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 9, 2023

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	
(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 9, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2023. The full text of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

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.

Exhibit No.	Description
99.1	Press Release, dated August 9, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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 9, 2023

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

Matinas BioPharma Reports Second Quarter 2023 Financial Results and Provides a Business Update

FDA indicated that approval of MAT2203 as a first-line treatment for invasive aspergillosis will require an adequately powered study with an active control group and an all-cause mortality non-inferiority margin of 10%

FDA provided alternative trial designs which include the highest-need patients, aligning with growing positive treatment success in Matinas' Compassionate/Expanded Use Program as highlighted by a recent case update from Nationwide Children's Hospital

Internal RNAi programs demonstrate compelling in vitro *activity;* in vivo *studies evaluating biological activity of LNC oral formulations of small oligonucleotides expected in second half of 2023*

Conference call begins at 4:30 p.m. Eastern time today

BEDMINSTER, N.J. (August 9, 2023) – Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, reports financial results for the three and six months ended June 30, 2023 and provides a business update.

"Feedback we recently received from the U.S. Food and Drug Administration (FDA) underscores the challenges in developing novel antifungal therapies, with a high bar for efficacy, rigorously defined comparator groups and significant patient numbers for a first-line indication. Nevertheless, we are pleased that during our meeting earlier this year, the FDA recognized the need for a therapy like MAT2203, which is designed for patients with limited or no treatment options who require longer-term treatment," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "Compassionate use cases both ongoing and completed represent powerful examples of the life-saving potential of MAT2203, and we remain committed to positioning this important drug for approval as quickly and efficiently as possible.

"We continue to refine the clinical development pathway to support registration of MAT2203, including the Limited Population Pathway for Antifungals (LPAD) Pathway, which we believe could require fewer patients. We plan to engage with the Biomedical Research and Development Authority (BARDA) as soon as possible to discuss next steps to fund MAT2203 through registration based on this feedback," he added.

Key Program Updates

MAT2203 (Oral Amphotericin B) Program

FDA Feedback

- For a first-line treatment indication for invasive aspergillosis, the FDA recommended a 10% non-inferiority margin for an all-cause mortality endpoint, which would require approximately 700 patients in a 1:1 randomization against standard of care.
- The Company believes that MAT2203 could be an attractive option for those patients who are intolerant of azole therapy or have azole-resistant infections, which represents an important unmet medical need. The FDA provided alternative study designs for consideration, which include these highest need patients and which we believe could ultimately position MAT2203 for registration under the LPAD Pathway. This approach could require significantly fewer patients than required for first-line, unrestricted use.

Compassionate Use Program

- Eight patients have been enrolled in the Company's Compassionate/Expanded Use Access Program, with an additional case pending. In these eight enrolled patients, MAT2203 has successfully treated numerous types of invasive fungal infections at various locations in the body. In addition to the compelling case presented earlier in 2023 at the European Congress of Clinical Microbiology and Infectious Disease (ECCMID), the following update was made available to the Company by the investigating physician:

  Nationwide Children's Hospital

  - MAT2203 was used to treat a critically ill 15-year-old female patient with acute myeloid leukemia and diabetes who suffered from invasive fungal infections in sinus, lung, and brain due to multiple, extremely resistant mucor species, as well as aspergillus species. The patient was initially treated with IV liposomal amphotericin B but developed treatment-limiting electrolyte abnormalities and renal toxicity as well as significant feeding intolerance that required hospitalization for intravenous hydration and electrolyte supplementation. Upon enrolling in the Expanded Access Program, IV-amphotericin B was discontinued, and the patient began treatment with MAT2203 and was discharged from the hospital to continue the remainder of her treatment at home.
  - The patient began to show clinical improvement following only three weeks of therapy on MAT2203, renal function returned to normal and repeated sinus/brain MRI showed no evidence of active mucormycosis infection. Similarly, repeated chest CT showed a reduction in pulmonary nodules with no new lesions. The patient continued MAT2203 therapy for a total of 17 weeks with no evidence of nephrotoxicity.
  - "Our decision to switch this patient to MAT2203 proved to be a turning point in our patient's journey," commented Eunkyung Song, MD, Infectious Disease/Host defense program, Nationwide Children's Hospital. "Rapidly, her gastrointestinal intolerance and renal dysfunction resolved, enabling her to continue MAT2203 therapy for an additional three months. Throughout this period, the patient displayed excellent tolerance to MAT2203, and subsequent imaging revealed radiologic improvement in the invasive fungal infections. We are delighted with the remarkable outcome achieved with MAT2203, which addressed this patient's very challenging condition effectively."

LNC Platform Updates

Internal Small Oligonucleotide Program

- *In vitro* studies of LNC formulations of small oligonucleotides (including an RNAi therapy) conducted during the second and third quarters of 2023 demonstrated efficient intracellular delivery with measurable knockdown of certain inflammatory markers. Based on these results, Matinas is working with its partners to generate *in vivo* data evaluating biological activity with LNC oral formulations and expects initial data later in 2023. Successful demonstration of *in vivo* efficacy would represent a first for the oral delivery of small oligonucleotides.

National Resilience

- Matinas' collaboration with National Resilience continues to focus on *in vitro* and *in vivo* delivery of mRNA and expects initial data later in 2023.

Second Quarter Financial Results

The Company reported no revenue for the second quarter of 2023 compared with $1.1 million of revenue for the second quarter of 2022, which was generated from the Company's research collaborations with BioNTech SE.

Total costs and expenses for the second quarter of 2023 were $6.2 million compared with $7.0 million for the second quarter of 2022. The decrease was primarily attributable to lower manufacturing costs of clinical trial materials and a decrease in clinical trial consulting fees, partially offset by higher headcount.

The net loss for the second quarter of 2023 was $6.1 million, or $0.03 per share, compared with a net loss for the second quarter of 2022 of $5.9 million, or $0.03 per share.

Six Month Financial Results

Revenue for the first six months of 2023 and 2022 was $1.1 million. Total costs and expenses for the first half of 2023 was $12.8 million versus $14.7 million for the first half of 2022.

The net loss for the first six months of 2023 was $11.6 million, or $0.05 per share, compared with a net loss for the first six months of 2022 of $11.9 million, or $0.06 per share.

Cash, cash equivalents and marketable securities as of June 30, 2023 were $22.5 million compared with $28.8 million as of December 31, 2022. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the third quarter of 2024. The Company is seeking to extend its cash runway by securing non-dilutive funding from potential third-party development partners and government grant programs through agencies such as BARDA, as well as from proceeds from potential public or private equity offerings.

Conference Call and Webcast

Matinas will host a conference call and webcast today beginning at 4:30 p.m. Eastern time. To participate in the call, please dial 877-484-6065 (Toll-Free) or 201-689-8846 (Toll). The live webcast will be accessible on the Investors section of the company's website and archived for 90 days.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology.

Matinas' lead LNC-based therapy is MAT2203, an oral formulation of the broad-spectrum antifungal drug amphotericin B, which although highly potent, can be associated with significant toxicity. Matinas' LNC platform provides oral delivery of amphotericin B without the significant nephrotoxicity otherwise associated with IV-delivered formulations. MAT2203 also allows for safe, longer-term use outside of a hospital setting, which could have substantial favorable pharmacoeconomic impact. MAT2203 successfully completed the Phase 2 EnACT program in cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 is being positioned for a single pivotal Phase 3 study in the treatment of aspergillosis and other invasive fungal infections, including mucormycosis, c. auris and other candidiasis, and certain endemic mycoses in patients with limited treatment options who are unable to be treated with azoles or echinocandins for reasons related to drug-drug interactions, resistance or for whom these antifungal agents are unable to be used for other clinical reasons.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges standing in the way of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos such as RNAi, antisense oligonucleotides and vaccines. The combination of its unique mechanism of action and flexibility with routes of administration (including oral) positions Matinas' LNC technology to potentially become a preferred next-generation intracellular drug delivery platform. For more information, please visit www.matinasbiopharma.com.

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 National Resilience, Inc., the potential of our LNC platform and PS-NP delivery technologies, and the future development of its product candidates, including MAT2203, the Company's ability to identify and pursue development, licensing and partnership opportunities for its products, including MAT2203, or platform delivery technologies 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 continue as a going concern, 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.

Investor Contact:

LHA Investor Relations
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[*Financial Tables to Follow*]

Matinas BioPharma Holdings, Inc.
Condensed Consolidated Balance Sheets
(in thousands, except for share data)

	June 30, 2023 (Unaudited)	December 31, 2022 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 9,743	$ 6,830
Marketable debt securities	12,770	21,933
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	1,437	5,719
Total current assets	24,000	34,532
Non-current assets:		
Leasehold improvements and equipment – net	2,103	2,091
Operating lease right-of-use assets – net	3,345	3,613
Finance lease right-of-use assets – net	24	30
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash – security deposit	200	200
Total non-current assets	10,025	10,287
Total assets	$ 34,025	$ 44,819
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 604	$ 618
Accrued expenses	1,372	3,099
Operating lease liabilities – current	608	562
Financing lease liabilities – current	5	7
Total current liabilities	2,589	4,286
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities – net of current portion	3,221	3,533
Financing lease liabilities – net of current portion	20	22
Total non-current liabilities	3,582	3,896
Total liabilities	6,171	8,182
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at June 30, 2023 and December 31, 2022; 217,264,526 issued and outstanding as of June 30, 2023 and December 31, 2022	22	22
Additional paid-in capital	192,550	190,070
Accumulated deficit	(164,204)	(152,631)
Accumulated other comprehensive loss	(514)	(824)
Total stockholders' equity	27,854	36,637
Total liabilities and stockholders' equity	$ 34,025	$ 44,819

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Revenue:				
Contract Revenue	$ -	$ 1,063	$ 1,096	$ 1,063
Costs and expenses:				
Research and development	3,559	4,127	7,530	9,105
General and administrative	2,600	2,861	5,311	5,606
Total costs and expenses	6,159	6,988	12,841	14,711
Loss from operations	(6,159)	(5,925)	(11,745)	(13,648)
Sale of New Jersey net operating losses & tax credits	-	-	-	1,734
Other income, net	99	2	172	13

Net loss	$ (6,060)	$ (5,923)	$ (11,573)	$ (11,901)
Net loss per share – basic and diluted	$ (0.03)	$ (0.03)	$ (0.05)	$ (0.06)
Weighted average common shares outstanding:				
Basic and diluted	217,264,526	216,864,526	217,264,526	216,755,261
Other comprehensive gain/(loss), net of tax				
Unrealized gain/(loss) on securities available-for-sale	81	(125)	310	(609)
Other comprehensive gain/(loss), net of tax	81	(125)	310	(609)
Comprehensive loss	$ (5,979)	$ (6,048)	$ (11,263)	$ (12,510)

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