

**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 11, 2022

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) 484-8805

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 August 11, 2022, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2022. 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 August 11, 2022.](#)
104 Cover Page Interactive Data File (embedded within the Inline XBRL document)

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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 11, 2022

By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour

Title: Chief Executive Officer

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Matinas BioPharma Reports Second Quarter 2022 Financial Results and Highlights Recent Progress

75% of Patients Enrolled to Date in Cohort 4 of EnACT (MAT2203 in Cryptococcal Meningitis); Topline Data in Late Q3/Early Q4 2022

FDA Provides Flexibility and Clarity on Phase 3 Program and Single Pivotal Registration Trial for MAT2203 in Cryptococcal Meningitis; Trial Expected to Commence Q1 2023

Initial Scientific Advice and Positive Opinion on Orphan Drug Designation from EMA Provide Global Regulatory Alignment for MAT2203 in Key Commercial Regions

Company Remains in Discussions with BioNTech for Option to License the LNC Platform for mRNA on an Exclusive Basis

\$38.5 million at June 30, 2022, Sufficient to Fund Planned Operations Through 2023

Management to Host Conference Call Today, Thursday, August 11th, at 8:30 a.m. ET

BEDMINSTER, N.J., August 11, 2022 – [Matinas BioPharma Holdings, Inc.](#) (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on improving the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform delivery technology, today reported financial results for the second quarter ended June 30, 2022, along with a corporate update.

“The second quarter of 2022 through today has been a period of significant execution for our Company, and especially for our lead, late stage clinical asset, MAT2203,” commented [Jerome D. Jabbour, Chief Executive Officer of Matinas](#). “Several meetings with the U.S. Food and Drug Administration (FDA) over the past few months have provided clarity around a flexible, streamlined approval pathway for this potentially game-changing drug, based on a single Phase 3 registration trial now scheduled to commence in the first quarter of 2023. We also remain very enthusiastic about our ongoing exclusive research collaboration with BioNTech and are diligently working toward what we believe will be a mutually beneficial licensing arrangement for the application of our proprietary LNC platform in the rapidly developing mRNA space. Additional validation of the capabilities of the LNC platform and developing an internal and external pipeline of LNC-based drug candidates continue to be key objectives for Matinas in the second half of 2022 and throughout 2023.”



Second Quarter 2022 Highlights and Recent Events

Internal Pipeline Progress

MAT2203

- Enrollment continues in Cohort 4 of the ongoing EnACT study (*Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial*) of MAT2203 (oral amphotericin B) for the treatment of cryptococcal meningitis (CM), with 42 patients (out of a total of 56) enrolled to date. Cohort 4 is testing an all-oral regimen of MAT2203 during the 14-day induction period, followed by four additional weeks of oral consolidation therapy with MAT2203. The Company anticipates reporting topline data from Cohort 4 either late in the third quarter or early in the fourth quarter of 2022. The Company recently opened an additional site in Uganda to facilitate enrollment.
- With guidance from multiple positive meetings with FDA over the last few months, the Company has finalized the design of a single pivotal Phase 3 registration trial for MAT2203 supporting submission of a New Drug Application (NDA) for a simplified blanket indication for the treatment of CM. The open-label trial, which the Company expects will be partially financially supported by the National Institutes of Health, involves a three arm non-inferiority design in HIV patients with CM: (A) step-down therapy with MAT2203 with treatment continuing for 2 weeks; (B) step-down therapy with MAT2203 with treatment out to 6 weeks; and (C) a standard of care (SOC) control arm of IV amphotericin induction transitioning to fluconazole. The non-inferiority margin for both the primary and key secondary endpoints will be 10% and total enrollment is expected to be approximately 270 patients, with an adaptive, de-risking design allowing for the potential for additional patients once enrollment has reached 75%.

Key trial elements include:

- A primary endpoint of 2-week all-cause mortality, with a pooled analysis across the two MAT2203 treatment arms compared with SOC control to support a potential indication for the treatment of CM for up to 2 weeks.
- To evaluate opportunities for extending MAT2203 therapy, a key secondary analysis of 10-week relapse free survival of optimized treatment (2-weeks or 6-weeks) against SOC will be evaluated for non-inferiority. Selection of the optimal treatment regimen will be based on predefined and protocolized clinical criteria and will then form the basis for a final NDA submission.



- The Company has also received recent positive feedback from EMA on both its Request for Scientific Advice and its Orphan Drug Application; this provides alignment with FDA and positions MAT2203 for global registration in key commercial markets.

External Collaborations

- In April 2022, Matinas and BioNTech entered an exclusive research collaboration centered on the combination of Matinas' proprietary LNC platform technology and BioNTech mRNA formats. The companies have initiated collaborative formulation work, ultimately directed toward planned preclinical testing. The parties remain in advanced discussions for a potential option to exclusively license the LNC platform for all mRNA applications.
- Additional recent data from an *in vivo* study of oral LNC-remdesivir in mice infected with SARS-CoV-2 demonstrated significant improvement in multiple histologic markers of lung injury with oral LNC remdesivir at both Day 2 and Day 5. The study was performed in collaboration with the National Institute of Allergy & Infectious Diseases and the Department of Epidemiology at the University of North Carolina at Chapel Hill. The Company expects to engage with Gilead Sciences to discuss the data and potential expansion of the LNC-remdesivir program.

LYPDISO™

- While data from the Company's clinical development program for LYPDISO are compelling, the process to identify a partner to continue the development of LYPDISO has been suspended.

Planned Retirement of Raphael J. Mannino, Chief Scientific Officer

The Company also announced the planned retirement of Raphael J. Mannino, Chief Scientific Officer of the Company, who joined Matinas in 2015 following its acquisition of Aquarius Biotechnologies, Inc. Dr. Mannino has informed the Company that he intends to retire from employment effective December 31, 2022, whereupon he has agreed to transition to a consulting role and will continue to serve as a key strategic advisor to the Company.

"On behalf of our board of directors, stockholders and employees, I want to thank Raphael for his tremendous contributions to Matinas BioPharma, and for his dedication to the LNC platform over the past 30+ years," said Jerome D. Jabbour, Chief Executive Officer of Matinas BioPharma. "Raphael has been a visionary in the world of intracellular drug delivery and has helped to position our Company and our technology for a very bright future. We wish him all the best in retirement, but also genuinely look forward to continued contributions from him as we seek to maximize the significant opportunity afforded by this disruptive drug delivery platform."



"I am extremely proud of all of the work that has been done on the LNC platform over the years and grateful to the talented and dedicated team at Matinas for helping us to achieve remarkable clinical results with MAT2203," commented Raphael J. Mannino, Chief Scientific Officer of Matinas. "Although I plan to take a step back in my retirement, I could not be more excited about the scientific talent we have been able to attract to the Company and the prospects for the LNC platform, especially in the field of nucleic acids. I look forward to being a key resource for Jerry and the rest of the organization as they advance and progress this exciting technology."

Second Quarter 2022 Financial Results

Cash, cash equivalents and marketable securities at June 30, 2022, were approximately \$38.5 million, compared to \$49.6 million at December 31, 2021. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

For the second quarter of 2022, net loss attributable to common shareholders was \$5.9 million, or a net loss of \$0.03 per share (basic and diluted), compared to a net loss attributable to common shareholders of \$5.0 million, or a net loss of \$0.02 per share (basic and diluted), for the same period in 2021. The increase was due primarily to an increase in research and development expenses, partially offset by \$1.1 million of revenue resulting from the research collaboration with BioNTech SE.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss these results today, Thursday, August 11, 2022, at 8:30 a.m. ET.

To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13730276. 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 nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.



Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides, and vaccines. The combination of a unique mechanism of action and flexibility with formulation and route of administration (including oral), positions Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

The Company is focused on developing an internal and external pipeline of drugs candidates based on the LNC platform. Internally, the Company has two clinical stage assets. MAT2203 is an oral, LNC formulation of the highly potent antifungal medicine amphotericin B, currently preparing to commence a Phase 3 registration trial in the first quarter of 2023; MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside, amikacin, primarily used to treat chronic and acute bacterial infections, and currently in

Phase 1. Externally, the Company has established a broad set of relationships with multiple global pharmaceutical collaborators, including BioNTech (mRNA), the National Institutes of Health and Gilead Sciences (antivirals), and Genentech, a member of the Roche Group (small molecules, antisense oligonucleotides, and antibody fragments).

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 our business activities, our strategy and plans, our collaboration with BioNTech, the potential of our LNC platform delivery technology, and the future development of its product candidates, including MAT2203, MAT2501, 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 31, 2022 (Unaudited)	December 31, 2021 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	\$ 10,398,544	\$ 21,029,806
Marketable securities	28,104,146	28,592,049
Restricted cash - security deposit	50,000	50,000
Prepaid expenses and other current assets	3,371,538	1,321,466
Total current assets	<u>41,924,228</u>	<u>50,993,321</u>
Non-current assets:		
Leasehold improvements and equipment - net	1,982,975	1,537,728
Operating lease right-of-use assets - net	3,944,158	4,218,890
Finance lease right-of-use assets - net	10,415	22,270
In-process research and development	3,017,377	3,017,377
Goodwill	1,336,488	1,336,488
Restricted cash - security deposit	200,000	200,000
Total non-current assets	<u>10,491,413</u>	<u>10,332,753</u>
Total assets	<u>\$ 52,415,641</u>	<u>\$ 61,326,074</u>
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	\$ 497,151	\$ 938,270
Accrued expenses	4,294,396	2,850,888
Operating lease liabilities - current	579,260	538,546
Financing lease liabilities - current	11,508	21,039
Total current liabilities	<u>5,382,315</u>	<u>4,348,743</u>
Non-current liabilities:		
Deferred tax liability	341,265	341,265
Operating lease liabilities - net of current portion	3,843,524	4,140,387
Financing lease liabilities - net of current portion	-	2,621
Total non-current liabilities	<u>4,184,789</u>	<u>4,484,273</u>
Total liabilities	<u>9,567,104</u>	<u>8,833,016</u>
Stockholders' equity:		
Common stock	21,685	21,627
Additional paid-in capital	187,116,333	184,251,138
Accumulated deficit	(143,535,065)	(131,634,208)
Accumulated other comprehensive loss	(754,416)	(145,499)
Total stockholders' equity	<u>42,848,537</u>	<u>52,493,058</u>
Total liabilities and stockholders' equity	<u>\$ 52,415,641</u>	<u>\$ 61,326,074</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Contract research revenue	\$ 1,062,500	\$ -	\$ 1,062,500	\$ 33,333
Costs and expenses:				
Research and development	4,126,529	2,480,764	9,104,634	5,722,196
General and administrative	2,861,421	2,308,926	5,605,616	5,453,936
Total costs and expenses	6,987,950	4,789,690	14,710,250	11,176,132
Loss from operations	(5,925,450)	(4,789,690)	(13,647,750)	(11,142,799)
Sale of New Jersey net operating loss & tax credits	-	-	1,734,133	1,328,470
Other income/(loss), net	2,866	(1,415)	12,760	66,904
Net loss	\$ (5,922,584)	\$ (4,791,105)	\$ (11,900,857)	\$ (9,747,425)
Preferred stock series B accumulated dividends	-	(184,899)	-	(395,799)
Net loss attributable to common shareholders	\$ (5,922,584)	(4,976,004)	\$ (11,900,857)	\$ (10,143,224)
Net loss available for common shareholders per share - basic and diluted	\$ (0.03)	(0.02)	\$ (0.05)	\$ (0.05)
Weighted average common shares outstanding - basic and diluted	216,864,526	205,215,259	216,755,261	204,547,251
Other comprehensive loss, net of tax				
Unrealized loss on securities available-for-sale	(125,242)	(85,163)	(608,917)	(176,929)
Other comprehensive loss, net of tax	(125,242)	(85,163)	(608,917)	(176,929)
Comprehensive loss attributable to shareholders	\$ (6,047,826)	\$ (4,876,268)	\$ (12,509,774)	\$ (9,924,354)

Investor and Media Contacts

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Source: Matinas BioPharma Holdings, Inc.