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 9, 2024

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 May 9, 2024, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended March 31, 2024. 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.

Exhibit No.	Description

	Press Release, dated May 9, 2024
99.1	
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: May 9, 2024

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

Matinas BioPharma Reports First Quarter 2024 Financial Results and Provides a Business Update

Recent $10 million financing expected to fund planned development programs and operations into the second quarter of 2025

Discussions to secure a partner to advance MAT2203 into the Phase 3 ORALTO trial remain on track

Company's strategy to expand its LNC platform into inflammation and oncology supported by favorable in vivo *data in multiple disease models*

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

BEDMINSTER, N.J. (May 9, 2024) – Matinas BioPharma Holdings, Inc. (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 months ending March 31, 2024 and provides a business update.

"We remain on track with active partnership discussions to advance oral MAT2203 into the ORALTO trial in invasive aspergillosis," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "These discussions aim to secure one or more development and commercial partners for this life-changing asset with a shared sense of urgency that can maximize its value in multiple geographies. Our confidence in oral MAT2203 continues to build as we see further evidence of favorable outcomes in extremely ill patients, some of whom have invasive fungal infections deemed even more difficult to treat than aspergillosis. We believe MAT2203 has the potential to change the treatment paradigm for a variety of invasive fungal infections by providing an effective, targeted, safer, and more convenient option.

"Last month's financing strengthened our balance sheet and better positioned us to advance other studies providing a strong foundation for our LNC platform programs," he added. "We are highly encouraged by results from *in vivo* studies demonstrating a substantial reduction in the well-recognized toxicity of IV-docetaxel. In inflammation, we have been successful in orally delivering biologically active small oligonucleotides in several inflammatory disease models. Strategically, we continue to pursue studies with our LNC technology designed to establish its role as a potentially preferred next-generation intracellular oral drug delivery platform, potentially facilitating a robust internal and external pipeline of drug candidates in multiple high-value indications."

Key Program Updates

MAT2203 (Oral Amphotericin B) Program

- Active negotiations are progressing to secure a partnership to commence the Phase 3 ORALTO registrational trial with oral MAT2203. The Phase 3 randomized, multicenter, open-label, adjudicator-blinded ORALTO trial will evaluate the efficacy and safety of MAT2203 as an oral step-down therapy following two days of treatment with AmBisome® (liposomal IV-amphotericin B) compared with the standard of care in patients with invasive aspergillosis who have limited treatment options.

- An *in vivo* study of oral MAT2203 demonstrated prolonged and enhanced survival, reduced fungal burden and improvement in lung infection compared with placebo in treating the pulmonary mucormycosis fungal infections in immunosuppressed mice. The results were reported in the manuscript "Efficacy of an oral lipid nanocrystal (LNC) formulation of amphotericin B (MAT2203) in the neutropenic mouse model of pulmonary mucormycosis" (Gu, et al.) published in the peer-reviewed *Journal of Antimicrobial Agents and Chemotherapy*.

- To date, Matinas has enrolled 22 patients with severe and sometimes life-threatening fungal infections in its Compassionate/Expanded Use Access Program, with additional patients under evaluation. The infections treated involve a variety of micro-organisms including Aspergillus, Mucorales species, Candidiasis, Fusarium, Histoplasmosis, and suspected Coccidioides at multiple sites of infection including brain, bladder/colon, bone, lung, sinus, and skin. The majority of enrolled patients are post-transplant or are undergoing treatment for underlying malignancies.

LNC Platform Update

- Two abstracts (one an oral presentation) highlighting recent favorable data from *ex vivo, in vitro* and *in vivo* studies evaluating the use of Matinas' LNC platform for the oral targeted delivery of small oligonucleotides are being presented at the American Society of Gene & Cell Therapy's (ASGCT) 27th Annual Meeting in May.

- A new formulation of LNC-miriplatin, an insoluble platinum chemotherapeutic approved in Japan for hepatocellular carcinoma has been developed. *In vitro* testing demonstrated strong cellular uptake and tumor cell-killing capabilities. Next steps are to assess the formulation *in vivo*. LNC-miriplatin would be the second cancer agent successfully formulated with LNCs.

First Quarter Financial Results

The Company reported no revenue for the first quarter of 2024, compared with $1.1 million for the first quarter of 2023, which was generated from research collaborations with BioNTech SE and Genentech Inc.

Total costs and expenses for the first quarter of 2024 were $5.9 million compared with $6.7 million for the first quarter of 2023. The decrease was primarily due to lower clinical development expenses, personnel costs, and administrative expenses.

The net loss for the first quarter of 2024 was $5.8 million, or $0.03 per share, compared with a net loss for the first quarter of 2023 of $5.5 million, or $0.03 per share.

Cash, cash equivalents and marketable securities as of March 31, 2024 were $8.1 million compared with $13.8 million as of December 31, 2023. Subsequent to the close of the quarter, in April the Company raised gross proceeds of $10.0 million through a registered direct offering. Based on current projections, the Company believes its cash position is sufficient to fund planned operations into the second quarter of 2025.

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 or 201-689-8846. 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. Combining comparable fungicidal activity with targeted delivery results in a lower risk of toxicity and potentially creates the ideal antifungal agent for the treatment of invasive fungal infections. MAT2203 was successfully evaluated in the completed Phase 2 EnACT study in HIV patients suffering from cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated in a single Phase 3 registration trial (the "ORALTO" trial) as an oral step-down monotherapy following treatment with AmBisome® (liposomal amphotericin B) compared with the standard of care in patients with invasive aspergillosis who have limited treatment options.

In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can potentially provide solutions to many challenges of achieving safe and effective intracellular delivery of both small molecules and larger, more complex molecular cargos including small oligonucleotides such as ASOs and siRNA. 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 orally available 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, the potential of our LNC platform technology, and the future development of our 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)

	March 31, 2024 (Unaudited)	December 31, 2023 (Audited)
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 1,071	$ 4,787
Marketable debt securities	7,039	8,969
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	2,129	1,737
Total current assets	10,289	15,543
Non-current assets:		
Leasehold improvements and equipment – net	1,829	1,923
Operating lease right-of-use assets – net	2,919	3,064
Finance lease right-of-use assets – net	20	21
In-process research and development	3,017	3,017
Goodwill	1,336	1,336
Restricted cash – security deposit	200	200
Total non-current assets	9,321	9,561
Total assets	$ 19,610	$ 25,104
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 473	$ 514
Accrued expenses	839	1,447
Operating lease liabilities – current	681	656

Financing lease liabilities – current	5	5
Total current liabilities	1,998	2,622
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities – net of current portion	2,697	2,877
Financing lease liabilities – net of current portion	16	18
Total non-current liabilities	3,054	3,236
Total liabilities	5,052	5,858
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at March 31, 2024 and December 31, 2023; 217,482,830 and 217,264,526 issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	22	22
Additional paid-in capital	196,067	195,018
Accumulated deficit	(181,397)	(175,573)
Accumulated other comprehensive loss	(134)	(221)
Total stockholders' equity	14,558	19,246
Total liabilities and stockholders' equity	$ 19,610	$ 25,104

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

	Three Months Ended March 31,	
	2024	**2023**
Revenue:		
Contract revenue	$ —	$ 1,096
Costs and Expenses:		
Research and development	3,446	3,970
General and administrative	2,456	2,712
Total costs and expenses	5,902	6.682
Loss from operations	(5,902)	(5,586)
Other income, net	78	73
Net loss	$ (5,824)	$ (5,513)
Net loss per share – basic and diluted	$ (0.03)	$ (0.03)
Weighted average common shares outstanding:		
Basic and diluted	217,358,085	217,264,526
Other comprehensive gain, net of tax		
Unrealized gain on securities available-for-sale	87	229
Other comprehensive gain, net of tax	87	229
Comprehensive loss	$ (5,737)	$ (5,284)

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