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 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 May 10, 2021, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 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 May 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: May 10, 2021

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

Exhibit 99.1

Matinas BioPharma Reports First Quarter 2021 Financial Results and Operational Highlights

– Enrollment continues in second cohort of EnACT study of MAT2203 (oral amphotericin b) in cryptococcal meningitis; Data and Safety Monitoring Board (DSMB) evaluation of safety and efficacy data from second cohort anticipated Q3 2021 –

– MAT2501 (oral amikacin) advanced into preclinical toxicology and efficacy studies; completion of Phase 1 SAD study in healthy volunteers anticipated by end of 2021 –

– Matinas to host virtual R&D Day on June 17, 2021 to highlight LNC platform and related programs –

– Data from ENHANCE-IT study of LYPDISO™ against Vascepa® reported in Q1 2021 support continued development of LYPDISO as a potential best-in-class prescription-only omega-3 for cardiovascular risk reduction; partnership process ongoing –

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

BEDMINSTER, N.J., May 10, 2021 – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a biopharmaceutical company focused on improving the intracellular delivery of critical therapeutics through its paradigm-changing lipid nanocrystal (LNC) delivery platform, today reported financial results for the first quarter ended March 31, 2021, along with a corporate update.

First Quarter Highlights and Looking Ahead

- Patient enrollment in Cohort Two of the EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) has reached approximately 70 percent; DSMB evaluation of full safety and efficacy data from Cohort Two is anticipated in the third quarter of 2021.
- The Company has advanced MAT2501 into preclinical toxicology and efficacy studies, with the goal of completing a Phase 1 single ascending dose (SAD) pharmacokinetic study in healthy volunteers by the end of 2021. The Company expects to initiate a Phase 2 program in cystic fibrosis patients with nontuberculous mycobacterial infections in 2022 following successful completion of the Phase 1 SAD study.
- Following the announcement of its collaboration with the National Institutes of Allergy and Infectious Disease (NIAID) in December 2020 to create and evaluate oral formulations of Gilead's antiviral remdesivir, the Company recently prepared and delivered several formulations to NIAID and expects to receive data from the first *in vitro* studies in the near term.

- The Company is pleased to announce that it will hold a virtual R&D Day on June 17, 2021. The management team plans to provide an overview of the Company's LNC platform, including a detailed discussion on the platform's clinical programs.
- The process of identifying and securing one or more partners for LYPDISO is ongoing, with interested parties globally, including in the United States, European Union and China.

"We are excited by the opportunities ahead for our LNC platform and associated drug candidates, and have made meaningful progress since the beginning of 2021," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "Specifically, we continue to advance MAT2203 in cryptococcal meningitis through Cohort 2 of the EnACT trial towards its next DSMB review, which is anticipated in the third quarter of 2021. We believe that Cohort 2 data will further validate the LNC platform and highlight its ability to facilitate oral bioavailability and carry molecules safely and effectively across the blood-brain barrier in combating this deadly invasive fungal infection. We will also take the opportunity to present these data to the U.S. Food and Drug Administration in discussions about further accelerating development of MAT2203. In addition, we have advanced MAT2501 into preclinical toxicology and efficacy studies, with the goal of developing the first oral aminoglycoside for the treatment of nontuberculous mycobacterial infections, as well as gram negative bacterial infections. Finally, we continue to expand the application of the LNC platform with our collaborations with Genentech and with the NIAID in creating an oral formulation of Gilead's remdesivir."

First Quarter 2021 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2021, were approximately $60.7 million, compared to $58.7 million at December 31, 2020.

In July 2020, the Company entered into an At-The-Market Sales Agreement (Sales Agreement) with BTIG, LLC (BTIG), pursuant to which the Company may offer and sell, from time to time, through BTIG, shares of its common stock having an aggregate offering price of up to $50 million, subject to certain limitations on the amount of common stock that may be offered and sold by the Company set forth in the Sales Agreement. During the first quarter of 2021, BTIG sold approximately 3 million shares of the Company's common stock under the Sales Agreement generating net proceeds to the Company of approximately $5.6 million.

Based on current projections, the Company believes that cash on hand is sufficient to fund operations into 2024.

For the first quarter of 2021, net loss attributable to common shareholders was $5.2 million, or a net loss of $0.03 per share (basic and diluted). These results are identical to

those of the first quarter of 2020.

Research and development expenses for the first quarter of 2021 were $3.2 million, compared to $4.1 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 first quarter of 2021 were $3.1 million, compared to $2.3 million in the same period in 2020. The increase was primarily due to higher compensation expense related to the exercise of stock options during the first quarter of 2021.

*Vascepa® is a registered trademark of the Amarin group of companies.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Monday, May 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 13719092. 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 proprietary lipid nanocrystal (LNC) delivery platform. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

Matinas is developing a portfolio of products based upon its proprietary LNC drug delivery platform, which can solve complex challenges relating to the safe and effective intracellular delivery of both small and larger, more complex molecules.

MAT2203 is an oral, LNC formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, primarily used to treat serious 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 currently enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the third quarter of 2021.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic medicine amikacin, primarily used to treat chronic and acute bacterial infections. The Company has been awarded up to $3.75 million from the Cystic Fibrosis Foundation (CFF) to support development of MAT2501 toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

Each of MAT2203 and MAT2501 has received Qualified Infectious Disease Product (QIDP) and Orphan Drug designations which, upon approval, could potentially provide up to twelve years of regulatory marketing exclusivity for each product.

LYPDISO™, the Company's product candidate intended for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, recently announced data from the ENHANCE-IT study, a head-to-head crossover study evaluating LYPDISO vs. Vascepa in patients with elevated triglycerides. Data demonstrating superior levels of eicosapentaenoic acid (EPA) in the blood with LYPDISO support the potential superior cardioprotective effect of LYPDISO vs. Vascepa. The Company has initiated a process to identity and secure a potential partner to continue development of LYPDISO toward a cardiovascular outcomes indication.

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 and LYPDISO, 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

	March 31, 2021 (Unaudited)	December 31, 2020 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 23,382,743	$ 12,432,481
Marketable securities	37,283,697	46,246,573
Restricted cash - security deposits	136,000	136,000
Prepaid expenses and other current assets	2,333,225	2,739,791
Total current assets	63,135,665	61,554,845
Non-current assets:		
Leasehold improvements and equipment - net	1,465,303	1,523,950
Operating lease right-of-use assets - net	3,149,744	3,276,639
Finance lease right-of-use assets - net	45,992	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	9,214,904	9,412,461
Total assets	$ 72,350,569	$ 70,967,306
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 421,645	$ 349,941
Accrued expenses	1,405,745	2,795,329
Operating lease liabilities - current	364,566	391,498
Financing lease liabilities - current	29,396	30,853
Total current liabilities	2,221,352	3,567,621
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,214,714	3,304,063
Financing lease liabilities - net of current portion	17,134	23,660
Total non-current liabilities	3,573,113	3,668,988
Total liabilities	5,794,465	7,236,609
Stockholders' equity:		
Series B Convertible preferred stock	3,673,176	3,797,705
Common stock	20,427	20,010
Additional paid-in capital	175,189,608	167,192,003
Accumulated deficit	(112,463,513)	(107,507,193)
Accumulated other comprehensive income/(loss)	136,406	228,172
Total stockholders' equity	66,556,104	63,730,697
Total liabilities and stockholders' equity	$ 72,350,569	$ 70,967,306

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

	Three Months Ended March 31,	
	2021	**2020**
Revenue:		
Contract research revenue	$ 33,333	$ -
Costs and expenses:		
Research and development	3,241,432	4,086,883
General and administrative	3,145,010	2,259,631
Total costs and expenses	6,386,442	6,346,514
Loss from operations	(6,353,109)	(6,346,514)
Sale of New Jersey net operating loss	1,328,470	1,073,289
Other income, net	68,319	227,327
Net loss	$ (4,956,320)	$ (5,045,898)
Preferred stock series B accumulated dividends	(210,900)	(170,700)
Net loss attributable to common shareholders	$ (5,167,220)	$ (5,216,598)
Net loss available for common shareholders per share - basic and diluted	$ (0.03)	$ (0.03)
Weighted average common shares outstanding - basic and diluted	203,871,820	191,671,153
Other comprehensive (loss)/income, net of tax		
Unrealized (loss)/gains on securities available-for-sale	(91,766)	523,246
Other comprehensive (loss)/income, net of tax	(91,766)	523,246
Comprehensive loss attributable to stockholders	$ (5,048,086)	$ (4,522,652)

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.