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): December 27, 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 7.01 Regulation FD Disclosure.

On December 27, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing results from a series of*in vivo* studies demonstrating successful oral delivery of two lipid nanocrystal ("LNC")-formulated small single-strand oligonucleotides that specifically target key inflammatory cytokines TNFα and IL-17A in well-established and validated animal models that mimic acute inflammatory responses seen in human diseases. 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 December 21, 2023, the Company announced results from a series of*in vivo* studies demonstrating successful oral delivery of two LNC-formulated small single-strand oligonucleotides that specifically target key inflammatory cytokines TNFα and IL-17A in well-established and validated animal models that mimic acute inflammatory responses seen in human diseases.

Acute Colitis Study ("TNFα")

A dextran sulfate sodium ("DSS")-induced murine colitis model was used to evaluate an orally administered LNC-delivered small oligonucleotide that specifically targets TNFα mRNA synthesis. Colon tissue TNFα mRNA levels, as assessed by quantitative real-time PCR analysis, were lower following orally administered active LNCs, resulting in statistically significant reductions of serum TNFα levels by 37% compared with diseased, but untreated animals. Importantly, clinical disease activity scores at key time points in the studies were also significantly improved with an active LNC formulation.

Acute Psoriasis Study ("IL-17A")

An imiquimod ("IMQ")-induced murine psoriasis model was used to evaluate an orally administered, LNC-delivered small oligonucleotide designed to inhibit IL-17A mRNA synthesis, which contributes significantly to the progression of psoriatic skin lesions. Similar to the DSS colitis model, skin tissue levels of IL-17A mRNA in the IMQ psoriasis model were lower with orally administered active LNCs compared with IMQ alone. In this model, while IL-17A serum levels were not expected to change, improvement was demonstrated in clinical disease markers of skin redness and scaling, further validating the biological activity of these small oligonucleotides.

Additional tissue and histologic analyses from both studies are ongoing and the Company plans to present these data at future scientific meetings.

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 business activities, the Company's strategy and plans, the potential of the Company's 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.

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 continue as a going concern, 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 its product candidates; the Company's ability to successfully complete research and further development and commercialization of its product candidates; the uncertainties inherent in clinical testing; the timing, cost and uncertainty of obtaining regulatory approvals; the Company's ability to protect its 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 the Company's 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 December 27, 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: December 27, 2023

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

Matinas BioPharma Demonstrates *in vivo* Biological Activity and Disease Improvement in Two Inflammatory Disease Models with Oral LNC-Delivered Small Oligonucleotides

In an acute colitis model, data show statistically significant knockdown of elevated levels of serum TNFα, reductions in tissue TNFα mRNA and improvement in disease activity scores

In an acute psoriasis model, data show reductions in tissue IL-17A mRNA and improvement in clinical disease markers including skin lesions

BEDMINSTER, N.J. (December 27, 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 results from a series of *in vivo* studies demonstrating successful oral delivery of two LNC-formulated small single-strand oligonucleotides that specifically target key inflammatory cytokines TNFα and IL-17A in well-established and validated animal models that mimic acute inflammatory responses seen in human diseases.

"These studies demonstrate successful oral delivery and biological activity of two different LNC-formulated small oligonucleotides targeting inflammatory cytokines with reductions in tissue cytokine mRNA in both colitis and psoriasis, along with significant reductions in serum TNFα levels in colitis. Commensurate improvements in clinical disease markers and scores were also documented in both models," said James Ferguson, M.D., Matinas' Chief Medical Officer.

"While additional study is warranted, the successful oral delivery of small oligonucleotides is very exciting and we believe these data demonstrate how Matinas' LNC platform could be used for the oral delivery of functional small oligonucleotides with potential therapeutic applications," Dr. Ferguson added. "Importantly, the unique nature of the particular oligonucleotides evaluated in these studies, which interfere with cytokine synthesis rather than simply targeting the cytokine itself, creates additional opportunities for potential future applications of LNC-delivered therapeutics, either alone or in combination with other therapeutics with different mechanisms of action."

Earlier this year, Matinas established the *in vitro* potency of these proprietary oligonucleotides and their LNC formulations in knocking down their respective cytokine targets in cultured cells. Both were advanced to *in vivo* studies to evaluate meaningful biological activity in relevant disease models.

Acute Colitis Study (TNFα)

A dextran sulfate sodium (DSS)-induced murine colitis model was used to evaluate an orally administered LNC-delivered small oligonucleotide that specifically targets TNFα mRNA synthesis. Colon tissue TNFα mRNA levels, as assessed by quantitative real-time PCR analysis, were lower following orally administered active LNCs, resulting in statistically significant reductions of serum TNFα levels by 37% compared with diseased, but untreated animals. Importantly, clinical disease activity scores at key time points in the studies were also significantly improved with an active LNC formulation.

Acute Psoriasis Study (IL-17A)

An imiquimod (IMQ)-induced murine psoriasis model was used to evaluate an orally administered, LNC-delivered small oligonucleotide designed to inhibit IL-17A mRNA synthesis, which contributes significantly to the progression of psoriatic skin lesions. Similar to the DSS colitis model, skin tissue levels of IL-17A mRNA in the IMQ psoriasis model were lower with orally administered active LNCs compared with IMQ alone. In this model, while IL-17A serum levels were not expected to change, improvement was demonstrated in clinical disease markers of skin redness and scaling, further validating the biological activity of these small oligonucleotides.

Additional tissue and histologic analyses from both studies are ongoing and the Company plans to present these data at future scientific meetings.

"We believe that our proprietary encapsulation and oral delivery methods could be applied to other small oligonucleotides, including RNAi therapeutics such as siRNA and antisense oligonucleotides," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "While a variety of methods for administering small oligonucleotides exist, most are primarily directed to the liver, and none provide oral administration and delivery capabilities. The opportunity to orally deliver small oligonucleotides with extra-hepatic targeting could be key differentiating features in rapidly advancing anti-inflammatory therapy.

"We plan to further review the data from these inflammatory disease models to determine the best path forward for this program," he added. "Further study and optimization of these LNC-delivered small oligonucleotides will be required to assess the most appropriate therapeutic targets and the associated magnitude of benefit."

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 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.

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