# 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): May 25, 2018

#### MATINAS BIOPHARMA HOLDINGS, INC.

(Exact name of registrant as specified in its charter)

Delaware001-3802246-3011414(State or other jurisdiction of incorporation)(Commission (IRS Employer Identification No.)

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

**07921** (Zip Code)

Registrant's telephone number, including area code: (908) 443-1860

#### Not Applicable

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under

any of the following provisions (see General Instruction A.2. below):

[] Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company [X]

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. [X]

#### Item 8.01 Other Events.

Matinas BioPharma Holdings, Inc. (the "Company") intends to use a slide presentation in connection with investor meetings to starting on Friday, May 25, 2018. The slide presentation is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

#### Item 9.01 Financial Statements and Exhibits.

(d)	Exhibit No.	Description.	
	99.1	Slide Presentation, dated May 25, 2018.	
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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: May 25, 2018 By: /s/Jerome D. Jabbour

Name: Jerome D. Jabbour
Title: Chief Executive Officer

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### 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 expectations regarding the terms and size of the proposed offering and the use of proceeds from the proposed offering; 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 and the preliminary prospectus for the proposed offering. Investors are cautioned not to place undue reliance on such forward-looking s

This presentation highlights basic information about us and the proposed offering. Because it is a summary, it does not contain all of the information that you should consider before investing.

We have filed a registration statement on Form S-3 (including a preliminary prospectus supplement) with the SEC for the offering to which this presentation relates. Before you invest, you should read the preliminary prospectus supplement (including the risk factors described therein), registration statement, and other documents incorporated by reference therein for more complete information about us and the proposed offering.

You may access these documents for free by visiting EDGAR on the SEC Web site at http://www.sec.gov. Alternatively, a copy of the preliminary prospectus supplement relating to the offering may be obtained by contacting ThinkEquity, a division of Fordham Financial Management, Inc., 17 State Street, 22nd Floor, New York, New York 10004, telephone: (646) 968-9355 or e-mail: prospectus@think-equity.com.



# Offering Summary

Issuer	Matinas BioPharma Holdings, Inc.	
Exchange / Symbol	NYSE American / MTNB	
Expected Offering Size	\$15,000,000	
Securities Offered	Series B Convertible Preferred Shares	
Use of Proceeds	Development of MAT2203 and general corporate purposes	
Placement Agent	ThinkEquity, a division of Fordham Financial Management, Inc.	



# Series B Convertible Preferred (the "Shares") Summary Terms

Offering Price / Stated Value per Share	\$1,000.00			
Conversion Price	\$0.50 (each Share is convertible into 2,000 shares of Common Stock)			
Conversion	<ul> <li>At any time at the option of the holder</li> <li>Automatic conversion upon the earlier of (i) the first FDA approval of one of the Company's products, (ii) the consent of holders of 50.1% of the Shares, or (iii) the third anniversary of the closing of this offering</li> </ul>			
Dividends	Common Stock dividends, as a % of the Common Stock into which the Shares are convertible, will be issued to holders of record as of the following anniversaries of the offering:  10% at the 12 month anniversary  15% at the 24 month anniversary  20% at the 36 month anniversary			



### **Strategy Overview**

### Enabling Delivery of Life-Changing Medicines Using a Proprietary Lipid Nano-Crystal (LNC) Technology Platform

# LNC Technology Platform

- Highly stable lipid crystals enable safe and natural intracellular delivery of:
  - siRNAs, mRNA, proteins, small molecule pharmaceuticals and the potential for gene-editing (CRISPR-Cas9) molecules
- · Validated in multiple preclinical and clinical studies
- Differentiated from other lipid nanoparticles (stability, intracellular delivery, flexible route of administration)
- Building substantial pipeline through strategic collaborations

# Lead Internal Development Candidate MAT2203

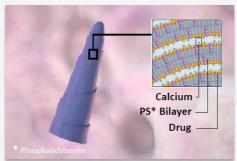
- Orally-administered amphotericin B, a broad spectrum fungicidal drug
- Demonstrated to be safe and well tolerated in two Phase 2 clinical studies
- Recent meeting with FDA provided clarity on clinical path forward
- Positioning to enter Phase 2 pivotal trial for prevention of invasive fungal infections (IFI) in patients with acute lymphoblastic leukemia (ALL)



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# LNC Platform Technology Enables Safe and Targeted Delivery of Potent Medicines

- · Highly stable lipid crystal particles
- Sheets roll up and capture drug molecules between the sheet
- Validated in multiple clinical and preclinical studies



#### Lipid Nano-Crystal vs. Lipid Nano-Particle

#### **Lipid Nano-Crystal**



- Multiple routes of administration
- Rigid, solid multilayered membrane
- Non-aqueous interior
- Resists environmental attack
- Non-toxic

#### **Lipid Nano-Particles**

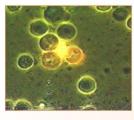
- No oral delivery
- Fluid membrane
- Induce membrane destruction
- Induces immunogenicity and toxicity



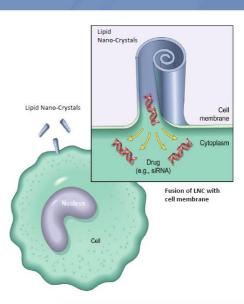
### Natural Targeted Intracellular Drug Delivery

- Naturally targeted to cells of the immune system (e.g. macrophage, dendritic cells, neutrophils) or virally infected cells
- Enter cells through non-destructive, natural membrane fusion
- Naturally unwind (low calcium environment) releasing drug payload

Fluorescent Labeled LNC Incubated with Mouse Spleenocytes









## MAT2203: Lead Development Product Candidate

## **Proof of Concept for LNC Technology Platform**



## MAT2203: C-Amphotericin B (CAmB)

#### QIDP with Fast Track Status for Treatment of Aspergillus, Invasive Candidiasis and Prevention of IFI

#### Broadest Spectrum Antifungal Agent



Gold standard of treatment for immunocompromised patients

#### Demonstrated to be Safe and Well Tolerated



No drug-related serious adverse events reported in either Phase 2 clinical study

# LNC Platform Technology Benefits



Oral bioavailability, reduction in toxicity and targeted delivery



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## IFI Prevention Represents a Significant Market Opportunity

#### **IFI Prevention:** Treatment period extended Significant reduction of morbidity and mortality in target patient population **US Prevalence** 340,000 over the entire high-risk episode: of Hematologic Malignancies is Approximately: 6-14 (111,000 acute forms of leukemia) + ~51,000 transplants annually (20,000 stem cell + 31,000 organ transplants) Significant savings in cost of treatment of IFI in high cost ICU or similar hospital environment, justifying economics of preventi WEEKS Limited population annually in US: 40-90% 46,000 candidiasis 1-3 + 5,000 Significant cost of treatment for IFI, adding ~\$50,000 per IFI case in 2016 dol aspergillosis cases WEEKS (>90% of IFI)



# NIH and VVC Studies Significantly Strengthen MAT2203 Human Safety and PK Database

Current Database:	Safety	24-hr PK in Serum	Other PK
Single Dose	36 patients	36 patients	none
Multiple Dose	96¹ patients	21 patients	70² patients

- NIH Study: Kidney and liver function remained within normal ranges
- Vulvovaginal Candidiasis (VVC) Study: Limited impact on liver and kidney function and remained within normal ranges



2: Includes four documented NIH patients, two of whom have now been dosed for more than a year
2: Serum Trough Amphotericin B Levels (observations indicate relative consistency across populations)

### Efficacy Results - NIH and VVC Phase 2 Studies

#### **NIH Study**

- 100% (4 out of 4) patients met the primary endpoint in achieving ≥ 50% clinical response
- Study met predetermined endpoint for success, which was 3/16 patients demonstrating clinical response
- · All patients reported improved quality of life
- There have been no signs of nephrotoxicity, hypokalemia or hepatoxicity after oral dosing:
  - Patient 1 467 days (800 mg/day)
  - Patient 2 476 days (400 mg/day)
  - Patient 3 189 days (800 mg/day)
  - Patient 4 91 days (800 mg/day)
- All patients have elected to enroll in the long-term extension study

#### **VVC Study**

 In the composite clinical cure score of signs and symptoms at Day 12, MAT2203 demonstrated an 81% improvement in clinical symptoms at 200 mg/day, 80% improvement at 400 mg/day, compared to 94% improvement in clinical symptoms for the patients on fluconazole





# Recent Meeting with FDA Provided Clarity on Clinical Development Path Forward

- FDA meeting held in January 2018 with purpose of gaining FDA perspectives on data from studies conducted and on future development of MAT2203
- FDA acknowledged efficacy was demonstrated in animal studies
- FDA acknowledged no evident safety or toxicity concerns in studies conducted to date
- FDA acknowledged significant unmet medical need for patients with acute lymphoblastic leukemia (ALL) at-risk for development of invasive fungal infections – no currently approved therapies
- Following successful FDA meeting, focus on combination of formulation and dose optimization and streamlined (adaptive design) development program designed to mitigate overall risk, cost and timeline for approval



### MAT2203 Formulation Optimization

- Current formulation is an oral suspension
- Recently completed formulation optimization program with a goal to reduce product volume and improve taste
  - Reformulation through concentration (improved from 5 mg/mL to 27.5 mg/mL)
  - Taste-masked, sweetened, flavored and colored to appeal to patient and improve compliance
- Currently scaling up formulation to supply MAT2203 for dose optimization in advance of Phase 2 clinical trial



# MAT2203 Dose Optimization Through Animal Studies & Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling



#### **Robust Studies in Neutropenic Animals**

Designed to provide data for input into the PK/PD Model



#### PK/PD Modeling with Existing Data

- Will run concurrently with Stage 1
- Population pharmacokinetic model development incorporating human PK data generated to date



#### **Dose Selection Simulations**

- Will run following completion of Stage 1 and Stage 2, incorporating data from both human and neutropenic animal studies
- Designed to select optimal dose for adaptive design pivotal trial



### Single Phase 2 Pivotal - Adaptive Design Study

#### Seeking Approval for Limited Use Indication for Prevention of IFI in ALL Patients

#### Stage 1:

PK/PD and Safety

- ~30 Patients with either AML or ALL
- Open-label



#### Stage 2:

PK/PD, Efficacy and Safety in ALL Patients

- Final number of patients for Stage 2 to be determined
- Designed to demonstrate statistical superiority over placebo
- Data Safety Monitoring Board to review blinded data every ~30-60 patients for safety & efficacy
  - Provides continuous evaluation of safety
  - Could determine if differences in efficacy warrants ending study early due to statistical superiority of MAT2203
  - Provides flexibility in sizing of study to meet statistical endpoint



# MAT2203 Clinical Development Plan

Study	H1 2018	H2 2018	H1 2019	H2 2019	2020	2021	2022
Dose Optimization							
Pharmacokinetic/Pharmacodynamic (PK/PD) Modeling							
Long Term Tox (90 Rat & Dog) and Food Effect Studies							
FDA Meeting			*				
Initiate Phase 2 Pivotal - Adaptive Design Study				*			
Phase 2 Pivotal Study Duration							NDA
MATINAS							1.

# LNC Platform Delivery Technology – The Future

# Enabling the Promise of Gene Therapy/Editing



### The Challenge of Delivery in Gene Therapy/Editing

Genetic drugs such as small interfering RNA (siRNA), messenger RNA (mRNA) or plasmid DNA provide potential gene therapies to treat most diseases by silencing pathological genes, expressing therapeutic proteins, or through gene-editing applications. In order for genetic drugs to be used clinically, however, sophisticated delivery systems are required.

The <u>central problem</u> preventing the widespread implementation of gene therapies based on RNA and DNA polymers is <u>delivery</u>

- The complexity of the problem is enormous
- · Naked RNA or DNA molecules are rapidly degraded in biological fluids
- Do not accumulate in target tissues following systemic administration
- Cannot penetrate into target cells even if they get to the target tissue
- Further, the immune system is designed to recognize and destroy vectors containing genetic information



# The LNC Platform Technology: A Demonstrated Gene Therapy Solution

#### Encapsulation of genetic information

- LNCs protect associated genetic information inside stable, solid crystal

#### Attachment and delivery into target cells

- Natural membrane fusion intermediates due to inherent physical/chemical properties
- Introduce contents into cytoplasm without cell membrane destruction and cell death typically seen with other lipid nanoparticle delivery

#### · Facilitating gene expression

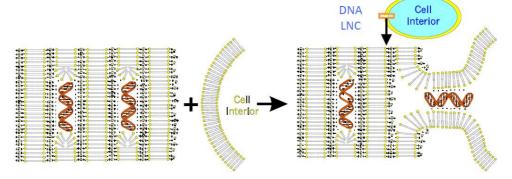
- Capacity to ensure integrity of DNA-protein complexes suggests substantial advantage in gene delivery
- Demonstrated ability to encapsulate DNA-protein complexes yields enhanced biological activity

#### · Route of administration flexibility and enhanced safety

- Ability to create oral, parenteral, intranasal and other formulations provides clear competitive advantage
- Non-viral vector enhances safety



# How LNCs Deliver RNA and DNA Polymers



The outer layer of the LNC interacts with the target cell membrane

Via a natural, non-destructive membrane fusion process, involving calcium and negatively charged phospholipids, the LNC membrane fuses with the target cell membrane delivering the nucleic acid into the interior of the cell



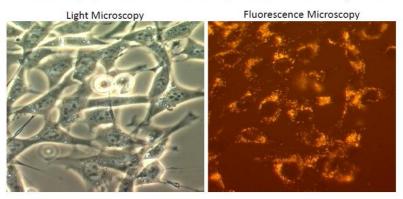
# Preclinical Data Support Formulation and Delivery of RNA and DNA Polymers

- Various strategies have been developed to prepare stable formulations of siRNA, mRNA and DNA plasmids
- Greater than 90% efficiency and demonstrated long shelf life stability (including at room temperature)
- Formulations demonstrated delivery of siRNA and DNA plasmids to cells in vitro at high efficiency
- siRNA formulations have shown activity in vivo in mouse model of influenza infection
- LNCs demonstrated safe, non-toxic and non-immunogenic
- DNA plasmids have shown activity in vivo in mouse models of gene expression and activation of the immune response
- In animal models, formulations of oligonucleotides demonstrate efficacy in the absence of toxicity
- Delivery strategy for plasma-based CRISPR-Cas9 system is similar to plasmid-based gene therapy indicating significant potential in solving delivery challenges for CRISPR-Cas9 in gene editing field



## siRNA LNC Delivery

#### Intracellular Localization of siRNA in RISC Complexes



- LNCs deliver siRNA at high efficiency to every cell in the culture
- Fluorescent siRNA localizes regions in the cytoplasm next to the nuclear membrane analogous to RISC complexes



# Pipeline Through Strategic Collaboration—Formulation Partner of Choice

#### **LNC Platform Benefits**

- Demonstrated oral, parenteral and topical delivery
- · Demonstrated intracellular delivery of drug
- Demonstrated reduction of toxicity
- · Potential to increase efficacy
- · Allows for room temperature storage
- Inexpensive cost of goods and manufacturing

#### **Broad Applicability**

Unique delivery platform that can formulate and stabilize a variety of molecules:

- siRNAs
- mRNA
- Proteins
- DNA plasmids
- Small molecule pharmaceuticals
- Antisense



## Manufacturing Capabilities

- 14,000+ sq. ft. GLP/GMP product development and manufacturing facility located in former Sanofi R&D building in Bridgewater, NJ
- Includes GMP scale-up and manufacturing suites
- ISO-8 compliant
- Highly scalable and reproducible manufacturing process from 1 mL to 100 liters+
- Protocols developed to control and stabilize particle size



## Management Team and Board of Directors

#### Strong Development and Commercialization Track Record

#### Management

#### Jerome D. Jabbour Chief Executive Officer, Director









**Board of Directors** 



Raphael J. Mannino, PhD Chief Scientific Officer











Dominick DiPaolo SVP, Quality and Regulatory Compliance





Matthew A. Wikler, MD, MBA FIDSA





Gary Gaglione, CPA Reliant VP, Finance, Acting-CFO



Adam Stern Director

Director

James S. Scibetta

STERNAEGIS VENTURES





Jerome D. Jabbour Chief Executive Officer, Director







### **Prominent Clinical Advisors**

#### J. Carl Craft, MD - Chair

- Former Chief Scientific Officer for Medicines for Malaria Venture (MMV)
- Former Venture Head at Abbott Laboratories Anti-Infective Development Group

#### Prof. Oliver Cornely, MD, FACP, FIDSA

- · Head of Translational Platform, Principal Investigator, Clinical Trials Center Cologne
- President of the European Confederation of Medical Mycology

#### Dimitrios P. Kontoyiannis, M.D., M.S., Sc.D., PhD (Hon), FACP, FIDSA, FECMM

- The Texas 4000 Distinguished Endowed Professor For Cancer Research, Department of Infectious Diseases, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX
- Frances King Black Endowed Professor, Department of Infectious Diseases, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX
- Deputy Head Research, Division of Internal Medicine, The University of Texas MD Anderson Cancer Center, Houston, TX

#### Peter G. Pappas, MD, FACP

- Professor of Medicine in the Division of Infectious Diseases and Tinsley Harrison Clinical Scholar at the University of Alabama in Birmingham
- Principal Investigator for the Mycoses Study Group



- Internationally renowned expert in infectious disease, with primary expertise in fungal infections and mechanisms of antifungal drug resistance
- · Executive Director of the Public Health Research Institute (PHRI)
- Professor of Microbiology, Biochemistry and Molecular Genetics at New Jersey Medical School



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THE UNIVERSITY OF ALABAMA AT BIRMINGHAM













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# Capitalization Table\*

Common Shares	93,981,562
Series A Preferred Stock (as converted)**	14,728,858
Options (\$1.33 WAEP)	11,613,820
Warrants (\$0.70 WAEP)	5,957,831

<sup>\*</sup> Pre-offering and excluding: the Series B Convertible Preferred Shares and Common Shares into which the Shares convert; 3,000,000 Common Shares issuable to Aquarius upon certain milestones; Placement Agent warrants issuable in connection with the offering

\*\* Holders of Series A Preferred Stock are entitled to receive cumulative dividends at the rate per share of 8% per annum,

payable in shares of our Common Stock and certain Royalty Payment Rights



