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 21, 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 December 21, 2023, Matinas BioPharma Holdings, Inc. (the "Company") issued a press release announcing receipt of written feedback from the U.S. Food and Drug Administration ("FDA") on its proposed revised protocol for a Phase 3 study of MAT2203 in patients with invasive aspergillosis with limited or no treatment options. 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 receipt of written feedback from the FDA on its proposed revised protocol for a Phase 3 study of MAT2203 in patients with invasive aspergillosis with limited or no treatment options. The preliminary written comments move the Company closer to alignment with the FDA on the design of a single Phase 3 registration trial for the approval of MAT2203. At the FDA's invitation, the Company is planning a meeting early in the first quarter of 2024 to discuss and finalize the Phase 3 protocol and position MAT2203 to commence Phase 3 as soon as possible thereafter.

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 December 21, 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 21, 2023

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

Exhibit 99.1

Matinas BioPharma Provides Update to MAT2203 Regulatory and Development Pathway Following Feedback from FDA

Written Preliminary Comments on the Phase 3 Registration Trial for MAT2203 Move Company Closer to Full Alignment with FDA

Matinas to Meet with FDA Early in the First Quarter of 2024 to Finalize Phase 3 Study Design

Partnership Discussions Remain Ongoing for MAT2203

BEDMINSTER, N.J. (December 21, 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 receipt of written feedback from U.S. Food and Drug Administration (FDA) on its proposed revised protocol for a Phase 3 study of MAT2203 in patients with invasive aspergillosis with limited or no treatment options. The preliminary written comments move the Company closer to alignment with FDA on the design of a single Phase 3 registration trial for the approval of MAT2203. At the FDA's invitation, Matinas is planning a meeting early in the first quarter of 2024 to discuss and finalize the Phase 3 protocol and position MAT2203 to commence Phase 3 as soon as possible thereafter.

"We remain grateful to FDA for the ongoing constructive dialogue around the Phase 3 program for MAT2203 and we believe we share the common goal of positioning MAT2203 for review and approval while minimizing regulatory risk," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "The latest feedback from FDA has moved us closer to agreement, and we believe accepting the FDA's invitation for a meeting in early 2024 will be the final step in achieving full alignment with FDA.

"Our goal remains to design and implement a feasible and interpretable Phase 3 clinical trial leading to an approval that will meet a significant unmet medical need for patients. We believe that this could lead to a promising commercial opportunity for Matinas. The data generated in our ongoing Expanded Access/Compassionate Use Access program has continued to increase our optimism for our Phase 3 study and its probability of success and has been impactful in our discussions with the FDA," he added. "We remain engaged in an active partnership process and have updated these parties as we continue to engage with the FDA. Importantly, we believe that achieving complete protocol alignment is not a prerequisite to consummating a potential transaction."

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.

Investor Contact

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