



## *To our Stockholders, Employees & Friends:*

Today we issued the attached press release regarding the expansion of our operations into South Korea through the formation of a subsidiary, as well as our plan to raise capital primarily from Korean institutional investors before the end of the year. The purpose of this letter is to provide you with more information regarding the rationale for our geographical expansion as well as to update you on the overall status of our business, including our go-forward plans and corporate strategy.

First, we would like to thank all of our investors for their financial support. We are very fortunate to have a wonderful stockholder base that includes boutique health care funds, physicians, pharmaceutical executives, industry luminaries as well as successful entrepreneurs and family offices. To date, we have raised approximately \$40 million, which has enabled us to hire a talented team and advance our microsphere platform. In particular, we have completed and presented compelling preclinical results for our lead product candidate, AB101, a potential once-weekly injectable basal insulin for patients with type 1 and type 2 diabetes. We continue to believe AB101's unique human insulin based formulation has the potential to disrupt the \$11 billion annual basal insulin market that is dominated by daily injections of insulin analogs.

Over the last 24 months, we have made tremendous progress, which is a testament to the dedication and experience of our team. Our primary objective remains advancing AB101 into clinical studies at a contract research organization in Southern California. In order to realize this goal, we need to raise additional capital to fund the cost of the first clinical study as well as ongoing operations, and manufacture sterile AB101 material suitable for human injection.

### **Capital Requirements**

As we reflect upon the last few years, the continual process of incrementally raising capital as a microcap company in the United States has been challenging. Given our ongoing financial needs as well as our desired strategy to scale the business while advancing AB101, we have reached a point in our evolution where we believe we need to raise capital in a different manner by conducting a relatively large institutionally focused round before the end of the year.

Fortunately, we have received a great deal of interest from the Korean investment community including large, sophisticated healthcare funds. Similar to the advancements we have witnessed in industrial manufacturing, electronics and transportation, Korea has made healthcare – including pharmaceutical investment and development – a top priority.

Concurrent with our planned capital raise in Q4 of this calendar year, we will establish a subsidiary in Seoul that will be led by our Founder and Chairman of the Scientific Advisory Board, Dr. Hoyoung Huh. As a bilingual Korean American with an M.D./Ph.D., Dr. Huh will be instrumental in our efforts to expand our operations and raise capital in the region. Furthermore, Dr. Huh and I share the vision of the strategic value of exploiting our microsphere platform while opportunistically in-licensing or acquiring other technologies that will allow us to further address diabetes and other major diseases that plague the world.

## **AB101 Update**

In accordance with the initial feedback we received from the FDA in 2015, as a precursor to filing an IND and starting a clinical study, we conducted a six-month stability study of the drug substance (PEGylated insulin) used in AB101, which was satisfactorily completed this past June. The American Diabetes Association's 76<sup>th</sup> Scientific Sessions also took place in June in New Orleans where Dr. Brian Roberts, our Vice President of Clinical Development, presented preclinical data on AB101 in a diabetic miniature swine model. As we had seen previously in our rodent and dog studies, the data demonstrated the slow and steady release of AB101 consistent with weekly dosing.

In addition, in April of this year we met face-to-face with the FDA in a pre-IND (Investigational New Drug) meeting to discuss our Phase 1 clinical study design. Given the complexity of microsphere products, the agency advised us to ensure our manufacturing process is robust before filing our IND and commencing a clinical study.

We have constructed a \$3 million manufacturing suite in our Louisville, Colorado facility to produce AB101 material suitable for injection into patients. Based on the guidance we received from the FDA in April and under the leadership of Mike Deperro, our Vice President of Operations who joined us nine months ago with an extensive background in clinical and commercial microsphere manufacturing experience, we have been methodically qualifying all new equipment used in the manufacturing suite. Over the summer we began testing our process by manufacturing sample batches of AB101 material at clinical scale. Prior to this summer we had only manufactured AB101 in small batches for use in animal studies and for analytical purposes.

As part of the process of testing our manufacturing environment, we discovered we needed to make adjustments to our equipment. This endeavor, coupled with delays that we have experienced in receiving parts and equipment from third party suppliers, have contributed to extending the timeline that we established in 2015 to commence clinical studies.

While we have made significant progress in demonstrating that we can manufacture AB101 at clinical scale, we have yet to demonstrate that our manufacturing process can be conducted in a sterile fashion prior to making AB101 material for the clinical study. Qualifying the sterility of a manufacturing process and environment is generally complex, particularly for microsphere products.

Based on our current timeline and assuming we complete a capital raise prior to the end of this year, we are planning to have our facility fully qualified to enable the manufacture of clinical material in the first quarter of calendar year 2017. Following the financing and manufacturing campaign, we plan to file an IND with the FDA and commence the clinical study in the first half of calendar year 2017.

## **AB301 Update**

In September 2015, we announced the addition of AB301 to our product development pipeline. As a potential treatment for patients with type 2 diabetes, AB301 is a once-weekly injectable combination of a PEGylated human GLP-1 agonist and AB101, our basal insulin lead product candidate. We believe



there is a potential advantage of combining a GLP-1 agonist with basal insulin to complement glycemic control while attenuating weight gain and risk of hypoglycemia.

Sanofi's iGlarLixi and Novo Nordisk's IDegLira are daily injectable GLP-1 agonist and basal insulin combination therapies that are currently under regulatory review by the FDA with approval decisions expected to be announced in late November and December, respectively. IDegLira was approved for commercial use in the European Union under the trade name Xultophy in September 2014. Adocia recently announced plans to develop BioChaperone Glargine Dulaglutide and BioChaperone Liraglutide, additional daily injectable GLP-1 agonist and basal insulin combination therapies consisting of insulin glargine (Lantus) and either Eli Lilly's Trulicity (dulaglutide) or Novo Nordisk's Victoza (liraglutide).

As a once-weekly injectable therapy, AB301 would be differentiated from these potential competing combination therapies that require daily injections. In vitro and in vivo studies completed to date indicate AB301 has the potential to be a well-tolerated, effective therapy for type 2 diabetes and we are engaged in ongoing preclinical studies of AB301. However, prior to initiating any IND-enabling studies for AB301, we are keeping a close eye on the FDA's decisions around Sanofi and Novo Nordisk's potential competing combination therapies as well as clinical studies for Adocia's potential competing combination therapies.

### **Other Pipeline Activities**

Our formulation scientists are actively using our microsphere platform to formulate and test additional compounds. We are engaged in preclinical animal studies and hope to add at least one more program to our pipeline in the next six to 12 months.

### **Naked Short Selling**

Our stock price has been under downward pressure for over a year. Following some investigation and with the assistance of outside advisors, including BuyIns.Net, a firm that tracks every short sale from stock exchanges and helps companies fight abusive market making and short selling, we believe we are the target of naked short selling. Naked short selling is when traders sell short shares they do not possess and have not confirmed their ability to possess. This means they are betting the price of the shares will go down and they do not intend to consummate the transaction, but instead intend to settle the transaction in cash.

Naked short selling, a practice that is prohibited by the SEC's Regulation SHO, damages the value of companies by artificially pushing a company's stock price down. In fact, the lower the price, the better. Upon tracking our trading activity, we have determined that approximately 44% of our daily trading volume is short selling and we believe that short sellers have been lax in complying with Regulation SHO. We will continue working with the team at BuyIns.net to address this problem.



## Closing

We believe our prospects as a company have never looked better. We look forward to commencing our first clinical study and are optimistic we will demonstrate human proof of concept for AB101. We are very close to manufacturing sterile AB101 material and filing our IND. Furthermore, our work continues on our product pipeline. We look forward to sharing more details with you as we progress. Finally, while we are thankful for the investments we have received to date, we are eager to complete an investment round in Korea and establish a solid balance sheet that will allow us to operate from a position of strength.

As always, please feel free to contact me with any questions.

With warm regards,

A handwritten signature in blue ink, appearing to read "N. Elam".

**Nevan C. Elam**

Chairman and Chief Executive Officer

September 22, 2016

## Forward-Looking Statements

This shareholder letter, like many written and oral communications presented by AntriaBio, Inc., and our authorized officers, may contain certain forward-looking statements regarding our prospective performance and strategies within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995, and are including this statement for purposes of said safe harbor provisions. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, and expectations of the Company, are generally identified by use of words "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "seek," "strive," "try," or future or conditional verbs such as "could," "may," "should," "will," "would," or similar expressions. Our ability to predict results or the actual effects of our plans or strategies is inherently uncertain. Accordingly, actual results may differ materially from anticipated results. Readers are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this release. Except as required by applicable law or regulation, AntriaBio undertakes no obligation to update these forward-looking statements to reflect events or circumstances that occur after the date on which such statements were made.