Zacks Small-Cap Research

February 3, 2015
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Matinas BioPharma Holdings, Inc. (MTNB-OTCQB)

MTNB: Matinas Acquires Privately-Held Aquarius Biotechnologies…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	10/28/2014
Current Price (02/03/15)	$0.58
Target Price	**$1.25**

UPDATE

On January 30, 2015, Matinas Biopharma Inc. (MTNB) announced the establishment of a lipid-based, anti-infective platform with the acquisition of Aquarius BioTechnologies, Inc. With the acquisition, Matinas significantly expands its technological portfolio while complementing the company's focus in lipidomics. Below, we discuss the technology acquired from Aquarius and how we believe it impacts the investment opportunity with Matinas. In addition, we provide an update on MAT9001, Matinas' clinical stage omega-3 fatty acid product for the treatment of severe triglyceridemia.

We are maintaining our 'Outperform' rating and $1.25 price target on the shares.

SUMMARY DATA

52-Week High	**$0.90**
52-Week Low	**$0.34**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**36,867**
Shares Outstanding (mil)	**32**
Market Capitalization ($mil)	**$19**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**36**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

Risk Level	**High**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 E	0 E
2015					0.8 E
2016					1.5 E

Earnings per Share
(EPS is report figures)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013					-$0.20 A
2014	-$0.07 A	-$0.08 A	-$0.08 A	-$0.09 E	-$0.31 E
2015					-$0.27 E
2016					-$0.19 E

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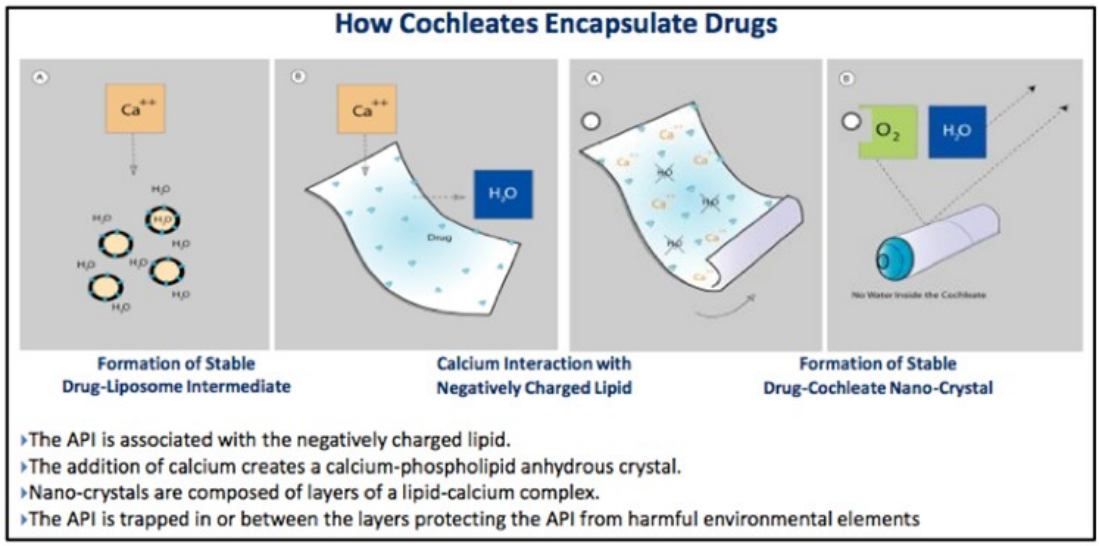
WHAT'S NEW?

On January 30, 2015, Matinas Biopharma Inc. (MTNB) announced the establishment of a lipid-based, anti-infective platform with the acquisition of Aquarius BioTechnologies, Inc. With the acquisition, Matinas significantly expands its technological portfolio while complementing the company's focus in lipidomics. Below, we discuss the technology acquired from Aquarius and how we believe it impacts the investment opportunity with Matinas. In addition, we provide an update on MAT9001, Matinas' clinical stage omega-3 fatty acid product for the treatment of severe triglyceridemia.

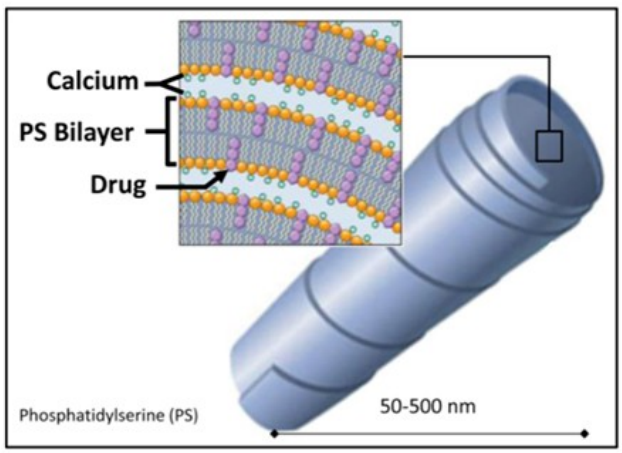
…Aquarius Cochleate Formulation Delivery Platform…

The drug delivery platform developed by Aquarius is centered on the use of cochleates, which are stable, crystalline phospholipid-cation delivery vehicles that are composed of soybean phosphatidylserine (PS) and calcium. The compounds have a unique multilayered structure and no internal aqueous space. "Encochleated" molecules within the interior of the cochleate structure remain intact resulting in an increase of oral bioavailability, lower toxicity, and the opportunity for intracellular targeting. As the following figure shows, cochleates are produced from a large, continuous, solid, lipid bilayer sheet rolled up in a spiral or as stacked sheets, with no internal aqueous space.

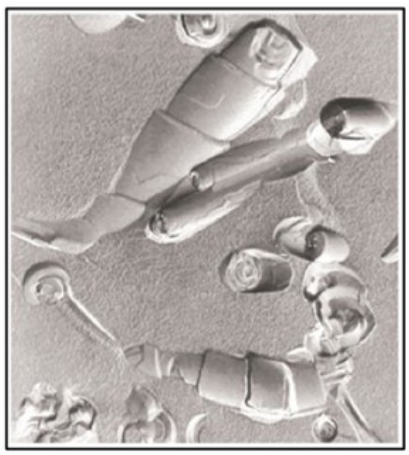


Source: Aquarius BioTechnologies, Inc.

The unique structure of the cochleate means that the compounds inside are protected, even though the outer layers of a cochleate may be exposed to harsh environmental conditions or enzymes. The arrangement of a drug product inside the cochleate is shown in the following figure along with an electron micrograph of the cochleate showing the elongated shape and the tightly packed bilayers.



Source: Aquarius BioTechnologies, Inc.



Source: Zarif *et al.*, 2002

Cochleates themselves appear to have a nontoxic profile and to improve the safety of toxic drugs. They are composed of safe products: phosphatidylserine and calcium. Phosphatidylserine is a natural component of all biological membranes and is most concentrated in the brain. In fact, it has been studied as a potential nutrient supplement that may play a role in the support of mental functions in the aging brain (Engel *et al*., 1992). Thus, there is little worry for adverse effects from the cochleates themselves.

…The Aquarius Pipeline…

At the time of the acquisition, Aquarius listed five products currently under development on its website, each of which was progressing in collaboration with the National Institute of Allergy and Infectious Diseases (NIAID), a part of the National Institutes of Health (NIH). Each of the encochleated compounds have high toxicity and/or poor bioavailability when administered on their own.

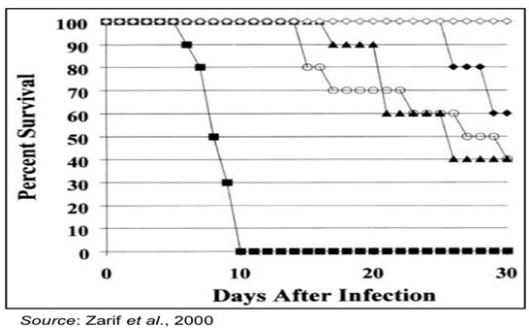
- CAmB - Encochleated Amphotericin B
- C-Amikacin - Encochleated Amikacin
- C-Capreomycin - Encochleated Capreomycin
- C-Atovaquone - Encochleated Atovaquone
- Enhancing Tissue Penetration of ARVs by Formulation into Lipid Nanocrystals

CAmB (MAT2203)

The most advanced product in Aquarius' pipeline is a lipid-crystal nano-particle formulation of Amphotericin B (CAmB) that Matinas has labeled as MAT2203. Amphotericin B (AmB), the gold standard for systemic antifungal drugs, is one example of a well-established, highly efficacious systemic antifungal drug that has a 50-year history of intravenous (IV) therapy. The drug is highly potent and has utility as an anti-parasitic agent as well. Intravenous formulations such as AmBisome® and Fungizone® remain among the most effective agents in the treatment of life-threatening systemic fungal infections, including aspergillosis, cryptococcosis (torulosis), North American blastomycosis, systemic candidiasis, coccidioido-mycosis, histoplasmosis, zygomycosis including mucormycosis due to susceptible species of the genera *Absidia, Mucor,* and *Rhizopus,* and infections due to related susceptible species of *Conidiobolus* and *Basidiobolus*, and sporotrichosis.

Surprisingly, no oral formulations of AmB are currently commercially available. Although some patients are able to tolerate the IV injection, many experience localized and systemic side effects associated with IV administration of the drug. For example, the Side Effect & Drug Interactions section of the AmBisome® prescribing information includes warnings on renal impairment, hepatic impairment, febrile reactions, fever accompanied by shaking chilies, normochromic and normocytic anemia, musculoskeletal pain, anaphylactic reactions, dermatologic reactions, including Steven-Johnson syndrome, neurologic reactions, including convulsions, tinnitus, and vertigo, hematological reactions, and injection site reactions. Some of these side effects can be eliminated or reduced, specifically the injection site reactions and potentially the hematological, hepatic, and renal impairments, by oral administration. Sales of the perceived "least toxic" formulation of AmB, AmBisome®, were $351 million in 2013.

A preclinical study of CAmB showed the drug to be efficacious *in vivo* against *C. albicans* infection (Zarif *et al*., 2000). ICR mice were infected IV through the tail vein with *C. albicans* and then treated 24 hours later with various doses of CAmB or Fungizone® (IV amphotericin B). The graph below shows that at a dose of 0.5 mg/kg, 100% survival was observed in mice treated with CAmB (◊) versus only 60% with Fungizone® (◆) at the same dose. Mice treated either with 0.1 mg/kg CAmB (▲) or Fungizone® (○) showed decreased survival rates, while all mice treated with empty cochleates (■) died by day 10.



Source: Zarif *et al*., 2000

A single dose, double blind, dose escalating Phase 1 human clinical trial was conducted with oral CAmB to study the safety and pharmacokinetics of the compound. A total of 48 subjects were planned for participation across three dosing cohorts, with 16 subjects per cohort. Within each cohort, 12 subjects received active drug (200, 400, or 800 mg CAmB) and four received placebo.

Overall, CAmB was well tolerated at single oral doses of 200 and 400 mg. All treatment-emergent adverse events (TEAEs) were mild except for one instance of "upper respiratory tract infection" that was moderate in a patient taking 800 mg CAmB. In addition, a number of subjects in the 800 mg dosing cohort reported mild gastrointestinal tract adverse events. The study provides support for multi-dose pharmacokinetic studies and Phase 2 efficacy studies.

Matinas plans to advance MAT2203 into Phase 2a studies as quickly as possible in 2015 with anticipated collaboration and grant support with the NIH. The initial target population will be those patients with refractory mucocutaneous candidiasis infections. These infections no longer respond to azole treatment and typically occur in patients who are immunocompromised (e.g advanced cancer, organ transplant, or viral infection). When this occurs, a patient will typically be treated with IV antifungal agents that are more likely to have toxic side effects.

Patients enrolled in the open-label Phase 2a study will initially be treated with 200 mg/day of CAmB with the dosage able to be titrated up or down depending upon whether the treating physician believes the patient is receiving too much or too little of the drug. This dose optimization will help guide the design of future clinical studies with CAmB. We anticipate the results becoming available late 2015.

…Current Antifungal Treatments…

There are a number of therapies currently available to treat fungal infections, with each type of treatment typically effective against certain species and each with its own limiting side effects or other drawbacks. There are three main types of anti-fungals:

- **Polyenes:** The compounds in this class include amphotericin B, nystatin, and natamycin. They work by binding to ergosterol, a component of the fungal cell membrane. This binding leads to increased cellular permeability and inhibition of fungal cell growth. Amphotericin B has activity against a broad spectrum of invasive fungi, and thus it was the standard of care for many systemic fungal infections. As discussed previously, the high rate of toxicity can limit its use in some patients. Liposomal formulations of amphotericin B have been shown to reduce the toxicity associated with the compound. Gilead Sciences, Inc. (GILD) markets AmBisome®, a lipid formulated version of amphotericin B, and reported $350 million in sales in 2013.

- **Azoles:** The azoles are categorized into two distinct sets, the imidizoles and the triazoles. The imidizoles include such compounds as clotrimazole, ketoconazole, and miconazole. The triazoles include fluconazole, itraconazole, terconazole, voriconazole, and posaconazole. Instead of binding to ergosterol like the polyenes, azoles exert their effect by inhibiting the production of ergosterol. However, the end result is the same with the fungi having increased cellular permeability and an inhibition of growth. Side effects from azoles are much milder than from polyenes, but still include gastrointestinal disturbances, hepatotoxicity, and rash. Another advantage of the azoles is that they are available in a wide variety of dosage forms, including creams, lotions, and tablets, and have a broad spectrum of activity. In 2013, Pfizer (PFE) reported $775 million in sales of voriconazole (Vfend®), while Merck (MRK) reported $309 million in sales of posaconazole (Noxafil®). The former market leading product, Pfizer's Diflucan® (fluconazole), now available as a generic, reported peak sales of $1.17 billion in 2003.

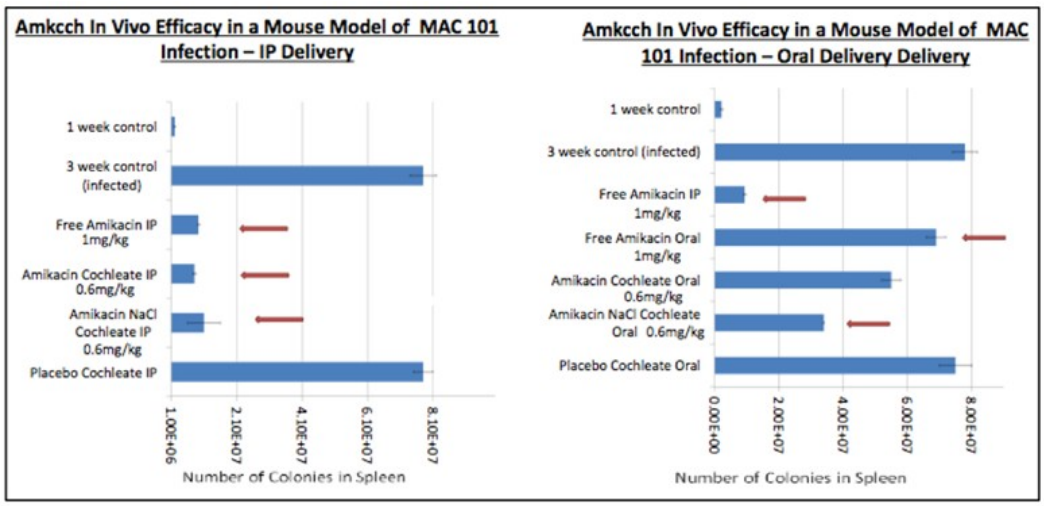
- **Echinocandins:** The echinocandins include such compounds as caspofungin, micafungin, and anidulafungin. This class of antifungal medications is one of the newer ones with a unique mechanism of action that involves inhibiting the synthesis of (1,3)-beta-d-glucan synthase, a vital component of the fungal cell wall, which leads to osmotic instability and fungal cell death. Each of the compounds from this class is only available IV and can be used to treat Candida and Aspergillus infections. In addition, all of the compounds have excellent safety profiles. In 2013, Merck reported $660 million in sales of caspofungin (Cancidas®) while Astellas reported $307 million in sales of micafungin (Mycamine®).

Depending upon the efficacy and safety profile, we believe encochleated amphotericin B could have similar success as a drug like AmBisome®, with peak revenues in the $350 million range. Of course, this number is highly contingent upon clinical trial results along with what patient cohorts the company intends to target.

C-Amikacin (MAT2501)

MAT2501 is a lipic-crystal nano-particle formulation of Amikacin that is currently in preclinical development. Amikacin is an aminoglycoside antibiotic most commonly used to treat severe, hospital-acquired infections, including Gram-negative infections. The drug is administered via IV or intramuscular administration. All aminoglycosides carry the potential risk of nephrotoxicity, with the risk being greatest in those with impaired renal function. A reduction in dosage is usually necessary if evidence of renal dysfunction occurs. In addition, treatment with aminoglycosides can cause neurotoxicity in the form of hearing loss, numbness, skin tingling, muscle twitching, and convulsions. For these reason, an aminoglycoside formulation that would reduce the potential for this toxicity and allow for oral dosing is clearly warranted.

Proof-of-concept testing in animals has been conducted with C-Amikacin by testing the efficacy of the compound in mice infected with *Mycobacterium avium* complex (MAC), a group of genetically related bacteria belonging to the genus *Mycobacterium*. Twelve mice for each tested group were infected by tail vein injection. After seven days, six mice were harvested and the number of MAC in the spleen was quantified to establish bacterial load. The mice were then treated with various amikacin preparations for two weeks, after which time the mice were harvested and the bacterial load in the spleens was quantified. The results shown below indicate that encochleated amikacin was just as effective as free amikacin when administered intraperitoneal (IP), and was also effective at decreasing bacterial load when administered orally.



Source: Aquarius BioTechnologies, Inc.

…Terms of the Acquisition…

Matinas acquired Aquarius by issuing up to five million shares of its common stock to the current shareholders of Aquarius. At closing, Matinas issued 4,608,020 shares of its common stock. While the number of shares issued may be adjusted after closing of the transaction, in no event shall the number of shares exceed five million. Based on today's price of around $0.55 per share for MTNB, the acquisition is valued at around $2.3 million. In addition, Matinas may issue up to an addition three million shares of common stock upon the achievement of certain milestones. These milestones include: 1) 1.5 million shares issuable upon the dosing of the first patient in a Phase 3 trial sponsored by Matinas for a product utilizing Aquarius' cochleate technology, and 2) 1.5 million shares issuable upon FDA approval of the first NDA submitted by Matinas for a product utilizing Aquarius' cochleate technology.

Upon closing of the acquisition, the former Aquarius shareholders own approximately 8% of the aggregate number of shares of common stock outstanding (on a fully diluted basis) while the stockholders of Matinas as of immediately prior to the acquisition own approximately 92%. We view the terms of the deal to be quite favorable for Matinas, as none of the company's cash was required for the transaction. In addition, the company does not anticipate any material increase in cash burn in the short term as a result of the acquisition, primarily because of the various grants and contracts from the NIH that are in place with Aquarius.

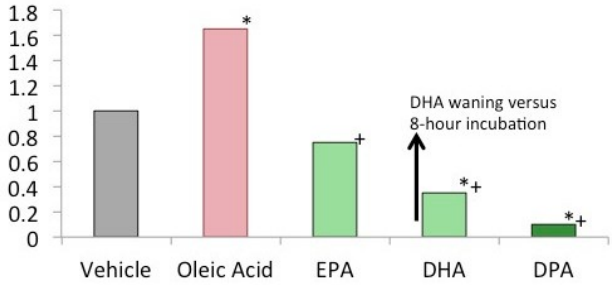
…Path Forward for MAT9001…

In addition to the technology acquired from Aquarius, Matinas is continuing to focus on the clinical development of MAT9001, a uniquely engineered omega-3 fatty acid formulation that Matinas is developing for the treatment of severe hypertriglyceridemia. A differentiating aspect of MAT9001 from other omega-3 prescription products is a focus on docosapentaenoic acid (DPA). DPA is a key component of MAT9001, with preclinical studies suggesting that DPA has the potential to confer a unique therapeutic profile compared to existing omega-3 products, particularly in its ability to exert synergistic anti-hyperlipidemic effects in combination with statins.

Lipids have historically been regarded as mainly having structural and functional roles. They serve as part of cellular and organelle membranes and as metabolic intermediates for energy production and the formation of signaling molecules. The omega-3 and omega-6 fatty acids have additionally been understood to serve as inhibitors of enzymes involved in triglyceride processing. But importantly, recent discoveries have pointed toward the ability of certain omega-3 fatty acids to modulate the expression of genes involved in lipid synthesis.

The gene regulatory effects of DPA in rat liver cells include the down-regulation of genes such as SREBP-1c, acetyl coenzyme-A carboxylase, ChREBP, and fatty acid synthetase that are known targets of other omega fatty acids. Notable, however, is DPA's unusual potency in reducing the expression of RNA encoding HMG-CoA reductase, the enzyme target of statins. By down-regulating gene expression DPA has the potential to act synergistically with statins in reducing the activity of this well-established drug target. Reduced enzyme production is a result of the action of DPA at the gene level, and the protein that is produced is inhibited by the statin.

Effect of Various Omega-3 Fatty Acids
on HMG-CoA Reductase RNA Levels in Rat Liver Cells



Relative mRNA expression levels after 48 hour incubation of Rat Liver Cells with FA
* Significant difference (p<0.05) from Control (EC)
\+ Significant difference (p<0.05) from Oleic Acid (OAC)

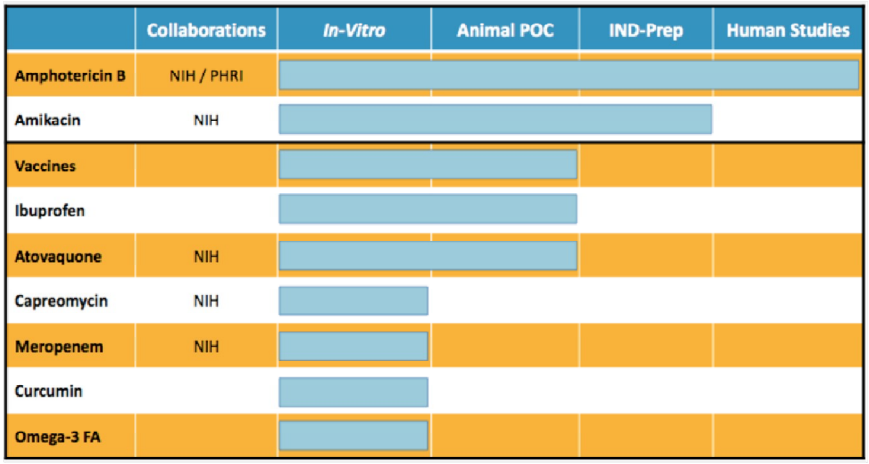
Source: Kaur et al.; PLEFA (2011) 85, 155-161

Currently, Matinas is conducting a pharmacokinetic and pharmacodynamics crossover study of MAT9001 versus an active comparator with approximately 50 patients in Canada. The goal of this study is to demonstrate better bioavailability than the active comparator along with providing data on the ability of MAT9001 to yield distinctive therapeutic response properties and an improved therapeutic profile. Topline results are expected in the second quarter of 2015.

Matinas has filed an investigational new drug (IND) application for MAT9001 with an initial indication for the treatment of severe hypertriglyceridemia. The company received feedback from the FDA indicating that before the Phase 3 registration program for MAT9001 can commence, Matinas will need to perform and report the results of a planned 4-way crossover single dose Fed/Fast pharmacokinetic study and a 28-day toxicity study in rats. We suspect these programs will take three months to complete. After the FDA has reviewed the results of those two studies, which we estimate will take approximately 2-3 months, Matinas will be able to initiate a Phase 3 trial, which is likely to be started in the fourth quarter of 2015.

Valuation and Recommendation

We believe the technology acquired from Aquarius is a nice strategic fit for Matinas, with the added benefit of an additional clinical stage compound now in the company's pipeline. As shown in the following chart, the cochleate technology may be applied to a wide range of pharmaceutical classes in the future, including vaccines, pain relievers, and omega-3 fatty acids.



***Source:* Matinas Biopharma**

Another positive aspect of the acquisition is that Matinas did not need to use any cash to acquire the technology. On the conference call to discuss the transaction it was mentioned that the company would likely be conducting a small financing in the near future to fund operations through the rest of 2015 and allow for the collection of data from both the Phase 2a study of CAmB and the pharmacokinetic and toxicity studies for MAT9001. We believe this amount to be in the area of $6 to 8 million. After the results of those studies are known, the company will likely conduct a much larger financing, potentially up to $25 million, in conjunction with an uplisting to a major stock exchange such as the NASDAQ.

In terms of valuation, for now we are only comfortable stating that the technology acquired by Matinas is currently worth what they paid for it, around $2.5 billion, with the caveat that there is considerable upside should the clinical trial results reveal the cochleate technology to be highly efficacious. Successful completion of the Phase 2a study would validate the opportunity that Matinas has with MAT2203, and we believe that an encochleated amphotericin B could be a potential $300-400 million drug if commercialized with a large pharmaceutical partner.

To arrive at a current valuation, we assume MAT2203 gets approved in 2019 and has peak sales of $350 million in 2024. In addition, we use a 25% discount rate and assume a price/sales ratio of 4x. Lastly, we assign a 20% probability of success to the program upon successful completion of a Phase 2a program. Thus, if the company is successful in the Phase 2a study, we believe MAT2203 has a current value of $38 million, or approximately $0.50 per share.

We are maintaining our current valuation of Matinas at $1.25 per share, while noting the potential to increase this depending upon the results of the upcoming Phase 2a trial and the ability of the company to successfully finance the upcoming Phase 3 program with MAT9001. For additional information on MAT9001, please see our Initiation report from October 2014 on Matinas Bio.

PROJECTED FINANCIALS

Matinas BioPharma – Income Statement

Matinas Biopharma	2013 A	Q1 A	Q2 A	Q3 A	Q4 E	2014 E	2015 E	2016 E
MAT9001	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
MAT2203	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Grants / Funded R&D	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.8**	**$1.5**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.8**	**$1.5**
YOY Growth	-					-	-	-
Cost of Goods	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Develop	$1.8	$1.1	$1.1	$1.1	$1.3	$4.6	$7.5	$8.5
General & Admin	$2.0	$1.1	$1.3	$1.5	$1.4	$5.3	$6.5	$7.0
Operating Income	($3.7)	($2.1)	($2.4)	($2.6)	($2.7)	($9.9)	($13.2)	($14.0)
Net Other Income	($0.0)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($3.7)	($2.1)	($2.4)	($2.6)	($2.7)	($9.9)	($13.3)	($14.1)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($3.7)	($2.1)	($2.4)	($2.6)	($2.7)	($9.9)	($13.3)	($14.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.20)**	**($0.07)**	**($0.08)**	**($0.08)**	**($0.09)**	**($0.31)**	**($0.27)**	**($0.19)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	19.0	32.0	32.0	32.0	32.0	32.0	50.0	75.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

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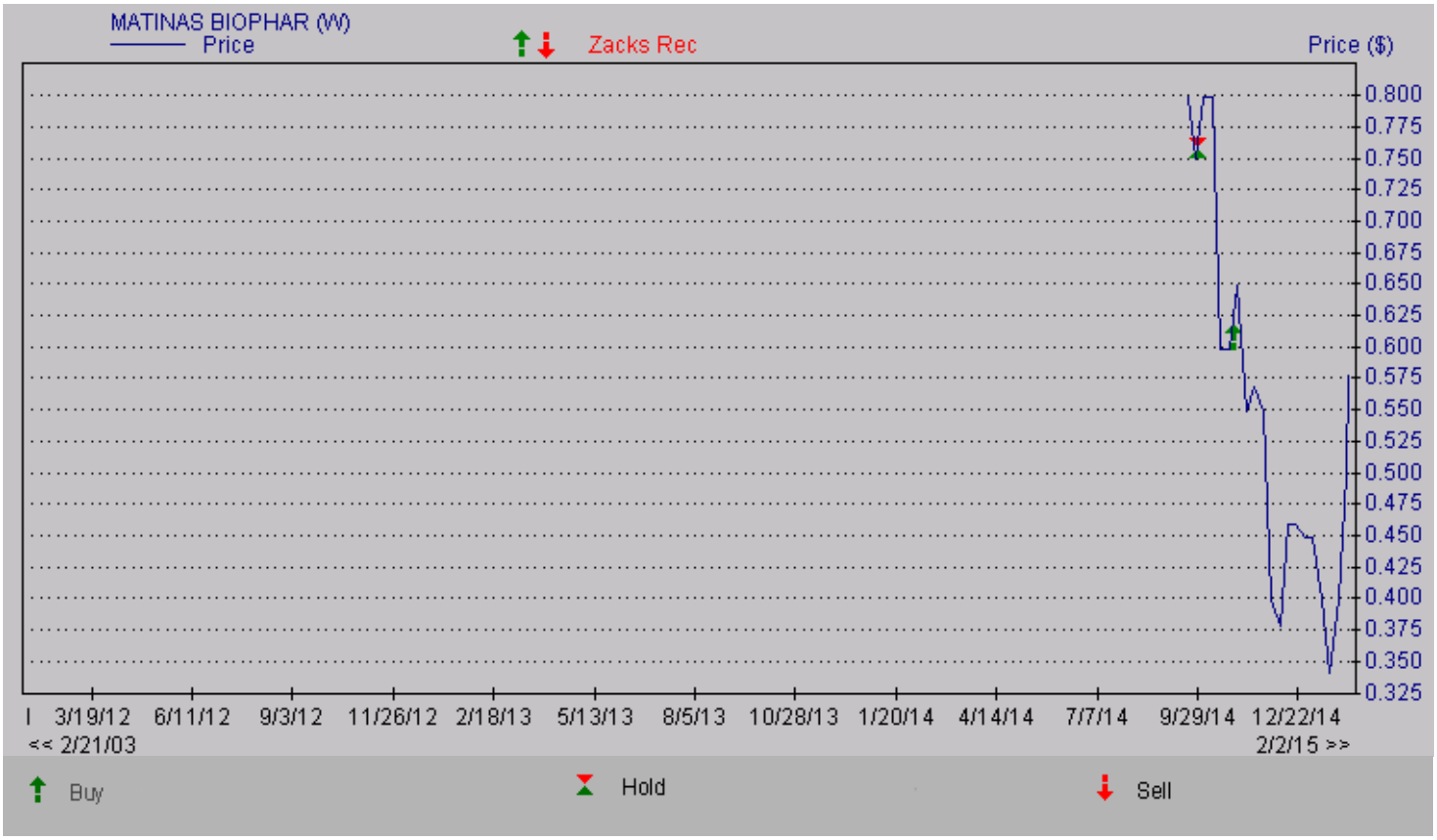
HISTORICAL ZACKS RECOMMENDATIONS



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Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 15.8%, Hold/Neutral- 78.3%, Sell/Underperform – 5.7%. Data is as of midnight on the business day immediately prior to this publication.