
**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 9, 2020

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))

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.

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

Item 2.02. Results of Operations and Financial Condition.

On March 9, 2020, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release announcing its financial results for the year and quarter ended December 31, 2019. 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated March 9, 2020.

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 9, 2020

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



**Matinas BioPharma Reports Fourth Quarter and Full Year 2019
Financial Results and Operational Highlights**

- Initiated ENHANCE-IT study of MAT9001 against Vascepa[®]. Topline data expected Q4 2020 –
- Initiated efficacy phase of NIH-funded EnACT study of MAT2203 in cryptococcal meningitis Q1 2020 –
- Management to host conference call today, Monday, March 9th, at 8:00 a.m. ET –

BEDMINSTER, N.J., March 9, 2020 (GLOBE NEWSWIRE) --Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today reported financial results for the fourth quarter and full year ended December 31, 2019, along with a corporate update and outlook for 2020.

“2019 was a year of significant operational progress for Matinas and we are very excited to have advanced both of our clinical stage assets, MAT9001 and MAT2203, into key efficacy trials early in 2020,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “ENHANCE-IT represents a significant opportunity to once again highlight the superior profile of MAT9001 against the leading therapy in the prescription omega-3 space. We are also enthusiastic about the EnACT study of MAT2203 in patients with cryptococcal meningitis. The potential to effectively and safely deliver amphotericin B orally while crossing the blood brain barrier utilizing our LNC platform delivery technology could be an important breakthrough for patients and physicians. Importantly, the timelines to impactful data from these studies are relatively compressed. We expect topline data from ENHANCE-IT in the fourth quarter of this year and should be in position to announce cohort progression in the EnACT trial as soon as the second quarter of this year.”

Mr. Jabbour added, “We have also taken meaningful steps to financially strengthen our Company well in advance of major potential value-creating clinical milestones for our lead assets. We capitalized on expressed interest from well-regarded current and new institutional investors, and successfully completed a transformational financing earlier this year which extends our cash runway into the second half of 2022. As a result, we can now focus exclusively on execution as we continue to advance our product candidates.”

MAT9001 Program Update (*next generation, prescription-only omega-3 fatty acid-based composition under development for treatment of cardiovascular or metabolic conditions, including hypertriglyceridemia*)

- Initiated 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 MAT9001 vs. Vascepa in the first quarter of 2020, and remain on track to announce topline data in the fourth quarter of 2020.
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- Pre-screened approximately 175 patients for ENHANCE-IT across eight clinical trial centers in the United States.
- Completed the clinical dosing for a comparative clinical bridging bioavailability study and the in-life portion of a 90-day comparative toxicology study in the first quarter of 2020. Each of these studies was conducted in support of a planned 505(b)(2) registration pathway. The Company anticipates holding an End-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in the third quarter of 2020 to discuss these data as well as the protocol for a Phase 3 registration trial of MAT9001 in patients with severe hypertriglyceridemia.

ENHANCE-IT is an open-label, randomized, 28-day crossover study to assess the pharmacodynamic (PD) effects of MAT9001 vs. Vascepa. The study will enroll approximately 100 adult men and women with elevated triglycerides (150-499 mg/dL), with at least 50% of study subjects with TGs \geq 200 mg/dL. The study will consist of two 28-day treatment periods, with a washout period of at least 28-days in-between treatments and will be conducted at approximately eight sites in the United States. MAT9001 and Vascepa will each be administered twice daily with food in accordance with currently approved Vascepa labeling. Measurements of lipid parameters (triglycerides, Total-, LDL-, VLDL-, HDL-, and non-HDL cholesterol, apolipoproteins A1, B and C3, and PCSK9) and omega-3 blood levels will be obtained at each baseline and at the end of each treatment period. The primary endpoint is the percent change from baseline to end-of-treatment in plasma triglycerides.

MAT2203 and Lipid Nano-Crystal (LNC) Platform Delivery Technology Update*(intracellular delivery of potentially life-saving medicines)*

- In the first quarter of 2020, MAT2203 advanced into the efficacy phase of the EnACT (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) study for the treatment of HIV-infected patients with cryptococcal meningitis, a life-threatening invasive fungal infection most commonly observed in immunocompromised patients.
 - The independent Data Safety Monitoring Board (DSMB) unanimously voted to proceed with dosing in the efficacy phase at 2g/day, the highest dose tested in the dose escalation phase of EnACT.
 - The Company plans to make announcements as to progression from cohort to cohort over the course of 2020, but full data from EnACT will not be available until the second half of 2021.
 - As previously reported, during the fourth quarter of 2019, FDA granted MAT2203 orphan drug designation for the treatment of cryptococcosis. This designation was made in addition to four separate Qualified Infectious Disease Product Designations (QIDP) with Fast Track status for MAT2203 including the treatment of cryptococcosis, the prevention of invasive fungal infections due to immunosuppressive therapy, the treatment of invasive candidiasis and the treatment of invasive aspergillosis. The combination of orphan drug and QIDP designations positions MAT2203 to potentially receive up to 12 years of regulatory exclusivity upon approval.
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- In the fourth quarter of 2019, the Company announced a feasibility evaluation with Genentech, a member of the Roche Group, for the development of oral formulations using Matinas' LNC platform delivery technology. This is the third agreement with a large biopharmaceutical company pairing the Company's LNC platform delivery technology with difficult-to-deliver molecules.

EnACT is an open-label, sequential cohort study of approximately 100 patients, financially supported by the National Institutes of Health (NIH), utilizing the Company's LNC platform delivery technology to orally deliver the traditionally IV-only fungicidal drug, amphotericin B. The part 2 efficacy phase is a prospective randomized trial evaluating the safety, tolerability and efficacy of MAT2203 in HIV-infected patients with cryptococcal meningitis, compared to treatment with standard IV-administered amphotericin B as induction therapy, followed by maintenance treatment with MAT2203. The induction period for all patients will be 14 days, followed by an additional 4 weeks of treatment with MAT2203 during the maintenance period. In total, there will be four cohorts of patients, with each cohort increasing the treatment duration of MAT2203 vs. IV amphotericin B. The first cohort of 10 patients will be administered IV amphotericin for the first five days of the induction period, followed by nine days of oral administration of MAT2203. The primary efficacy endpoint will be measured at Day 14, the last day of the induction period and will include a measure of reduction in fungal count in the cerebral spinal fluid. The independent DSMB will review all data for safety and efficacy and make the recommendation to proceed to the next cohort of patients.

Fourth Quarter and Full Year 2019 Financial Results

Cash, cash equivalents and marketable securities at December 31, 2019 were approximately \$27.8 million, compared to \$12.4 million at December 31, 2018. In January 2020, the Company completed a follow-on financing and sold an aggregate of 32,260,000 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. Based on current projections, the Company believes that cash on hand is sufficient to fund operations into the second half of 2022.

For the fourth quarter of 2019, net loss attributable to common shareholders was \$5.8 million, or a net loss per share of \$0.04 (basic and diluted), compared to a net loss attributable to common shareholders of \$3.9 million, or a net loss per share of \$0.04 (basic and diluted) for the same period in 2018. For the full year of 2019, net loss attributable to common shareholders was \$18.3 million, or a net loss per share of \$0.13 (basic and diluted), compared to a net loss attributable to common shareholders of \$15.0 million, or a net loss per share of \$0.15 (basic and diluted) for the full year of 2018. The increases for both periods were due primarily to an increase in research and development expenses.

Research and development (R&D) expenses for the fourth quarter of 2019 were \$3.4 million, compared to \$1.7 million for the same period in 2018. For the full year of 2019, R&D expenses were \$11.2 million, compared to \$6.8 million for the full year of 2018. The increases for both the three-month and 12-month periods were due primarily to higher preclinical and clinical development expenses, employee compensation and manufacturing process development costs related to the development of MAT9001 and MAT2203.

General and administrative (G&A) expenses for the fourth quarter of 2019 were \$2.3 million, compared to \$2.5 million in the same period in 2018. For the full year of 2019, G&A expenses were \$7.8 million, compared to \$8.0 million for the full year of 2018. The slight decreases for both the three-month and 12-month periods were due primarily to decreased employee compensation expense.

*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 9, 2020 at 8:00 a.m. ET.

To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The [livewebcast](#) will be available on the [Events](#) page of the [Investors](#) section of the Company's website (www.matinasbiopharma.com) and archived for 60 days

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on development of its lead product candidate, MAT9001, for the treatment of cardiovascular and metabolic conditions. MAT9001 is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia, that was specifically designed to overcome the shortcomings seen from other agents in the omega-3 class. Company leadership has a deep history and knowledge of cardiovascular drug development and is supported by a world-class team of scientific advisors.

In addition, the Company is developing MAT2203, an oral, encochleated formulation of amphotericin B, to treat serious invasive fungal infections. The drug is based on the Company's proprietary lipid nano-crystal (LNC) platform delivery technology, which can help solve complex challenges relating to the safe and effective delivery of potent medicines, potentially making them more targeted, less toxic and orally bioavailable.

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 Company’s anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT9001 and MAT2203, 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
(in thousands)

	December 31,	
	2019	2018
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 22,170	\$ 12,447
Marketable securities	5,605	-
Restricted cash	250	100
Prepaid expenses	1,898	538
Total current assets	<u>29,923</u>	<u>13,085</u>
Non-current assets:		
Leasehold improvements and equipment - net	1,750	2,044
Operating lease right-of-use assets - net	3,761	-
Finance lease right-of-use assets - net	117	-
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash - security deposit	336	461
Total non-current assets	<u>10,317</u>	<u>6,858</u>
Total assets	<u>\$ 40,240</u>	<u>\$ 19,943</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 679	\$ 296
Note payable	-	200
Accrued expenses	1,939	1,086
Stock dividends payable	-	1,174
Operating lease liabilities - current	424	-
Financing lease liabilities - current	55	83
Total current liabilities	<u>3,097</u>	<u>2,839</u>
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities - net of current portion	3,696	-
Financing lease liabilities - net of current portion	55	108
Deferred rent liability	-	514
Total non-current liabilities	<u>4,092</u>	<u>963</u>
Total liabilities	<u>7,189</u>	<u>3,802</u>
Stockholders' equity:		
Series A Convertible preferred stock	-	5,583
Series B Convertible preferred stock	3,986	4,197
Common stock	16	11
Additional paid in capital	113,428	72,295
Accumulated deficit	(84,378)	(65,945)
Accumulated other comprehensive loss	(1)	-
Total stockholders' equity	<u>33,051</u>	<u>16,141</u>
Total liabilities and stockholders' equity	<u>\$ 40,240</u>	<u>\$ 19,943</u>



Matinas BioPharma Holdings, Inc.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except per share data)

	Three Months Ended December 31,		For the Year Ended December 31,	
	2019	2018	2019	2018
Revenue:				
Contract research revenue	\$ -	\$ -	\$ 90	\$ 120
Costs and expenses:				
Research and development	3,420	1,692	11,235	6,788
General and administrative	2,316	2,474	7,776	7,979
Total costs and expenses	5,736	4,166	19,011	14,767
Loss from operations	(5,736)	(4,166)	(18,921)	(14,647)
Sale of New Jersey net operating loss	-	-	1,007	-
Other income/(expense), net	163	33	541	57
Benefit for income taxes	-	507	-	507
Net loss	\$ (5,573)	\$ (3,626)	\$ (17,373)	\$ (14,083)
Preferred stock series A accumulated dividends	-	(148)	(339)	(588)
Preferred stock series B accumulated dividends	(236)	(120)	(585)	(317)
Net loss attributable to common shareholders	\$ (5,809)	(3,894)	\$ (18,297)	\$ (14,988)
Net loss available for common shareholders per share - basic and diluted	\$ (0.04)	\$ (0.04)	\$ (0.13)	\$ (0.15)
Weighted average common shares outstanding - basic and diluted	162,791,879	109,995,037	145,195,196	98,103,210

Investor and Media Contact

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