Zacks Small-Cap Research

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Omni Bio Pharma, Inc. (OMBP-OTCQB)

OMBP: Insights From Meeting With Management…

Current Recommendation	**Neutral**
Prior Recommendation	N/A
Date of Last Change	04/15/2013
Current Price (01/22/14)	$0.27
Target Price	**$0.50**

UPDATE

On Sunday, January 12, 2014, we arrived in San Francisco, CA for the annual JP Morgan Healthcare Conference, as well as the parallel Biotech showcase and OneMedForum Conferences. This was the eighth year in a row that we made the trip to San Francisco for these events, which are a must-attend for serious healthcare investors.

During my three days in San Francisco, I conducted 25 one-on-one meetings with various managements of small and mid-cap biotechnology and specialty pharmaceutical companies. Below are some "notes" from our meeting with Omni Bio Pharma, Inc.

SUMMARY DATA

52-Week High	**$0.44**
52-Week Low	**$0.13**
One-Year Return (%)	**N/A**
Beta	**N/A**
Average Daily Volume (sh)	**9,654**
Shares Outstanding (mil)	**38**
Market Capitalization ($mil)	**$11**
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 2013 Estimate	**N/A**
P/E using 2014 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 E	0 A	0 E	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	-$0.05 E	-$0.04 E	-$0.13 E
2015					-$0.15 E
2016					-$0.15 E

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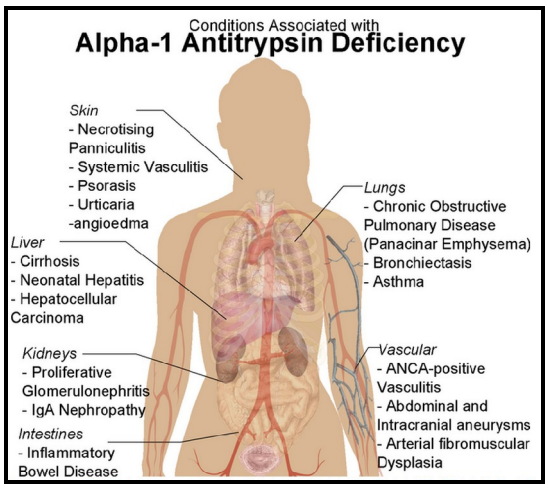
WHAT'S NEW

Omni Bio Pharmaceuticals (OMBP)
Meeting took place with Bruce Schneider, PhD, CEO

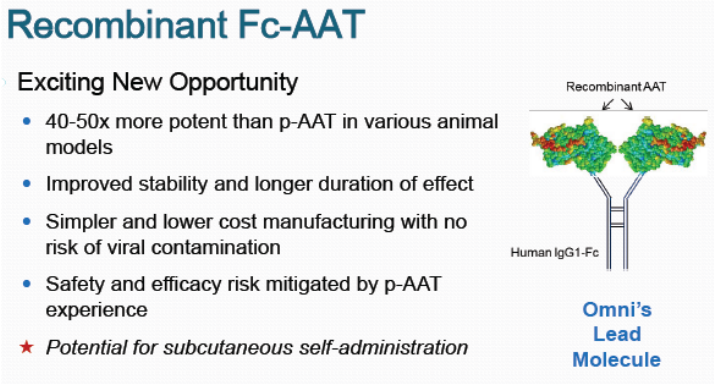
We were really looking forward to our meeting with Bruce Schneider at Omni Bio Pharma. We like the work that Omni is doing, but our biggest concern to date has always been the cash position. Before we get into the details of the meeting, investors may want to familiarize themselves with the Omni Bio story. Below is a quick summary from our most recently report:

> Omni Bio Pharmaceuticals is focused on the discovery and development of novel applications of the endogenous anti-inflammatory protein alpha-1-antitrypsin (A1AT), and on the development of novel and more conveniently dosed versions of the A1AT molecule. A1AT deficiency is a homozygous genetic disorder resulting from abnormal production of A1AT that affects an estimated 100,000 individuals in the U.S. In the absence or low levels of circulating A1AT, proteases such as neutrophil elastase break down the connective tissue fiber elastin that contributes to the elasticity of the lungs. This results in respiratory complications such as emphysema or chronic obstructive pulmonary disease (COPD) in adults and hepatic cirrhosis in children. Severe A1AT deficiency is treated by the IV administration of plasma-derived A1AT (p-AAT). Remarkably, in the era of recombinant insulin, clotting factors, and monoclonal antibody products, all of the currently available A1AT replacement therapy products are derived from pool human plasma (p-AAT).



> There are four manufacturers of p-AAT worldwide, Grifols, Baxter, CSL Behring, and Kamada. The two largest products we found are Grifols' Prolastin-C, with sales at an estimated $500 million and Baxter's Aralast-NP with sales at an estimated $60 million. Thus, we estimated the total market for p-AAT is around $600-700 million on a global basis. Omni Bio is developing a recombinant A1AT product would have several important advantages over the currently available plasma-derived products. Firstly, it would avoid the potential risk of infection inherent in the use of pooled plasma-derived products. While the currently available products are extensively treated to reduce the potential for viral contamination, the potential for contamination by unknown and unrecognized pathogens remains an important risk. Secondly, the cost of manufacturing would be greatly reduced due to the ability to avoid the complex, multi-step procedure needed to isolate A1AT from pooled donor blood. The expense of the current process arises from the very modest concentration of A1AT in human plasma, as well as the extensive procedures needed to reduce the risk of pathogen contamination. And finally, a recombinant product could be designed to incorporate structural modifications that provide improved properties, such as a more extended serum half-life.

We've been keeping a close eye on Omni Bio since we first identified the name back in April 2013 (see our Seeking-Alpha article for a detailed overview of the story). 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 A1AT deficiency, but also in expanding the use of the A1AT molecule into new areas of therapeutic treatment such as Type-1 diabetes, GvHD, and gout. Interest in p-AAT for Type-1 diabetes has been gaining steam over the past few years, but use is limited by supply. Omni Bio is supporting several independent studies, and Kamada, one of the largest p-AAT suppliers, is doing clinical studies in Europe in this regard. Omni Bio owns the intellectual property to expanding indications with p-AAT. But it is with the Fc-AAT formulation where we see the biggest potential. This is the kind of molecule we think has the potential to qualify for 'Breakthrough Therapy' designation by the U.S. FDA.



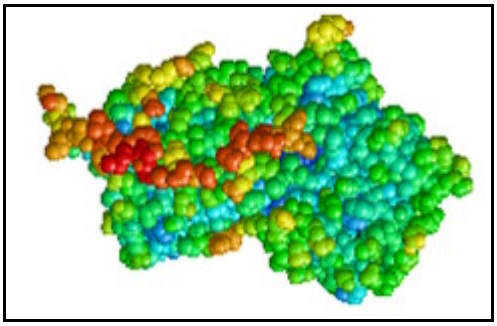


Figure-4A

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

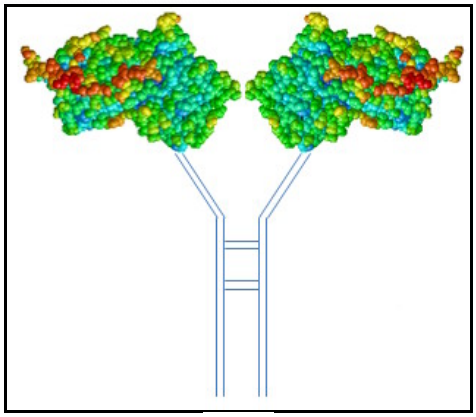


Figure-4B

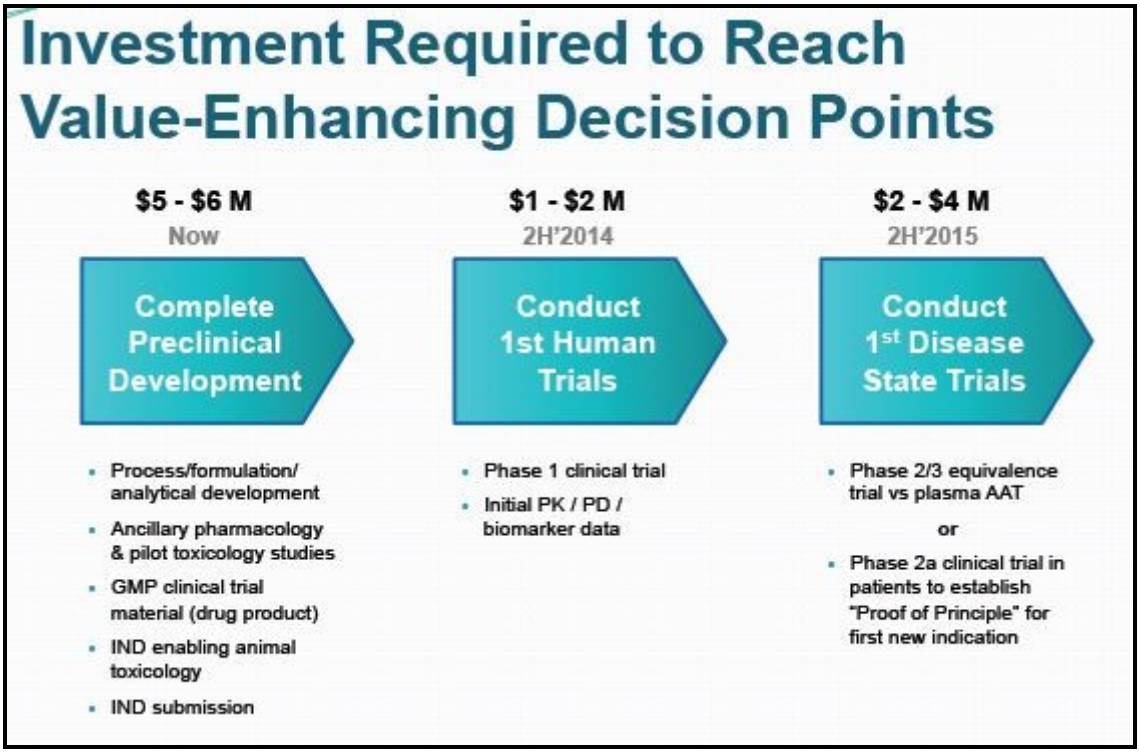
As noted above, funding as always been an issue. Management tells us they are finally nearing securing funding to complete the necessary preclinical development. Delays in funding probably stem from questions about the intellectual property of the new molecule. However, the company has been active lately filing and receiving new use patents. And the company tells us a new composition of matter patent should be issued shortly. We believe this may be the final hurdle to securing long-term funding at Omni Bio. Below we present a slide from management's investor presentation highlighting the plans to move forward once funds are secured. This is definitely a name investors should put on their radar. A recombinant AAT molecule is a potential blockbuster in our view. Omni Bio could easily be a "ten-bagger" given the current market value of only $10 million.

Lead Indications Under Consideration

Disease	Market Size (US/EU)
Type 1 Diabetes (Early Onset)	>$1B
Graft vs Host Disease	~$500M
Gout (Treatment Refractory)	>$1B

Options For Life Cycle Management

Disease	Market Size (US/EU)
Rheumatoid Arthritis	>$1B
Inflammatory Bowel Disease (Crohn's Disease, Ulcerative Colitis)	>$1B
Chronic Obstructive Pulmonary Disease	>$1B
Cardiac Remodeling	>$1B


Investment Required to Reach Value-Enhancing Decision Points
$5 - $6 M
Now
Complete Preclinical Development
Process/formulation/ analytical development
Ancillary pharmacology & pilot toxicology studies
GMP clinical trial material (drug product)
IND enabling animal toxicology
IND submission
$1 - $2 M
2H'2014
Conduct 1st Human Trials
Phase 1 clinical trial
Initial PK / PD / biomarker data
$2 - $4 M
2H'2015
Conduct 1st Disease State Trials
Phase 2/3 equivalence trial vs plasma AAT
or
Phase 2a clinical trial in patients to establish "Proof of Principle" for first new indication

PROJECTED FINANCIALS

Omni Bio Pharmaceuticals, Inc.
Income Statement

	FY'12 A	FY'13A	June-13A	Sept-13A	Dec-13E	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	$0.200	$0.250	$0.577	$0.750	$1.000
% R&D	-	-	-	-	-	-	-	-	-
SG&A	$4.237	$5.423	$0.503	$0.540	$1.400	$1.450	$3.893	$6.000	$6.500
% SG&A	-	-	-	-	-	-	-	-	-
Operating Income	**($4.635)**	**($5.720)**	**($0.531)**	**($0.638)**	**($1.600)**	**($1.700)**	**($4.469)**	**($6.750)**	**($7.500)**
Operating Margin	-	-	-	-	-	-	-	-	-
Interest & Other Income	($0.760)	($1.734)	($0.150)	($0.002)	($0.352)	($0.100)	($0.604)	($0.250)	($0.250)
Pre-Tax Income	($5.395)	($7.454)	($0.681)	($0.640)	($1.952)	($1.800)	($5.074)	($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)	($1.952)	($1.800)	($5.074)	($7.000)	($7.750)
Net Margin	-	-					-	-	-
Reported EPS	**($0.17)**	**($0.23)**	**($0.02)**	**($0.02)**	**($0.05)**	**($0.04)**	**($0.13)**	**($0.15)**	**($0.15)**
YOY Growth	-	-	-	-	-	-	-	-	-
Basic Shares Outstanding	31.4	32.0	34.1	38.2	42.0	46.0	40.1	48.0	52.0

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

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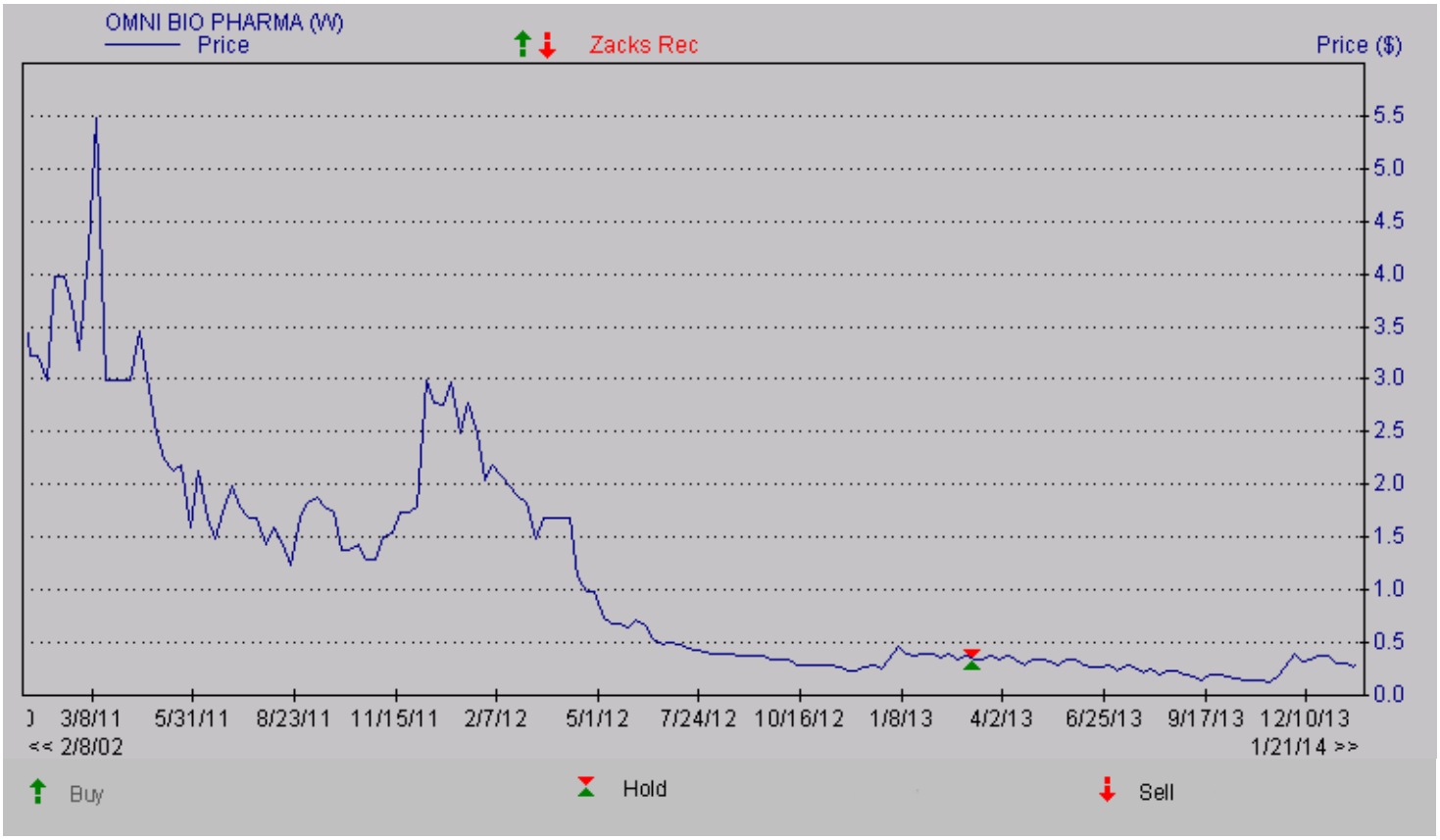

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