
**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 11, 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
Common Stock

Trading Symbol
MTNB

Name of Each Exchange on Which Registered
NYSE American

Item 2.02. Results of Operations and Financial Condition.

On May 11, 2020, Matinas BioPharma Holdings, Inc. (the “Company”) issued a press release announcing its financial results for the quarter ended March 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 this Current Report on Form 8-K and Exhibits 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 May 11, 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: May 11, 2020

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



Matinas BioPharma Reports First Quarter 2020 Financial Results and Operational Highlights

- *ENHANCE-IT study of MAT9001 against Vascepa® set to resume in June 2020* –
- *EnACT study of MAT2203 in cryptococcal meningitis expected to resume in June 2020* –
- *Management to host conference call today, Monday, May 11th, at 4:30 p.m. ET* –

BEDMINSTER, N.J., May 11, 2020 (GLOBE NEWSWIRE) — Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today reported financial results for the first quarter ended March 31, 2020, along with a corporate update and outlook for 2020.

“During the past few months, our team has worked diligently to adjust to the impacts of the COVID-19 pandemic. We believe we have taken all appropriate and necessary steps to ensure the safety of clinical trial participants and caregivers, to preserve trial integrity and to ensure successful delivery of clinically meaningful data,” commented Jerome D. Jabbour, Chief Executive Officer of Matinas. “We are pleased to announce today that we expect to resume both the ENHANCE-IT study of MAT9001 and the EnACT study of MAT2203 in June of 2020. With these adjusted timelines, we now anticipate announcing cohort progression in EnACT in the second half of this year and topline data from the ENHANCE-IT study in the first quarter of 2021. We believe each of these studies represent important milestones for our Company, and we remain focused on advancing these clinical studies as rapidly and carefully as possible.”

Mr. Jabbour added, “Overall, the COVID-19 pandemic has not had a material impact on our business, and we remain in a strong financial position. Based on current projections, we have sufficient cash resources to fund our operations into the first half of 2023, well beyond potentially clinically meaningful data points for our clinical stage 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*)

- Enrollment in 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, was temporarily paused in the first quarter of 2020. The Company expects to resume enrollment in June of 2020, with topline data available in the first quarter of 2021.
 - In an effort to help mitigate the impact COVID-19 has had on timelines for the ENHANCE-IT trial, the Company has increased the number of clinical trial sites from 6 to 8 in order to facilitate rapid enrollment. In addition, the Company has selected a number of back-up clinical trial sites to reduce the risk for any further disruptions.
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- The Company is actively preparing for an End-of-Phase 2 meeting with the Food and Drug Administration (FDA), which is expected to occur in the third quarter of 2020. Central to this FDA interaction are the recently completed comparative clinical bridging bioavailability study and a 90-day comparative toxicology study to support a 505(b)(2) registration pathway. During this meeting, the Company will also review the protocol for the planned 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 Program Update (*intracellular delivery of potentially life-saving medicines*)

- During the first quarter of 2020, enrollment of new patients into the efficacy phase of the EnACT (*Encocleated Oral Amphotericin for Cryptococcal Meningitis Trial*) study for the treatment of HIV-infected patients with cryptococcal meningitis was temporarily suspended by mandate of the Uganda National Drug Authority due to the COVID-19 pandemic. The two patients who had been enrolled and dosed in the efficacy phase were discontinued and transitioned onto standard of care therapy consistent with established guidelines. These actions were taken to mitigate any potential risk to the integrity of clinical data.
 - Following discussion with the clinical site in Uganda, the Company believes that the EnACT study will resume in June 2020 with the first cohort of 10 patients. Based upon this timeline, the Company expects to make an announcement as to progression from the first cohort of patients to the second cohort of patients during the second half of 2020. Full data from EnACT could be available in the second half of 2021, depending on the progression of patients through each cohort.
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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.

First Quarter 2020 Financial Results

Cash, cash equivalents and marketable securities at March 31, 2020 were approximately \$71.2 million, compared to \$27.8 million at December 31, 2019. In January 2020, the Company 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 first half of 2023.

For the first quarter of 2020, net loss attributable to common shareholders was \$5.2 million, or a net loss per share of \$0.03 (basic and diluted), compared to a net loss attributable to common shareholders of \$4.3 million, or a net loss per share of \$0.04 (basic and diluted) for the same period in 2019. The increase was due primarily to an increase in research and development expenses.

Research and development (R&D) expenses for the first quarter of 2020 were \$4.1 million, compared to \$2.3 million for the same period in 2019. The increase was due primarily to higher clinical development expenses and employee compensation related to the development of MAT9001 and MAT2203.

General and administrative (G&A) expenses for the first quarter of 2020 were \$2.3 million, compared to \$1.8 million in the same period in 2019. The increase was due primarily to higher 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, May 11, 2020, at 4:30 p.m. ET.



To participate in the call, please dial (877) 407-5976 (domestic) or (412) 902-0031 (international). The live webcast 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.
Condensed Consolidated Balance Sheets
(in thousands)

	<u>March 31, 2020</u>	<u>December 31, 2019</u>
	<u>(Unaudited)</u>	<u>(Audited)</u>
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 10,078	\$ 22,170
Marketable securities	61,090	5,605
Restricted cash - security deposits	150	250
Prepaid expenses and other current assets	2,671	1,898
Total current assets	73,989	29,923
Non-current assets:		
Leasehold improvements and equipment - net	1,698	1,750
Operating lease right-of-use assets - net	3,643	3,761
Finance lease right-of-use assets - net	94	117
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash - security deposits	336	336
Total non-current assets	10,124	10,317
Total assets	\$ 84,113	\$ 40,240
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 953	\$ 679
Accrued expenses	1,106	1,939
Operating lease liabilities - current	441	424
Financing lease liabilities - current	43	55
Total current liabilities	2,543	3,097
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities - net of current portion	3,579	3,696
Financing lease liabilities - net of current portion	47	55
Total non-current liabilities	3,967	4,092
Total liabilities	6,510	7,189
Stockholders' equity:		
Series B Convertible preferred stock	3,964	3,986
Common stock	20	16
Additional paid-in capital	162,520	113,428
Accumulated deficit	(89,423)	(84,378)
Accumulated other comprehensive income/(loss)	522	(1)
Total stockholders' equity	77,603	33,051
Total liabilities and stockholders' equity	\$ 84,113	\$ 40,240



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

	Three Months Ended March 31,	
	2020	2019
Costs and expenses:		
Research and development	\$ 4,087	\$ 2,315
General and administrative	2,260	1,788
Total costs and expenses	<u>6,347</u>	<u>4,103</u>
Loss from operations	(6,347)	(4,103)
Sale of New Jersey net operating loss	1,073	-
Other income, net	228	52
Net loss	<u>\$ (5,046)</u>	<u>\$ (4,051)</u>
Preferred stock series A accumulated dividends	-	(147)
Preferred stock series B accumulated dividends	(171)	(118)
Net loss attributable to common shareholders	<u>\$ (5,217)</u>	<u>\$ (4,316)</u>
Net loss available for common shareholders per share - basic and diluted	<u>\$ (0.03)</u>	<u>\$ (0.04)</u>
Weighted average common shares outstanding - basic and diluted	<u>191,671</u>	<u>117,367</u>
Other comprehensive income/(loss), net of tax		
Unrealized gains on securities available-for-sale	523	-
Other comprehensive income/(loss), net of tax	523	-
Comprehensive loss attributable to stockholders	<u>\$ (4,523)</u>	<u>\$ (4,051)</u>

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Source: Matinas BioPharma Holdings, Inc.