Zacks Small-Cap Research

April 15, 2015
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Matinas BioPharma Holdings, Inc. (MTNB-OTCQB)

MTNB: With Cash In Hand, Matinas Starts To Looking Very Interesting…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/28/2014
Current Price (04/15/15)	$1.05
Target Price	**$2.25**

UPDATE

On April 9, 2015, Matinas closed on an $8.5 million private placement financing that included significant insider participation. The company issued 20.0 million shares of common stock at $0.50 per share. The company also issued 20.0 million five-year warrants to investors at $0.75 per share. The warrants are callable by Matinas if the stock trades above $3.00 per share for 20 consecutive days. If exercised, the warrants would provide an additional $14.25 million in cash to the company. The placement agent, Aegis Capital, also received 2.0 million warrants at $0.50 per share and 2.0 million warrants at $0.75 per share. We believe the company now has enough cash to fund operations for the next twelve months. We are maintaining our 'Buy' rating and raising our price target on the shares to $2.25.

SUMMARY DATA

52-Week High	**$1.19**
52-Week Low	**$0.34**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**60,388**
Shares Outstanding (mil)	**37**
Market Capitalization ($mil)	**$42**
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)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 E	0 E	0 E	0 E	0 E
2016					1.5 E
2017					1.5 E

Earnings per Share
(EPS is report figures)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.07 A	-$0.08 A	-$0.08 A	-$0.09 A	-$0.32 A
2014	-$0.08 E	-$0.05 E	-$0.05 E	-$0.05 E	-$0.27 E
2015					-$0.19 E
2016					-$0.14 E

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WHAT'S NEW?

Financial Update

On March 31, 2015, Matinas Biopharma Inc. (MTNB) filed its Form 10K reporting financial results for the year ending December 31, 2014. The company did not report any revenues in 2014. This was in-line with our expectations. Net loss for the full year 2014 was $10.2 million, or $0.32 per share. Cash burn was $8.0 million, of which $2.1 million took place in the fourth quarter. Matinas exited 2014 with $2.6 million in cash on the books.

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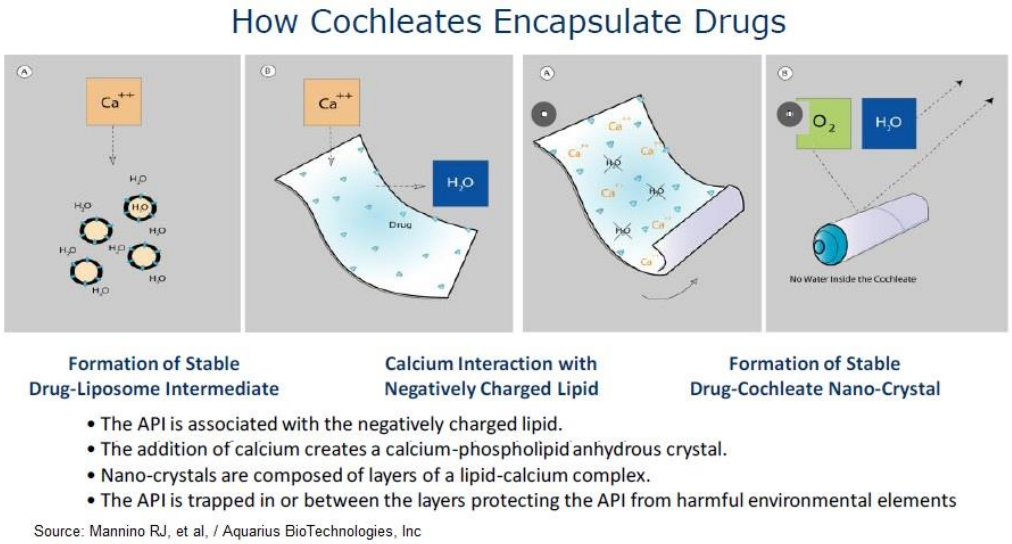
Pipeline Update

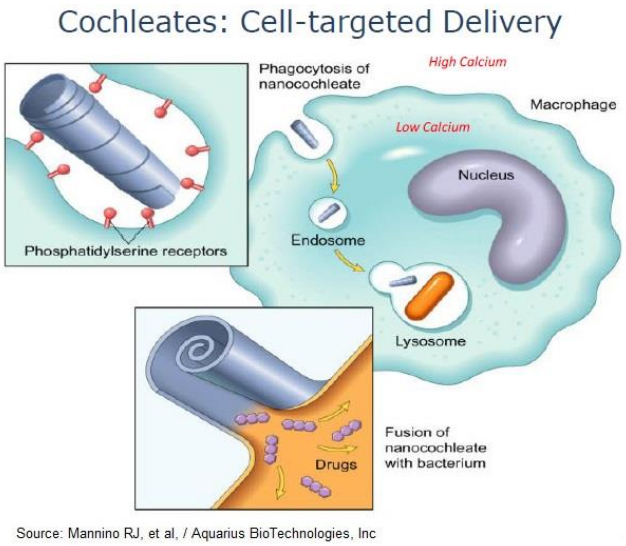
On January 30, 2015, Matinas announced the establishment of a lipid-based, anti-infective platform with the acquisition of Aquarius BioTechnologies, Inc. This was the Bioral™ technology previously owned by BioDelivery Sciences International (BDSI) from 2002 to 2009. BioDelivery was unable to move forward with the technology because sourcing the key raw material to create the cochleate technology, dileoylphosphatidylserine, was just too expensive (~$60 per gram). Inventors of the technology have been able to redesign the formulation to source phosphatidylserine from soy protein. As such, the cost is now less than $1 per gram, thus making it viable drug delivery technology worth pursuing in clinical development. Ultimately, BDSI decided to focus on its BEMA™ technology instead of Bioral™, throwing all available resources to obtain approval for BEMA Fentanyl. With the acquisition of the technology, Matinas significantly expands its pipeline while complementing the company's focus in lipidomics.

Quick Review of the 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.



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 figure below shows how cochleates deliver target drug within the cell. Macrophages readily engulf (phagocytosis) cochleates into vesicles (endosomes), which become free in the cytoplasm and can merge into lysosomes. Cochleates open when exposed to the cytoplasmic low calcium concentration, releasing the entrapped target drug.



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.

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.

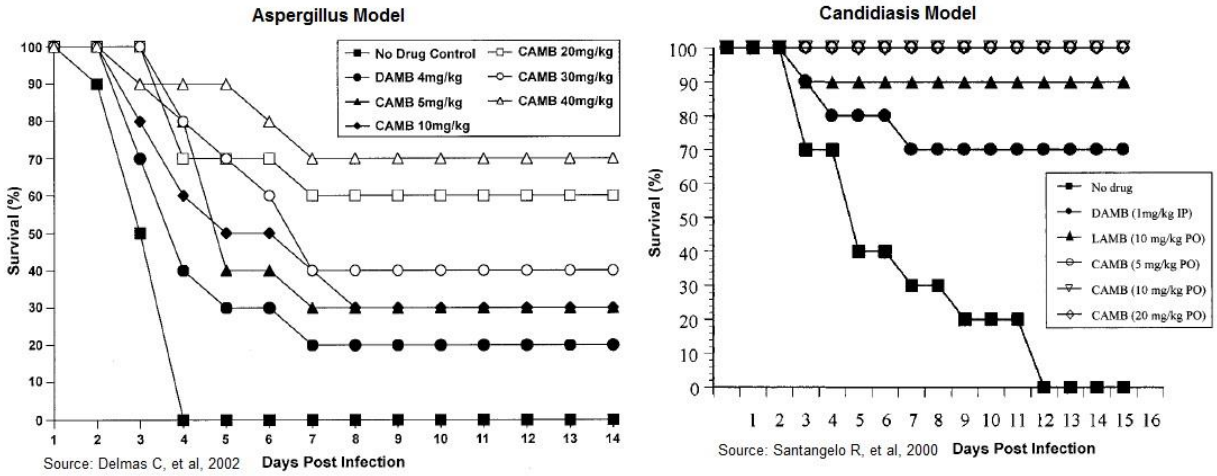
No oral formulations of AmB are currently commercially available given the poor bioavailability of the drug. Although some patients are able to tolerate the IV injection, many experience localized and systemic side effects associated with IV administration of the drug. For example, the Side Effect & 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. Sales of the perceived "least toxic" formulation of AmB, AmBisome®, were $388 million in 2014, up 10% from 2013.

Some of the above side effects can be eliminated or reduced, specifically the injection site reactions and potentially the hematological, hepatic, and renal impairments, by oral administration. As such, we believe there would be a significant market for an orally-available AmB product that offered superior convenience of dose, superior tolerability and safety, and comparable efficacy.

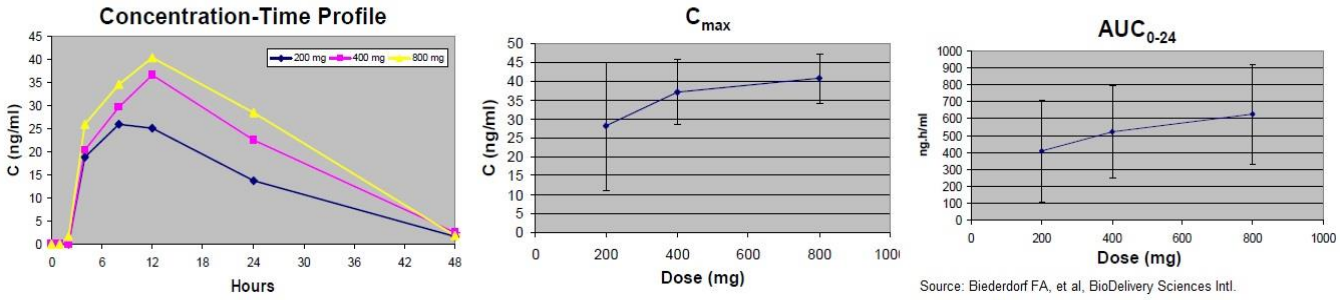
- ***CAmB Proof-of-Concept***

We found several papers showing the efficacy and CAmB in murine models of Aspergillosis and Candidiasis. The graph on the left below shows the efficacy of CAmB in a murine model of Aspergillosis. Survival of mice pretreated with cyclophosphamide at 200 mg/kg and then infected with *A. fumigatus* and given oral CAmB daily at a dose of 5, 10, 20, 30, or 40 mg/kg/day was compared to intraperitoneally-delivered amphotericin B (DAmB) at a dose of 4 mg/kg/day. Results show a significant increase in survival relative to that of untreated (sham-treated) control animals, with high statistical significance (Antimicrobial Agents and Chemotherapy, August 2002: 46,8:2704-2707).

The graph on the right below shows the survival of mice infected with *C. albicans,* treated oral CAmB at 5, 10, and 20 mg/kg, compared to oral liposomal amphotericin B (LAmB, AmBisome®) at 10 mg/kg and intraperitoneally-delivered amphotericin B (DAmB, Fungizone®) at a dose of 1 mg/kg per day. The results show impressive survival for the oral CAmB formulation, superior to both the LAmB and DAmB formulations (Antimicrobial Agents and Chemotherapy, Sept 200: 44,9:2356-2360).



A single dose, double blind, dose escalating Phase 1 human clinical trial was conducted by BioDelivery Sciences International (BDSI) with oral CAmB (Bioral™) designed to assess 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. Results show that CAmB was well tolerated at single oral doses of 200 and 400 mg, with good dose proportionality and pharmacokinetics.



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, but no laboratory abnormalities of other serious safety issues were reported in the Phase 1 study. The study provides support for a planned multi-dose pharmacokinetic study and Phase 2 efficacy studies.

- ***Planned Phase 2a Study***

The next step in the clinical development of CAmB is to move into Phase 2a study in the second quarter 2015. The company is working with the National Institutes of Health to fund the planned Phase 2a study. The NIH will provide funding, clinical sites, physicians, and patients. Matinas only has to supply drug. That's a heck of a good deal, as it not only greatly reduces the cost to the company but also provides access to some of the best doctors and facilities in the country to run the trial. The final protocol is still being agreed upon with the NIH, but we suspect that the study will enroll roughly 25-30 patients in a dose titration, open-label format where each patient starts out on 3 mg/kg CAmB, with the potential to up-titrate to a higher dose after two weeks of treatment based on the physician's discretion.

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. This dose optimization will help guide the design of future clinical studies with CAmB. We believe the trial will take only a few months to complete, and that data will be available by the fourth quarter 2015.

- ***How Big is CAmB?***

Compounds like amphotericin B 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. The drug is fungicidal, which means it kills the invading fungal infection, as oppose to azoles like fluconazole or voriconazole that are fungistatic (only halt the spread of the infection). Unfortunately, the high toxicity of intraperitoneal amphotericin B, which shows up at around 1 mg/kg is roughly equal to the therapeutic dose, thus creating a very small therapeutic window for DAmB use. Gilead's liposomal formulation, AmBisome® (LAmB) has improved tolerability up to the 10 mg/kg range. Work done by BioDelivery science shows that oral delivery of CAmB resulted in no overt adverse events at doses up to 90 mg/kg in animal studies.

We believe amphotericin B, a broadly effective and power drug, has limited use today ($388 million in sales in 2014) because of the toxicity, mainly nephrotoxicity, of the drug. As a result of this toxicity, amphotericin is primarily used either very early on in the treatment paradigm until toxicity shows up, or as a last resort for patients with few other options. Because the drug is administered via intravenous infusion, there is no out-patient use. As a result, when patients leave the hospital, they often leave on less effective azoles or echinocandins. 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. In 2013, Merck reported $660 million in sales of caspofungin (Cancidas®) while Astellas reported $307 million in sales of micafungin (Mycamine®). These are less effective drugs with usage far greater than AmB due to the fact that they are much less toxic.

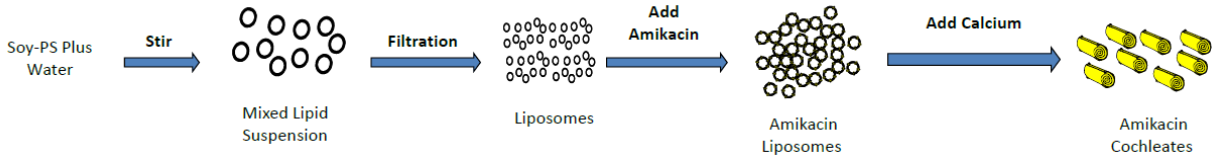
We believe the value proposition for CAmB – being able to prescribe an oral amphotericin B product both in the hospital and after the patient goes home, in a broad population, without overt fears of nephrotoxicity – is rather powerful. CAmB, a fungicidal drug, has significantly less developing resistance, unlike what is now being seen with azoles and echinocandins (Kauffman A, et al, 2015). We believe this is something payors will look very favorably upon, as long hospital stays and resistant infections add significant cost to the system.

Depending upon the efficacy and safety profile, we believe an orally-available encochleated amphotericin B could have tremendous uptake. As noted above, Pfizer's Diflucan® (fluconazole) posted peak sales in excess of $1.1 billion, and we see the drug as far less powerful than amphotericin B. There is potential for paradigm shift in how invasive fungal infections are treated in this country based on the concept of CAmB. Of course, this is all highly contingent upon clinical trial results. This is why we see the Phase 2a data coming in the fourth quarter 2015 as a significant catalyst for Matinas shares.

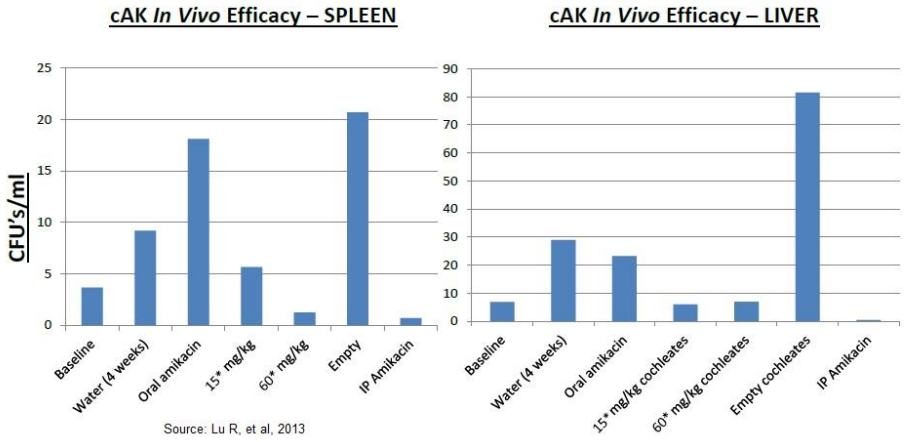
CAK (MAT2501)

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.

Due to the fact that the drug can generally only be tolerated at low doses, and the inherent difficulty in treating Gram-negative infections, amikacin is often used with other antibiotics, such as beta lactams. For these reason, an improved formulation of amikacin that would reduce the potential for toxicity and allow for oral dosing is clearly warranted. Formulation work with amikacin and the cochleate technology has been optimized to achieve maximum efficiency for delivery of the target drug.



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 far superior to non-optimized orally administered amikacin or an "empty" cochleate control.



The concept of CAK is similar to that of CAmB. Amikacin is a powerful, effective drug with low use today due to the toxic effects of the drug and the rather poor in vivo efficacy compared to the in vitro efficacy. Matinas believes that formulating amikacin with the cochleate technology has the potential to greatly improve the in vivo efficacy of the drug while reducing the toxic side-effects. Management is currently conducting pre-clinical toxicology studies with MAT2501. Similarly to MAT-2203, Matinas is working closely with the NIH on MAT2501 development. We anticipate the company wrapping up the animal toxicology studies this summer, which could position management to meet with the U.S. FDA for a pre-IND meeting in the third quarter 2015. If all goes well, we could see the U.S. IND filing before the end of the year.

Next-Gen Omega-3 (MAT9001)

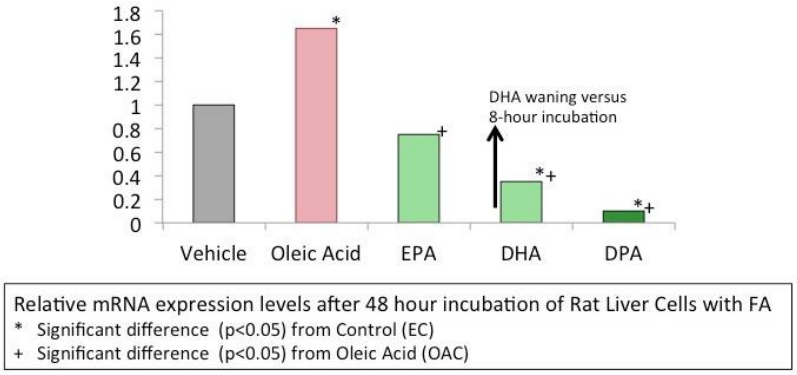
Clinical development of MAT9001 continues on plan. As a reminder, MAT9001 is a uniquely engineered omega-3 fatty acid formulation that Matinas is developing for the treatment of severe hypertriglyceridemia. A differentiating aspect of MAT9001 from other omega-3 prescription products is a focus on docosapentaenoic 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 commercially available omega-3 products, particularly in its ability to exert synergistic anti-hyperlipidemic effects in combination with statins.

…Quick Background Info…

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 in 42 patients with high triglycerides (200-499 mg/dL) in Canada. Enrollment completed in late March 2015. The goal of this study is to demonstrate better bioavailability than a commercially available prescription omega-3 comparator (either Lovaza® or Vascepa®), along with providing data on the ability of MAT9001 to yield distinctive therapeutic response properties and an improved therapeutic profile. As a point of reference, Glaxo sold $1.1 million of Lovaza in 2013 before the first generic approval in April 2014; Amarin sold $54 million of Vascepa in 2014. Top-line results of the Canadian pk/pd study are expected in late April / early May.

Matinas filed an investigational new drug (IND) application for MAT9001 in the fourth quarter 2014, with an initial indication for the treatment of severe hypertriglyceridemia. The path forward in the U.S., following the completion of the comparative bioavailability study being conducted in Canada discussed above, will include a quick Phase 1 study, followed by the initiation of the Phase 3 registration program.

The U.S. Phase 1 study will be a 4-way crossover single dose Fed/Fast pharmacokinetic study. Management will also conduct 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 start in the first quarter of 2016.

Valuation and Recommendation

We are very pleased to see Matinas secure roughly $8.5 million in cash. The poor balance sheet was likely restricting broad-scale investment from institutional investors into the Matinas story prior to completing that financing. Based on our financial model, we believe the company now has enough cash to fund operations over the next twelve months, but more importantly, over these next twelve months we see several catalysts on the horizon that could lead to valuation expansion and position the company for a NASDAQ listing and public offering in 2016. These catalysts include:

- → Comparative bioavailability and pk/pd data with MAT9001 vs. Lovaza®/Vascepa®
- → Approval from the U.S. FDA to begin the Phase 3 registration program with MAT9001
- → Initiation of a Phase 2a study with MAT-2203, with data expected in the fourth quarter 2015
- → Pre-IND meeting and U.S. IND filing on MAT2501 in the fourth quarter 2015

In terms of valuation, successful completion of the CAmB Phase 2a study would validate the opportunity that Matinas has with MAT2203, and we believe that an encochleated amphotericin B could be a potential $500 million or more drug if commercialized with the right pharmaceutical partner. Post the Phase 2a data, we believe MAT2203 will begin to factor more into the market value of Matinas. For example, if we assume MAT2203 gets approved in 2019 and has peak sales of $500 million in 2024, with a 25% discount rate and price/sales ratio of 5x, with only a 20% probability of success to the program, the asset is worth approximately $65 million in value. We see CAK, another potential $500 million or more opportunity, as worth $25 million today given the early-stage nature of the compound.

For MAT9001, we are concerned with the fact that Amarin could only muster $54 million in sales of Vascepa® in 2014. As of right now, it is difficult to say just how differentiated MAT9001 will be from branded Vascepa®, Epanova®, and generic Lovaza®. We understand the attributes of DPA, specifically the symbiotic effect the drug seems to have when coupled with statins, but at this time we are just not convinced there is sufficient differentiation between MAT9001 and commercially available omega-3 products to drive meaningful market share. Perhaps the comparative bioavailability Phase 1 data coming in May 2015 will convince us otherwise. That being said, if MAT9001 has peak sales of $200 million, our valuation analysis pegs the NPV at around $55 million in value right now given the high likelihood of approval (~50%) and the relatively straightforward path to market with a Phase 3 registration trial planned for 2016.

Summing up these parts, we believe that Matinas is worth approximately $145 million in total value. We note that the company has significant potential to raise additional cash through calling outstanding warrants. Our calculated fair-value equates to a target price of $2.25 on a basic share count ($1.75 on a fully diluted basis that includes adding in $29 million from warrant exercising plus 39.25 million shares).

PROJECTED FINANCIALS

Matinas BioPharma – Income Statement

Matinas Biopharma	2014 A	Q1 E	Q2 E	Q3 E	Q4 E	2015 E	2016 E	2017 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**	**$1.5**	**$1.5**
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0.0**	**$1.5**	**$1.5**
YOY Growth	-					-	-	-
Cost of Goods	$0	$0	$0	$0	$0	$0.0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Develop	$5.2	$1.3	$1.3	$1.3	$1.3	$7.5	$8.5	$8.5
General & Admin	$5.3	$1.4	$1.4	$1.4	$1.4	$6.5	$7.0	$7.0
Operating Income	($10.5)	($2.7)	($2.7)	($2.7)	($2.7)	($14.0)	($14.0)	($14.0)
Net Other Income	$0.2	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($10.2)	($2.7)	($2.7)	($2.7)	($2.7)	($14.1)	($14.1)	($14.1)
Taxes	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($10.2)	($2.7)	($2.7)	($2.7)	($2.7)	($14.1)	($14.1)	($14.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.32)**	**($0.08)**	**($0.05)**	**($0.05)**	**($0.05)**	**($0.27)**	**($0.19)**	**($0.14)**
YOY Growth	-	-	-	-	-	-	-	-
Wt. Ave Shares Outstanding	32.1	36.5	56.5	57.0	58.0	52.0	75.0	100.0

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

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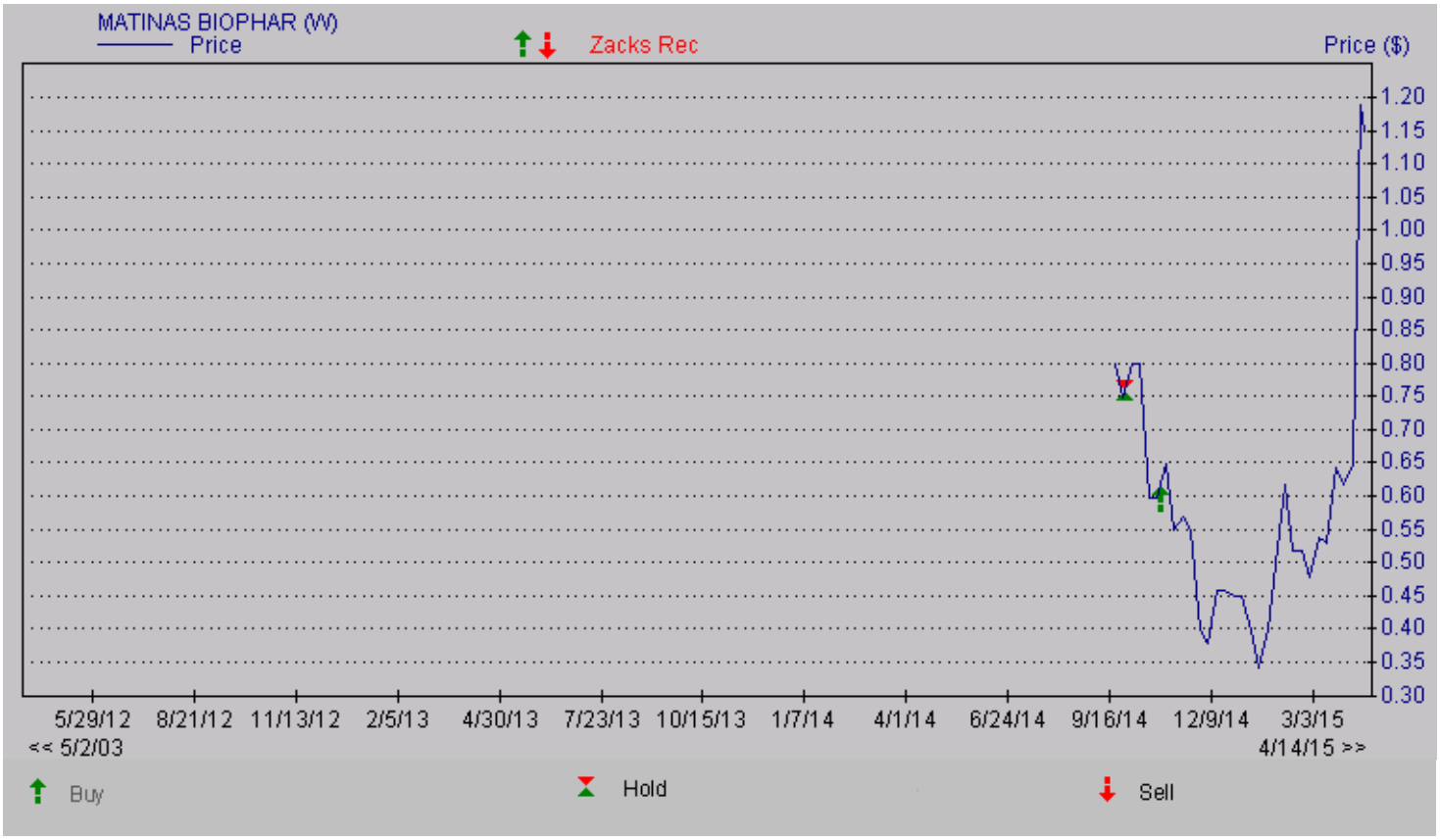
HISTORICAL ZACKS RECOMMENDATIONS



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