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): February 26, 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	**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 February 26, 2024, Matinas BioPharma Holdings, Inc. (the "Company") provided an update for its ongoing Compassionate/Expanded Use Access Program (the "Program") with MAT2203, the Company's proprietary, LNC-delivered oral formulation of the broad-spectrum antifungal drug amphotericin B. 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 February 26, 2024, the Company announced that all patients who transitioned to its MAT2203 product candidate after developing renal toxicity following treatment with AmBisome® (liposomal amphotericin B) saw a reversal of renal impairment with a return to baseline renal function with no subsequent renal issues. 19 patients to date have been enrolled in the Program at multiple healthcare 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. The majority of enrolled patients are post-transplant or are undergoing treatment for underlying malignancies. The infections being treated with MAT2203 include a variety of micro-organisms (including *Aspergillus*, *Mucorales species*, *Candidiasis*, *Fusarium* and suspected *Coccidioides*) occurring at multiple sites of infection, including brain, bladder/colon, bone, lung, sinus, and skin. Most patients were receiving AmBisome® prior to enrollment but developed treatment-limiting nephrotoxicity and most also required treatment for either azole-resistant organisms or had clinically failed azole therapy and had no other treatment options.

Of the 19 patients enrolled in the Program, 15 have available follow-up and 4 recently initiated or will soon commence treatment with MAT2203.

- 12 of the 15 patients had either complete clinical resolution or objective improvement in clinical markers of infection (including radiologic and mycologic).
- Of the 5 patients who completed their full individually specified course of treatment (ranging from 2 weeks to 1 year, depending on the infection) - all have had complete clinical resolution with no relapses or recurrence of their infection.
- 5 additional patients have shown objective improvement in clinical markers and are continuing treatment with MAT2203 as planned.
- 5 of the 15 patients were unable to complete their individually specified course of treatment, although 2 saw significant clinical improvement of their fungal infection and are included in the 12 overall successful cases.

  - 2 patients transitioned to palliative care shortly after starting therapy with MAT2203 because of unanticipated progression of their malignant disease.
  - 1 patient discontinued therapy after two days due to underlying GI issues (i.e., Crohn's disease).
  - 1 patient passed away due to progression of their underlying disease approximately 8 weeks into therapy (but previously experienced significant clinical improvement of their fungal infection).
  - 1 patient discontinued MAT2203 treatment following 10 weeks of therapy due to underlying GI issues (long-standing nausea/vomiting), but with improvement in their fungal infection.

Importantly, all patients who experienced renal toxicity following treatment with AmBisome saw their renal function return to baseline after transitioning to MAT2203 therapy and suffered no further renal side effects over the course of extended treatment with MAT2203.

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 February 26, 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: February 26, 2024

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

MATINAS BIOPHARMA

Matinas BioPharma Provides Positive Outcomes Update on the MAT2203 Compassionate/Expanded Use Access Program, Including Multiple Patients with Complete Clinical Resolution

A total of 19 patients with serious/life-threatening invasive fungal infections have been enrolled, including aspergillosis, mucormycosis, fusarium, candidiasis, cryptococcosis, and endemic mycoses such as coccidioidomycosis and histoplasmosis

All 5 patients who completed the desired course of treatment had complete clinical resolution of their infection; patients with ongoing treatment continue to experience significant clinical improvement

All patients who transitioned to MAT2203 after developing renal toxicity following treatment with AmBisome® (liposomal amphotericin B) saw a reversal of renal impairment with a return to baseline renal function with no subsequent renal issues

BEDMINSTER, N.J. (February 26, 2024) – Matinas BioPharma (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, today provided an update from its ongoing Compassionate/Expanded Use Access Program (the "Program") with MAT2203, the Company's proprietary, LNC-delivered oral formulation of the broad-spectrum antifungal drug amphotericin B.

To date, 19 patients have been enrolled in the Program at prestigious healthcare 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.

The majority of enrolled patients are post-transplant or are undergoing treatment for underlying malignancies. The infections being treated with MAT2203 include a variety of micro-organisms (including *Aspergillus*, *Mucorales species*, *Candidiasis*, *Fusarium* and suspected *Coccidioides*) occurring at multiple sites of infection, including brain, bladder/colon, bone, lung, sinus, and skin. Most patients were receiving AmBisome prior to enrollment but developed treatment-limiting nephrotoxicity and most also required treatment for either azole-resistant organisms or had clinically failed azole therapy and had no other treatment options.

"We are encouraged by the positive clinical impact of MAT2203 in each of our patients who faced few or no treatment options," said Dr. Marisa Miceli, an internationally recognized infectious disease physician specializing in the treatment of invasive fungal infections and Professor of Medicine in the Division of Infectious Diseases at the University of Michigan. "Of the seven patients we have treated to date under the Program, all were either unable to receive azole therapy due to drug-drug interactions, intolerance or resistance and some of them experienced serious treatment-limiting toxicities while attempting therapy with IV-administered amphotericin B. Treatment with MAT2203 was well tolerated and led to favorable clinical and radiological response and we did not observe any renal toxicity. While additional study is warranted, MAT2203 may be particularly promising for the treatment of invasive fungal infections in patients with limited options and therefore satisfy a currently significant unmet medical need."

Of the 19 patients enrolled in the Program, 15 have available follow-up and 4 recently initiated or will soon commence treatment with MAT2203.

- 12 of the 15 patients had either complete clinical resolution or objective improvement in clinical markers of infection (including radiologic and mycologic).
- Of the 5 patients who completed their full individually specified course of treatment (ranging from 2 weeks to 1 year, depending on the infection) all have had complete clinical resolution with no relapses or recurrence of their infection.
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Importantly, all patients who experienced renal toxicity following treatment with AmBisome saw their renal function return to baseline after transitioning to MAT2203 therapy and suffered no further renal side effects over the course of extended treatment with MAT2203.

"We continue to be excited about the ongoing, consistent positive clinical impact of MAT2203, seen in these extremely ill patients," saidTheresa Matkovits, PhD, Chief Development Officer at Matinas. "We look forward to advancing MAT2203 into Phase 3 development in the ORALTO registration trial and to validating these results in a well-controlled clinical trial in which we believe the clinical probability of success is quite high. If approved, oral, effective, and safe MAT2203 could represent a dramatic improvement to current clinical standard of care and become the treatment of choice for patients and physicians battling invasive fungal infections. We are grateful to the participants in the Program and to their physicians for recognizing the clinical potential of MAT2203 in treating a broad spectrum of deadly invasive fungal infections."

MAT2203 is not yet licensed or approved anywhere globally.

About MAT2203

Matinas BioPharma is developing MAT2203 as a potential oral broad-spectrum treatment for invasive deadly fungal infections. Although amphotericin B is a fungicidal agent, it is currently only available through an intravenous route of administration, which is known to be associated with several significant safety issues such as renal toxicity and anemia due to very high circulating levels of amphotericin B. MAT2203 has the potential to overcome the significant limitations of the currently available amphotericin B products due to its targeted oral delivery. 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.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology.

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 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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