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): November 19, 2020

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 1.01. Entry into a Material Definitive Agreement.

On November 19, 2020, Matinas BioPharma Holdings, Inc. (the "Company") entered into a Therapeutic Development Award Agreement with the Cystic Fibrosis Foundation ("CFF") (the "Agreement") pursuant to which the Company received an award for up to $4,234,249 million in funding (the "Award") (of which $484,249 had been previously received) to support the preclinical development (the "Development Program") of the Company's MAT2501 product candidate (the "Product"), a lipid nano-crystal oral formulation of the broad-spectrum aminoglycoside amikacin, for the treatment of pulmonary non-tubercular mycobacteria infections and other pulmonary diseases (the "Field").

Upon the execution of the Agreement, the Company will receive $650,000. The remainder of the Award will be paid to the Company incrementally upon the achievement of certain milestones related to the progress of the Development Program, as set forth in the Agreement. Pursuant to the terms of the Agreement, the Company is obligated to make royalty payments to CFF contingent upon commercialization of the Product in the Field up to a maximum of five (5) times the Award or approximately $21.2 million (the "Royalty Cap"), payable in three equal annual installments following the first commercial sale of the Product, the first of which is due within 90 days following the first commercial sale of the Product. The Company is also obligated to make royalty payment(s) to CFF if the Company transfers, sells or licenses the Product for use in the Field, or if the Company enters into a change of control transaction which will be applied against the Royalty Cap. Lastly, the Company is also obligated to make up to two royalty payment to CFF of up to approximately $4.2 million each, due in the calendar years in which specified net sales milestones are achieved.

Either CFF or the Company may terminate the Agreement for cause, which includes the Company's material failure to achieve certain commercialization and development milestones. The Company's payment obligations survive the termination of the Agreement. The Agreement includes customary indemnification provisions.

The foregoing descriptions of the Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Agreement. A copy of the Agreement will be filed with the Securities and Exchange Commission as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2020 (the "Form 10-K"). Certain terms of the Agreement have been omitted from this Current Report on Form 8-K and will be omitted from the version of the Agreement to be filed as exhibit to the Form 10-K.

Item 2.03. Creation of a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement of a Registrant.

As of November 19, 2020, the Agreement constitutes a direct financial obligation of the Company, the material terms of which are described above under Item 1.01 and are incorporated herein by reference.

Item 7.01 Regulation FD Disclosure.

On November 20, 2020, the Company issued a press release announcing receipt of the Award, a copy of which is attached hereto as Exhibit 99.1.

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 (the "Securities Act"), or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release, dated November 20, 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: November 25, 2020

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

Exhibit 99.1

Matinas BioPharma Awarded up to $3.75 Million from the Cystic Fibrosis Foundation to Support Development of Oral Amikacin (MAT2501) for the Treatment of NTM Infections in Cystic Fibrosis Patients

BEDMINSTER, N.J., November 20, 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 it has been awarded up to $3.75 million from the Cystic Fibrosis Foundation (CFF). The award will support preclinical development of MAT2501, Matinas' lipid nano-crystal (LNC) oral formulation of the broad-spectrum aminoglycoside amikacin, toward an indication to treat nontuberculous mycobacterial (NTM) lung disease, including infections in patients with cystic fibrosis (CF).

"We are grateful to the Cystic Fibrosis Foundation for their support in accelerating the development of MAT2501 as a potential best in class treatment for NTM lung disease. These are debilitating, potentially life-threatening, and increasingly prevalent pulmonary infections, especially in patients with cystic fibrosis," commented Jerome D. Jabbour, Chief Executive Officer of Matinas. "We believe that an orally bioavailable amikacin, which takes advantage of our LNC delivery platform, would be the first oral aminoglycoside and would represent a significant improvement over currently available therapy. Furthermore, an oral, well tolerated, and targeted aminoglycoside would also potentially be of considerable value in treating other acute bacterial infections, especially gram-negative infections, where oral options are very limited and drug resistance is an increasing challenge. We look forward to continuing to work with the CF Foundation on realizing the potential of our LNC delivery platform."

The CFF award will allow Matinas to rapidly advance the development of MAT2501 and will support preclinical *in vitro* and *in vivo* studies, along with several of the toxicology studies necessary to progress MAT2501 into Phase 2. Pending a successful preclinical program, the CFF has indicated to Matinas a willingness to consider a request for further monetary support for the continuation of clinical studies, including dose determination and Phase 2 efficacy studies in CF patients suffering from NTM lung disease.

MAT2501 has been designated as a Qualified Infectious Disease Product (QIDP) and as an Orphan Drug for the treatment of NTM by the U.S. Food and Drug Administration (FDA). Orphan Drug designation of MAT2501 provides for a seven-year marketing exclusivity period against competition in the United States upon FDA approval, as well as other incentives and exemptions, including waiver of Prescription Drug User Fee Act (PDUFA) filing fees and tax credits for the cost of the clinical research. If MAT2501 is ultimately approved by the FDA, the seven-year period of marketing exclusivity from orphan designation combined with the additional five years of marketing exclusivity provided by the QIDP designation, provides for a potential total of 12 years of marketing exclusivity.

About NTM Lung Disease

NTM lung disease is a chronic, debilitating condition arising from an NTM infection in the lungs and is associated with significant patient morbidity and mortality. The signs and symptoms of NTM lung disease often overlap with the underlying lung conditions that increase risk for NTM, like cystic fibrosis, bronchiectasis, COPD, and asthma. The most common pathogens for NTM infections in the United States are *Mycobacterium avium complex* (MAC), which accounts for more than 80% of all NTM infections in the U.S. Patients with NTM lung infections frequently require lengthy hospital stays and prolonged courses of antibiotics to manage their disease.

The prevalence of human disease attributable to NTM has increased over the past two decades and is now growing at more than 8% per year and is even more prevalent than tuberculosis in the U.S. In 2018, it was estimated that between 75,000 and 100,000 patients were diagnosed with NTM lung disease in the U.S. alone.

About MAT2501

MAT2501 is an oral, encochleated formulation of the broad-spectrum aminoglycoside antibiotic agent amikacin, which utilizes the Company's proprietary LNC platform to achieve oral bioavailability, limit toxicity and enable targeted delivery to sites of infection. Currently, amikacin can only be delivered parenterally or through inhalation and is used to treat a variety of chronic and acute bacterial infections, including both NTM infections and various multidrug-resistant gram-negative bacterial infections. IV and inhaled amikacin, however, are associated with major side effects including nephrotoxicity and ototoxicity (permanent loss of hearing) with long-term use. Matinas believes that MAT2501's ability to orally deliver high levels of amikacin directly to the lung and without use-limiting toxicity, distinguishes it from all available therapies and could provide an important solution for patients and physicians.

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® (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 nano-crystal (LNC) drug delivery platform, which can solve complex challenges relating to the safe and effective delivery of potent medicines, making them more targeted, less toxic and orally bioavailable.

MAT2203, the Company's lead product candidate utilizing its LNC platform, is an oral, encochleated formulation of the well-known, but highly toxic, antifungal medicine amphotericin B, 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 will promptly begin enrolling patients in its second cohort, with the next DSMB evaluation of safety and efficacy data anticipated to occur in the middle of 2021.

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 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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