

**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): March 29, 2021

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) 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 March 29, 2021, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the year and quarter ended December 31, 2020. 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 March 29, 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: March 29, 2021

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



Matinas BioPharma Reports Fourth Quarter and Full Year 2020 Financial Results and Operational Highlights

– Matinas to internally focus on its Lipid Nanocrystal (LNC) platform to improve the intracellular delivery of critical therapeutics –

- Enrollment continues in second patient cohort of EnACT study of MAT2203 in cryptococcal meningitis; Data and Safety Monitoring Board (DSMB) evaluation of safety and efficacy data of key second patient cohort anticipated Q3 2021 –
- Collaboration with National Institute of Allergy and Infectious Disease (NIAID) to formulate Gilead's antiviral COVID-19 medication remdesivir has progressed into in vitro studies –
- Data from ENHANCE-IT study of LYPDISO™ against Vascepa® support continued development of LYPDISO as a potential best-in-class prescription-only omega-3 with robust EPA-levels; partnership process ongoing –

– Management to host conference call today, Monday, March 29th, at 8:00 a.m. ET –

BEDMINSTER, N.J., March 29, 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 fourth quarter and full year ended December 31, 2020, along with a corporate update.

“2020 was a year of significant progress and timely execution for Matinas, despite the ongoing global pandemic. The completion of the head-to-head ENHANCE-IT trial of LYPDISO vs. Vascepa® and the results which support the potential for LYPDISO to demonstrate a superior cardioprotective effect to Vascepa®, have positioned us to identify and potentially secure a global partner for the continued development of this promising, next-generation drug,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “This process provides us the opportunity, as we move forward, to re-focus our internal expertise and financial resources on our LNC platform delivery technology. We believe that the unique capability of our LNC formulations to mimic enveloped viruses and efficiently deliver small and large molecules intracellularly without causing adverse immune responses or damage to cellular membranes, differentiates our technology from any other available intracellular delivery technology being applied today.”



Mr. Jabbour continued, “There are three key areas which highlight tangible progress with the LNC platform. First, DSMB review and cohort progression in the EnACT study of MAT2203 in cryptococcal meningitis is anticipated in the third quarter of 2021 and provides a near-term opportunity to further validate the LNC platform and highlight its ability to facilitate oral bioavailability and then carry molecules effectively across the blood-brain barrier in combating deadly invasive fungal infections. Second, with the support of the Cystic Fibrosis Foundation, we are rapidly advancing our second LNC platform drug, MAT2501 (oral amikacin), into preclinical toxicology and efficacy studies with the ultimate 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 make important progress in expanding the utilization of the LNC platform through our collaborations with Genentech and with NIAID in creating an oral formulation of Gilead's remdesivir. We are also evaluating additional opportunities to expand application of our LNC platform in other innovative areas, such as mRNA and gene therapy. 2021 will be an exciting and potentially transformational year for our Company, and we look forward to continuing to execute on our corporate strategy and keeping investors informed as to our progress.”

MAT2203 Program Update (orally bioavailable amphotericin B, with targeted delivery, under development for the treatment and prevention of invasive fungal infections, including cryptococcal meningitis)

- Data from the Phase 1 portion of the EnACT study were published in the *Antimicrobial Agents and Chemotherapy*, (ACC), a journal of the American Society of Microbiology, in a manuscript entitled “Safety and tolerability of a novel oral formulation of amphotericin B: Phase I EnACT trial”. In the published manuscript, trial investigators concluded that MAT2203 was well-tolerated when administered in 4-6 divided daily doses without the toxicities commonly seen with IV amphotericin B, with nearly 100% of patients expressing a preference for oral MAT2203 relative to amphotericin B delivered intravenously.
- In October 2020, the Company announced that the independent DSMB of the EnACT study completed a pre-specified review of the first cohort and unanimously recommended progression to the second cohort.
- We have recently reached 50 percent of patient enrollment (28/56) in Cohort Two of the EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*); DSMB evaluation of full safety and efficacy data from Cohort Two is anticipated in the third quarter of 2021.
- As previously reported, the U.S. Food and Drug Administration (FDA) has designated MAT2203 as a Qualified Infectious Disease Product (QIDP) with Fast Track status for four indications, specifically, the prevention of invasive fungal infections due to immunosuppressive therapy, and the treatment of invasive candidiasis, invasive aspergillus and cryptococcal meningitis. In addition, the FDA has granted orphan drug designation to MAT2203 for the treatment of cryptococcosis. If MAT2203 is ultimately approved by the FDA, the seven-year period of marketing exclusivity from orphan designation combined with the additional five years of marketing exclusivity provided by the QIDP designation, provides for a potential total of 12 years of marketing exclusivity.



EnACT is a Phase 2 prospective, randomized, open-label, sequential cohort study, financially supported by the National Institutes of Health (NIH), evaluating the safety, tolerability and efficacy of MAT2203 in approximately 140 HIV-infected patients with cryptococcal meningitis. MAT2203 utilizes the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B. In total, the trial includes four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The primary efficacy endpoint includes a measure of reduction in fungal count in the cerebral spinal fluid. A control arm, which includes standard of care IV amphotericin B, is included with each cohort.

MAT2501 Program Update (*orally bioavailable amikacin, with targeted delivery, under development for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF)*)

- In November 2020, the Company received a commitment for \$3.75 million of funding from the Cystic Fibrosis Foundation (CFF) to support preclinical development of MAT2501 toward an indication to treat NTM lung disease, including infections in patients with CF.
- The Company is progressing development of MAT2501 through preclinical toxicology and efficacy studies in 2021, with the goal of completing a Phase 1 single ascending dose pharmacokinetic study in healthy volunteers by the end of 2021.
- MAT2501 has been designated as a QIDP and as an Orphan Drug for the treatment of NTM by the FDA. If MAT2501 is ultimately approved by the FDA, the seven-year period of marketing exclusivity from orphan designation combined with the additional five years of marketing exclusivity provided by the QIDP designation, provides for a potential total of 12 years of marketing exclusivity.

LNC Platform Update

- The Company's feasibility agreement with Genentech, which involves the formulation of up to three different Genentech compounds, was extended for an additional two years in November of 2020.
- In December 2020, the Company announced a collaboration with the NIAID to evaluate oral formulations of Gilead's antiviral remdesivir utilizing Matinas' LNC platform delivery technology. The Company recently prepared and delivered several formulations to NIAID, which will commence planned preclinical studies promptly.



LYPDISO™ Program Update (*next generation, prescription-only omega-3 fatty acid-based composition under development for treatment of cardiovascular and metabolic conditions, including hypertriglyceridemia*)

- In February 2021, the Company announced topline results from ENHANCE-IT (*Pharmacodynamic Effects of a Free-fatty Acid Formulation of Omega-3 Pentaenoic Acids to ENHANCE Efficacy in Adults with Hypertriglyceridemia*), a second head-to-head comparative study of LYPDISO vs. Vascepa®. The study assessed LYPDISO's effectiveness in reducing triglyceride levels and other important lipid markers, as well as characterizing bioavailability and blood levels of eicosapentaenoic acid (EPA) and other omega-3 fatty acids. While the primary endpoint of percent change in triglycerides (TGs) from baseline to end-of-treatment did not meet statistical significance in the pre-specified pharmacodynamic population, analysis of the per protocol population demonstrated statistically significant improvement and superiority of LYPDISO over Vascepa® in reducing TGs, total cholesterol and very-low-density lipoprotein cholesterol. A key secondary endpoint in ENHANCE-IT was the measurement of EPA levels in the blood, as that has become a key surrogate marker in determining cardiovascular risk reduction. In ENHANCE-IT, plasma EPA concentrations were significantly higher with LYPDISO vs. Vascepa® (46% relative percent increase in the change from baseline EPA level vs. Vascepa®), which the Company believes indicates the potential for superior cardioprotection with LYPDISO vs. Vascepa®.
- The Company believes that the results from ENHANCE-IT suggest potential for LYPDISO as a best-in-class prescription-only omega-3 drug for cardiovascular risk reduction and is pursuing a partnership to continue further development of LYPDISO toward a cardiovascular outcomes indication. Accordingly, the Company no longer plans to pursue an indication for the treatment of severe hypertriglyceridemia.

Fourth Quarter and Full Year 2020 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2020 were approximately \$58.7 million, compared to \$27.8 million at December 31, 2019.

In January 2020, the Company sold an aggregate of 32.3 million shares of its common stock at a price of \$1.55 per share for net proceeds of approximately \$46.7 million, after deducting underwriting discounts and commissions and other offering expenses.



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. As of December 31, 2020, the Company did not sell any shares of its common stock under the Sales Agreement. During January 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, including net proceeds from issuances under the Sales Agreement in January 2021, is sufficient to fund operations into 2024.

For the fourth quarter of 2020, net loss attributable to common shareholders was \$6.6 million, or a net loss of \$0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of \$5.8 million, or a net loss of \$0.04 per share (basic and diluted) for the same period in 2019. For the full year of 2020, net loss attributable to common shareholders was \$23.2 million, or a net loss per share of \$0.12 (basic and diluted), compared to a net loss attributable to common shareholders of \$18.3 million, or a net loss per share of \$0.13 (basic and diluted) for the full year of 2019. The increase for both periods was due primarily to an increase in operating expenses, as more fully described below.

Research and development (R&D) expenses for the fourth quarter of 2020 were \$3.5 million, compared to \$3.4 million for the same period in 2019. For the full year of 2020, R&D expenses were \$14.4 million, compared to \$11.2 million for the full year of 2019. The increase for full year 2020 was due primarily to higher preclinical and clinical development expenses and employee compensation related to the development of LYPDISO, MAT2203 and MAT2501.

General and administrative (G&A) expenses for the fourth quarter of 2020 were \$3.0 million, compared to \$2.3 million in the same period in 2019. For the full year of 2020, G&A expenses were \$10.0 million, compared to \$7.8 million for the full year of 2019. The increase was due primarily to employee related expenses and professional fees.

*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 on Monday, March 29, 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 13716272. 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. 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).

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 identify 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.
Consolidated Balance Sheets**

	December 31,	
	2020	2019
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 12,432,481	\$ 22,170,438
Marketable securities	46,246,573	5,604,634
Restricted cash	136,000	250,000
Prepaid expenses and other current assets	2,739,791	1,897,784
Total current assets	<u>61,554,845</u>	<u>29,922,856</u>
Non-current assets:		
Leasehold improvements and equipment - net	1,523,950	1,749,259
Operating lease right-of-use assets - net	3,276,639	3,761,207
Finance lease right-of-use assets - net	58,007	116,968
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	200,000	336,000
Total non-current assets	<u>9,412,461</u>	<u>10,317,299</u>
Total assets	<u>\$ 70,967,306</u>	<u>\$ 40,240,155</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 349,941	\$ 679,310
Accrued expenses and other liabilities	2,795,329	1,939,510
Operating lease liabilities - current	391,498	423,741
Financing lease liabilities - current	30,853	54,673
Total current liabilities	<u>3,567,621</u>	<u>3,097,234</u>
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,304,063	3,695,561
Financing lease liabilities - net of current portion	23,660	54,513
Total non-current liabilities	<u>3,668,988</u>	<u>4,091,339</u>
Total liabilities	7,236,609	7,188,573
Stockholders' equity:		
Series B Convertible preferred stock, stated value \$1,000 per share, 8,000 shares authorized as of December 31, 2020 and 2019, respectively; 4,361 and 4,577 shares issued and outstanding as of December 31, 2020 and 2019, respectively; (liquidation preference - \$4,361,000 at December 31, 2020)	3,797,705	3,985,805
Common stock par value \$0.0001 per share, 500,000,000 shares authorized at December 31, 2020 and 2019, respectively; 200,113,431 and 163,156,984 issued and outstanding as of December 31, 2020 and 2019, respectively	20,010	16,315
Additional paid-in capital	167,192,003	113,427,897
Accumulated deficit	(107,507,193)	(84,377,555)
Accumulated other comprehensive income/(loss)	228,172	(880)
Total stockholders' equity	<u>63,730,697</u>	<u>33,051,582</u>
Total liabilities and stockholders' equity	<u>\$ 70,967,306</u>	<u>\$ 40,240,155</u>



**Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss**

	Three Months Ended December 31,		For the Year Ended December 31,	
	2020	2019	2020	2019
Revenue:				
Contract research revenue	\$ 62,500	\$ -	\$ 158,333	\$ 89,812
Costs and expenses:				
Research and development	3,525,573	3,419,706	14,358,918	11,234,548
General and administrative	3,025,812	2,316,277	10,005,967	7,776,300

Total costs and expenses	<u>6,551,385</u>	<u>5,735,983</u>	<u>24,364,885</u>	<u>19,010,848</u>
Loss from operations	(6,488,885)	(5,735,983)	(24,206,552)	(18,921,036)
Sale of New Jersey net operating loss	-	-	1,073,289	1,007,082
Other income, net	148,005	163,152	686,425	541,303
Net loss	<u>\$ (6,340,880)</u>	<u>\$ (5,572,831)</u>	<u>\$ (22,446,838)</u>	<u>\$ (17,372,651)</u>
Preferred stock series A accumulated dividends	-	-	-	(338,613)
Preferred stock series B accumulated dividends	<u>(218,050)</u>	<u>(236,047)</u>	<u>(793,442)</u>	<u>(585,547)</u>
Net loss attributable to common shareholders	<u>\$ (6,558,930)</u>	<u>\$ (5,808,878)</u>	<u>\$ (23,240,280)</u>	<u>\$ (18,296,811)</u>
Net loss available for common shareholders per share - basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>	<u>\$ (0.12)</u>	<u>\$ (0.13)</u>
Weighted average common shares outstanding - basic and diluted	<u>199,347,750</u>	<u>162,791,879</u>	<u>196,894,628</u>	<u>145,195,196</u>
Other comprehensive (loss)/income, net of tax				
Net unrealized (loss)/gain on securities available-for-sale	(129,596)	(880)	237,537	(880)
Reclassification of realize gain on securities available-for-sale to net loss	<u>(5,777)</u>	<u>-</u>	<u>(8,485)</u>	<u>-</u>
Other comprehensive (loss)/income, net of tax	<u>(135,373)</u>	<u>(880)</u>	<u>229,052</u>	<u>(880)</u>
Comprehensive loss attributable to stockholders	<u>\$ (6,476,253)</u>	<u>\$ (5,573,711)</u>	<u>\$ (22,217,786)</u>	<u>\$ (17,373,531)</u>

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.