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 22, 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 March 22, 2024, Matinas BioPharma Holdings, Inc. (the "Company") announced the complete clinical response in three patients with serious invasive fusarium infection following treatment with the Company's MAT2203 product candidate, an oral formulation of the antifungal 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 March 22, 2024, the Company announced the complete clinical response in three patients with serious invasive fusarium infection following treatment with MAT2203. All three patients were enrolled in the Company's Compassionate/Expanded Use Access Program and were treated by Marisa H. Miceli, MD, Professor of Medicine, Specializing in Fungal Infections and Transplant Diseases, Division of Infectious Diseases, Internal Medicine, at the University of Michigan.

A 40-year-old female patient with extensive burns on more than 34% of her body developed complications of a urinary tract infection, ventilator-associated pneumonia, and C. difficile colitis. Her treatment required multiple surgical operations for debridement of wounds and skin grafting and a soft tissue fusarium infection of the left foot at a skin grafting site developed, which was resistant to voriconazole. Treatment with IV-amphotericin B led to nephrotoxicity and the fusarium infection showed resistance to all other antifungals. The patient was transitioned to oral MAT2203 for two weeks, which led to clinical resolution of her fungal infection.

A 48-year-old female renal transplant recipient with a weakened immune system developed chronic non-healing leg wounds. A fungal skin lesion culture was positive for an azole-resistant fusarium infection, which was only susceptible to amphotericin B. The patient was unable to receive long-term treatment with IV-amphotericin B due to an underlying condition, including risk for development of nephrotoxicity, and was transitioned to oral MAT2203. The patient began to show clinical improvement following two weeks of oral MAT2203 treatment and the skin wounds completely healed following six months of MAT2203 treatment.

A 69-year-old man with coronary artery disease, hyperlipidemia, hypertension, emphysema, aortic valve replacement, with small cell lung cancer being treated with chemotherapy, developed fever. CT scans exhibited a left upper lobe consolidation of the lung with a culture showing positive for an azole-resistant fusarium species. The patient was treated with oral MAT2203 on an out-patient basis for six months. Repeat CT scans following MAT2203 treatment showed improvement in fungal infection, with some new nodules due to progression of malignancy.

The outcome of these three patients with fusarium infection are included in the 19 total patients discussed in the Company's previous update to the MAT2203 Compassionate/Expanded Use Access Program; however two of the three patients had not yet achieved complete clinical resolution at the time of that report.

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 22, 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 22, 2024

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

Exhibit 99.1

Three Patients with Invasive Fusarium Infection in Matinas BioPharma's Oral MAT2203 Compassionate/Expanded Use Access Program Achieve Complete Clinical Response

BEDMINSTER, N.J. (March 22, 2024) – Matinas BioPharma Holdings, Inc. (NYSE American: MTNB), a clinical-stage biopharmaceutical company focused on delivering groundbreaking therapies using its lipid nanocrystal (LNC) platform delivery technology, announces complete clinical response in three patients with serious invasive fusarium infection following treatment with MAT2203, Matinas' oral formulation of the potent antifungal amphotericin B. All three patients were enrolled in the Company's Compassionate/Expanded Use Access Program and were treated by Marisa H. Miceli, MD, Professor of Medicine, Specializing in Fungal Infections and Transplant Diseases, Division of Infectious Diseases, Internal Medicine, at the University of Michigan.

"Invasive fusarium infection is often difficult to treat as clinically relevant fusarium species are resistant to almost all currently used antifungals including azoles and echinocandins, making it highly gratifying to announce the complete clinical response following treatment with oral MAT2203 for these seriously ill patients with limited treatment options," said Theresa Matkovits, PhD, Chief Development Officer of Matinas. "While we don't have the exact isolates and corresponding minimum inhibitory concentrations for all these patients, we do know that effective treatment of fusarium generally requires higher concentrations of amphotericin B than invasive aspergillosis, for example. The successful MAT2203 treatment outcome in these patients therefore adds to our confidence for the upcoming ORALTO Phase 3 trial in patients suffering from invasive aspergillosis with limited treatment options. We are grateful to these patients for participating in our program."

A 40-year-old female patient with extensive burns on more than 34% of her body developed complications of a urinary tract infection, ventilator-associated pneumonia, and C. difficile colitis. Her treatment required multiple surgical operations for debridement of wounds and skin grafting and she developed a soft tissue fusarium infection of the left foot at a skin grafting site, which was resistant to voriconazole. Treatment with IV-amphotericin B led to nephrotoxicity and her fusarium infection showed resistance to all other antifungals. She was transitioned to oral MAT2203 for two weeks, which led to clinical resolution of her fungal infection.

A 48-year-old female renal transplant recipient with a weakened immune system developed chronic non-healing leg wounds. A fungal skin lesion culture was positive for an azole-resistant fusarium infection, which was only susceptible to amphotericin B. The patient was unable to receive long-term treatment with IV-amphotericin B due to her underlying condition, including risk for development of nephrotoxicity, and was transitioned to oral MAT2203. She began to show clinical improvement following two weeks of oral MAT2203 treatment and her skin wounds completely healed following six months of MAT2203 treatment.

A 69-year-old man with coronary artery disease, hyperlipidemia, hypertension, emphysema, aortic valve replacement, with small cell lung cancer being treated with chemotherapy, developed fever. CT scans exhibited a left upper lobe consolidation of the lung with a culture showing positive for an azole-resistant fusarium species. The patient was treated with oral MAT2203 on an out-patient basis for six months. Repeat CT scan following MAT2203 treatment showed improvement in fungal infection, with some new nodules due to progression of malignancy.

These three patients with fusarium infection are included in the 19 total patients discussed in Matinas' recently announced update to theMAT2203 Compassionate/Expanded Use Access Program; however, two of the three patients had not yet achieved complete clinical resolution at the time of that report.

"MAT2203 continues to demonstrate its potential to effectively treat invasive fungal infections and help patients achieve complete clinical resolution. These very sick patients unfortunately are faced with a variety of complex medical challenges in addition to their fungal disease. MAT2203 has demonstrated the ability to resolve these deadly infections, allowing physicians to concentrate their efforts on the patients' other underlying conditions," said Jerome D. Jabbour, Chief Executive Officer of Matinas. "If approved, an oral, effective and safe MAT2203 could represent a new treatment paradigm for the unmet medical need in the treatment of 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.

Matinas' lead LNC-based therapy is MAT2203, an oral formulation of the broad-spectrum antifungal drug amphotericin B. In addition to MAT2203, preclinical and clinical data have demonstrated that this novel technology can 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

LHA Investor Relations
Jody Cain
Jcain@lhai.com
310-691-7100

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