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):
August 10, 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 August 10, 2021, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 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 August 10, 2021.

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: August 10, 2021

By: */s/ Jerome D. Jabbour*
Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Reports Second Quarter 2021 Financial Results and Operational Highlights

– Enrollment complete in second cohort of EnACT study of MAT2203 (oral amphotericin B) in cryptococcal meningitis; Data and Safety Monitoring Board (DSMB) review of safety and efficacy data from second cohort anticipated September 2021 –

– Positive recent FDA feedback on MAT2501 (oral amikacin) development program allows for initiation of Phase 1 study in healthy volunteers in Q4 2021 –

– 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 –

– Management to host conference call today, Tuesday, August 10th, at 8:00 a.m. ET –

BEDMINSTER, N.J., August 10, 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 second quarter ended June 30, 2021, along with a corporate update.

Second Quarter Highlights and Looking Ahead

- Completed patient enrollment in Cohort 2 of the EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*); DSMB evaluation of available safety and efficacy data from Cohort 2 expected in September 2021. The Company plans to announce efficacy and safety data from the first two cohorts of EnACT together with Dr. David Boulware, Principal Investigator, following the DSMB evaluation.

- Following the EnACT data announcement, the Company plans to meet with the U.S. Food and Drug Administration (FDA) in the fourth quarter of 2021 to discuss the potential for approval of MAT2203 under one or more accelerated regulatory pathways for important anti-infective medicines that address significant unmet medical needs in small or vulnerable patient populations.

- The Company expects to initiate a Phase 1 single ascending dose (SAD) pharmacokinetic study of MAT2501 in healthy volunteers in the fourth quarter of 2021. 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).

- The Company and NIAID have successfully completed *in vitro* studies of various LNC formulations of Gilead's antiviral drug remdesivir. Selected LNC-remdesivir formulations were tested for antiviral activity against SARS-CoV2 WA strain in Caco-2 cells. Unformulated remdesivir active (GS-5734, in DMSO) was tested as a comparison. LNC formulations tested in this model demonstrated meaningful antiviral activity compared to free remdesivir, with a favorable toxicity profile. Based on these results, NIAID is preparing to initiate an *in vivo* efficacy study of the most potent LNC-remdesivir formulation. Results are expected in the fourth quarter of 2021.

"We are very excited to have provided an in-depth look at our LNC platform during our R&D Day in June. We believe that our platform has the potential to become the next generation in safe and effective intracellular drug delivery," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "We have made great progress with MAT2203 and MAT2501, both of which represent large potential commercial opportunities for Matinas. Completion of Cohort 2 of EnACT provides an important milestone and further validation for our LNC platform. In addition to potentially demonstrating that MAT2203 can be a safe and effective step-down oral therapy for patients with cryptococcal meningitis, we believe that the data from Cohort 2 will support a key regulatory interaction later in 2021 for a potential early registration pathway for MAT2203 as step-down therapy for patients suffering from cryptococcal meningitis. In addition, recent positive feedback from the FDA on our ongoing preclinical program with MAT2501 now positions us to initiate the Phase 1 SAD study for MAT2501 in the fourth quarter of 2021."

"Finally, we are extremely pleased with the positive *in vitro* data that we have reviewed from NIAID with our LNC-remdesivir formulations," continued Mr. Jabbour. "The success of our LNC platform *in vitro* has provided further evidence that our LNC platform can be utilized to orally administer drugs currently otherwise limited to intravenous delivery. An oral version of Gilead's remdesivir could become an essential tool in the fight against COVID-19, as it may permit administration earlier in the disease course as well as potential for prophylactic use, should clinical studies validate such an approach. We are honored to continue to partner with NIAID on this important project and look forward to additional *in vivo* data later in 2021."

Second Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2021, were approximately $59.8 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 operations into 2024.

For the second quarter of 2021, net loss attributable to common shareholders was $5.0 million, or a net loss of $0.02 per share (basic and diluted), compared to a net loss

attributable to common shareholders of $5.8 million, or a net loss of $0.03 per share (basic and diluted), for the same period in 2020. The decrease was due primarily to a reduction in research and development expenses, as more fully described below.

Research and development expenses for the second quarter of 2021 were $2.5 million, compared to $3.4 million for the same period in 2020. The decrease was primarily due to the completion of the ENHANCE-IT study of LYPDISO in January 2021.

General and administrative expenses for the second quarter of 2021 were $2.3 million, essentially unchanged compared to $2.4 million in the same period in 2020.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Tuesday, August 10, 2021, at 8:00 a.m. ET.

To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13720567. 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 is nearing the completion of enrollment of its second cohort of patients, with the next DSMB evaluation of safety and efficacy data anticipated to occur in September 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.

Matinas BioPharma Holdings Inc.
Condensed Consolidated Balance Sheets

	June 30, 2021 (Unaudited)	December 31, 2020 (Audited)
ASSETS:		

Current assets:		
Cash and cash equivalents	$ 30,352,359	$ 12,432,481
Marketable securities	29,490,430	46,246,573
Restricted cash - security deposits	136,000	136,000
Prepaid expenses and other current assets	960,422	2,739,791
Total current assets	60,939,211	61,554,845
Non-current assets:		
Leasehold improvements and equipment - net	1,406,748	1,523,950
Operating lease right-of-use assets - net	3,034,155	3,276,639
Finance lease right-of-use assets - net	37,350	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	9,032,118	9,412,461
Total assets	$ 69,971,329	$ 70,967,306
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 450,461	$ 349,941
Accrued expenses	2,762,736	2,795,329
Operating lease liabilities - current	351,257	391,498
Financing lease liabilities - current	26,870	30,853
Total current liabilities	3,591,324	3,567,621
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,123,482	3,304,063
Financing lease liabilities - net of current portion	11,508	23,660
Total non-current liabilities	3,476,255	3,668,988
Total liabilities	7,067,579	7,236,609
Stockholders' equity:		
Series B Convertible preferred stock	-	3,797,705
Common stock	21,462	20,010
Additional paid-in capital	180,929,263	167,192,003
Accumulated deficit	(118,098,218)	(107,507,193)
Accumulated other comprehensive income	51,243	228,172
Total stockholders' equity	62,903,750	63,730,697
Total liabilities and stockholders' equity	$ 69,971,329	$ 70,967,306

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	**2020**	**2021**	**2020**
Revenue:				
Research and development	$ -	$ -	$ 33,333	$ -
Costs and expenses:				
Research and development	2,480,764	3,410,237	5,722,196	7,497,120
General and administrative	2,308,926	2,356,310	5,453,936	4,615,941
Total costs and expenses	4,789,690	5,766,547	11,176,132	12,113,061
Loss from operations	(4,789,690)	(5,766,547)	(11,142,799)	(12,113,061)
Sale of New Jersey net operating loss & tax credits	-	-	1,328,470	1,073,289
Other income, net	(1,415)	156,000	66,904	383,327
Net loss	$ (4,791,105)	$ (5,610,547)	$ (9,747,425)	$ (10,656,445)
Preferred stock series B accumulated dividends	(184,899)	(177,092)	(395,799)	(347,792)
Net loss attributable to common shareholders	$ (4,976,004)	(5,787,639)	$ (10,143,224)	$ (11,004,237)
Net loss available for common shareholders per share - basic and diluted	$ (0.02)	(0.03)	$ (0.05)	$ (0.06)

Weighted average common shares outstanding - basic and diluted	205,215,259	197,601,500	204,547,251	194,636,326
Other comprehensive (loss)/income, net of tax				
Unrealized (loss)/gains on securities available-for-sale	(85,163)	(41,954)	(176,929)	481,303
Reclassification to net loss	-	(2,708)	-	(2,719)
Other comprehensive (loss)/income, net of tax	(85,163)	(44,662)	(176,929)	478,584
Comprehensive loss attributable to stockholders	$ (4,876,268)	$ (5,655,209)	$ (9,924,354)	$ (10,177,861)

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.