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 8, 2021

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

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

1545 Route 206 South, Suite 302 **Bedminster, New Jersey** **(Address of principal executive offices)**	**07921** **(Zip Code)**

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

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

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

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

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

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

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

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

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock	MTNB	NYSE American

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02. Results of Operations and Financial Condition.

On November 8, 2021, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended September 30, 2021. The full text of the press release is furnished as Exhibit 99.1 hereto and is incorporated by reference herein.

The information in Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 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 (the "Securities Act"), 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.

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

Exhibit No.	Description

99.1	Press Release, dated November 8, 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: November 8, 2021

By: */s/ Jerome D. Jabbour*

Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Reports Third Quarter 2021 Financial Results and Operational Highlights

– Positive efficacy and safety data announced from first two cohorts of patients in ongoing EnACT study of MAT2203 (oral amphotericin B) for treatment of cryptococcal meningitis; DSMB unanimously recommended progression to second half of study –

– Dosing initiated in Phase 1 study of potential first oral aminoglycoside antibiotic drug MAT2501 (oral amikacin) –

– Accomplished biotechnology executive, Kathryn Penkus Corzo, joined Company's Board of Directors –

– Management to host conference call today, Monday, November 8th, at 8:30 a.m. ET –

BEDMINSTER, N.J., November 8, 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 reported financial results for the third quarter ended September 30, 2021, along with a corporate update.

"We continue to achieve significant pipeline progress, having advanced to the second half of the EnACT study with MAT2203 following positive and impressive data from the first two cohorts of patients, and, recently, initiating our Phase 1 study with MAT2501, our second clinical stage LNC asset," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "Importantly, we have also commenced an *in vivo* efficacy study of LNC remdesivir with our partners at the National Institutes of Health and Gilead and look forward to potentially sharing data later this year as an additional proof of concept of the effective oral delivery of an antiviral prodrug. Finally, we continue to evaluate opportunities to capitalize on what we believe is the enormous potential of our LNC platform delivery and its unique ability to solve the oral administration and intracellular delivery challenges presented by vaccines and complex nucleic acid polymers, such as mRNA."

Third Quarter Highlights and Recent Events

- Positive efficacy and safety data announced from the first two cohorts of patients in the ongoing EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis, exceeding the prespecified primary endpoint. 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. The EnACT independent Data and Safety Monitoring Board (DSMB) unanimously recommended progression to the second half of the study. Cohort 3 of EnACT (the safety lead-in for Cohort 4, which will be an all-oral MAT2203 treatment regimen) has enrolled 13 out of 14 patients and the DSMB evaluation and cohort progression assessment is expected by the end of 2021.

- The Company plans to meet with the U.S. Food and Drug Administration in December of 2021 to review the data to date and discuss the potential for approval of MAT2203 as step-down therapy from IV amphotericin B under one or more accelerated regulatory pathways for important anti-infective medicines that address significant unmet medical needs in small or vulnerable patient populations.

- In August 2021, the U.S. Patent and Trademark Office (USPTO) issued a patent protecting the use of MAT2203 to treat or prevent cryptococcus infections. The allowed patent application, entitled, "*Encochleated Antifungal Compounds for Central Nervous System Delivery and Treatment of Cryptococcus Infections*," includes claims directed to using an orally administered amphotericin B LNC composition in combination with a second antifungal compound, such as 5-Flucytosine or an azole antifungal, to treat or prevent a Cryptococcus infection of the central nervous system. The base patent term extends to 2037, excluding any patent term adjustments or patent term extensions that may provide additional protection.

- In October 2021, the Company announced it has dosed the first patient in a Phase 1 single ascending dose (SAD) pharmacokinetic study of MAT2501 in healthy volunteers. The Company expects to complete enrollment of the Phase 1 SAD study in the first quarter of 2022, with data anticipated during the second quarter of 2022. Pending successful completion of the Phase 1 SAD study, the Company expects to start a Phase 2 program in patients with nontuberculous mycobacterial (NTM) infections by the first quarter of 2023, following required longer-term preclinical toxicology studies to be conducted during 2022. Initiation of the Phase 1 SAD study follows positive feedback received from the FDA on the Company's ongoing preclinical toxicology and efficacy studies of MAT2501 conducted in collaboration with the Cystic Fibrosis Foundation (CFF).

- Accomplished biotechnology executive, Kathryn Penkus Corzo, has received shareholder approval to join the Company's Board of Directors, effective November 1, 2021. Ms. Corzo brings to Matinas over 25 years of successful biopharma experience, including an extensive record of drug development accomplishments at Takeda, Sanofi Genzyme, and Eli Lilly.

- The *in vivo* efficacy study of LNC remdesivir being conducted in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), with cooperation from Gilead Sciences, Inc., has commenced at the University of North Carolina, with data expected in the fourth quarter of 2021.

Third Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at September 30, 2021, were approximately $53.8 million, compared to $58.7 million at December 31, 2020. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations into 2024.

For the third quarter of 2021, net loss attributable to common shareholders was $6.8 million, or a net loss of $0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of $5.7 million, or a net loss of $0.03 per share (basic and diluted), for the same period in 2020. The increase was due primarily to an increase in research and development expenses.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Monday, November 8, 2021, at 8:30 a.m. ET.

To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13723555. 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.

MATINAS BIOPHARMA

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. Enrollment in Cohort 3 of EnACT has commenced following unanimous approval from the Data and Safety Monitoring Board (DSMB), with enrollment completion and DSMB evaluation of Cohort 3 data expected in the fourth quarter 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 commenced a Phase 1 human clinical trial in the fourth quarter of 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.

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 our business activities, our strategy and plans, 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

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Balance Sheets

	September 30, 2021	December 31, 2020
	(Unaudited)	(Audited)

ASSETS:		
Current assets:		
Cash and cash equivalents	$ 24,922,760	$ 12,432,481
Marketable securities	28,907,045	46,246,573
Restricted cash – security deposits	50,000	136,000
Prepaid expenses and other current assets	2,601,126	2,739,791
Total current assets	56,480,931	61,554,845
Non-current assets:		
Leasehold improvements and equipment - net	1,568,717	1,523,950
Operating lease right-of-use assets - net	4,352,588	3,276,639
Finance lease right-of-use assets - net	28,707	58,007
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	200,000	200,000
Total non-current assets	10,503,877	9,412,461
Total assets	$ 66,984,808	$ 70,967,306
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 661,998	$ 349,941
Accrued expenses	2,893,903	2,795,329
Operating lease liabilities - current	518,786	391,498
Financing lease liabilities - current	24,309	30,853
Total current liabilities	4,098,996	3,567,621
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	4,284,552	3,304,063
Financing lease liabilities - net of current portion	5,745	23,660
Total non-current liabilities	4,631,562	3,668,988
Total liabilities	8,730,558	7,236,609
Stockholders' equity:		
Series B Convertible preferred stock	-	3,797,705
Common stock	21,625	20,010
Additional paid-in capital	183,168,987	167,192,003
Accumulated deficit	(124,934,768)	(107,507,193)
Accumulated other comprehensive (loss)/income	(1,594)	228,172
Total stockholders' equity	58,254,250	63,730,697
Total liabilities and stockholders' equity	$ 66,984,808	$ 70,967,306

The accompanying notes are an integral part of these condensed consolidated financial statements

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MATINAS BIOPHARMA

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Research and development	$ -	$ 95,833	$ 33,333	$ 95,833
Costs and expenses:				
Research and development	4,621,255	3,336,225	10,343,451	10,833,345
General and administrative	2,256,689	2,364,214	7,710,625	6,980,155
Total costs and expenses	6,877,944	5,700,439	18,054,076	17,813,500
Loss from operations	(6,877,944)	(5,604,606)	(18,020,743)	(17,717,667)
Sale of New Jersey net operating loss & tax credits	-	-	1,328,470	1,073,289
Other income, net	41,394	155,093	108,298	538,420
Net loss	$ (6,836,550)	$ (5,449,513)	$ (16,583,975)	$ (16,105,958)
Preferred stock series B accumulated dividends	-	(227,600)	(395,799)	(575,392)
Net loss attributable to common shareholders	$ (6,836,550)	(5,677,113)	$ (16,979,774)	$ (16,681,350)

Net loss available for common shareholders per share - basic and diluted	$ (0.03)	(0.03)	$ (0.08)	$ (0.09)
Weighted average common shares outstanding – basic and diluted	215,179,949	198,909,016	208,130,431	196,070,952
Other comprehensive (loss)/income, net of tax				
Unrealized (loss)/gains on securities available-for-sale	(52,837)	(114,159)	(229,766)	367,144
Reclassification to net loss	-	-	-	(2,719)
Other comprehensive (loss)/income, net of tax	(52,837)	(114,159)	(229,766)	364,425
Comprehensive loss attributable to stockholders	$ (6,889,387)	$ (5,563,672)	$ (16,813,741)	$ (15,741,533)

The accompanying notes are an integral part of these condensed consolidated financial statements

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.