Matinas BioPharma

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Matinas BioPharma advances the promise of heart-healthy omega-3 fatty acids

- Developing lead product MAT9001 to treat cardiovascular and metabolic conditions
- Conducting head-to-head study of MAT9001 versus FDA-approved rival Vascepa
- Flush with nearly $70 million in cash to fund clinical studies and operations into 2022

What Matinas BioPharma does:

Matinas BioPharma Holdings Inc (NYSEAMERICAN:MTNB) is a clinical-stage biopharmaceutical company focused on the development of its lead product candidate, MAT9001 for the treatment of cardiovascular and metabolic conditions.

The Bedminster, New Jersey-based company is also working on the advancement of its proprietary lipid nano-crystal (LNC) platform technology for the safe delivery of therapies previously limited by toxicity or bioavailability issues.

MAT9001 is a prescription-only omega-3 fatty acid-based formulation, comprised primarily of EPA and DPA (both essential polyunsaturated fatty acids) under development for the specific treatment of hypertriglyceridemia. Triglycerides are a type of fat in human blood, and having too many can lead to heart disease or acute pancreatitis.

MAT2203 is the company's lead product candidate utilizing its LNC platform. It is an oral-delivered formulation of the well-known but highly toxic antifungal medicine Amphotericin-B to treat serious invasive fungal infections.

How is it doing:

Matinas is well-capitalized to fund operations for the next three years. In fact, it has nearly $70 million in cash thanks to a $50 million registered public offering, giving the company a long runway to further the development of MAT9001 and MAT2203.

WIth MAT9001, Matinas recently concluded what it calls a positive End of Phase 2 meeting with the US Food and Drug Administration (FDA) on the development and registration pathway for the omega-3 therapy to treat severe hypertriglyceridemia (SHTG), a clinical disorder associated with major complications such as pancreatitis and atherosclerotic cardiovascular disease.

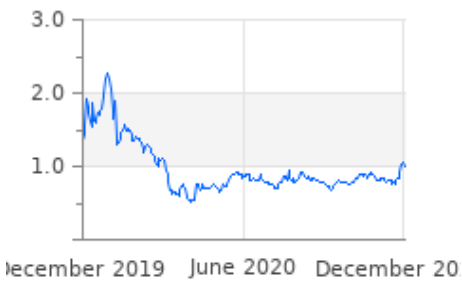
The company and the agency are in alignment on how to proceed for a Phase 3 development program to support a New Drug Application (NDA) filing, including the requirement for a single 12-week study to support efficacy in SHTG. Moreover, the FDA has provided Matinas with flexibility concerning the patient safety data needed to meet regulatory requirements. As a result, Matinas remains on track to initiate its Phase 3 program in the first half of 2021.

In another study, Matinas in August completed enrollment for its ENHANCE-IT, a second head-to-head comparative

Price: 1.04

Market Cap: $207.22 m

1 Year Share Price Graph



Share Information

Code:		MTNB
Listing:		NYSE
52 week	**High**	**Low**
	2.48	**0.491**

Sector: Pharma & Biotech

Website: www.matinasbiopharma.com

Company Synopsis:

Matinas BioPharma is a clinical-stage biopharmaceutical company focused on development of its lead product candidate, MAT9001, for the treatment of cardiovascular and metabolic conditions.

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study of MAT9001 versus rival Vascepa to determine how effectively both drugs reduce triglyceride levels and other important lipid markers, in addition to gathering data on bioavailability and omega-3 fatty acids in the blood. Vascepa is made by Amarin Corporation PLC and is the only FDA-approved drug designed to fight high triglyceride levels

MAT9001 and Vascepa will each be administered twice daily to a target of 100 enrolled patients over two 28-day treatment periods. The company expects topline results from the study in the first quarter of 2021.

The company said ENHANCE-IT builds on an earlier study comparing MAT9001 with Vascepa that "provided significantly greater reductions in PD (pharmacodynamic) markers known to be associated with increased risk of cardiovascular disease, including triglycerides."

Matinas' senior managers are confident that MAT9001 is superior to Vascepa in reducing serum triglycerides and cholesterol. They are also not worried about generic versions of the rival drug that could hit the market following a US District Court ruling in March that invalidated some of Amarin patents protecting the drug.

When it comes to protecting MAT9001, Matinas believes that the drug, if approved by the FDA, will be eligible for five-year New Chemical Entity exclusivity and subject to the Hatch Waxman Amendments, which could prevent generic alternatives for more than seven years.

To further MAT9001's development and eventual commercialization the company recently appointed James A Underberg to its scientific advisory board. He is director of the Bellevue Hospital Lipid Clinic and a clinical assistant professor of medicine at the NYU School of Medicine and NYU Center for Prevention of Cardiovascular Disease.

MAT2203 EnAct Study

As for MAT2203, the company is moving ahead with the antifungal drug's development as well. In Uganda, Matinas is currently running Part 2 of its EnACT study of the drug as a treatment for HIV patients with cryptococcal meningitis, a life-threatening fungal infection most commonly observed in immuno-compromised patients.

The open-label, sequential cohort study, financially sponsored by the National Institutes of Health (NIH), applies Matinas' LNC drug delivery technology to orally deliver amphotericin B, an otherwise IV-only, highly toxic drug. Oral MAT2203 is designed to target delivery directly to infected tissues, protecting the body from unnecessary exposure to amphotericin B with a lower propensity for kidney toxicity.

Part 1 demonstrated that MAT2203 was safe and well-tolerated across three different daily dosing regimes and its data were published online in Antimicrobial Agents and Chemotherapy, a journal of the American Society of Microbiology. Part 2 is a randomized trial evaluating the safety, tolerability, and efficacy of MAT2203 in about 100 patients, compared to treatment with standard IV-administered amphotericin B.

The FDA has designated MAT2203 as a Qualified Infectious Disease Product with Fast Track status for four indications: The prevention of invasive fungal infections due to immuno-suppressive therapy as well as the treatment of invasive candidiasis, invasive aspergillus, and cryptococcal meningitis. In addition, the FDA granted orphan drug designation to MAT2203 for the treatment of cryptococcosis.

Inflection points:

- Expects topline results from ENHANCE-IT study in 1Q 2021
- Planning Phase 3 clinical program of MAT9001 to treat severe hypertriglyceridemia
- Expects data from NIH-funded Part 2 EnAct study of MAT2203 in 1H 2021

What the boss says:

"MAT9001's potential position as best-in-class prescription-only omega-3 continues to be contingent on, among other things, the results of the planned ENHANCE-IT study and the outcome of our potential Phase 3 clinical program in

severe hypertriglyceridemia," Matinas BioPharma CEO Jerome Jabbour has said.

"We are excited to have the opportunity to let the data speak for themselves and we look forward to building upon the existing data for MAT9001 which demonstrates superiority to Vascepa, and therefore to any generic alternative to Vascepa."

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