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 25, 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 7.01 Regulation FD Disclosure.

On March 25, 2024, Matinas BioPharma Holdings, Inc. (the "Company") announced positive results from an*in vivo* study in healthy mice with its lipid nanocrystal (LNC) platform technology formulation of docetaxel. A copy of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Item 7.01 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, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 8.01. Other Events.

On March 25, 2024, the Company announced positive results from an*in vivo* study in healthy mice with its LNC formulation of docetaxel. The data demonstrate that oral LNC-docetaxel formulation can reduce the well-recognized toxicity of IV-docetaxel, as primarily manifested by weight loss in this model. The Company believes that this illustrates how the crystalline structure of LNCs encapsulates and protects the body from the docetaxel cargo prior to selectively delivering it directly to tumor cells, reducing the amount of circulating free drug, and thereby avoiding one of the primary drivers of chemotherapy-associated toxicity. The phosphatidylserine composition of LNCs allows for selective tumor targeting and delivery, potentially making LNC-docetaxel a targeting vehicle and an oral delivery platform for oncology applications. The Company intends to evaluate higher doses in additional tumors, including those that have not historically responded well to docetaxel therapy, as well as potential improvements in the

therapeutic indices of other toxic chemotherapies.

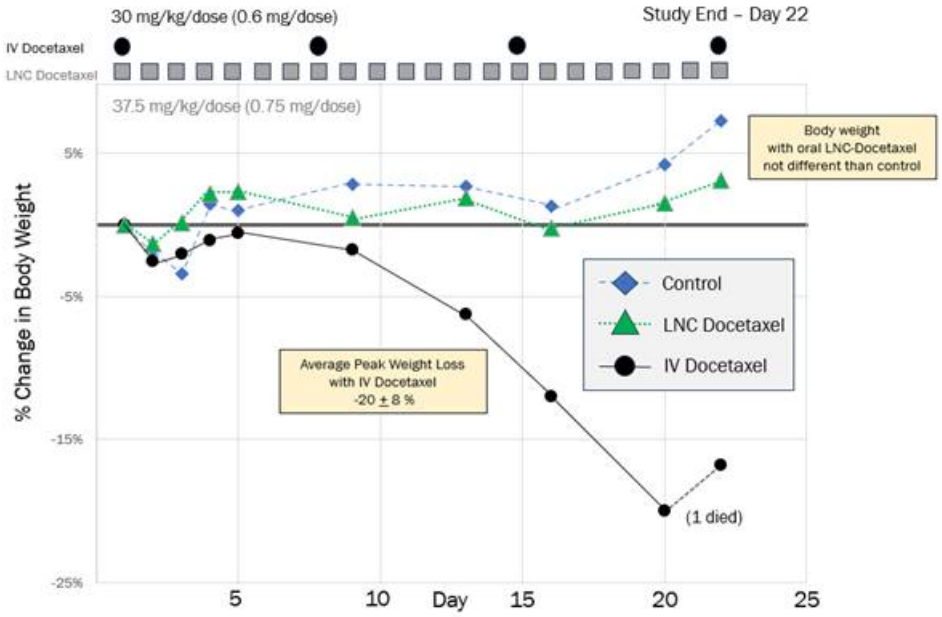
Study Design

The goal of the study was to determine whether an oral LNC formulation of docetaxel could improve the overall safety profile of conventional IV-administered docetaxel. The study included healthy BALB/c mice (n=24) divided into three treatment groups:

- Control animals treated with oral saline.
- IV-docetaxel (30 mg/kg, or 0.6 mg/dose) administered once a week for three weeks.
- Oral LNC-docetaxel (37.5 mg/kg, or 0.75 mg/dose) administered once daily over three weeks.

The primary endpoint was change in body weight over the treatment period.

Findings



Key Takeaways

- Through Day 22, the total amount of docetaxel administered with the oral LNC-docetaxel formulation was more than 8x greater than with IV-docetaxel (the final IV dose was used to measure pharmacokinetics).
- All mice treated with IV-docetaxel lost a significant amount of weight (toxicity), with an average peak loss of 20% of their original body weight.
- 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.
- One mouse in the IV-docetaxel group died prior to the conclusion of the study and was censored from the analysis (last measurement was -32% body weight loss); the curve of the IV-docetaxel group also reflects the expected 7-day recovery following an IV dose of docetaxel.
- The daily administered oral LNC-docetaxel dose was 50% higher, and the total amount of drug administered was 3.5x greater, than the LNC-docetaxel dose administered in a previous study that demonstrated anti-tumor activity comparable to IV-docetaxel in a syngeneic mouse melanoma model.

Forward- Looking Statements

This Current Report on Form 8-K contains certain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and Private Securities Litigation Reform Act, as amended, including those relating to the Company's strategic focus and the future development of its product candidates, including 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.

These statements may be identified by the use of forward-looking expressions, including, but not limited to, "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, the Company's ability to obtain additional capital to meet its 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; the 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 hereof. 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. The Company's product candidates are all in a development stage and are not available for sale or use.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated March 25, 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 25, 2024

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

Matinas BioPharma Announces Positive *in vivo* Safety Data with its Oral LNC-Docetaxel Formulation

Daily oral LNC-docetaxel, at a total administered dose of more than 8x greater than IV-docetaxel, showed no evidence of weight loss, compared to an average peak weight loss of 20% with IV-docetaxel

Results build on data from prior in vivo *study of oral LNC-docetaxel showing reductions in tumor size comparable to IV-docetaxel*

Management to host to 2023 Financial Results and Business Update Conference Call on March 27, 2024

BEDMINSTER, N.J. (March 25, 2024) – Matinas BioPharma Holdings, Inc. (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform technology, announces positive results from an additional *in vivo* study in healthy mice with an oral LNC formulation of docetaxel, a well-established chemotherapeutic agent used in the management of multiple metastatic and unresectable tumors. Docetaxel is currently only administered intravenously and is frequently associated with significant side effects and treatment-limiting toxicities.

"These recent data show how our oral LNC-docetaxel formulation can dramatically reduce the well-recognized toxicity of IV-docetaxel, as primarily manifested by weight loss in this model," said James J. Ferguson, M.D., Chief Medical Officer of Matinas. "Our previous *in vivo* study 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 evident toxicity. We have now corroborated this lack of toxicity in a more comprehensive safety study with a longer treatment duration and even higher doses of oral LNC-docetaxel.

"This illustrates how the crystalline structure of our LNCs encapsulates and protects the body from the docetaxel cargo prior to selectively delivering it directly to tumor cells, markedly reducing the amount of circulating free drug, and thereby avoiding one of the primary drivers of chemotherapy-associated toxicity. Importantly, the unique phosphatidylserine composition of LNCs allows for selective tumor targeting and delivery, making LNC-docetaxel both an effective targeting vehicle and an efficient oral delivery platform for oncology applications," he added. "With data from our *in vivo* studies that suggests a broader therapeutic index for oral LNC-docetaxel, we plan to evaluate higher doses in additional tumors – including those that have not historically responded well to docetaxel therapy – as well as potential improvements in the therapeutic indices of other toxic chemotherapies."

Study Design

The goal of this study was to determine whether an oral LNC formulation of docetaxel could improve the overall safety profile of conventional IV-administered docetaxel. The study included healthy BALB/c mice (n=24) divided into three treatment groups:

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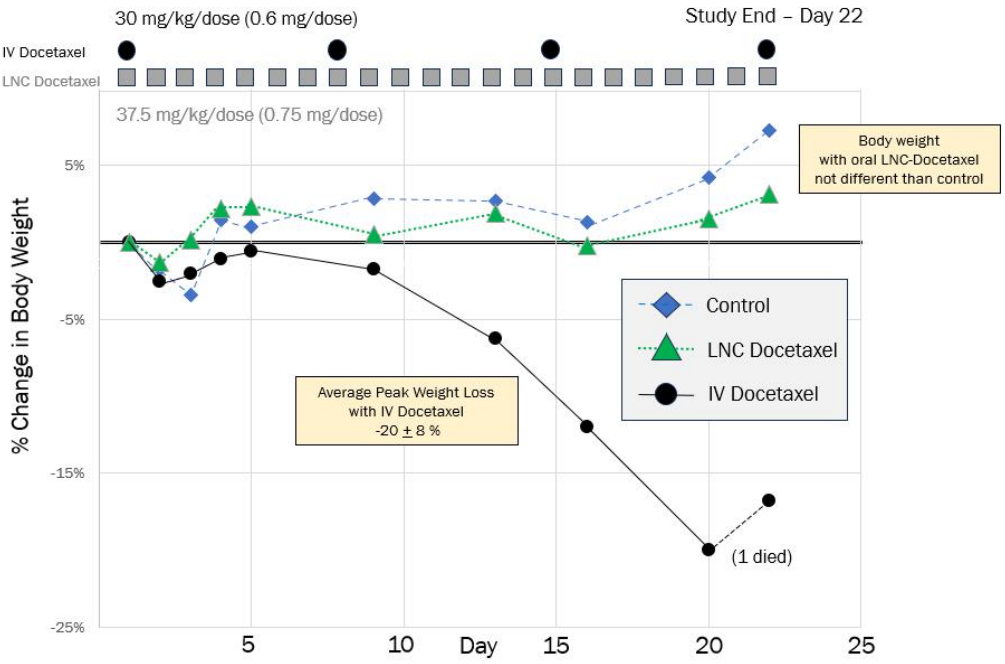

Key Takeaways

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Conference Call

Matinas BioPharma will report 2023 financial results after market close on Wednesday, March 27, 2024. Matinas management will host an investment community conference call and webcast to discuss financial results and provide a business update that day at 4:30 p.m. Eastern time (1:30 p.m. Pacific time). To participate in the call, please dial 877-484-6065 (Toll-Free) or 201-689-8846 (Toll). The webcast will be available on the IR Calendar page of the Matinas website and will be archived for six months.

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 infection, inflammation and oncology. 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 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 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 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

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