
**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): September 11, 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 §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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On September 11, 2020, director Adam Stern informed the Board of Directors (the “Board”) of Matinas BioPharma Holdings, Inc. (the “Company”) that he will not stand for re-election to the Board at the upcoming annual meeting of stockholders (the “Annual Meeting”) which will be held on November 2, 2020 due to other commitments. Mr. Stern’s term of service will expire at the Annual Meeting. As of the date of the Annual Meeting, the Company and Mr. Stern will enter into a consulting agreement (the “Consulting Agreement”) pursuant to which Mr. Stern will provide ongoing strategic and operational advice for a period of one year in exchange for 100,000 shares of restricted stock of the Company and the extension of the vesting and exercisability terms of outstanding stock options and warrants of the Company held by Mr. Stern. Pursuant to the Consulting Agreement, Mr. Stern has agreed to certain specified restrictions on sales of the Company’s stock through the period ending August 1, 2021.

(d) On September 11, 2020, the Board of the Company, on the recommendation of its Nominating and Corporate Governance Committee, appointed Natasha Giordano as director of the Company, effective September 14, 2020. Ms. Giordano will also become a member of the Audit Committee of the Board.

Ms. Giordano, age 59, has been President, Chief Executive Officer and director of PLx Pharma Inc. (NASDAQ: PLXP) since January 2016. Previously, Ms. Giordano served as the Interim Chief Executive Officer of ClearPoint Learning, Inc., a privately held learning and training platform company, from May 2015 through November 2015. She also served on the ClearPoint board of directors from December 2009 through November 2015. Previously, Ms. Giordano served as the Chief Executive Officer of Healthcare Corporation of America (NYSE: HCA), a leading healthcare provider, from January 2014 through August 2014. From June 2009 to August 2012, Ms. Giordano served as Chief Operating Officer and then as Chief Executive Officer, President and a member of the board of directors of Xanodyne Pharmaceuticals, Inc., a privately-held branded specialty pharmaceutical company with development and commercial capabilities focused on pain management and women’s health. Prior to that, she served as President, Americas, for Cegedim Dendrite (formerly Dendrite International Inc.), a global technology services company, from 2007 to 2008, and as Senior Vice President of the Global Customer Business Unit of Cegedim Dendrite from 2004 to 2007. Ms. Giordano holds a Bachelor of Science degree in nursing from Wagner College. The Company believes Ms. Giordano is qualified to serve as a director due to her extensive experience in commercialization, general management and knowledge of the pharmaceutical and health care industries.

In connection with her appointment to the Board, the Board awarded Ms. Giordano 287,917 stock options, which vest in equal monthly installments over a 36-month period from the date of issuance and are exercisable at \$0.693 per share.

There are no arrangements or understandings pursuant to which Ms. Giordano was appointed as a director, and there are no related party transactions between the Company and Ms. Giordano reportable under Item 404(a) of Regulation S-K.

A copy of the press release announcing Ms. Giordano’s appointment to the Board is filed as Exhibit 99.01 to, and incorporated by reference in, this report.

Item 8.01 Other Events.

On September 15, 2020, the Company issued a press release announcing the outcome of its End of Phase 2 Meeting with the U.S. Food and Drug Administration (“FDA”) concerning the development and registration pathway for MAT9001. The official minutes of the meeting confirmed that the FDA and the Company are aligned on key next steps for MAT9001’s Phase 3 development program and registration pathway for an initial indication to treat severe hypertriglyceridemia (“SHTG”), a clinical disorder associated with major complications such as pancreatitis and atherosclerotic cardiovascular disease. The Company remains on track to initiate its Phase 3 program in the first half of 2021.

The Company and the FDA agreed on key elements of the Phase 3 program to support a New Drug Application (“NDA”) filing, including the requirement for a single 12-week study to support efficacy in SHTG. Moreover, FDA provided flexibility to the Company in the totality of patient safety data needed to meet regulatory requirements for NDA submission. The Company is evaluating several ways to both meet these requirements and to potentially provide additional data differentiating MAT9001 from other prescription omega-3 drugs.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are being furnished with this report:

| <u>Exhibit No.</u> | <u>Description</u> |
|--------------------|---|
| 99.1 | <u>Press Release, dated September 14, 2020.</u> |
| 99.2 | <u>Press Release, dated September 15, 2020.</u> |

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: September 15, 2020

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



Matinas BioPharma Appoints Industry Veteran Natasha Giordano to Board of Directors

BEDMINSTER, N.J., September 14, 2020 – Matinas BioPharma Holdings, Inc. (NYSE AMER: MTNB), today announced the appointment of Natasha Giordano to its Board of Directors as an independent director and a member of the audit committee, effective Monday, September 14, 2020.

Ms. Giordano brings over 25 years of extensive experience in healthcare, including senior leadership positions and board director roles spanning across several pharmaceutical companies and sales and marketing service providers. She has served as President, Chief Executive Officer, and a director of PLx Pharma Inc. since January 2016. Previously, Ms. Giordano served as the President and Chief Executive Officer of both ClearPoint Learning, Inc., and Healthcare Corporation of America. From June 2009 to August 2012, Ms. Giordano served as Chief Operating Officer and then as Chief Executive Officer, President and a director of Xanodyne Pharmaceuticals, Inc. Ms. Giordano also served as a director for Aceto Corporation from December 2011 through September 2019. Prior to that, she served as President, Americas, for Cegedim Dendrite (formerly Dendrite International Inc.) from 2007 to 2008 and as Senior Vice President, Global Customer Business Unit of Cegedim Dendrite from 2004 to 2007. Earlier in her career, she worked for Parke-Davis/Warner Lambert then Pfizer, in several sales and marketing leadership positions.

“We are delighted to welcome Natasha to the Matinas Board,” commented Herbert Conrad, Chairman of the Matinas BioPharma Board of Directors. “Natasha’s background includes significant commercial and strategic expertise and will complement the experience of our other Board members. This will be invaluable as our lead products move through clinical development. We are honored she has chosen to join us.”

Ms. Giordano commented, “I am extremely pleased to join the team at Matinas at such an exciting time. With several important clinical and strategic milestones over the next few quarters, I look forward to working with Herb, Jerry and the entire Matinas team to help maximize our opportunities and position the Company for commercial success to drive significant shareholder value.”

The Company also announced today that Adam Stern will not stand for re-election to the Company’s Board of Directors at the Company’s Annual Meeting of Stockholders on November 2, 2020, instead transitioning to a consulting role where he will be available to the Chief Executive Officer and the Board of Directors on matters related to overall corporate and financial strategy.

“Adam has served on our Board of Directors since inception, providing tremendous leadership, insight and guidance throughout his long-standing tenure,” said Jerome D. Jabbour, Chief Executive Officer of Matinas. “Our Company, as well as I personally, have benefited greatly from his extensive expertise and deep relationships within the investment community. On behalf of our entire Board and senior management team, we are extremely grateful for Adam’s dedication and commitment over these past seven years, and I am thrilled that we will be able to continue to work closely with Adam in his new role.”

“I am extremely grateful to Jerry, as well as the entire Board of Directors, for the opportunity to serve the Company as a board member,” commented Adam Stern. “I believe that Matinas is extremely well-positioned for the future and look forward to continuing to help the Company. I would also like to welcome Natasha Giordano to the Matinas family. Her significant commercial expertise comes at exactly the right time and makes her an ideal board member at this pivotal time for the Company.”

About Matinas BioPharma

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on developing next generation therapeutics to advance the standard 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, with potential cohort progression anticipated in the fourth quarter of 2020.

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.



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Matinas BioPharma Announces Positive End of Phase 2 Meeting with the FDA for MAT9001 in Severe Hypertriglyceridemia (SHTG)

*- FDA Agreement to Move Directly into Phase 3 –
- FDA to Require a Single Phase 3 Trial of 12 Weeks Duration to Support Efficacy for an NDA filing in SHTG -*

BEDMINSTER, N.J. (September 15, 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 the result of its End of Phase 2 Meeting with the U.S. Food and Drug Administration (FDA) concerning the development and registration pathway for MAT9001, a potential best-in-class prescription omega-3 therapy. The official minutes of the meeting confirmed that the FDA and Matinas are aligned on key next steps for MAT9001’s Phase 3 development program and registration pathway for an initial indication to treat severe hypertriglyceridemia (SHTG), a clinical disorder associated with major complications such as pancreatitis and atherosclerotic cardiovascular disease. The Company remains on track to initiate its Phase 3 program in the first half of 2021.

“We are extremely pleased with the outcome of our meeting with FDA and are encouraged by the highly collaborative and strategic input we received for our program. I am very proud of what we have accomplished as a team and look forward to initiating the Phase 3 trial in SHTG and maximize the clinical opportunities for MAT9001,” said Theresa Matkovits, Ph.D., Chief Development Officer of Matinas BioPharma.

The Company and the FDA agreed on key elements of the Phase 3 program to support a New Drug Application (NDA) filing, including the requirement for a single 12-week study to support efficacy in SHTG. Moreover, FDA provided flexibility to Matinas in the totality of patient safety data needed to meet regulatory requirements for NDA submission. The Company is evaluating several ways to both meet these requirements and to potentially provide additional data differentiating MAT9001 from other prescription omega-3 drugs.

“Alignment with the FDA on our Phase 3 development program provides clarity about our development pathway for MAT9001 in SHTG,” said Jerome D. Jabbour, CEO of Matinas BioPharma. “With this important feedback from FDA, we can confidently move forward with our streamlined 505(b)2 registration for MAT9001. Our level of enthusiasm for this potential best-in-class omega-3 therapy remains high, and we look forward to forthcoming near-term data from our ongoing ENHANCE-IT head to head trial of MAT9001 vs. Vascepa to once again highlight the differentiation between these two products and the potential significant clinical benefits of MAT9001 for patients with hypertriglyceridemia and cardiovascular disease.”

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