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): November 7, 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	**07921**
(Address of principal executive offices)	**(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 November 7, 2023, Matinas BioPharma Holdings, Inc. (the "Company") announced results from an*in vivo* animal study of its oral lipid nanocrystal ("LNC") 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 November 7, 2023, the Company announced positive results from an*in vivo* animal study of its oral LNC formulation of docetaxel, a chemotherapeutic agent used in the management of multiple metastatic and unresectable tumors. Currently, docetaxel is administered intravenously and can be associated with significant side effects and toxicities. The study demonstrated reductions in tumor size comparable to systemic intravenous docetaxel in a well-validated mouse melanoma model. No toxicity was observed with the LNC formulations over the 10 days of oral dosing. The course of treatment primarily targeted efficacy and requires further study and evaluation with longer periods of administration.

Study Design

Purpose: Document the efficacy of an oral LNC docetaxel formulation to target and treat tumors, with both negative (untreated) and positive (IV docetaxel) controls.

- Syngeneic tumor model (C57BL/6 mice injected with B16F10 murine melanoma cells)
- Four treatment groups
    - Untreated controls
    - Low-dose oral LNC docetaxel
    - High-dose oral LNC docetaxel
    - IV docetaxel
- Dosing of oral LNCs and IV docetaxel initiated at Day 5 following tumor cell injection
- Low-dose and high-dose oral LNC arms dosed daily through Day 14
- IV docetaxel administered on Day 5 and Day 10
- Tumor volume (caliper measurements) measured throughout the course of treatment
- Toxicity monitored throughout treatment and assessment of hematologic parameters at Day
- Animal sacrifice at Day 14
- Tumor volume measured at Day 14

Key Findings

- Efficacy: Anti-tumor effect of daily oral LNC docetaxel in both the high-dose and low-dose arms were comparable to intravenous docetaxel with statistically significant reductions in tumor volume compared with untreated controls at Day 14 (high dose oral LNC -63%; low dose oral LNC -57%; IV docetaxel -68%), and similar reductions in tumor weight at Day 14.
- Safety: No systemic toxicities were noted. Body weight was stable over treatment duration and hematologic parameters were similar to untreated controls.

The Company is considering evaluating the efficacy of the current LNC docetaxel formulation in other tumor models and evaluating longer-term treatment regimens to confirm lack of toxicity. The Company plans to evaluate the potential anti-tumor activity of LNC formulations of small oligonucleotides.

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 November 7, 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: November 9, 2023

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

Matinas BioPharma Announces Positive *in vivo* Efficacy Results of Oral LNC Docetaxel Formulation in a Melanoma Model

Study results show reduction in tumor size comparable to IV docetaxel and no systemic toxicity

BEDMINSTER, N.J. (November 7, 2023) – 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 *in vivo* animal study of an oral LNC formulation of docetaxel, a well-known chemotherapeutic agent used in the management of multiple metastatic and unresectable tumors. Currently, docetaxel is administered intravenously and can be associated with significant side effects and toxicities.

"We are excited to report new *in vivo* data demonstrating the therapeutic efficacy of an oral LNC formulation of docetaxel," saidDr. James J. Ferguson, Chief Medical Officer of Matinas. "We believe this is a step forward for Matinas' unique drug delivery platform, taking us beyond our successes in infectious disease by providing convincing proof-of-principle that orally administered LNCs can effectively target tumors and successfully deliver small molecule therapeutics to those tumors.

"The study shows reductions in tumor size comparable to systemic intravenous docetaxel in a well-validated mouse melanoma model," he added. "We observed no toxicity with our LNC formulations over the 10 days of oral dosing, noting this relatively short course of treatment was primarily targeting efficacy and will require further study and evaluation with longer periods of administration. Additional analyses of the data are ongoing, and we are preparing them for presentation at upcoming scientific meetings."

Study Design

Purpose: Document the efficacy of an oral LNC docetaxel formulation to target and treat tumors, with both negative (untreated) and positive (IV docetaxel) controls.

- Syngeneic tumor model (C57BL/6 mice injected with B16F10 murine melanoma cells)
- Four treatment groups
    - Untreated controls
    - Low-dose oral LNC docetaxel
    - High-dose oral LNC docetaxel
    - IV docetaxel
- Dosing of oral LNCs and IV docetaxel initiated at Day 5 following tumor cell injection
- Low-dose and high-dose oral LNC arms dosed daily through Day 14
- IV docetaxel administered on Day 5 and Day 10
- Tumor volume (caliper measurements) measured throughout the course of treatment
- Toxicity monitored throughout treatment and assessment of hematologic parameters at Day 14
- Animal sacrifice at Day 14
- Tumor volume measured at Day 14

Key Findings

- Efficacy: Anti-tumor effect of daily oral LNC docetaxel in both the high-dose and low-dose arms were comparable to IV docetaxel with statistically significant reductions in tumor volume compared with untreated controls at Day 14 (high dose oral LNC -63%; low dose oral LNC -57%; IV docetaxel -68%), and similar reductions in tumor weight at Day 14.
- Safety: No systemic toxicities were noted. Body weight was stable over treatment duration and hematologic parameters were similar to untreated controls.

Potential next steps for Matinas include evaluating the efficacy of the current LNC docetaxel formulation in other tumor models and evaluating longer-term treatment regimens to confirm lack of toxicity. Additionally, Matinas plans to evaluate the potential anti-tumor activity of LNC formulations of small oligonucleotides.

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 was successfully evaluated in the completed Phase 2 EnACT study in cryptococcal meningitis, meeting its primary endpoint and achieving robust survival. MAT2203 will be further evaluated as an oral step-down monotherapy treatment following IV amphotericin B in a single pivotal Phase 3 study in the treatment of aspergillosis in persons with limited treatment options who are unable to be treated with azoles 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 potentially 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 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, our collaboration with National Resilience, Inc., 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
Jody Cain
Jcain@lhai.com
310-691-7100

# # #