

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

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**FORM 8-K**

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**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 23, 2014

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**MATINAS BIOPHARMA HOLDINGS, INC.**

(Exact name of registrant as specified in its charter)

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Delaware  
(State or other jurisdiction  
of incorporation)

(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.)

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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:

- 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))
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## Item 8.01 Other Events.

On October 20, 2014, Matinas BioPharma Holdings, Inc. (the “Company”) submitted an Investigational New Drug application, or IND, to the United States Food and Drug Administration, or FDA, for its lead drug candidate, MAT9001, with an initial indication for the treatment of severe hypertriglyceridemia (TG>500 mg/dL).

Recently, the Company received feedback from FDA with respect to its IND submission for MAT9001. Although FDA did not raise any clinical hold issues, FDA has provided recommendations for certain revisions to the planned four-week rat comparative bridging toxicity study as well as the Company’s planned 4-way crossover single dose Fed/Fast PK study of MAT9001 in comparison to another omega-3 product. Previously, the Company had planned to initiate and complete each of these studies concurrently with its Phase III clinical study for MAT 9001. Based on FDA’s comments, the Company now intends to submit modified protocols for the four-week rat comparative bridging toxicity study, as well as the Company’s 4-way crossover single dose Fed/Fast PK study early in the first quarter of 2015 and, following dialogue with FDA, to initiate and complete these two studies. There can be no guarantee that FDA will meet with the Company in a timely fashion. As such, there may be a delay in the commencement of these two studies and therefore in the commencement of the Company’s planned Phase III clinical study for MAT9001. As recommended by FDA, the Company will submit the results of these two studies to FDA for review and comment in advance of initiating dosing with MAT9001 in its planned Phase III clinical study. As previously disclosed, the final protocol and clinical trial design for the Company’s Phase III clinical program is also subject to FDA review and comment. In addition, the Company needs to raise at least \$20.0 to \$60.0 million of additional financing to initiate and complete its intended Phase III clinical program for MAT9001 and to compile and submit its New Drug Application (NDA) to FDA for MAT9001. We do not currently have any arrangements or credit facilities in place as a source of funds, and there can be no assurance that we will be able to raise sufficient additional capital on acceptable terms, or at all.

This Current Report on Form 8-K, including exhibit 99.1, contains “forward-looking statements” made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995, including those relating to the Company’s product development, clinical and regulatory timelines, market opportunity, cash flow 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 successfully complete research and further development and commercialization of MAT9001; 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 for MAT9001; 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. Prospective investors are cautioned not to place undue reliance on such forward-looking statements, which speak only as of the date of this presentation. Matinas does not undertake any obligation to release publicly any revisions to such forward-looking statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma’s lead product candidate MAT9001 is in a development stage and is not available for sale or use.

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All forward-looking statements are expressly qualified in their entirety by this cautionary notice. You are cautioned not to place undue reliance on any forward-looking statements, which speak only as of the date of this Current Report on Form 8-K. We have no obligation, and expressly disclaim any obligation, to update, revise or correct any of the forward-looking statements, whether as a result of new information, future events or otherwise.

**Item 9.01. Financial Statements and Exhibits**

<b>Exhibit</b>	<b>Description</b>
99.1	Press Release dated December 23, 2014.

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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.**

Date: December 23, 2014

/s/ Roelof Rongen

Roelof Rongen, President and Chief Executive Officer

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## **Matinas BioPharma Receives FDA Feedback on IND Submission and Provides Update on Clinical Development Program for MAT9001**

**BEDMINSTER, NJ (December 23, 2014)** – Matinas BioPharma Holdings, Inc. (“Matinas BioPharma” or the “Company”) (OTCQB: MTNB), an emerging biopharmaceutical company focused on the development and commercialization of omega-3 fatty acid-based prescription therapeutics for the treatment of cardiovascular and metabolic conditions, announced today that the Company has received recommendations from the United States Food and Drug Administration (FDA) on its Investigational New Drug Application (IND) for its product candidate, MAT9001.

In October 2014, Matinas BioPharma filed an IND for MAT9001 with an initial indication for the treatment of severe hypertriglyceridemia (TG>500 mg/dL). MAT9001 is a uniquely engineered, prescription-only omega-3 fatty acid medication comprising docosa-pentaenoic acid (DPA), and other omega-3 fatty acids, and is specifically designed to provide a differentiated pharmacotherapy for the treatment of dyslipidemia.

The Company has received feedback from FDA on its IND submission for MAT9001. Although FDA’s guidance indicated that there were no clinical holds placed on MAT9001, it did suggest certain revisions to Matinas BioPharma’s development program for MAT9001, including specific requests to conduct and submit results of its planned 28-day rat comparative bridging toxicity study and its planned 4-way crossover single dose Fed/Fast PK study in advance of commencing a proposed Phase 3 registration program. The Company had previously planned to conduct each of these studies concurrently with the Phase 3 program.

Based on FDA’s recommendations, Matinas BioPharma is in the process of revising the protocols for the two studies and plans to submit them to FDA early in the first quarter of 2015. Following expected dialogue with the FDA, the Company plans to initiate the two studies as soon as possible. However, there can be no guarantee that FDA will meet with the Company in a timely fashion.

“While FDA’s requirement to conduct these two studies in advance of commencing our Phase 3 study for MAT9001 represents a change to our planned development strategy, this important guidance will help bring the Company into closer alignment with FDA’s perspectives on our overall proposed clinical development plan for MAT9001,” commented Roelof Rongen, President and Chief Executive Officer of Matinas BioPharma. “Despite facing a likely delay in commencing our Phase 3 study, we intend to promptly submit these updated protocols and meet with FDA as soon as possible thereafter. We remain committed to advancing MAT9001 into Phase 3 registration studies on an expedited basis, subject to our ability to raise the funds necessary to initiate and complete this pivotal program.”

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### **About MAT9001**

MAT9001 is a proprietary prescription-only omega-3 fatty acid-based composition, comprising docosa-pentaenoic acid (DPA) and other omega-3 fatty acids, which is under development for therapeutic applications with severe hypertriglyceridemia (TG>500 mg/dL) as the lead indication. Promising pre-clinical studies with DPA and MAT9001 indicate distinctive therapeutic response properties. The Company has recently filed an IND for MAT9001 and initiated its first human study in the fourth quarter of 2014. The Company believes that its development program and related clinical investigations may yield an improved therapeutic profile compared to existing therapies, based on MAT9001's differentiating mechanistic features associated with its unique composition.

### **About Matinas BioPharma**

Matinas BioPharma is a development stage biopharmaceutical company, founded in 2011, with a focus on identifying and developing novel pharmaceutical products for the treatment of abnormalities in blood lipids, referred to as dyslipidemia, and the treatment of cardiovascular and metabolic diseases. Led by an experienced management team and a board of directors with a history of building pharmaceutical companies, Matinas is focused on creating the next generation of omega-3-fatty-acid-based pharmaceutical products. Our lead product, MAT9001, which takes advantage of advancements in the field of lipidomics, has been specifically designed and formulated for therapeutic applications in the dyslipidemia field. For more information, please visit [www.matinasbiopharma.com](http://www.matinasbiopharma.com) and connect with the Company on [Twitter](#), [LinkedIn](#), [Facebook](#), and [Google+](#).

**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 product development, clinical and regulatory timelines, market opportunity, cash flow 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 successfully complete research and further development and commercialization of MAT9001; 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 for MAT9001; 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. Prospective 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 statement to reflect events or circumstances after the date hereof or to reflect the occurrence of unanticipated events. Matinas BioPharma's lead product candidate MAT9001 is in a development stage and is not available for sale or use.*

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Source: Matinas BioPharma Holdings, Inc.

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