Zacks Small-Cap Research

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Omni Bio Pharma, Inc. (OMBP-OTCQB)

OMBP: Omni Bio Gets A Lifeline, Pushes Forward with Fc-AAT

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	04/15/2013
Current Price (04/30/14)	$0.25
Target Price	**$0.50**

UPDATE

On April 24, 2014, Omni Bio Pharma entered into a $3 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. This is clearly good news for the company, as Omni Bio exited 2013 with only $485K in cash. We really like the Omni Bio story too. In fact, when we've written on Omni Bio in the past, our chief concern was the company's ability to fund the necessary clinical trials to maximize value for shareholders. Clearly securing a $2.0 million loan is not going to be enough to drive Omni Bio to profitability, or even into clinical trials with Fc-AAT, but it's a start. And given where Omni Bio was heading, it's a nice lifeline for this very interesting little biotech company.

SUMMARY DATA

52-Week High	**$0.45**
52-Week Low	**$0.13**
One-Year Return (%)	**-37.14**
Beta	**3.22**
Average Daily Volume (sh)	**37,917**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$9**
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
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	-$0.04 E	-$0.10 E
2015					-$0.15 E
2016					-$0.15 E

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WHAT'S NEW

Omni Bio Gets A Lifeline

On April 24, 2014, Omni Bio Pharma (OMBP) entered into a $3 million private financing plan that secured $2 million as needed and $1 million in future funds from yet to be named sources. This is clearly good news for the company, as Omni Bio exited 2013 with only $485K in cash. Burn for the three months ended December 31, 2013 was $295K, and that was because the company was – for all intents and purposes – dark during that time. Burn for the two previous quarters averaged $450K. As such, we believe that cash as of March 31, 2014 was down to less than $200K.

The secured financing took place with Bohemian Investments, LLC, a Fort Collins, Colorado-based investment company with affiliation to Fort Collins-based BOCO Investments, LLC, a previous investor in Omni Bio Pharma. BOCO President, Mr. Joseph C. Zimlich is also CEO of Bohemian. Needless to say, he must really like the story. Of course, Bohemian and BOCO got a really good deal. The $2 million loan ($500K upfront with commitment for another $1.5 million) comes at a hefty price. The loan matures in one year, and Omni Bio will pay 12% interest. After one year, or at any time prior, Bohemian can convert to common shares at $0.20 per share, a slight discount to the current price of $0.25 per share. Bohemian received 1.0 million warrants at $0.25 per share; and BOCO, perhaps for brokering the deal, received 3.0 million warrants at $0.01 per share, along with a reset on all existing warrants to $0.25 per share. We calculated around 5.55 million in total that reset.

We really like the Omni Bio story too. In fact, when we've written on Omni Bio in the past, our chief concern was the company's ability to fund the necessary clinical trials to maximize value for shareholders. Clearly securing a $2 million loan is not going to be enough to drive Omni Bio to profitability, or even into human clinical trials with Fc-AAT, but it's a start. And given where Omni Bio was heading, it's a nice lifeline for this very interesting little biotech company.

Then Immediately Pushes Forward

Management at Omni Bio wasted no time putting that good cash to work. On April 29, 2014, the company announced an agreement with Gallus Biopharmaceuticals, LLC, a contract development and manufacturing organization (CMO), on a multi-stage manufacturing services agreement. According to the release, the agreement includes cell line optimization, analytical development, and manufacturing scale-up activities for Omni Bio's alpha-1 antitrypsin (AAT) Fc fusion protein. The goal is for Gallus to provide Omni cGMP product to support animal pharmacology and toxicology studies, and early human clinical trials of with Fc-AAT.

Besides these initial process/formulation, manufacturing, and preclinical IND enabling activities, Omni Bio is also funding outside investigator studies of plasma-derived AAT (p-AAT) in steroid refractory graft-vs-host disease (GvHD). There are two ongoing pilot studies, one under the direction of Dr. Pavan Reddy, MD at the University of Michigan (NCT01700036) and another under the direction of Dr. H. Joachim Deeg at the Fred Hutchinson Cancer Research Center (NCT01523821). We discuss the opportunity for use of p-AAT in GvHD and how it relates to Omni Bio below. However, beside GvHD, several additional outside sponsored studies are currently ongoing. These include:

- ✓ A pilot study in patients with acute myocardial infarction under direction of lead investigator, Dr. Antonio Abbate, MD, PhD of the Virginia Commonwealth University (NCT01936896)
- ✓ A Phase 2/3 placebo controlled trial of Kamada (KMDA) & Baxter's (BAX) Glassia® in recent onset Type-1 diabetics (NCT02005848). This is a fairly-large trial that just began in November 2013 with a goal of enrolling 192 newly diagnosed Type-1 diabetics at four clinical sites in Israel. The primary endpoint is beta cell function at twelve months vs. baseline.
- ✓ A Phase 2 placebo controlled trial of Grifols Therapeutics' Prolastin-C® in recent onset Type 1 diabetics (NCT02093221). This is a slightly smaller trial at only 75 patients compared to the one Kamada and Baxter are running, but the trial is being conducted at a dozen sites in the U.S. so many garner more U.S. investor attention.

The reason we mention these outside studies is because Omni Bio Pharma controls the intellectual property to an issued method and composition patent for the treatment of diabetes (Type-1 or Type-2) using p-AAT. The company

also controls the rights to method of use patents covering p-AAT in GvHD, non-organ transplant rejection, post myocardial infarction remodeling, certain bacterial and viral infections, and radioprotection.

That means if Kamada or Grifols wants to seek approval to market their respective p-AAT products for diabetes or GvHD, or any other indication for which Omni Bio Pharma controls the IP, they need to come to Omni Bio for a sub-license. This creates an interesting potential bidding war between some very big players in Baxter, Kamada, and Grifols, all with significant skin-in-the-game already with their p-AAT products for the treatment of alpha-1-antitripsan deficiency (AATD). In a sense, it's a race for these companies to generate data in these additional indications and then come to Omni Bio to negotiate a deal. While it's too early to strike a deal right now for any of these indications – Baxter, Kamada, and Grifols want to get the data first so they know if it is worth sub-licensing the IP – in two or three years, the IP alone that Omni Bio controls could be worth hundreds of millions.

For example:

…In GvHD…

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 Figure-1 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).

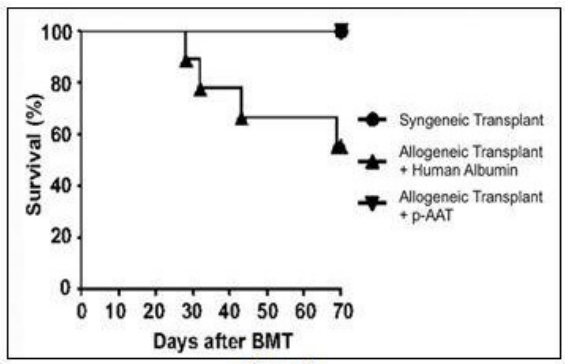

Figure-1

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.

…In post-MI…

Significant interest exists in seeking to reduce inflammatory response during and following an acute myocardial injury. Data shows that p-AAT may play a role in preserving tissue integrity and reducing scar formation thanks to its potent anti-inflammatory characteristic. Evidence also shows protection from ischemia reperfusion injury in renal mouse models by p-AAT (Daemen et al, 2000).

Work published in the Journal of Molecular Cell Cardiology shows the effects of exogenously administered p-AAT on caspase-1 activity and on the outcome of ischemia-reperfusion injury in a mouse model of acute myocardial infarction. Mice underwent 30 min of coronary artery ligation followed by reperfusion and were randomly assigned to receive clinical-grade p-AAT or albumin at reperfusion. Infarct size was evaluated after 1 and 7 days. AAT-treated mice had significantly smaller infarct sizes (-30% day 1 and -55% day 7) compared with mice treated with albumin (Figure-2). AAT-treated mice also exhibited a >90% smaller increase in left ventricular end-diastolic diameter and end-systolic diameter, and smaller reduction in ejection fraction. The authors conclude that exogenous administration of clinical grade A1AT reduces caspase-1 activity in the ischemic myocardium leading to preservation of viable myocardium and prevention of adverse cardiac remodeling (Toldo S et al, 2011).

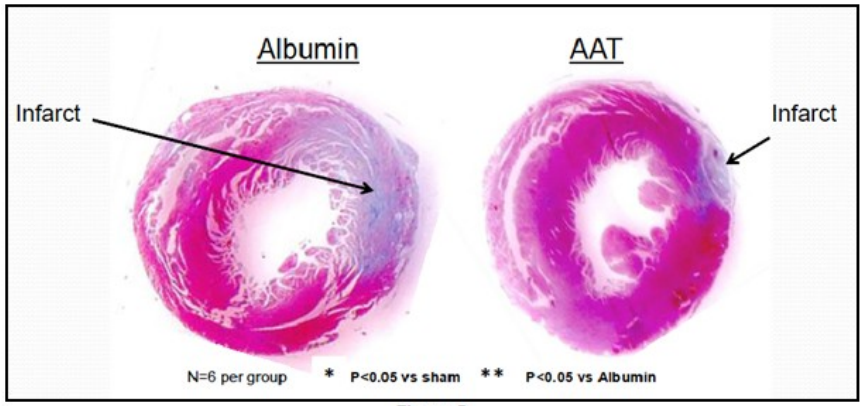

Figure-2

…In Diabetes…

Type-1 diabetes is an autoimmune disorder resulting in the destruction of insulin-producing B-cells of the pancreas. The lack of insulin leads to increased blood and urine glucose. Type-1 diabetes must be treated by injection (or inhalation) of insulin. Protection of the islet cells is the obvious target for new therapeutic methods of treatment, and new clinical studies are focusing on stopping the T-cell-mediated autoimmune attack. Anti-inflammatory agents, such as anti-CD3 antibodies, have shown encouraging signs of efficacy. Data show that blockage of the

inflammatory molecule IL-1, a direct B-cell toxic agent, results in reduced insulin dependence when tested on children with early-stage disease (Sumpter et al, 2011).

Research on non-obese diabetic (NOD) mice show that inflammatory mechanisms trigger insulitis, insulin resistance, faulty insulin signaling, and the loss of immune tolerance to islets. The data demonstrate that treatment with p-AAT, an agent that dampens inflammation, does not directly inhibit T cell activation, ablates invasive insulitis, and restores euglycemia (normal blood glucose levels), immune tolerance to B cells, normal insulin signaling, and insulin responsiveness in NOD mice with recent-onset type-1 diabetes through favorable changes in the inflammation cascade (Figure-3) (Koulmanda et al., 2008).

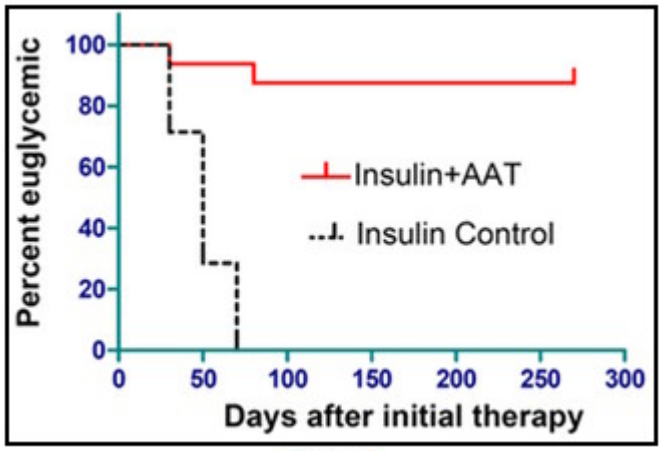

Figure-3

There are essentially three key points that lead us to believe p-AAT may have therapeutic utility in Type-1 diabetes.

- ✓ Firstly, non-functional circulating AAT has been shown to exist in most individuals with Type-1 diabetes (Yaghmaei et al, 2009), suggesting that AAT levels may play a role in disease progression.
- ✓ Secondly, multiple preclinical animal models also show consistent benefit of AAT on protection of insulin producing islet B-cells (Kamada, Ltd., November 2012; Koulmanda et al., 2008).
- ✓ Thirdly, AAT is endogenously produced under inflammatory stimuli by human islet cells (Bosco et al, 2005). These three conclusions strengthen the case for testing p-AAT in human clinical trials in children recently diagnosed with Type-1 diabetes.

Omni Bio just recently announce publication of a Phase 1 pilot study sponsored by the University of Colorado, Barbara Davis Center for Childhood Diabetes under the direction of Dr. Peter Gottlieb. Published results show that AAT may have a beneficial effect on Type-1 diabetes in recently diagnosed patients through the down-modulation of IL-1β and other pro-inflammatory cytokines. IL-1β is known to be harmful to insulin-producing cells. The authors further concluded that targeting inflammation with inhibitors of the innate immune system, such as p-AAT, might represent an efficient therapeutic strategy for disease prevention.

Key findings of the 12-patient, 8 week study (80 mg/kg per week) were as follows:

- ✓ AAT led to increased or unchanged levels of C-peptide responses in four patients during 18 months' follow up.
- ✓ The total content of TLR4-induced cellular IL-1β in monocytes at 12 months among all patients was reduced 3-fold compared to baseline ($p<0.05$).
- ✓ Monocyte production of IL-1β was reduced from 82% at baseline to 42% at 12 months.
- ✓ Similar reductions were seen using TLR7/8 and TLR3 agonists in monocytes and myeloid dendritic cells (mDCs).
- ✓ Unexpectedly, the reduction in cellular IL-1β was observed at 9-12 months post-treatment but not in a cohort of untreated diabetics.
- ✓ Improved islet cell function in the four responder patients correlated with the reduced monocytes and mDC production levels of IL-1β ($p<0.04$ and $p<0.02$, respectively).
- ✓ No significant adverse effects were reported in the study

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 (Figure 4A) 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 (Figure 4B).

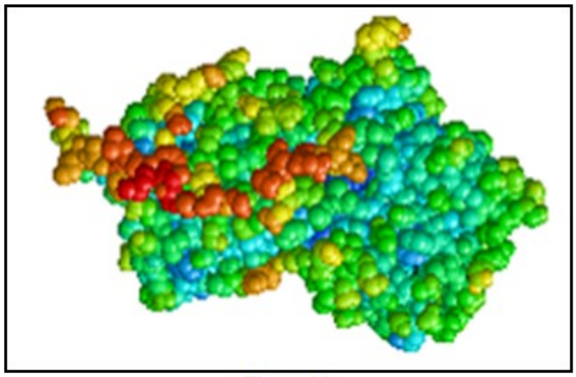

Figure-4A

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

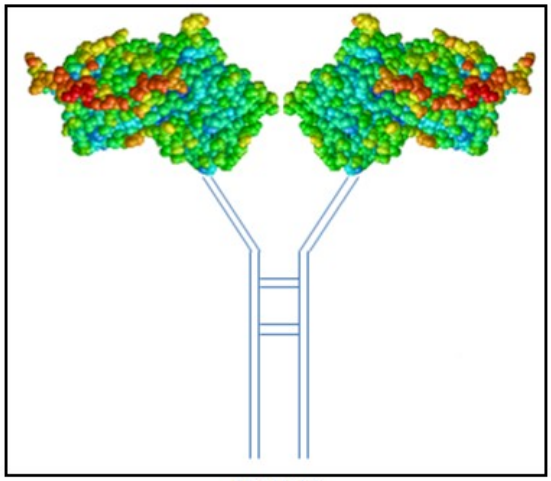

Figure-4B

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 secured $2 million last week. That's not enough. They need more. Take a look at this slide from the company's February 2014 investor presentation (Figure 5).

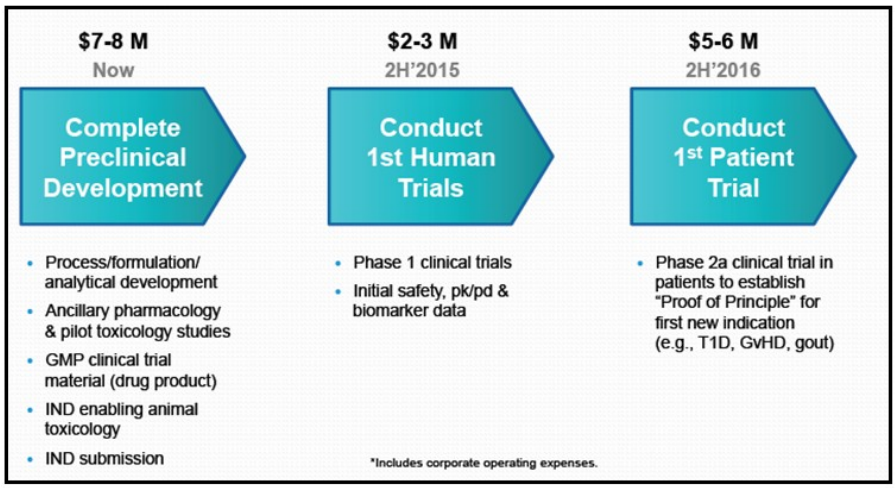

Figure 5

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 $0.25 per share. As of today, the basic share count is around 38.2 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 20 million shares at $0.25 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'12 A	FY'13A	June-13A	Sept-13A	Dec-13A	Mar-14E	FY'14E	FY'15E	FY'16E
Product Sales (Fc-AAT)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Licensing & Collaborative Payments	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	*100.0%*	-					-	-	-
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
Product Gross Margin	-	-					-	-	-
R&D	$0.398	$0.297	$0.028	$0.099	$0.036	$0.250	$0.413	$0.750	$1.000
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$4.237	$5.423	$0.503	$0.540	$0.410	$1.450	$2.903	$6.000	$6.500
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	**($4.635)**	**($5.720)**	**($0.531)**	**($0.638)**	**($0.446)**	**($1.700)**	**($3.316)**	**($6.750)**	**($7.500)**
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Income	($0.760)	($1.734)	($0.150)	($0.002)	($0.309)	($0.100)	($0.561)	($0.250)	($0.250)
Pre-Tax Income	($5.395)	($7.454)	($0.681)	($0.640)	($0.755)	($1.800)	($3.877)	($7.000)	($7.750)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($5.395)	($7.454)	($0.681)	($0.640)	($0.755)	($1.800)	($3.877)	($7.000)	($7.750)
Net Margin	-	-					-	-	-
Reported EPS	**($0.17)**	**($0.23)**	**($0.02)**	**($0.02)**	**($0.02)**	**($0.04)**	**($0.10)**	**($0.15)**	**($0.15)**
YOY Growth	-	-	-	-	-	-	-	-	-
Basic Shares Outstanding	31.4	32.0	34.1	38.2	38.4	46.0	39.2	48.0	52.0

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

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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- 16.8%, Hold/Neutral- 75.4%, Sell/Underperform – 6.8%. Data is as of midnight on the business day immediately prior to this publication.