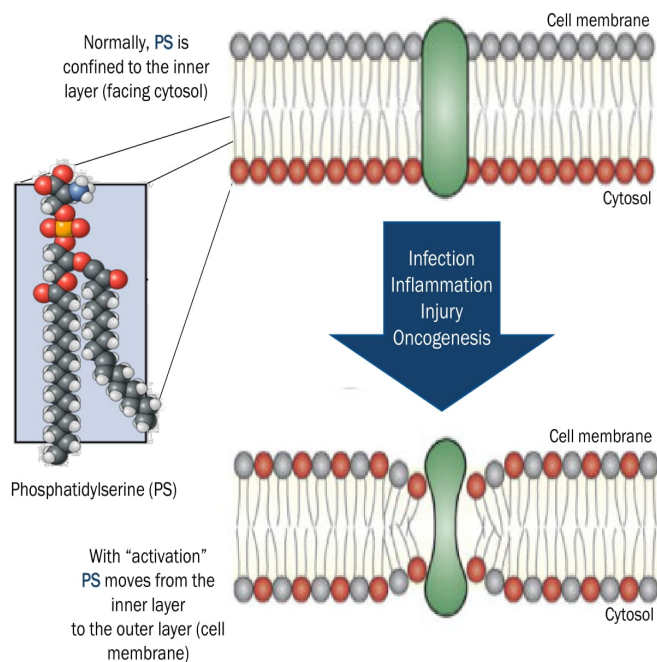
- No evidence of immunogenicity
- No cytotoxicity
- Delivers high tissue concentrations of drug with low plasma levels
- No off-target toxicity observed to date



Versatile

- Delivery of small molecules, proteins, nucleic acid polymers (ASOs, siRNA, DNA, mRNA), and vaccines - without membrane damage
- Multiple routes of administration (including oral)
- Improved stability and shelf-life

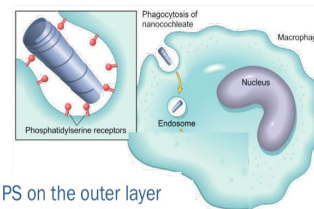
Phosphatidylserine Enables Intracellular Delivery



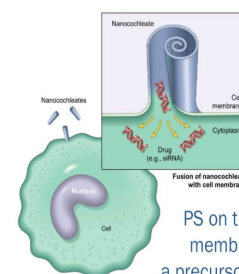
LNCs achieve effective intracellular delivery via BOTH phagocytosis and fusion.



LNC Delivery

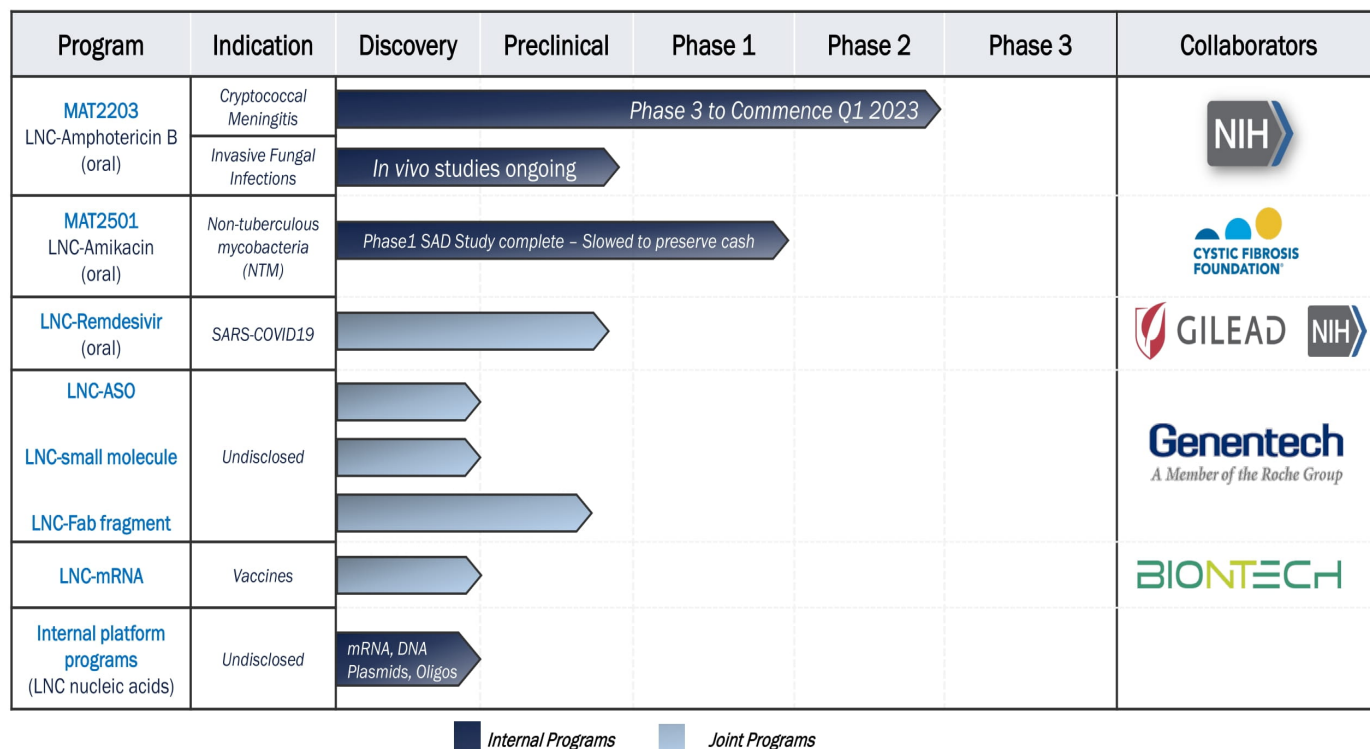


PS on the outer layer is an "eat-me" signal enabling phagocytosis



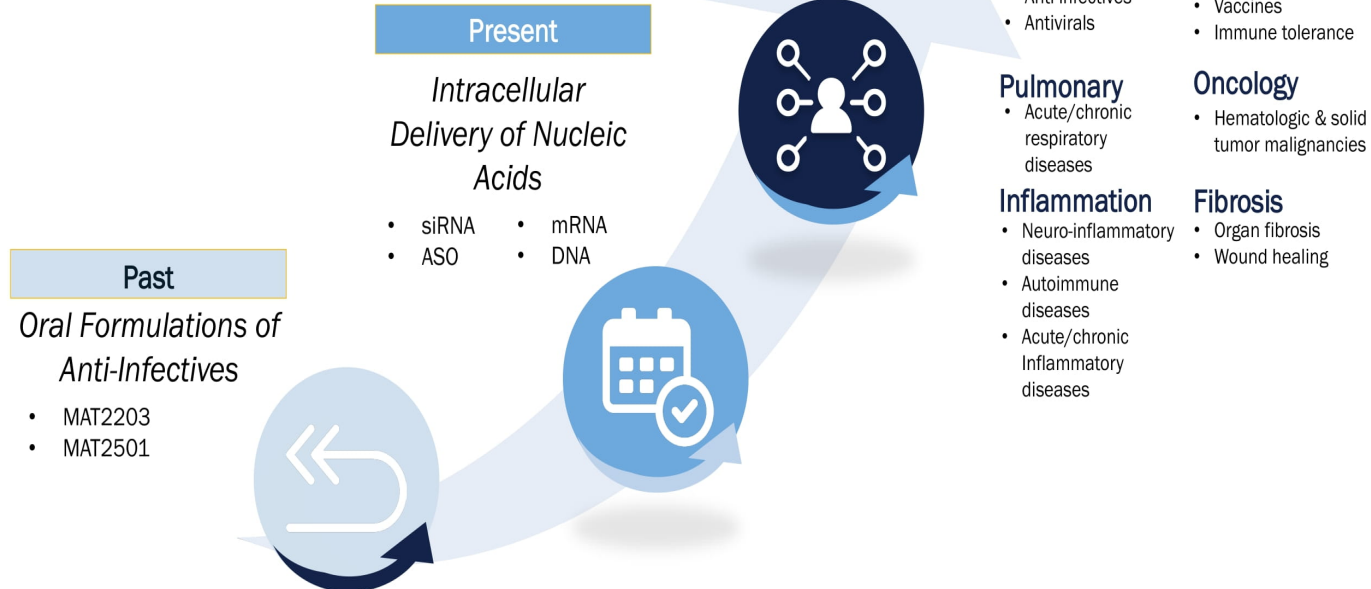
PS on the outer cell membrane is also a precursor for cell-to-cell fusion

Matinas' Pipeline and Discovery Programs: Internal and Collaborative



Unlocking the Full Potential of the LNC Platform

Matinas is working internally and with third parties to push the boundaries of LNC delivery



Bandwidth to Execute on Multiple Milestones

Financial Summary



Runway into 2024



\$33.1M¹ in Cash, Cash
Equivalents and Marketable
Securities



Non-Dilutive financing options

Capitalization Summary














Shares O/S	216.86M
Stock Options ¹	27.782M
Warrants ¹	.988M (weighted avg. strike is \$0.56)
Market Cap ²	~\$170.0M
Cash & Equivalents ¹	\$33.1M
30 Day VWAP ²	\$0.7467

Analyst Coverage

- **Robert (Bert) Hazlett**
BTIG
- **Andrew S. Fein**
H.C. Wainwright
- **Jason McCarthy, Ph.D.**
Maxim Group
- **Greg D. Fraser, MD**
Truist Securities

Leveraging our financial position to deliver value-add milestones

Matinas Has Executed on Multiple Milestones..... With More to Come

	1H 2022 Milestones & Catalysts	2H 2022 and Beyond Milestones & Catalysts
MAT2203	<ul style="list-style-type: none">  FDA approval on Phase 3 of EnACT  Initiate preclinical studies in <i>C. auris</i> and <i>mucormycosis</i>  Data available from Phase 1 SAD study in healthy volunteers 	<ul style="list-style-type: none">  Feedback from EMA (ODD and Scientific Advice)  PoC data from preclinical studies in <i>mucormycosis</i>  Interim topline data from Cohort 4 of EnACT (all oral regimen) October 2022  Initiate Phase 3 confirmatory study for treatment of CM (Q1 2023)  Potential Global or Regional Commercialization partner
LNC Platform & Collaborations	<ul style="list-style-type: none">  Initiate & receive data from 2nd <i>in vivo</i> study of oral LNC-RDV (sponsored by NIAID/Gilead)  <i>In vivo</i> & <i>in-vitro</i> studies with mRNA, DNA, oligonucleotides  Nucleic acid research collaboration with large pharma 	<ul style="list-style-type: none">  Potential BioNTech License Agreement & expansion of established research collaboration  Potential additional platform collaborations



MATINAS

BIOPHARMA

Matinas BioPharma Holdings

(NYSE AMER: MTNB)

1545 Route 206 South

Suite 302

Bedminster, NJ 07921

(908) 484-8805

www.matinasbiopharma.com
