Zacks Small-Cap Research

March 8, 2016
Nisha Hirani, MD
312-265-9442 / nhirani@zacks.com
David Bautz, PhD
312-265-9471 / dbautz@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Suite 1600, Chicago, IL 60606

AntriaBio, Inc. (ANTB-OTC)

ANTB: Continues to Raise Capital and Announces Strategic Collaboration & License Agreement; Upgrading Stock to a "Buy"…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	10/07/2014
Current Price (03/08/16)	$1.11
Target Price	**$2.25**

Update

On March 2, 2016, AntriaBio, Inc. (ANTB) filed a Form 8-K announcing a strategic collaboration and license agreement with a specialty Korean healthcare firm, pH Pharma Co., Ltd for the manufacture and/or sale of AB101 in certain Asian territories. This license will only become effective when pH Pharma has purchased approximately $8 million of AntriaBio's securities, of which $1 million is closed and another $1 million is anticipated to close by the end of March 2016. Including the initial pH Pharma transaction, AntriaBio has closed on a total of $5.3 million of Preferred Stock since December 2015.

We continue to believe that AB101 has potential as a basal insulin therapy given its once-weekly dosing schedule. With ultra long-acting insulin, AntriaBio is targeting an $11 billion global market. Additionally, preclinical studies for AB301, a weekly injectable combination of a PEGylated human glucagon-like peptide-1 (GLP-1) agonist and AB101, AntriaBio's lead basal insulin product candidate for the treatment of type 2 diabetes, are ongoing.

We believe AntriaBio remains focused on getting the FDA what it has requested as it pertains to the stability data for AB101's drug substance (peginsulin), and remains on track for the IND filing to occur in the first half of 2016. We also believe AntriaBio remains focused on raising additional cash in order to support the upcoming Phase 1 clinical trial for AB101. At the current price, we view AntriaBio shares as undervalued, and as providing long-term upside potential. We are maintaining our price target of $2.25 per share, and upgrading the stock to a 'Buy'.

SUMMARY DATA

52-Week High	**$2.25**
52-Week Low	**$0.90**
One-Year Return (%)	**-37.99**
Beta	**-0.67**
Average Daily Volume (sh)	**20,513**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$27**
Short Interest Ratio (days)	**0.23**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**35**
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 2015 Estimate	**N/A**
P/E using 2016 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue

(In millions of $)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2014	0 A	0 A	0 A	0 A	0 A
2015	0 A	0 A	0 A	0 A	0 A
2016	0 A	0 A	0 E	0 E	0 E
2017					0 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Sep)	Q2 (Dec)	Q3 (Mar)	Q4 (Jun)	Year (Jun)
2014	-$0.12 A	-$0.27 A	-$0.76 A	-$0.11 A	-$1.04 A
2015	-$0.12 A	-$0.16 A	-$0.14 A	-$0.13 A	-$0.54 A
2016	-$0.14 A	-$0.17 A	-$0.18 E	-$0.15 E	-$0.63 E
2017					-$0.65 E

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WHAT'S NEW

Financial Update

On February 16, 2016, AntriaBio, Inc. (OTCQB:ANTB) filed its Form 10-Q reporting financial results for the second quarter of fiscal year 2016 ended December 31, 2015. As expected, the company did not generate any revenues for the 2016 quarter. Net loss for the quarter was $4.1 million, or $0.17 per share.

Research and development costs were approximately $2.5 million in the 2016 quarter compared to $1.6 million in the same quarter in 2015, and the increase is due to the company having significant research and development activities during the 2016 period as compared to the 2015 period. The company also hired significant staff as well as begun preparing to manufacture clinical material in the 2016 period as compared to the 2015 period in which the company was still getting the facilities established.

General and administrative costs were approximately $1.5 million in the 2016 quarter and comparable to G&A expenses in the 2015 quarter. G&A costs were approximately $2.9 million for the six months ended December 31, 2015 as compared to $3.6 million for the six months ended December 31, 2014. The decrease is due to reduced consulting fees and investor relations fees for the 2016 quarter as the company has hired staff and brought significant portions of those roles in house. R&D expenses were slightly above expectations while G&A was slightly below expectations.

As of December 31, 2015, the company held $1.7 million in cash and cash equivalents. AntriaBio burned $2.5 million in cash from operations and investments for the three-month period ended December 31, 2015. Burn for the previous quarter ended September 30, 2015 was approximately $2.9 million, and $4.2 million for the quarter ended June 30, 2015. Although the burn rate has been decreasing over the last few quarters, we continue to believe the burn rate will rise over the next few quarters as the company prepares for IND filing for AB101, the clinical trial programs for AB101 and newly announced pipeline candidate AB301, and manufacturing materials at the newly completed cGMP facility.

On December 10, 2015, AntriaBio announced that it closed the first $2 million of a planned $15 million private placement transaction. AntriaBio will use the proceeds from the transaction for general corporate purposes, including Phase 1 clinical studies for AB101, a once-weekly basal insulin for patients with type 1 and type 2 diabetes. AntriaBio issued 1,025,699 shares of Series A Convertible Preferred Stock and received net proceeds of approximately $1.8 million after the placement agent compensation and issuance costs paid of $105,715 and a warrant with a fair value of $90,852 recorded as issuance costs. The issuance costs are being accreted over the ten-year life of the Series A Stock. Under the terms of the transaction, AntriaBio is issuing up to 7,692,308 shares of Series A Preferred Stock to institutions and accredited investors at $1.95 per share. The initial close of the transaction included the participation of members of the company's management team and Board of Directors, as well as other accredited investors. On March 2, 2016, AntriaBio completed an additional close of the offering with six accredited investors, including pH Pharma Co., Ltd. (see below). As per the agreement, AntriaBio issued the investors an aggregate of 1,716,667 shares at the Series A Purchase Price. AntriaBio received gross proceeds of approximately $3.3 million, excluding Placement Agent compensation, transaction costs, fees and expenses. The company has received net proceeds of approximately $5 million from the two closings of the planned $15 million private placement transaction.

On March 3, 2016, AntriaBio filed a Form 8-K stating that on February 29, 2016, the company entered into a strategic collaboration and license agreement with a new specialty Korean healthcare firm, pH Pharma Co., Ltd. As per the agreement, AntriaBio conditionally granted pH Pharma an exclusive, transferable, license under AB101 patents, patent applications and all other relevant AntriaBio intellectual property to manufacture and or offer for the sale of lead product candidate, AB101, in Korea, Cambodia, Laos, Myanmar, Thailand, Malaysia, Singapore and Vietnam. This license will only become effective when pH Pharma has purchased a minimum of $8 million of AntriaBio's securities in the following manner: pH Pharma agreed to purchase $1 million of AntriaBio's Series A Preferred Stock under the same terms and conditions as all other purchasers of such securities. Additionally, pH Pharma must purchase an additional $1 million of Series A Preferred Stock on the same terms and conditions prior to March 31, 2016, and at least $6 million of AntriaBio's Common Stock in one or more private placement transactions at prices to be negotiated by the parties based upon commercially reasonable terms. In addition, under the terms of the agreement, AntriaBio and pH Pharma have agreed to work together to explore synergistic opportunities to utilize the company's proprietary microsphere platform for various therapeutic opportunities. We

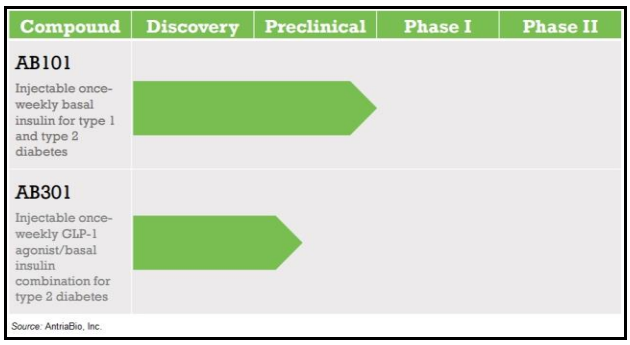
look forward to hearing more about the partnership between AntriaBio and pH Pharma. We think this is an interesting opportunity for AntriaBio to raise approximately $8 million of capital without creating significant dilution or giving up upside in its core potential markets. However, we would like to point out that there are various conditions that must be met in order to obtain the $8 million cash.

In the past, we have emphasized that AntriaBio needed to focus on raising more cash, and so we are happy to see the company make progress on its fundraising goals. We believe that AntriaBio should have approximately $3.4 million in cash by the end of March 2016 after accounting for the new transactions, net of transaction fees and assuming a monthly cash burn of approximately $800,000. AntriaBio will continue to need to raise more cash as it will likely burn through most of its cash balance midway through the fiscal fourth quarter of 2016. We believe that in order to accomplish the primary objective of conducting its first clinical study for AB101, which is now anticipated to begin during the second half of 2016 as per the recently adjusted timeline, the company will require additional funding. We expect this study to cost approximately $4-5 million, and believe AntriaBio will require an additional $10-15 million in capital to get them through the end of calendar year 2016. Raising capital, in our opinion, is critical in order to carry on with AB101 and AB301. If AntriaBio is able to close on the remainder of the pH Pharma deal, it will raise another $7 million and will be well on its way.

Business Update

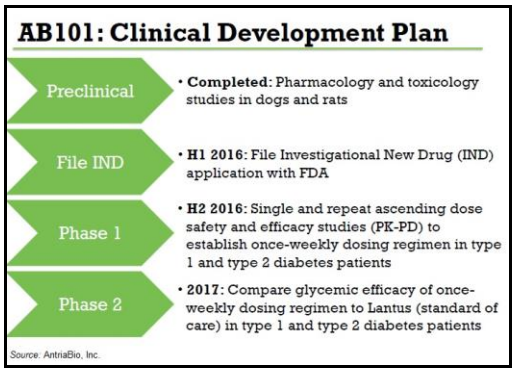
We recently spoke to AntriaBio management, and things appear to be moving forward with all programs. As a reminder, management adjusted the timeline for the AB101 U.S. IND filing and clinical trial initiation due to the FDA requiring an additional 5 months of stability data. If all goes well, we now expect that AntriaBio will file the U.S. IND by the first half of 2016, and that the Phase 1 clinical trial should commence during the second half of 2016.

AntriaBio also recently added a once-weekly injectable GLP-1 agonist/basal insulin product for type 2 diabetes to its pipeline (AB301), and we will provide a review of the candidate below. We will also provide a quick review of the AntriaBio story and conclude with some thoughts on valuation, and long-term potential for investors.



Clinical Development Plan for AB101

AntriaBio has completed all preclinical pharmacology and toxicology studies in dogs and rats with AB101, as well as the build-out of the manufacturing facility in Louisville, CO and plans to produce AB101 material in accordance with current good manufacturing practices (cGMP). The facility is now producing fresh cGMP clinical material in preparation for the upcoming Phase 1 trial set to start during the second half of 2016.



AntriaBio has a near-term AB101 clinical development plan in place, and it consists of:

Step 1. File U.S. IND

Management has adjusted the timeline for filing the IND application to the first half of 2016. We were hoping to see the IND filed prior to the end of the fourth quarter of calendar year 2015, but learned that AntriaBio was in contact with the FDA through a pre-IND meeting request in order to gain guidance regarding its preclinical and clinical trials for AB101, and that the timeline has been slightly adjusted. Management initially believed that the FDA would require one month of stability data for AB101's drug substance (peginsulin) for the filing of the IND, however the FDA came back stating that it would like at least six months of stability data. Management is working with the appropriate regulatory consultants, and does not believe that there will be any issues providing or regarding the stability data. This additional data requirement will result in a delay in the IND filing and initiation of the Phase 1 trial and subsequent trials. We hope that AntriaBio will be able to file the IND by the end of the first half of 2016 with no other hurdles so that clinical work can commence shortly thereafter. We believe that AntriaBio remains focused on getting the IND filed in a timely fashion once the stability data is collected.

AntriaBio believes that AB101 will likely qualify as a new molecular entity (NME) for listing in the U.S. FDA's Orange Book. However, because the company plans to reference significant historical information on insulin, PEGylation, dissolution, and emulsification, management believes the regulatory hurdle may be more favorable, including the low likelihood the company would have to conduct a dedicated cardiovascular (CV) outcomes study to gain approval or marketing rights. With the FDA requesting more stability data before filing the IND application for AB101, we are not sure if there will be more hurdles down the road. We will have to wait and see.

AntriaBio believes the AB101 intellectual property will be protected by existing patents around the PEG attachment to insulin and the mixture of the PEG-insulin with PLGA that do not expire until 2024. New patents have been filed around the manufacturing process that would likely protect AB101 until 2034-2035 based on priority date. On November 17, 2015, AntriaBio received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for U.S. Patent Application No. 14/324,734 titled, "Solvent Extraction From Biodegradable Microparticles." The application covers the methods around solvent extraction and rinse in the manufacturing process for product candidates AB101 and AB301, as well as other internal and external potential pipeline therapies that use AntriaBio's proprietary microsphere drug delivery platform. This Notice of Allowance indicates that the review of the patient application is complete, and that issuance of the patent is pending.

Step 2. Initiate Phase 1 Clinical Study in the U.S.

The objectives of the first clinical study will be to assess the single dose of AB101 in type 1 and type 2 diabetes patients currently using Sanofi's Lantus (insulin glargine). The Phase 1 study will be a single-center, randomized, open label, single ascending dose trial. This will be an in-hospital stay where roughly 40-50 patients will come in stable on Lantus and transitioned to receive one dose of AB101 and then monitored continuously for the next week. The euglycemic clamp technique will be performed on dosing day and at selected time points throughout the anticipated duration of action and is a way to quantify insulin sensitivity. The goal of the study is to demonstrate absence of peak and sustained duration of insulin levels. We believe results will be pretty cut-and-dry with respect to the utility of AB101. If a patient can effectively transition from daily Lantus to once-weekly AB101 with no issues over the following week in terms of glucose control and safety/tolerability, AntriaBio has a blockbuster on its hands. If there are significant issues in terms of patients experiencing hypo- or hyperglycemia or severe adverse events, then AntriaBio needs to go back to the drawing board with respect to the formulation of AB101.

With the FDA now requiring six months of stability data prior to the IND filing, this will result in a delay of the initiation of the AB101 clinical program. According to the new timeline, management now believes that the study should begin at some point during the second half of 2016. We will have a better sense of the exact timing of this first study once the IND has been filed. With the adjusted timeline, we now believe data from the first clinical study can be generated by the end of 2016. We believe this study will cost an estimated $4-5 million all-in for AntriaBio.

Step 3. Move into Phase 2 Clinical Studies in the U.S.

Following successful completion of the Phase 1 clinical studies noted above, Phase 2 trials should begin in both type 1 and type 2 diabetics. These will primarily be longer-duration safety and tolerability studies, with accepted biomarkers for glucose efficacy (i.e. HbA1c) comparing AB101 to a standard of care basal insulin such as Sanofi's Lantus. If the proof-of-concept trials are successful, we expect the company to expand the clinical program to include Phase 3 registration trials in various regions around the world, including the U.S. and Europe.

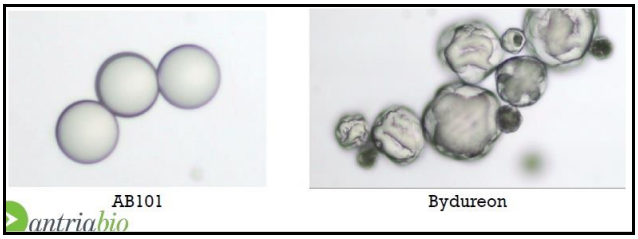
Ultimately, if all goes well and the data are positive, we expect AntriaBio to look to partner AB101 with a larger pharmaceutical company with a heavy presence in the diabetes market, such as Novo Nordisk, Sanofi, and Eli Lilly. Other major players include Merck, Bristol-Myers, Roche, Novartis, Boehringer Ingelheim, and AstraZeneca. However, to get to the point where partnering AB101 is feasible, we believe the company will need to complete through Phase 2 clinical testing in the U.S. The goal is to show endpoints of glycemic control and safety comparable to a product like Lantus. Management believes there may also be an earlier opportunity to evaluate whether a partnership would make sense after the data readout from the Phase 1 clinical trial (in advance of completion of Phase 2 testing).

A Review of New Product Candidate AB301

On September 16, 2015, AntriaBio announced the addition of a new product candidate to its pipeline. AB301 is a weekly injectable combination of a PEGylated human glucagon-like peptide-1 (GLP-1) agonist and AB101, AntriaBio's basal insulin lead product candidate for the potential treatment for patients with type 2 diabetes. As per management, *in vitro* and *in vivo* studies that have been completed to date show that AB301 has the potential to be a well-tolerated, effective therapy for type 2 diabetes. Currently, AntriaBio is working on additional ongoing preclinical studies of AB301, and believes that a combination therapy has the potential to complement glycemic control while attenuating weight gain and hypoglycemic risk. Although it is still early on in the process, we will have a better sense of the potential when preclinical data and additional details become available.

GLP-1 agonists are now well-established treatment options for type 2 diabetes, and so we view this as good news for AntriaBio. There are numerous marketed daily and weekly GLP-1 agonists, and so AB301 hopes to differentiate itself by offering a combination therapy with extended duration of action. GLP-1 agonists work by stimulating the pancreas to produce and secrete insulin in response to eating meals. The benefit of this type of state-dependent stimulation is that once the blood sugar levels decrease to normal, the pancreatic response to produce insulin is reduced, unlike exogenously delivered insulin which can be over-dosed and creates the risk of hypoglycemia. GLP-1 agonists also work by suppressing the pancreatic release of glucagon in response to eating, which helps stop the liver from over-producing unneeded sugar. This helps to reduce the risk of hyperglycemia.

As a reminder, Amylin/Astrazeneca's Bydureon (exenatide), a currently marketed GLP-1 agonist for type 2 diabetes, is also formulated using PLGA microspheres (*below*). We have discussed Bydureon in previous updates, but as a quick recap, it is a long-acting form of the medication Byetta. Bydureon had worldwide sales of $440 million in 2014, and is projected to have over $1 billion in peak sales.



We would also like to point out that there are currently some big players in the GLP-1 agonist/basal insulin combination therapy space but they are targeting once-daily dosing, as opposed to AntriaBio's AB301 which is proposed to be a weekly injectable. Novo Nordisk's Xultophy (IDegLira) is a fixed-dose once-daily combination of Tresiba (insulin degludec) and Victoza (liraglutide), and recently completed Phase 3 development in the U.S. and was approved in all 28 EU member states and Switzerland in September 2014. Novo Nordisk submitted the NDA for Xultophy to the FDA in September 2015. As way of background, Tresiba, the basil insulin component of Xultophy, was not approved by the FDA in 2013 due to concerns related to cardiovascular risk. Xultophy could not be submitted to the FDA until Tresiba received FDA approval, which finally occurred on September 25, 2015. We are not exactly sure when Xultophy will be approved in the U.S., but want to reiterate that it is a once-daily combination therapy.

Sanofi's LixiLan (new molecular entity) is a fixed-ratio once-daily combination of Lantus (insulin glargine) and Lyxumia (lixisenatide). Sanofi reported positive Phase 3 top-line results with LixiLan meeting the primary endpoint of showing superior reduction in HbA1c vs. insulin glargine. The New Drug Application for Lixilan was submitted on December 23, 2015 with a priority review voucher (PRV) for an expedited 6-month review. The NDA was subsequently accepted on February 22, 2016 under priority review, and an FDA decision is expected in August

2016. LixiLan is currently in Phase 3 development in the EU, and we believe regulatory submissions are planned for the first quarter 2016 in the EU. Once again, LixiLan is proposed to be a once-daily dosing for type 2 diabetes.

We think it is worth highlighting the November 2015 worldwide license agreement between Sanofi and Hanmi Pharmaceutical Co., Ltd. According to the agreement, the two parties will work together to advance a portfolio of long-acting diabetes treatment candidates with Hanmi receiving an upfront payment of €400 million (approximately $440 million USD), potential milestone payments of up to €3.5 billion ($3.9 billion USD), and double digit royalties on net sales, while Sanofi will obtain an exclusive worldwide license to develop and commercialize efpeglenatide (a long-acting glucagon-like peptide-1 receptor agonists (GLP1-RA)), a weekly insulin, and a weekly GLP-1-RA/insulin drug combination. The development of the above mentioned three therapeutic candidates will use Hanmi's proprietary LAPSCOVERY Long Acting Protein/Peptide Discovery Platform technology which intends to extend the period of action of biologics, and thus reduces frequency and dosage of the treatment. We believe that Hanmi's platform that was licensed is quite similar to AntriaBio's platform with having a weekly insulin, insuling/GLP-1 combo, and weekly/monthly GLP-1 product candidates, and such a deal should highlight the importance and value of long-acting therapies targeting diabetes. In our opinion, this deal further validates AntriaBio's pipeline and platform. We believe the Hanmi-Sanofi deal shows the potential value that AntriaBio can generate in the near term as the company prepares to initiate its first human clinical of AB101 later this year.

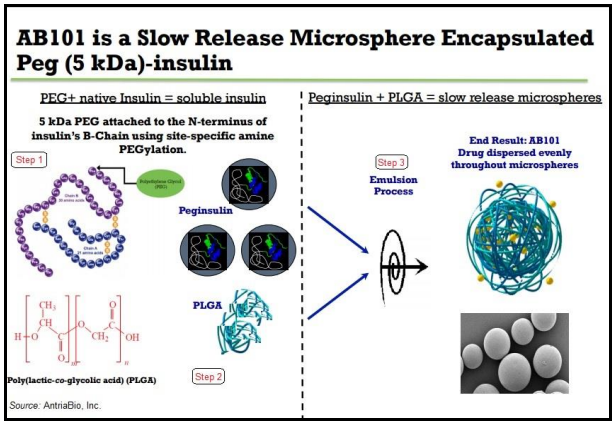
We believe that pursuing this combination therapy is the next logical step for AntriaBio, given the success with GLP-1 agonists, and some larger names moving forward with GLP-1 agonists/basil insulin combination therapies. We think the combination of a GLP-1 agonist with basal insulin on a weekly dosing regimen makes a lot of sense as we continue to believe that there is a need for effective sustained release drug delivery systems that would minimize dosing frequency, improve patient compliance and therapeutic effectiveness, as well as potentially reduce costs. Although it is still early on in the process, we are looking forward to reviewing the preclinical AB301 data once it is available.

Quick Review of AB101

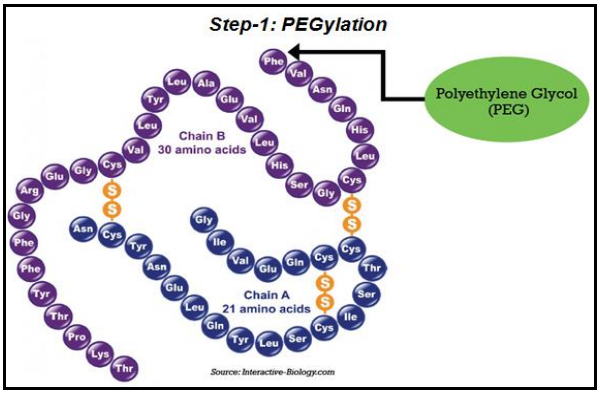
AntriaBio is developing AB101, a product that aims to be the first once-weekly basal insulin. AB101 is a formulation of human recombinant insulin (non-analog) for subcutaneous injection that is designed to release insulin slowly and uniformly over a period of approximately one week without an adverse initial burst. AB101 is a proprietary formulation developed by the company to preserve the integrity and biological activity of insulin through the manufacturing process. Despite the once-weekly dosing regimen, the dose of AB101 can be administered in an acceptable volume through a relatively small (narrow gauge) needle. AB101 was engineered to provide desired release kinetics using a common biodegradable material called PLGA or poly(lactic-co-glycolic acid). PLGA biodegrades through a very predictable and consistent hydrolysis, eliminating an initial undesirable burst of insulin release. With these characteristics, AB101 should provide high quality basal insulin for the majority of insulin-dependent diabetics without significant injection site reaction or burst of serum insulin levels.

- ***How Is AB101 Made?***

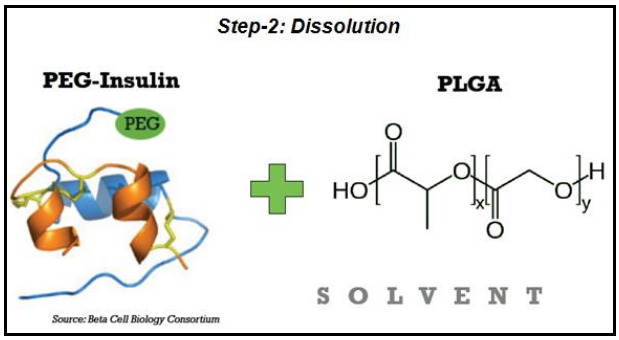
AntriaBio is not the first company to attempt to develop a once-weekly basal insulin injection. Many have failed in formulation work prior to AntriaBio's AB101. There are essentially two strategies to develop a weekly basal insulin injection, either formulate with polyethylene glycol (PEG) or encapsulate in PLGA or polyglutamate (pGlu) microspheres.



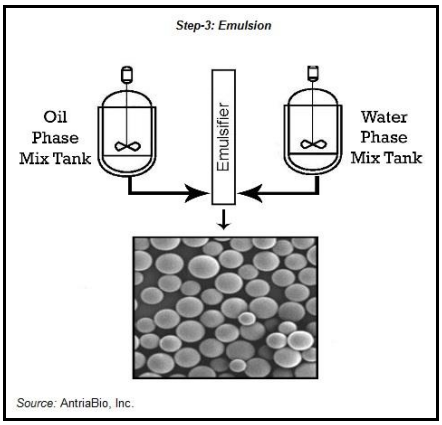
Step-1: PEGylation: Formulation with PEG has been a well-documented strategy for improving half-life and extending duration of action. PEGylation is known to enhance protein stability and solubility, reducing dosing frequency, and enhancing plasma circulation. Numerous pharmaceutical products have been attached to PEG, including granulocyte colony-stimulating factor (Amgen's Neulasta), certolizumab (UCB's Cimzia), anti-VEGF aptamer (Pfizer's Macugen), alpha-interferon (Merck's PEGintron, Roche's Pegasys), adenosine deaminase (Enzon's Adagen), and uricase (Savient's Pegloticase), to name a few.



Step-2: Dissolution: Dissolving PEG-insulin with a polymer such as PLGA is a strategy designed to facilitate delivery of dose and allow extended release of the PEG-insulin into the body by hydrolysis. Dissolution of PLGA allows a slow release of the PEG-insulin at a controlled rate designed by AntriaBio scientists based on the monomers used in the formulation.



Step-3: Emulsion: After the PEG-Insulin and PLGA are dissolved in a solvent, the mixture is put through an emulsification process to create uniform, monolithic microspheres. An oil-in-water emulsion is generated by passing both the oil and water phases through a packed glass bead bed emulsifier. After the solution is delivered, the microspheres are degraded by hydrolysis at a uniform and controlled rate, releasing the PEG-insulin into circulation.



AB101 Preclinical Studies

As a reminder, AntriaBio announced preclinical results for its once-weekly basal insulin candidate, AB101, in a presentation titled "*The in Vitro and in Vivo Pharmacology of AB101, a Potential Once-Weekly Basal Subcutaneous Insulin*" at the American Diabetes Association 75th Scientific Sessions® in June 2015. The data support our belief that AB101 will be the first once-weekly basal insulin product. We discussed the data in depth in previous updates. The results from the preclinical proof of concept pharmacology studies showed that AB101 has comparable *in vitro* pharmacology to native insulin, and in two animal species (rats and dogs) displayed an extended subcutaneous insulin absorption profile, leading to slow onset, peakless and sustained insulin levels with corresponding reductions in glucose levels, without acute hypoglycemia caused by an initial insulin burst. As per management, these observations occurred at clinically relevant dose projections, demonstrating proof of concept of the potential for AB101 as a weekly subcutaneous basal insulin therapy in patients with diabetes mellitus. We view these results as encouraging, with no initial undesirable effects of insulin bursts or hypoglycemia seen in the animal models. We believe the preclinical data supports moving forward with clinical program for AB101.

Conclusion

We continue to believe there is a huge need for novel, and safe therapeutics that allow for proper glucose control, less frequent dosing in addition to slow and uniform insulin release without an adverse initial burst in diabetics. We believe that if the clinical data for AB101 resembles the preclinical data and are positive, AntriaBio could have a blockbuster product on its hands. If there are any issues with hypo- or hyperglycemia or severe adverse events, then AntriaBio will need to look at reformulation of AB101.

Diabetes remains a major public health challenge. According to the American Diabetes Association, 29.1 million Americans, or 9.3% of the population, had diabetes in 2012. In 2012, 86 million Americans over the age of 20 had pre-diabetes, which is up from 79 million in 2010. The International Diabetes Federation estimates that there are 387 million individuals worldwide with diabetes, and this number is projected to grow to over 470 million by 2035.

With the news of the FDA requiring six months of stability data, we view the delay in filing the IND for AB101 to be unfortunate, however we do believe that AntriaBio remains focused and on track to get this done by the end of the first half of 2016. We are not sure if the FDA will have any other regulatory requirements down the road, but if there are any, there may be additional delays to the timeline. We believe that path forward for AB101 may not be as straightforward as AntriaBio had hoped, and there may be several other hiccups along the way that could further derail the timeframe. That being said, we continue to view AB101 as a promising new insulin option for individuals with diabetes, and are looking forward to the near-term IND filing for AB101.

As of December 31, 2015, the company held $1.7 million in cash and investments, and burned $2.4 million in cash from operations and investments for the three-month period ending December 31, 2015. In order to complete the clinical work to generate data sufficient to secure a global development and commercialization partnership on AB101, AntriaBio will require significant cash. We believe that AntriaBio will need to raise an additional $10-15 million to get through calendar year 2016. We are unsure if AntriaBio will be able to do it in a timely fashion in order to adhere to the newly adjusted timeline, however, if it is able to complete the full $8 million close with pH Pharma, that will make a significant dent in fundraising goals. AntriaBio's current basic market capitalization is approximately $27 million. We should have a better sense of the path forward once the IND is filed and the clinical program for AB101 has commenced. Other upcoming milestones that the company is focused on achieving include preparing for the initiation of AB101 Phase 1 first-in-human clinical study, and the continuation of preclinical studies for new product candidate AB301.

Upon reviewing the preclinical proof of concept pharmacology data from June 2015, we continue to remain optimistic regarding the AB101 story. In our opinion, it was very reassuring to see that no acute undesirable insulin bursts or glucose reductions were observed. Furthermore, we believe that the slow onset, sustained insulin increases with corresponding glucose reductions over the course of about one week in both the dog and rat species support a once-weekly dosing of basal insulin for patients with diabetes. Obviously, it is still early on in the process, but we view these results as encouraging. We are hopeful that the efficacious doses used in the animal models will be readily translated to human clinically relevant doses and dose volumes. Management believes that the inter-species homology of insulin/receptor predicts insulin activity in humans, and we are hoping, that in the future, results from human trials show this predictable pattern. At this point, we continue to view AB101 as a promising new insulin therapy option for individuals with diabetes as well as clinicians. The preclinical data shows that the once-weekly injection offers a reproducible, slow and sustained release of insulin and reduction in glucose over the

intended weekly dosing period, which if translated to patients with diabetes should provide uniform glycemic control with the convenience and compliance of a once-weekly injection and a lower risk of hyperglycemia.

We also believe that AntriaBio's new pipeline candidate, AB301, could have potential if all goes well with AB101 and if the data are positive. It is still early for us, but as mentioned above, we believe that the combination of a GLP-1 agonist with basal insulin on a weekly dosing regimen makes a lot of sense as there is a need for effective sustained release drug delivery systems that would minimize dosing frequency, improve patient compliance and therapeutic effectiveness. AntriaBio's product is proposed to be a once weekly candidate, while other big pharmaceutical companies are developing daily candidates.

We believe AB101 has peak sales in the area of $3.5 billion by 2028 if the clinical data are positive. We believe there are a number of value-creating inflection points on the horizon over the next several years, culminating with the signing of a major development and commercialization partnership for AB101 after the Phase 1/2 data has been generated. As noted above, we expect the results of the Phase 1 proof-of-concept study to be pretty straightforward and hope to see the data by the end of 2016. We will be able to see the insulin profile, and either AB101 works or it does not. If it works, we believe that AB101 could see a ten-fold increase in valuation as big pharmaceutical companies like Sanofi, Novo Nordisk and Eli Lilly, now become interested in acquiring the company.

Based on historical "big pharma / small-biotech" take-outs, we believe a deal will get done prior to the initiation of the pivotal registration program if the Phase 1/2 data are positive. We believe a company like Sanofi or Eli Lilly would be quite comfortable paying a premium to acquire AB101 if their internal numbers agree with our modeling that peak sales are in the $3.5 billion range by 2028. Additionally, large deals, like the one we highlight above between Hanmi and Sanofi should emphasize the importance,value, and need of long-acting therapeutics targeting diabetes. In our opinion, the Hanmi-Sanofi deal further validates AntriaBio's pipeline and platform, and shows the potential value that AntriaBio can generate with AB101 and AB301.

We have built a financial model forecasting the risk-adjusted potential cash flow from selling AB101 on a global basis. Our assumptions include filing the U.S. NDA in 2020 and launching the product in 2021. We model peak sales of $3.5 billion in 2028 with 70% net operating margin at peak. We assuming exclusivity at 100% until 2024 and then risk-adjust the cash flow from 2025 to 2035 down by 50% until the new patents around the manufacturing process have been granted. At this stage, we are still assuming 10% probability of success. Positive AB101 Phase 1/2 data would provide meaningful upside to the AntriaBio story and would cause us to raise our probability of success from 10% to 30%, bringing the valuation to roughly $7 per share. We have not yet factored in AB301 to our model, as it is still early. We believe the shares are worth approximately $2.25 right now, and are upgrading the stock to a "Buy" rating.

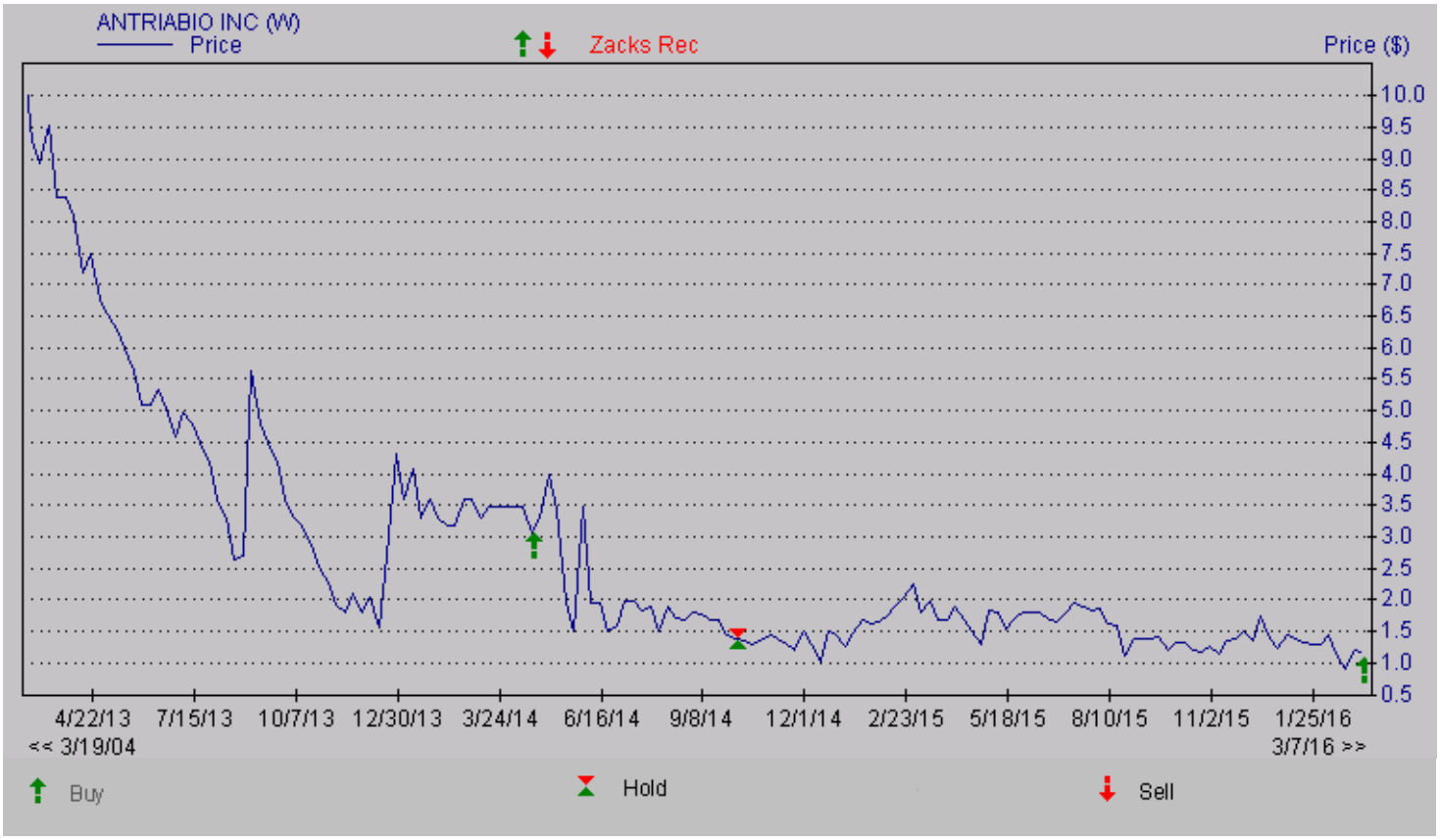
PROJECTED FINANCIALS

AntriaBio, Inc. - Income Statement

AntriaBio, Inc.	Jun. 2015 FY-15 A	Sept. 2015 Q1 A	Dec. 2015 Q2 A	Mar. 2016 Q3 E	Jun. 2016 Q4 E	Jun. 2016 FY-16 E	Jun. 2017 FY-17 E
AB101 Sales / Royalties	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
AB301 Sales / Royalties	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Licensing / Collaborative	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-
CoGS	$0	$0	$0	$0	$0	$0.0	$0.0
Product Gross Margin	-	-	-	-	-	-	-
R&D	$4.7	$2.0	$2.5	$2.6	$2.6	$9.7	$14.7
SG&A + Other	$6.0	$1.3	$1.5	$1.8	$1.9	$6.6	$8.0
Operating Income	**($10.7)**	**($3.3)**	**($4.1)**	**($4.4)**	**($4.5)**	**($16.3)**	**($22.7)**
Operating Margin	-	-	-	-	-	-	-
Interest & Other Income	($0.7)	$0.0	$0.0	$0.0	$0	$0.0	$0.0
Pre-Tax Income	($11.4)	($3.3)	($4.1)	($4.4)	($4.5)	($16.3)	($22.7)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($11.4)	($3.3)	($4.1)	($4.4)	($4.5)	($16.3)	($22.7)
Net Margin	-	-	-	-	-	-	-
Reported EPS	**($0.54)**	**($0.14)**	**($0.17)**	**($0.18)**	**($0.15)**	**($0.63)**	**($0.65)**
YOY Growth	-	-	-	-	-	-	-
Basic Shares Outstanding	21.0	24.3	24.3	24.3	30.0	25.8	35.0

Source: Company Filing // Zacks Investment Research, Inc. Estimates

HISTORICAL ZACKS RECOMMENDATIONS



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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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