Zacks Small-Cap Research

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Omni Bio Pharma, Inc. (OMBP-OTCQB)

OMBP: FY 2014 Results…

UPDATE

On June 16, 2014, Omni Bio Pharma filed form 10-K for the fiscal year ending March 31, 2014. For the year, Omni Bio reported a net loss of $2.52 million, or $0.07 per share. The company exited the most recent quarter with $271K in cash. However, in April 2014, the cash balance was fortified by a $3.0 million private financing plan that secured $0.5 million upfront, with a committed source for another $1.5 million as needed and $1.0 million in future funds from yet to be named sources. These funds should be enough to get work initiated on pre-clinical development activities for Fc-AAT. We believe the company will require significantly more money in the future in order to get Fc-AAT into the clinic.

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	04/15/2013
Current Price (06/18/14)	$0.20
Target Price	**$0.50**

SUMMARY DATA

52-Week High	**$0.45**
52-Week Low	**$0.13**
One-Year Return (%)	**-28.57**
Beta	**3.34**
Average Daily Volume (sh)	**8,039**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$8**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**N/A**
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 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 A	0 A	0 E	0 E
2015	0 E	0 E	0 E	0 E	0 E
2016					0 E

Earnings per Share
(EPS is operating earnings)

	Q1 (Jun)	Q2 (Sep)	Q3 (Dec)	Q4 (Mar)	Year (Mar)
2013	-$0.04 A	-$0.04 A	-$0.07 A	-$0.09 A	-$0.23 A
2014	-$0.02 A	-$0.02 A	-$0.02 A	-$0.01 E	-$0.07 A
2015	-$0.02 E	-$0.02 E	-$0.02 E	-$0.02 E	-$0.07 E
2016					-$0.08 E

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WHAT'S NEW

Financial Update

On June 16, 2014 Omni Bio reported financial results for the 2014 fiscal year that ended March 31, 2014. For the year, the company had a net loss of $2.52 million, compared to $7.45 million for the 2013 fiscal year. G&A expenses were $1.75 million for the year, compared to $5.42 million in fiscal year 2013, which included $4.17 million in share based compensation. Excluding share-based compensation, G&A expenses for fiscal 2014 were $1.26 million as compared to $1.25 million in fiscal 2013. R&D expenses for fiscal 2014 were $0.16 million, compared to $0.29 million for fiscal 2013.

Non-operating expenses for the 2014 fiscal year were $0.60 million compared to $1.13 million in 2013. The decrease was mostly attributable to a decrease in expenses associated with the equity interest in BioMimetix Pharamaceutical, Inc.

The company reported $0.271 million in cash and cash equivalents as of March 31, 2014. For fiscal 2014, Omni Bio used $1.43 million in cash for operations compared to $1.70 million in 2013. Financing activities provided $1.36 million, while there were no cash flows from investing activities. We estimate the company's current cash position at approximately $0.7 million based on the disclosed cash position plus the private financing plan that was announced on April 24, 2014. Management has forecasted that cash on hand and the subsequent financing plan should be enough to fund the company through the fourth quarter of fiscal year 2015 ending March 31, 2015.

Appointment of Dr. Bruce Forrest as Chief Development Officer

On May 1, 2014, Omni Bio announced the appointment of Dr. Bruce Forrest to the position of Chief Development Officer. Omni Bio has retained Dr. Forrest for the previous 18 months to provide the company with scientific strategy and business development support. As Chief Development Officer, Dr. Forrest will now oversee implementation of the development plan for Omni Bio's Fc-AAT molecule, which will include interface and leadership responsibilities for work being performed by the company's cell line optimization and product manufacturing partner Gallus BioPharmaceuticals, Inc.

Dr. Forrest has over 25 years of industry experience in pharmaceutical development of vaccines and biopharmaceuticals. He was previously the Senior Vice President in Vaccines R&D at Wyeth Pharmaceuticals where he was responsible for clinical and developmental activities for all late phase programs. From 2004-2008 Dr. Forrest was the head of Wyeth's R&D organization in Japan where he oversaw the successful regulatory approval of several new drug entities. Dr. Forrest's background and wealth of experience should prove to be very helpful for Omni Bio as they continue the development of Fc-AAT.

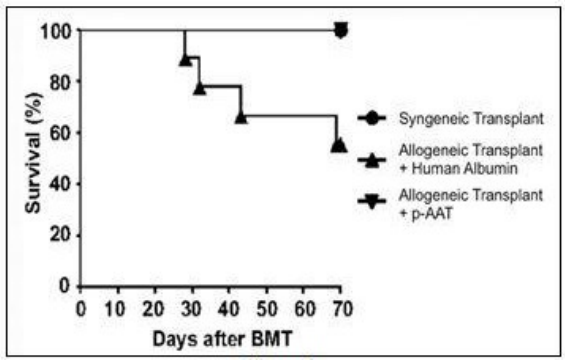
New Use Patent Granted in Europe

On May 8, 2014, Omni Bio announced receipt of a Grant Notice from the European Patent Office for the use of AAT in reducing the risks of non-organ transplant rejection and graft versus host disease (GvHD) in patients who have received a cornea, bone marrow, or pancreatic islet cell transplant.

GvHD is a common complication following allogeneic (genetically-mismatched) tissue transplant, most often associated with stem cell or bone marrow transplant. Common treatment options for patients post allogenic stem cell transplant includes drugs that suppress the T cell mediated immune onslaught on the host tissues, including glucocorticoids such as prednisone. These drugs often have poor tolerability, may illicit harmful side effects on the kidneys and liver, and create risk of infection or cancer relapse. Despite treatment with high-dose prednisone, 40% to 50% of unrelated allogeneic tissue transplant patients will develop GvHD.

Thus, there exists a significant unmet medical need to develop a new immune modulating agent that can allow the T cell mediated graft-versus-leukemia response while sparing the recipient from an injurious inflammatory and immunological assault (Lewis EC, 2011). Along with its potent anti-inflammatory profile, research shows that p-AAT has the ability to modify dendritic cells toward a tolerogenic phenotype (Subramanian et al, 2011; Lewis et al, 2008).

Data published in the Proceedings of the National Academy of Sciences (PNAS) shows that administration of p-AAT early after bone marrow transplant decreased mortality in three models of GvHD and reduced serum levels of pro-inflammatory cytokines such as TNF-a and IL-1b in the allogeneic recipients compared with the control (see below). Furthermore, p-AAT treatment reduced the expansion of alloreactive T effector cells but enhanced the recovery of T regulatory T cells, thus reducing the pathological harmful response. Treatment with p-AAT also resulted in increased production of anti-inflammatory cytokines, IL-10 (Tawara I et al, 2012).



We see a number of key points and preclinical findings that support the utility of p-AAT in the treatment and prevention of GvHD:

- ✓ Data shows a loss of A1AT during intestinal GvHD in children (Hagen et al, 2011).
- ✓ Significant scientific evidence exists to support the involvement of IL-1 during the progression of GvHD, and treatment with IL-1 receptor antagonists have been shown to slow progression and reduce disease severity (Dinarello CA, 2011; Antin et al, 1994).
- ✓ Animal model data shows p-AAT provides a clear benefit to immune profile, body weight, and survival (Marcondes et al, 2011; Tawara et al, 2012).

We see GvHD as a potential enormous opportunity. According to data from the Center for International Blood and Marrow Transplant, the incidence of acute GvHD ranges from 26% to 34% in recipients of full matched sibling donor grafts, to 42% to 52% in recipients of matched unrelated donor grafts. The incidence is directly related to the degree of human leukocyte antigens (HLA) disparity. The median onset of acute GvHD is typically 21 to 25 days after transplantation. Chronic GvHD ranges in incidence from 30% in recipients of fully histocompatible transplants to 60% to 70% in recipients of mismatched hematopoietic cells or hematopoietic cells from an unrelated donor. The median time of diagnosis of chronic GvHD is 4.5 months after HLA-identical sibling transplantation and four months after unrelated donor transplantation.

GvHD is listed as a "rare disease" by the Office of Rare Diseases (ORD) of the NIH. Given the number of Americans that undergo a transplant per year, we estimate there are approximately 7,500 cases of acute GvHD per year in the U.S. According to data from the NIH, 30% to 50% of patients respond to high doses of corticosteroids, such as methylprednisolone. This would place the refractory-treatment population in the U.S. at approximately 4,000 patients per year. Including Europe and the rest of the developed world, Omni Bio is probably looking at an addressable patient population of approximately 10,000 individuals.

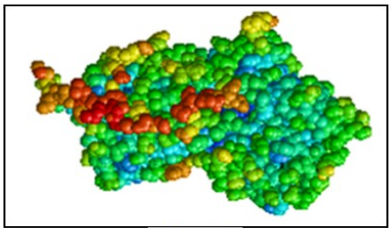
This represents a very attractive label expansion opportunity for the four big manufacturers of p-AAT: Grifols, Baxter, CSL Behring, and Kamada. It essentially doubles the market from the $600-700 million now with AATD. With positive proof-of-concept data, we think Omni Bio can strike a deal with one of these major players. A deal with Grifols, the market leader, makes sense from a defensive standpoint. Grifols could acquire the rights to use p-AAT in GvHD from Omni Bio to protect its market-leading position. A deal with Baxter or Kamada makes sense if one of these smaller players wants to make an offensive move on the market leader.

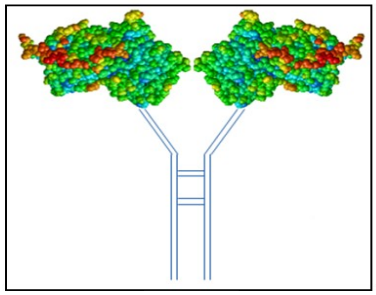
Fc-AAT – A Game Changer

Despite all the promise and potential for p-AAT, the drug remains horribly inefficient to manufacture. In an era of recombinant insulin, synthetic clotting factors, monoclonal antibodies, interference RNA, exon-skipping technology, and the ability to transplant living human neural stem cells, all of the currently available AAT replacement therapy products are derived from pool human plasma. There are four manufacturers of p-AAT worldwide, Grifols, Baxter, CSL Behring, and Kamada. The market leading product, Prolastin-C, is prepared by cold ethanol fractionation from pooled human plasma purified by polyethylene glycol (PEG) precipitation, anion exchange chromatography, and cation exchange chromatography. Two additional steps, a solvent / detergent treatment and 15 nm virus removal nanofiltration are also included in the process to reduce risk of transmission of enveloped and non-enveloped viruses.

The product also has a short half-life of only 3-5 days, meaning that administration for patients with AATD must be done through weekly infusions. The infusion process takes about 2 hours and must be performed at an infusion clinic. The average cost of therapy is around $2,000 per 60 mg/kg weekly infusion, or around $100,000 per year! It's pretty simple - p-ATT is expensive, inconvenient, and though the products are treated extensively to reduce the risk, potentially exposes patients to blood-borne pathogens.

Omni Bio's lead Fc-AAT molecule, which they refer to internally as Fc-AAT-2, is a fusion protein that combines human AAT (below left) with an Fc fragment of human IgG1 immunoglobulin molecule. This fusion protein spontaneously binds together to form a dimer. Each dimer contains two AAT molecules and two Fc molecules connected by molecular bonds (below right).





Plasma-Derived A1AT (p-AAT) = 52 kDa
Recombinant Fc-AAT-2 = 174 kDa

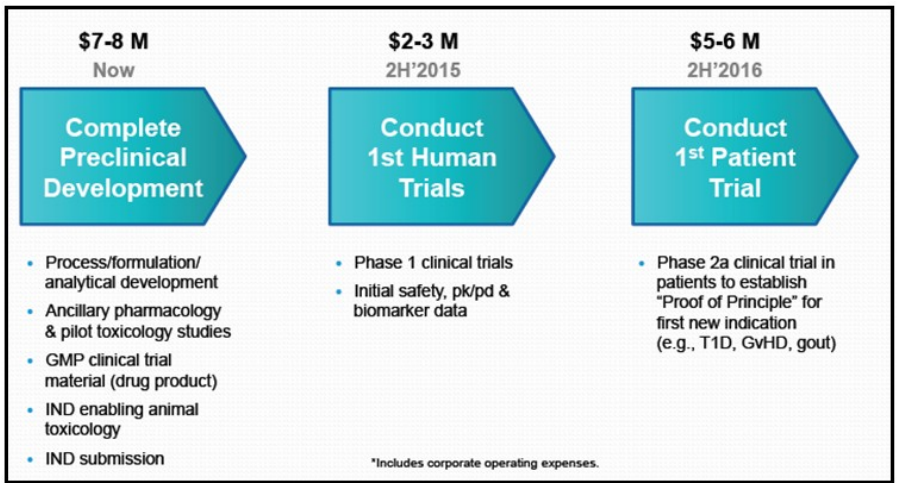
Omni Bio believes the technology used to construct Fc-AAT is similar to that already used to create highly successful drugs for human application, such as Amgen / Pfizer's Enbrel. Enbrel was jointly developed by Immunex (acquired by Amgen) and Wyeth (acquired by Pfizer). Omni Bio's CEO, Dr. Bruce Schneider, was a senior R&D executive at Wyeth and was intimately involved in the development of Enbrel. Through our conversations with Dr. Schneider, he tells us that many of the experiences with Enbrel are transferrable to the development of Omni Bio's Fc-AAT molecule. Other Fc drugs include Regeneron's Zaltrap, Biogen's Alprolix and Eloctate, and Eli Lilly's dulaglutide.

We think the company's Fc-AAT molecule has the potential to be a game-changer in this market; not only for replacement therapy in patients with AAT deficiency, but also in expanding the use of the AAT molecule into new areas of therapeutic treatment such as Type-1 diabetes, GvHD, and myocardia infarction. Currently, all available supply of p-AAT is delegated for patients with AATD. The new indications noted above have significant interest, but uptake would be limited by supply and cost. That's why we think the Fc-AAT formulation has the potential to big a big seller, and we suspect even quality for 'Breakthrough Therapy' designation by the U.S. FDA.

Omni Bio's recombinant Fc-AAT is 40-50x more potent than p-AAT based on early-stage animal trials. For example, Fc-AAT in models of gout and myocardial infarction that show good dose response and also that a 50 ug dose of Fc-AAT performed at least as well as a 2 mg dose of p-AAT. The drug offers improved stability and longer duration of effect. Omni Bio expects that Fc-AAT will be administered via self-administered subcutaneous injections, a huge improvement over 2+ hour trips to the local infusion center. Plus, the drug has a simple and low-cost manufacturing that would allow for dramatically improved supply and economics to patients.

Conclusion

We really like the concept of Fc-AAT and Omni Bio's business strategy with cornering the intellectual property around the existing p-AAT products. We think there is potential for huge returns here. However, the story is not without risk. Omni Bio recently secured $2 million. That's not enough. They need more. Take a look at the following slide from the company's June 2014 investor presentation.



Omni Bio needs at least another $10 million between now and the end of 2015 to see this strategy through. That includes another $5+ million to complete preclinical development and $2-3 million to conduct the first human clinical trial. That's going to be a challenge given the current stock price of $0.20 per share. As of today, the basic share count is around 38.7 million, but the fully-diluted number is closer to 90 million, and will be going up as the company raises more money. For example, if Omni Bio were to go out and raise another $5 million later in 2014, that would equate to issuing 25 million shares at $0.20 before we starting throwing in warrants or backing-out fees to the placement agent. Take note, on April 24, 2014, the company retained investment bank Dawson James to advise and assist the company in its capital market activities.

Unfortunately, that makes it difficult for us to tell investors to buy the shares today. That's an awful lot of new stock coming to the market, no matter how good the science is. What Omni Bio needs is a "White Knight" – perhaps Grifols or Kamada will generate impressive data in Type-1 diabetes and decide Omni is too good to pass up at even 3-4x this price? That's not unrealistic to believe. In the meantime, we'll be keeping a close watch on the development of both p-AAT and Fc-AAT.

PROJECTED FINANCIALS

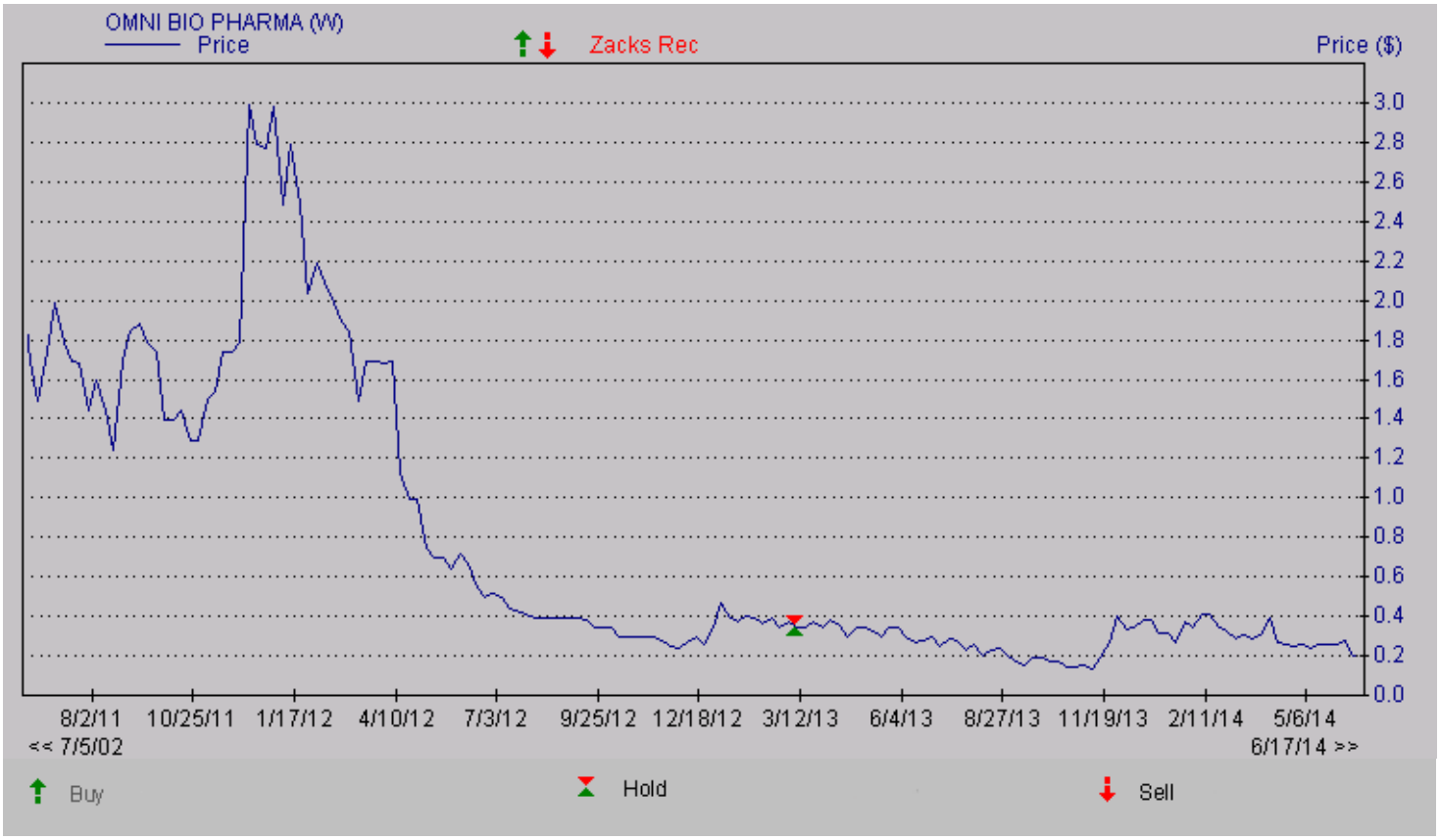
Omni Bio Pharmaceuticals, Inc.
Income Statement

Omni Bio Pharma	FY'13A	FY'14A	June-14E	Sept-14E	Dec-14E	Mar-15E	FY'15E	FY'16E
Product Sales (Fc-AAT)	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Licensing & Collaborative Payments	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0.0
Product Gross Margin	-	-					-	-
R&D	$0.297	$0.163	$0.040	$0.050	$0.055	$0.060	$0.205	$0.400
% R&D	-	-	-	-	-	-	-	-
SG&A	$5.423	$1.750	$0.500	$0.550	$0.600	$0.700	$2.350	$3.500
% SG&A	-	-	-	-	-	-	-	-
Operating Income	**($5.720)**	**($1.912)**	**($0.540)**	**($0.600)**	**($0.655)**	**($0.760)**	**($2.555)**	**($3.900)**
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	($1.734)	($0.604)	($0.100)	($0.100)	($0.100)	($0.100)	($0.400)	($0.250)
Pre-Tax Income	($7.454)	($2.517)	($0.640)	($0.700)	($0.755)	($0.860)	($2.955)	($4.150)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($7.454)	($2.517)	($0.640)	($0.700)	($0.755)	($0.860)	($2.955)	($4.150)
Net Margin	-	-					-	-
Reported EPS	**($0.23)**	**($0.07)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.07)**	**($0.08)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	32.0	37.3	39.5	41.0	43.0	45.0	42.1	50.0

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

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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