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): March 27, 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 March 27, 2024, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing its financial results for the year and quarter ended December 31, 2023. 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
99.1	Press Release, dated March 27, 2024
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: March 27, 2024

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

Exhibit 99.1

MATINAS BIOPHARMA

Matinas BioPharma Reports 2023 Financial Results and Provides a Business Update

Clear registration pathway and FDA agreement on the ORALTO Phase 3 trial for MAT2203 represent critical steps forward and supports partnership discussions

Continued success of Compassionate/Expanded Use Access Program demonstrates potential of MAT2203 in treating multiple severe invasive fungal infections, including invasive aspergillosis

Successful in vivo *LNC platform studies demonstrating (a) the oral delivery of small oligonucleotides with biological activity and (b) the dramatically improved safety of LNC-docetaxel over IV-docetaxel, with similar efficacy, supports the future use of the LNC platform in inflammation and oncology*

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

BEDMINSTER, N.J. (March 27, 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 2023 financial results and provides a business update.

"A clear regulatory approval pathway for oral MAT2203 is a critical step toward future commercialization in its initial indication of the treatment of invasive aspergillosis in patients with limited treatment options," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "Reaching agreement with FDA on the design of the ORALTO registration trial and the consistent successful treatment outcomes in our ongoing Compassionate/Expanded Use Access Program have elevated our confidence that, if approved, MAT2203 could represent a new treatment paradigm for addressing the unmet medical need in the treatment of a variety of difficult to treat invasive fungal infections. With these important elements secured, we are actively pursuing partnership opportunities to advance MAT2203 into Phase 3 as quickly as possible.

"We have also advanced the application of our LNC platform into exciting areas, including oncology and inflammation. In the oncology space, our *in vivo* data demonstrate that treatment with oral LNC-docetaxel at dosages substantially higher than those proven effective in targeting melanoma tumors resulted in tumor size reductions comparable to IV-docetaxel and was associated with none of the toxicity (body weight loss) observed with conventional IV-docetaxel. In the field of inflammation, we have demonstrated the successful oral delivery of biologically active – and potentially therapeutic – small oligonucleotides in several inflammatory disease models.

"Overall, we are pleased with all of the progress made by our team throughout 2023 and so far in 2024, and our focus remains on executing our strategic plan to make the LNC platform the preferred next-generation orally available intracellular drug delivery technology, facilitating an internal and external pipeline of drug candidates."

Key Program Updates

MAT2203 (Oral Amphotericin B) Program

Phase 3 ORALTO Registration Trial

- Matinas reached alignment with the FDA on the design of a single Phase 3 registration trial of oral MAT2203 in patients with invasive aspergillosis who have limited treatment options. This is a serious and life-threatening invasive fungal infection that occurs primarily in severely immunocompromised patients, including those with hematological malignancies and in transplant recipients. In 2022, the World Health Organization released its Fungal Priority Pathogen List that designated the most common invasive aspergillosis, *Aspergillus fumigatus*, to be in the Critical Priority group, which is designated as the highest perceived public health threat. *Aspergillus fumigatus* is also included in the FDA qualified designation list of pathogens that pose a serious and life-threatening risk.

- The Phase 3 randomized, multicenter, open-label, adjudicator-blinded ORALTO trial will evaluate the efficacy and safety of MAT2203 as an oral step-down treatment 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. The primary efficacy endpoint in this non-inferiority study is all-cause mortality at study day 42. Key secondary objectives include demonstration of superiority for treatment-related toxicities leading to changes in treatment, long-term survival benefit of MAT2203 using all-cause mortality at study day 84 and the impact of MAT2203 on healthcare resource utilization and quality of life.

- The Phase 3 ORALTO trial is expected to include approximately 65 investigator sites in the U.S., Europe, South America, the Middle East and Asia Pacific. Enrollment is expected to include approximately 216 adults with recently diagnosed probable or proven invasive aspergillosis who are being treated with AmBisome due to their inability to receive an IV mold-active azole and with limited alternative treatment options. Following up to two days of treatment with AmBisome, eligible participants will be randomized 2:1 to receive either oral MAT2203 or continued AmBisome treatment followed by standard of care. All study participants will receive up to 12 weeks of treatment starting from the first day of treatment with AmBisome. All study participants are expected to be hospitalized during the initial AmBisome treatment period. After step-down to oral MAT2203, study participants may be discharged to continue treatment on an outpatient basis, as clinically appropriate. An independent Data Review Committee, which will be blinded to treatment, will adjudicate primary and secondary endpoints, including clinical, radiological, and mycological responses.

- Once approximately 75% of participants are enrolled, an independent Data Safety Monitoring Board will review the pooled all-cause mortality rate in a blinded fashion to ensure sample size assumptions are reasonable and the study is adequately powered. Should the pooled event differ substantially from expected levels, a sample size adjustment can be made to the trial.

- The Company is engaged in active dialogues with potential partners and is seeking to finalize a partnership as soon as possible in order to commence the Phase 3 ORALTO trial.

MAT2203 Compassionate/Expanded Use Access Program

- A total of 19 patients with serious/life-threatening invasive fungal infections have been enrolled in the program to date, with others being evaluated. The infections treated include a variety of micro-organisms (including Aspergillus, Mucorales species, Candidiasis, Fusarium 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.

- Patients have been enrolled in the Program at prestigious institutions including the University of Michigan, Johns Hopkins, Nationwide Children's Hospital, City of Hope, Vanderbilt University Medical Center, the National Institutes of Health, Children's Hospital of Philadelphia, Memorial Sloan Kettering Cancer Center and the University of California, San Diego School of Medicine.

- Most patients were receiving AmBisome prior to enrollment but developed treatment-limiting nephrotoxicity, and most also required treatment for azole-resistant organisms or had failed azole therapy and had no other treatment options. All patients who transitioned to MAT2203 after developing renal toxicity following treatment with AmBisome experienced a reversal of renal impairment with a return to baseline renal function and no subsequent renal issues. In addition, most patients to date were able to be discharged from the hospital setting and effectively treated at home, supporting the potential significant pharmacoeconomic impact of MAT2203.

- Eight patients who completed the desired course of treatment with oral MAT2203 had complete clinical resolution of their infection and patients with ongoing treatment continue to experience significant clinical improvement.

LNC Platform Updates

Internal Oral LNC Oncology Program

- Conventional docetaxel, a well-known chemotherapeutic agent used in the management of multiple metastatic and unresectable tumors, is only administered intravenously, and is associated with significant side effects and toxicities.

- LNC's crystalline structure encapsulates and protects the body from the docetaxel cargo and selectively delivers drug to tumor cells. This markedly reduces the amount of free drug circulated systemically, avoiding one of the primary drivers of toxicity.

- LNC-docetaxel is an effective targeting vehicle and an efficient delivery platform for oncology applications due to its unique phospholipid composition that allows for targeting and delivering docetaxel to tumor cells that express phosphatidylserine on their surface.

- *In vivo* study data reported in November 2023 demonstrated that oral LNC-docetaxel effectively targeted melanoma tumors and was able to reduce tumor sizes to a degree comparable to that of IV-docetaxel with no apparent toxicity.

- Additional *in vivo* study data reported in March 2024 corroborated the lack of toxicity in a more comprehensive safety study with a longer treatment duration and higher doses of oral LNC-docetaxel. Healthy mice administered oral LNC-docetaxel at doses more than 8x greater than IV-docetaxel showed no weight loss, versus an average 20% peak weight loss in mice treated with IV-docetaxel. Mice treated with oral LNC-docetaxel maintained their body weight, which was statistically no different than the weight of control mice treated with oral saline.

Internal Oral LNC Small Oligonucleotide Inflammation Program

- *In vivo* studies documented the successful oral delivery and biological activity of two different LNC-formulated small oligonucleotides targeting inflammatory cytokines IL-17A and TNFα with reductions in tissue cytokine mRNA in both colitis and psoriasis, along with significant reductions in serum TNFα levels in colitis.

- The LNC-formulated small oligonucleotides evaluated in these studies interfered with cytokine synthesis rather than simply targeting the cytokine itself, which creates additional opportunities for potential future applications of LNC-delivered therapeutics.

Corporate Development

- The Company received notification from the NYSE American LLC that it has regained compliance with the NYSE American LLC continued listing standards by resolving the continued listing deficiency with respect to the low selling price of its common stock as described in Section 1003(f)(v) of the NYSE American Company Guide.

2023 Financial Results

Revenue for 2023 was $1.1 million, which was generated from the Company's research collaborations with BioNTech SE and Genentech Inc. This compares with revenue for 2022 of $3.2 million, which was generated from the Company's research collaboration with BioNTech SE.

Total costs and expenses for 2023 were $24.9 million compared with $27.8 million for 2022. The decrease was primarily due to lower clinical trial expenses and lower professional and consulting fees. Income from selling unused New Jersey net operating losses (NOLs) and research and development tax credits was $0.5 million and $3.5 million for 2023 and 2022, respectively.

The net loss for 2023 was $22.9 million, or $0.11 per share, compared with a net loss for 2022 of $21.0 million, or $0.10 per share.

Cash, cash equivalents and marketable securities as of December 31, 2023 were $13.8 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 through the third quarter of 2024.

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 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.
Consolidated Balance Sheets
(in thousands, except for share data)

	December 31, 2023	December 31, 2022
ASSETS:		
Current assets:		
Cash and cash equivalents	$ 4,787	$ 6,830
Marketable debt securities	8,969	21,933
Restricted cash – security deposit	50	50
Prepaid expenses and other current assets	1,737	5,719
Total current assets	15,543	34,532
Non-current assets:		
Leasehold improvements and equipment - net	1,923	2,091
Operating lease right-of-use assets - net	3,064	3,613
Finance lease right-of-use assets - net	21	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	9,561	10,287
Total assets	$ 25,104	$ 44,819
LIABILITIES AND STOCKHOLDERS' EQUITY:		
Current liabilities:		
Accounts payable	$ 514	$ 618
Accrued expenses and other liabilities	1,447	3,099
Operating lease liabilities - current	656	562
Financing lease liabilities - current	5	7
Total current liabilities	2,622	4,286
Non-current liabilities:		
Deferred tax liability	341	341
Operating lease liabilities - net of current portion	2,877	3,533
Financing lease liabilities - net of current portion	18	22
Total non-current liabilities	3,236	3,896
Total liabilities	5,858	8,182
Stockholders' equity:		
Common stock par value $0.0001 per share, 500,000,000 shares authorized at December 31, 2023 and 2022, respectively; 217,264,526 issued and outstanding as of December 31, 2023 and 2022, respectively	22	22
Additional paid-in capital	195,018	190,070

Accumulated deficit	(175,573)	(152,631)
Accumulated other comprehensive loss	(221)	(824)
Total stockholders' equity	19,246	36,637
Total liabilities and stockholders' equity	$ 25,104	$ 44,819

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

	For the Year Ended December 31,	
	2023	**2022**
Revenue:		
Contract Revenue	$ 1,096	$ 3,188
Costs and Expenses:		
Research and development	14,489	16,678
General and administrative	10,373	11,100
Total costs and expenses	24,862	27,778
Loss from operations	(23,766)	(24,590)
Sale of New Jersey net operating loss & tax credits	484	3,491
Other income, net	340	102
Net loss	$ (22,942)	$ (20,997)
Net loss per share – basic and diluted	$ (0.11)	$ (0.10)
Weighted average common shares outstanding:		
Basic and diluted	217,264,526	216,811,439
Other comprehensive gain/(loss), net of tax		
Unrealized gain/(loss) on securities available-for-sale	603	(679)
Other comprehensive gain/(loss), net of tax	603	(679)
Comprehensive loss	$ (22,339)	$ (21,676)

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