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, 2020

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	**07921**
(Address of principal executive offices)	**(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 August 10, 2020, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 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:

Exhibit No.	Description
99.1	Press Release, dated August 10, 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: August 10, 2020

By: */s/ Jerome D. Jabbour*

Name: Jerome D. Jabbour
Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Reports Second Quarter 2020 Financial Results and Operational Highlights

– ENHANCE-IT study of MAT9001 against Vascepa® expected to be fully enrolled in August 2020; topline data anticipated Q1 2021 –

– EnACT study of MAT2203 in cryptococcal meningitis resumed enrollment; on track for potential cohort progression Q4 2020 –

– Management to host conference call today, Monday, August 10th, at 4:30 p.m. ET –

BEDMINSTER, N.J., August 10, 2020 (GLOBE NEWSWIRE) — Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company, today reported financial results for the second quarter ended June 30, 2020, along with a corporate update and outlook for 2020.

"We are pleased to announce that both the ENHANCE-IT study of MAT9001 and the EnACT study of MAT2203 have resumed rapid enrollment after a temporary pause due to the COVID-19 pandemic," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "We continued meaningful progress across our business in the first half of 2020, despite challenging circumstances and conditions. As we look ahead to the second half of 2020 and into 2021, we are well positioned and approaching a number of important catalysts and milestones for the Company and our lead product candidates. We expect potential cohort progression in EnACT in the fourth quarter of this year and topline data from ENHANCE-IT in the first quarter of 2021. In addition, our team continues to advance our key collaborations with our partners applying our LNC platform, as well as identifying opportunities and advancing discussions on potential new applications for this promising and unique delivery technology."

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

- Rapidly approaching completion of 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. Enrollment resumed in early June after having temporarily paused in the first quarter of 2020 due to the COVID-19 pandemic. The Company expects to complete enrollment in ENHANCE-IT in August and have topline data available in the first quarter of 2021.

- The Company remains on track to meet with the U.S. Food and Drug Administration (FDA) in an End-of-Phase 2 meeting. During this meeting, the Company will discuss data from the completed comparative clinical bridging bioavailability study and 90-day comparative toxicology study to support a potential 505(b)(2) registration pathway. In addition, the Company will review and seek approval for the protocol for a planned Phase 3 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 ≥ 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 eight sites in the United States. MAT9001 and Vascepa will each be administered as 2g 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 *(orally bioavailable amphotericin B, with targeted delivery, under development for the treatment and prevention of invasive fungal infections, including cryptococcal meningitis)*

- Enrollment has resumed in the EnACT (Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial) study for the treatment of HIV-infected patients with cryptococcal meningitis after temporary suspension by mandate of the Uganda National Drug Authority due to the COVID-19 Pandemic earlier this year.

- To date, several patients have been randomized and dosed in the first cohort of 10 patients in the Phase 2 portion of EnACT. The Company expects to make an announcement as to potential progression from the first cohort of patients to the second cohort of 40 patients during the fourth quarter of 2020. More complete data from EnACT could be available in the second half of 2021, depending on the progression of patients through each cohort.

EnACT is a Phase 2 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. This study 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, and then 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. An independent DSMB will review all data for safety and efficacy and make the recommendation to proceed to the next cohort of patients.

Second Quarter 2020 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2020 were approximately $68.0 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 continues to believe that cash on hand is sufficient to fund operations into the first half of 2023.

For the second quarter of 2020, net loss attributable to common shareholders was $5.8 million, or a net loss of $0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of $3.6 million, or a net loss of $0.03 per share (basic and diluted) for the same period in 2019. The increase in net loss attributable to common shareholders was due primarily to an increase in operating expenses.

Research and development (R&D) expenses for the second quarter of 2020 were $3.4 million, compared to $2.8 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 second quarter of 2020 were $2.4 million, compared to $1.8 million in the same period in 2019. The increase was due primarily to higher employee compensation expense associated with increased headcount.

*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, August 10, 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

	June 30, 2020 (Unaudited)	December 31, 2019 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 14,903,928	$ 22,170,438
Marketable securities	53,053,709	5,604,634
Restricted cash	200,000	250,000
Prepaid expenses and other current assets	1,051,219	1,897,784
Total current assets	69,208,856	29,922,856
Non-current assets:		
Leasehold improvements and equipment - net	1,639,575	1,749,259
Operating lease right-of-use assets - net	3,523,298	3,761,207
Finance lease right-of-use assets - net	75,290	116,968
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposits	286,000	336,000
Total non-current assets	9,878,028	10,317,299
Total assets	$ 79,086,884	$ 40,240,155
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 494,577	$ 679,310
Accrued expenses	1,434,880	1,939,510
Operating lease liabilities - current	443,801	423,741
Financing lease liabilities - current	34,573	54,673
Total current liabilities	2,407,831	3,097,234
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,474,739	3,695,561
Financing lease liabilities - net of current portion	38,378	54,513
Total non-current liabilities	3,854,382	4,091,339
Total liabilities	6,262,213	7,188,573
Stockholders' equity:		
Series B Convertible preferred stock	3,964,034	3,985,805
Common stock	19,886	16,315
Additional paid-in capital	164,079,847	113,427,897
Accumulated deficit	(95,716,800)	(84,377,555)
Accumulated other comprehensive income/(loss)	477,704	(880)
Total stockholders' equity	72,824,671	33,051,582
Total liabilities and stockholders' equity	$ 79,086,884	$ 40,240,155

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenue:				
Contract research revenue	$ -	$ 89,812	$ -	$ 89,812
Costs and expenses:				
Research and development	3,410,237	2,828,776	7,497,120	5,143,477
General and administrative	2,356,310	1,781,717	4,615,941	3,570,131
Total costs and expenses	5,766,547	4,610,493	12,113,061	8,713,608
Loss from operations	(5,766,547)	(4,520,681)	(12,113,061)	(8,623,796)
Sale of New Jersey net operating loss	-	1,007,082	1,073,289	1,007,082
Other income/(expense), net	156,000	168,872	383,327	221,279
Net loss	$ (5,610,547)	$ (3,344,727)	$ (10,656,445)	$ (7,395,435)
Preferred stock series A accumulated dividends	-	(146,786)	-	(293,572)
Preferred stock series B accumulated dividends	(177,092)	(115,750)	(347,792)	(234,000)
Net loss attributable to common shareholders	$ (5,787,639)	$ (3,607,263)	$ (11,004,237)	$ (7,923,007)
Net loss available for common shareholders per share - basic and diluted	$ (0.03)	$ (0.03)	$ (0.06)	$ (0.06)
Weighted average common shares outstanding - basic and diluted	197,601,500	143,104,941	194,636,326	130,306,907
Other comprehensive (loss)/income, net of tax				
Net unrealized (loss)/gain on securities available-for-sale	(41,954)	-	481,303	-
Reclassifications to net loss	(2,708)	-	(2,719)	-
Other comprehensive (loss)/income, net of tax	(44,662)	-	478,584	-
Comprehensive loss attributable to shareholders	$ (5,655,209)	$ (3,344,727)	$ (10,177,861)	$ (7,395,435)

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