

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 7, 2020

**MATINAS BIOPHARMA HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction  
of incorporation)

001-38022  
(Commission  
File Number)

46-3011414  
(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 Sec.230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR Sec.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 announcing a collaboration with the National Institute of Allergy and Infectious Diseases (“NIAID”) to evaluate oral formulations of Gilead’s Sciences, Inc.’s (“Gilead”) antiviral remdesivir utilizing the Company’s lipid nanocrystal (“LNC”) platform delivery technology. A copy of the press release is furnished as Exhibit 99.1 hereto and incorporated herein by reference.

The Company also issued a press release announcing the filing of a preliminary proxy for a special meeting of stockholders on January 26, 2021. A copy of the press release is furnished as Exhibit 99.2 hereto and incorporated herein by reference.

The information in this Item 7.01 and Exhibits 99.1 and 99.2 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 (the “Securities Act”), 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 7, 2020, the Company announced that it plans to collaborate with the NIAID, part of the National Institutes of Health, to test one or more oral formulations of Gilead’s remdesivir in preclinical models using the Company’s LNC platform delivery technology. Any product generated as a part of efforts by the Company and NIAID would require a license from Gilead for the use of remdesivir and a license from the Company for the use of the LNC formulation. The Company plans to utilize NIAID’s suite of preclinical services to carry out antiviral testing with selected formulations. Gilead will provide remdesivir and work with the Company to evaluate the data generated from the planned series of preclinical studies.

Also on December 7, 2020, the Company announced the filing of a preliminary proxy for a special meeting of stockholders on January 26, 2020 (the “Special Meeting”). The Company’s Board of Directors approved a proposal, to be submitted to stockholders for approval at the Special Meeting, to authorize the Board of Directors to potentially effect a reverse split of the Company’s common stock. The reverse stock split proposal includes a proposed range between 1-for-2 and 1-for-15 shares of outstanding common stock. Approval of the reverse stock split requires the affirmative vote of a majority of the Company’s outstanding shares. The final ratio will be determined, if at all, by the Company’s Board of Directors following stockholder approval at the Special Meeting.

*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 collaboration with the NIAID, a potential reverse stock split, anticipated capital and liquidity needs, 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.

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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.**

<u>Exhibit No.</u>	<u>Description</u>
<a href="#"><u>99.1</u></a>	Press Release, dated December 7, 2020.
<a href="#"><u>99.2</u></a>	Press Release, dated December 7, 2020.

**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 7, 2020

By: /s/ Jerome D. Jabbour

Name: Jerome D. Jabbour

Title: Chief Executive Officer

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**Matinas BioPharma Announces Collaboration with the National Institute of Allergy and Infectious Diseases to Evaluate Oral Formulations of Gilead's Antiviral Remdesivir Utilizing Matinas' LNC Platform Delivery Technology**

**BEDMINSTER, N.J. (December 7, 2020)** – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced that they plan to collaborate with the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH), to test oral formulations of remdesivir in preclinical models. Remdesivir is owned by Gilead Sciences, Inc. (Nasdaq: GILD) and the lipid nanocrystal (LNC) platform is owned by Matinas. Any product generated as a part of efforts by Matinas and NIAID would require a license from Gilead for the use of remdesivir and a license from Matinas for the use of the LNC formulation.

One or more formulations of remdesivir will be developed using Matinas' Lipid Nanocrystal (LNC) platform delivery technology, which enables the development of a wide range of difficult-to-deliver molecules. Matinas plans to utilize NIAID's suite of preclinical services to carry out antiviral testing with selected formulations. Gilead will provide remdesivir and work with Matinas to evaluate the data generated from the planned series of preclinical studies.

"We believe that our LNC technology may be applied to remdesivir to allow for the potential for oral administration of this important drug in the fight against COVID-19," commented Jerome D. Jabbour, Chief Executive Officer of Matinas.

Matinas' LNC platform delivery technology offers an oral intracellular drug delivery solution with potential advantages over other delivery technologies across a broad range of therapeutics. The Company has demonstrated in preclinical animal models the ability to formulate and deliver a wide variety of molecules and drugs (including oligonucleotides, peptides, proteins, vaccines, and small molecules) which, (a) require delivery technology to improve the stability of molecules inside and outside of the body; (b) could benefit from efficient delivery and cellular uptake by target cells; (c) are currently only available in IV formulations or (d) otherwise experience significant toxicity-related adverse events.

**About Matinas BioPharma**

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care for patients in areas of significant unmet medical need. Company leadership has a deep history and knowledge of drug development and is supported by a world-class team of scientific advisors.

MAT9001, the Company's lead product candidate for the treatment of cardiovascular and metabolic conditions, is a prescription-only omega-3 fatty acid-based composition, comprised primarily of EPA and DPA, under development for hypertriglyceridemia. MAT9001 is currently in a second head-to-head comparative study against Vascepa<sup>(R)</sup> (ENHANCE-IT), with topline data expected in the first quarter of 2021.

In addition, Matinas is developing a portfolio of products based upon its proprietary lipid nanocrystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them orally bioavailable, less toxic and targeted to cells and tissues.

MAT2203 is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, primarily used to treat serious invasive fungal infections. MAT2203 is currently in a Phase 2 open-label, sequential cohort study (EnACT) in HIV-infected patients with cryptococcal meningitis. EnACT is preparing to enroll patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

MAT2501 is an oral, encochleated formulation of the broad-spectrum aminoglycoside antibiotic medicine amikacin, primarily used to treat chronic and acute bacterial infections. The Company recently announced that it has been awarded up to \$3.75 million from the Cystic Fibrosis Foundation (CFF) to support development of MAT2501 toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

*Gilead is a trademark of Gilead Sciences, Inc., or its related companies.*

#### **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 the Company’s anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT9001 and 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. 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**

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**Matinas BioPharma Files Preliminary Proxy for Special Meeting of Stockholders**

*– Special Meeting of Stockholders Scheduled for January 26, 2021 Seeking Authorization to Potentially Effectuate a Discretionary Reverse Stock Split Prior to January 26, 2022 –*

*– Company’s Proposal to Stockholders Intended to Enhance Appeal of Common Stock to Institutional Investors, Position its Common Stock for Potential Eligibility for Inclusion in Certain Biotechnology and Pharmaceutical Trading Indices and for Potential Inclusion on the NYSE “Big Board” or NASDAQ Global Market –*

**BEDMINSTER, N.J., December 7, 2020** – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance standards of care in areas of significant unmet medical need, today announced that its Board of Directors has approved a proposal, to be submitted to stockholders for approval at a Special Meeting of Stockholders anticipated to be held on January 26, 2021, to authorize the Board of Directors to potentially effect a reverse split of the Company’s common stock. The reverse stock split proposal includes a proposed range between 1-for-2 and 1-for-15 shares of outstanding common stock. The final ratio will be determined, if at all, by Matinas’ Board of Directors following stockholder approval at the Special Meeting.

“We believe the filing of this preliminary proxy statement to authorize a potential reverse split of stock is an important proactive and strategic step to position Matinas for long term success and to potentially be able to capitalize on some of the important milestones and catalysts we have in front of us during 2021,” said Jerome D. Jabbour, Chief Executive Officer of Matinas. “We believe that there are many potential benefits to increasing the price per common share, including making the Company’s stock more attractive to institutional investors, potentially position us for eligibility and inclusion in certain biotechnology and pharmaceutical trading indices and exchange traded funds, and even potentially position Matinas for an “uplisting” to the NYSE “Big Board” or NASDAQ Global Market. However, we only intend to make a reverse split effective if we believe that doing so would be in the best interests of the Company and our stockholders.”

Matinas filed a preliminary proxy statement with the U.S. Securities and Exchange Commission as required by SEC rules. The proposal requires the affirmative vote of a majority of the Company's outstanding shares. Stockholders may obtain a free copy of the preliminary proxy statement or the definitive proxy statement (once available), as well as other documents that the Company files with the SEC at the SEC's website at [www.sec.gov](http://www.sec.gov). The Company will file with the SEC and distribute to its stockholders a definitive proxy statement regarding the special meeting and the reverse stock split proposal.

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## **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 the reverse stock split proposal, the Company’s anticipated capital and liquidity needs, strategic focus and the future development of its product candidates, including MAT9001, MAT2203 and 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.

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