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): January 25, 2022

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) 443-1860

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.

Matinas BioPharma Holdings, Inc. (the "Company") issued a press release providing a business update on each of its ongoing programs and discussing its strategic outlook for 2022. 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 January 25, 2022, the Company announced, among other things, that:

MAT2203 Program

- it believes it may be in a position to submit a New Drug Application with the U.S. Food and Drug Administration ("FDA") for its MAT2203 (oral amphotericin B) product candidate for the treatment of cryptococcal meningitis in late 2023, and anticipates a chemistry, manufacturing, and controls (CMC) meeting with the FDA in the first quarter of 2022;
- it anticipates expanding the application of proprietary and differentiated intracellular delivery technology to complex nucleic acids internally and potentially in partnership with third parties during 2022;
- additional analyses of final data from Cohort 2 of the Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial ("EnACT") of MAT2203 demonstrated (i) survival at Day 30 (early survival) of 98% in patients receiving MAT2203 vs. 88% in patients receiving IV Amphotericin B ("SOC"), and (ii) culture conversion (sterility) assessed at any time during the trial of 97% in patients receiving MAT2203 and 76% in patients receiving SOC;
- the FDA expressed no concerns with any data generated to date related to the efficacy, safety, or tolerability of MAT2203 during a meeting in December 2021, requested additional confirmatory evidence for an indication for step-down therapy during induction treatment, and expressed openness to an expansion of EnACT to include a new Cohort 5 to run alongside the ongoing Cohort 4 in Uganda, increasing the number of clinical sites from two to five;
- the Company is planning to meet with FDA in the second quarter of 2022 to finalize Cohort 5 design and discuss potential primary endpoint of 30-day survival;
- the Company anticipates financial support of EnACT expansion by the National Institute of Health;
- data from additional preclinical studies of MAT2203 for the treatment of invasive fungal infections, such as *Candida auris* and *mucormycosis* (black fungus), to position MAT2203 for label expansion, is expected in the second half of 2022;

LNC Platform Collaborations

- an in vivo test of the Company's LNC formulation of Gilead Science's remdesivir (LNC-RDV) in a standard genetically modified mouse model of SARS-CoV-2 infection conducted by the National Institute of Allergy and Infectious Diseases ("NIAID") and Department of Epidemiology at the University of North Carolina at Chapel Hill ("UNC") demonstrated that orally administered LNC-RDV reduced viral titers and improved clinical parameters of body weight and congestion scores five days following infection, with effects similar to those seen with subcutaneous administered remdesivir, positioning LNC-RDV for further in vivo work to be conducted at UNC and supported by NIAID commencing in the first quarter of 2022, with data expected in the second half of 2022;
- the Company's collaboration with Genentech, which was extended through 2022, demonstrated the successful intracellular delivery of LNC-formulated small molecules and oligonucleotides, without accompanying toxicity, in completed *in vitro* studies. The Company anticipates data from a third program in 2022;

MAT2501 Program

- a single ascending dose study of MAT2501 in healthy volunteers is ongoing with data expected later in the second quarter of 2022;
- in the fourth quarter of 2021, the Cystic Fibrosis Foundation ("CFF") provided an additional grant award in connection with ongoing preclinical work in support of MAT2501, bringing the total amount of CFF financial support for MAT2501 to over $4.5 million; and
- long-term preclinical toxicology studies planned for 2022 and protocol design for Phase 2 in consultation with the CFF are ongoing, and Phase 2 trials of MAT2501 for the treatment of nontuberculous mycobacterial are expected to commence in 2023, pending additional financial support from the CFF.

Financial Outlook

- the Company's preliminary estimate of cash, cash equivalents and marketable securities at December 31, 2021, is approximately $49.9 million, subject to completion of the audit of the Company's consolidated financial statements for the year ended December 31, 2021, compared to $58.7 million at December 31, 2020. This amount may differ from the amount that will be reflected in the Company's audited 2021 financial statements. Additional information and disclosures are required for a more complete understanding of the Company's financial position and results of operations as of December 31, 2021. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

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 results of the EnACT study, the LNC platform delivery technology, the Company's strategic focus and the future development of its product candidates, including MAT2203, MAT2501, 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.

Forward-looking 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, 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; 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 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 January 25, 2022.
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: January 25, 2022

By: */s/ Jerome D. Jabbour*

Name: Jerome D. Jabbour

Title: Chief Executive Officer

Exhibit 99.1

Matinas BioPharma Provides Business Update and 2022 Strategic Outlook

– End of Phase 2 Meeting with FDA Provides Pathway to NDA Submission for MAT2203 Following Confirmatory Data to be Generated in an Additional Cohort; Cohort 5 in Ongoing EnACT Trial –

– Cohort 4 of EnACT (all oral induction regimen) Underway With Six Patients Enrolled and Topline Interim Data Expected Q3 2022 –

– In Vivo Study of Orally Administered LNC Remdesivir Demonstrated Reduced Viral Titers and Effects Similar to Subcutaneous Administered Remdesivir; NIAID to Support an Additional Preclinical Study –

– Ended 2021 with $49.9 Million, Sufficient to Fund Planned Operations Through 2023 –

– Conference Call and Live Audio Webcast Scheduled Today, January 25th at 8:30 a.m. ET –

BEDMINSTER, N.J., January 25, 2022 –Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on redefining the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology, today is providing a business update on each of its ongoing programs and discussing its strategic outlook for 2022.

"We made tremendous progress in 2021, completely transitioning our Company and significantly advancing our LNC platform technology," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "Despite the resurgence of COVID-19 with both Delta and Omicron variants, our team was able to deliver compelling data for MAT2203 in the first three cohorts of the EnACT trial, which then facilitated an important and highly productive End of Phase 2 meeting with the U.S. Food and Drug Administration (FDA) in December of 2021. Based upon FDA's support and feedback, we are preparing to expand the EnACT trial to provide additional confirmatory data in support of MAT2203 as step-down therapy for induction treatment, which we believe could position us to submit a New Drug Application (NDA) in late 2023."

Jabbour added, "We continue to be pleased with our collaborations with Genentech and NIAID/Gilead, and each has yielded encouraging data in support of our LNC platform which will lead to further studies during 2022. Finally, during 2021 we conducted an internal evaluation of our LNC platform and believe that applying our proprietary and differentiated intracellular delivery technology to complex nucleic acids represents a highly promising opportunity. We anticipate expanding the application of our technology into this area, both internally and in partnership with carefully selected third parties during 2022."

Key Program Updates and Anticipated Upcoming Milestones

MAT2203 Program *(oral amphotericin B, with targeted delivery, under development for the treatment and prevention of invasive fungal infections, including cryptococcal meningitis)*

- Additional analyses of final data from Cohort 2 of EnACT demonstrated (i) survival at Day 30 (early survival) of 98% in patients receiving MAT2203 vs. 88% in patients receiving IV Amphotericin B (SOC); and (ii) culture conversion (sterility) assessed at any time during the trial of 97% in patients receiving MAT2203 and 76% in patients receiving SOC.

- Positive FDA Meeting in December 2021 reinforced FDA's ongoing commitment to anti-infective drug development generally and to MAT2203 specifically. The FDA expressed no concerns with any data generated to date related to the efficacy, safety, or tolerability of MAT2203. Additional confirmatory evidence was requested for an indication for step-down therapy during induction treatment, but there was no requirement for a separate stand-alone study or enrollment of U.S. patients. The FDA expressed openness to an expansion of EnACT to include a new Cohort 5 to run alongside Cohort 4 in Uganda, increasing the number of clinical sites from two to five to streamline the development program in support of an accelerated NDA submission. The Company is planning to meet with FDA in the second quarter of 2022 to finalize cohort design, including sample size required for non-inferiority and discussing potential primary endpoint of 30-day survival. NIH financial support of EnACT expansion anticipated and the Company continues to evaluate the timing for submission of an application for Breakthrough Designation.

- Key chemistry, manufacturing, and controls (CMC) meeting with FDA to be scheduled late in the first quarter of 2022 to discuss and evaluate MAT2203 formulation in support of a potential NDA submission in late 2023.

- Cohort 4 of EnACT has commenced in Uganda, with six patients enrolled to date. Cohort 4 is designed to study an all-oral regimen of MAT2203 during the 14-day induction period, followed by four additional weeks of oral consolidation therapy with MAT2203. Cohort 4 is comprised of 40 patients on MAT2203 and a control group of 16 patients receiving IV amphotericin B. Enrollment in this open-label cohort is expected to complete in the second quarter of 2022, with availability of topline interim data anticipated in the third quarter of 2022.

- Additional preclinical studies of MAT2203 are planned to investigate the treatment of invasive fungal infections, such as *Candida auris* and *mucormycosis* (black fungus), to position MAT2203 for label expansion. Data is expected in the second half of 2022.

- Company plans to submit a formal Request for Scientific Advice to the European Medicines Agency (EMA) by the second quarter of 2022 to align and plan for expanding the regulatory footprint for MAT2203 globally.

LNC Platform Collaborations

- ***NIAID/Gilead*** – In the fourth quarter of 2021, the National Institute of Allergy and Infectious Diseases (NIAID), together with the Department of Epidemiology at the University of North Carolina at Chapel Hill (UNC), conducted an *in vivo* test of our LNC formulation of Gilead Science's remdesivir (LNC-RDV) in a standard genetically modified mouse model of SARS-CoV-2 infection. In this animal model, orally administered LNC-RDV reduced viral titers and improved clinical parameters of body weight and congestion scores five days following infection, with effects similar to those seen with subcutaneous administered remdesivir. Following discussion with both NIAID and Gilead, these highly encouraging results position LNC-RDV for further *in vivo* work to be conducted at UNC and supported by NIAID. This preclinical study is anticipated to commence late in the first quarter of 2022, with data expected in the second half of 2022.

- ***Genentech*** – Genentech recently extended this collaboration for another year, through 2022. The original agreement provided for cooperation on up to three proprietary Genentech compounds for initial *in vitro* testing. Two of the programs have been completed. Each demonstrated the successful intracellular delivery of LNC-formulated small molecules and oligonucleotides, without accompanying toxicity. Genentech is evaluating the third proprietary compound to provide the Company for testing, and the Company anticipates additional data from this program during 2022.

MAT2501 Program *(oral amikacin, with targeted delivery, under development for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF))*

- A single ascending dose (SAD) study of MAT2501 in healthy volunteers is ongoing with data expected later in the second quarter of 2022.

- In the fourth quarter of 2021, the Cystic Fibrosis Foundation (CFF) provided an additional grant award in connection with ongoing preclinical work in support of MAT2501, bringing the total amount of CFF financial support for MAT2501 to over $4.5 million.

- Long-term preclinical toxicology studies planned for 2022 and protocol design for Phase 2 in consultation with the CFF are ongoing. Phase 2 trials of MAT2501 for the treatment of NTM are expected to commence in 2023, pending additional financial support from the CFF.

LYPDISO™ Program *(next generation, prescription-only omega-3 fatty acid-based composition under development for treatment of cardiovascular and metabolic conditions, including hypertriglyceridemia)*

- A global process to identity and potentially secure a partner to continue development of LYPDISO remains ongoing. Interest in this legacy non-LNC based cardiovascular asset has emerged from a collection of companies and Matinas is evaluating several strategic alternatives. Further update is anticipated in the second quarter of 2022.

Financial Outlook

The Company's preliminary, unaudited estimate of cash, cash equivalents and marketable securities at December 31, 2021, is approximately $49.9 million, subject to completion of the audit of the Company's consolidated financial statements for the year ended December 31, 2021. This compares to $58.7 million at December 31, 2020. Based on current projections, the Company believes that cash on hand is sufficient to fund planned operations through 2023.

At the Special Meeting of Stockholders held on January 26, 2021, stockholders of Matinas approved an amendment to the Company's Certificate of Incorporation to effect a reverse stock split of our common stock at a ratio in the range of 1-for-2 to 1-for-15, with such reverse stock split to be effected at such ratio, time, and date, if at all, as determined by the Company's Board of Directors in its sole discretion. Following a review of the Company and its strategic positioning, the Board of Directors has determined that it is not in the best interest of the Company or its stockholders to effect a reverse split.

Conference Call and Webcast Details

The Company will host a live conference call and webcast to discuss this corporate update and 2022 business outlook today, Tuesday, January 25th at 8:30 a.m. ET. To participate in the call, please dial (877) 407-5976 (Toll-Free) or (412) 902-0031 (Toll) and reference conference ID 13726163. The live webcast will be accessible on the Investors section of Matinas BioPharma's website, www.matinasbiopharma.com, and archived for 90 days.

About Matinas BioPharma

Matinas BioPharma is a biopharmaceutical company focused on redefining the intracellular delivery of nucleic acids and small molecules with its lipid nanocrystal (LNC) platform technology. The Company is developing its own internal portfolio of products as well as partnering with leading pharmaceutical companies to develop novel formulations that capitalize on the unique characteristics of the LNC platform.

Preclinical and clinical data have demonstrated that this novel technology can provide solutions to many of the challenges in achieving safe and effective intracellular delivery, for both small molecules and larger, more complex molecules, such as mRNA, DNA plasmids, antisense oligonucleotides and vaccines. The combination of a unique mechanism of action and flexibility with formulation and in route of administration (including oral), position Matinas' LNC technology to potentially become the preferred next-generation intracellular drug delivery vehicle with distinct advantages over both lipid nanoparticles and viral vectors.

MAT2203 is an oral, LNC formulation of the highly effective, but also highly toxic, antifungal medicine amphotericin B, primarily used as a first-line treatment for invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. The DSMB unanimously approved the progression of EnACT into Cohort 4 in December of 2021. Cohort 4 commenced in January of 2022, with data expected in the second half of 2022.

MAT2501 is an oral, LNC formulation of the broad-spectrum aminoglycoside antibiotic amikacin, primarily used to treat chronic and acute bacterial infections. With the support of the Cystic Fibrosis Foundation, MAT2501 is currently undergoing important preclinical studies and commenced a Phase 1 human clinical trial in the fourth quarter of 2021. MAT2501 would be the first and only oral aminoglycoside, and is being positioned with an initial indication for the treatment of nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis.

LYPDISO™, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, intended for the treatment of cardiovascular and metabolic conditions. This next-generation omega-3 therapy has been shown in two head-to-head studies to provide effective triglyceride-lowering and significantly higher EPA blood levels than Vascepa®. A global process to identity and potentially secure a partner to continue development of LYPDISO remains ongoing.

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 delivery technology, and the future development of its product candidates, including MAT2203, MAT2501, 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. 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 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 and Media Contacts

Peter Vozzo
ICR Westwicke
443-213-0505
peter.vozzo@westwicke.com

Source: Matinas BioPharma Holdings, Inc.
