Amarillo Biosciences, Inc. Announces Investor Update (Sept 6, 2017)

Marketwired September 6, 2017
https://finance.yahoo.com/news/amarillo-biosciences-inc-announces-investor-133000022.html

AMARILLO, TX--(Marketwired - Sep 6, 2017) - Amarillo Biosciences, Inc. (ABI) (OTC PINK : AMAR) has identified certain goals for its future business development, and wishes to share this information with both its shareholders and the general public. ABI recognizes that it needs to create new products and get them to market, monetize and commercialize its intellectual property, leverage core technology, and develop research capabilities to become an integrated healthcare enterprise of global distinction. Additionally, ABI must transform itself from the historically narrow focus in biotechnology to a wide variety of development opportunities in several industry sectors. By doing so, we can create multiple revenue streams through the implementation of programs (including but not limited to in-licensing) of novel medical, healthcare, and scientific products and processes. For this strategy to be successful, we have to transform ABI from the traditional single-business unit into three modern, diversified, self-contained business operations: Pharmaceutical, Medical, and Consumer Products.

Pharmaceutical Division: Management has determined that our unique expertise in the treatment of human and animal diseases is solid and should be maintained and further developed. This revamped business unit, now called the Pharmaceutical Division, will utilize our extensive, thirty-year data library by applying the Company's experience in the use of low-dose oral interferon (IFN) to the treatment of neoplastic, viral, and autoimmune diseases.

Patents: In addition to the clinical pharmaceutical data, we possess an intellectual property portfolio containing five issued patents (four U.S. and one in Taiwan) and a registered trademark, in the U.S. The fifth and newest patent, "Treatment of Thrombocytopenia Using Orally Administered Interferon", was issued on July 21, 2017, and will expire in 2033. The scientific proof for this patent came out of a clinical trial conducted between 2009 and 2012. This trial was designed to use low dose oral interferon to help prevent viral recurrence in hepatitis C patients who have received the combination conventional therapy high-dose injectable interferon-α and ribavirin. As a result of receiving this conventional therapy, numerous patients suffered thrombocytopenia[1]. Surprisingly, platelet counts of the treatment group in which patients received 500IU (international units) of low dose oral interferon daily, quickly recovered back to the normal range of platelet count within 4 weeks and these patients experienced almost no adverse side effects. In technical terms, the results were highly statistically significant ($p = 0.003$). This discovery signaled the beginning of the creation of a product that has been shown to treat this widespread condition in society -- thrombocytopenia**.** We intend to apply our core technology, low-dose oral interferon (IFN-α), to treat the effects of this prolific and serious condition. The Company has begun broadening the scope of these new patents by filing two Continuation Applications with the U.S. Patent Trademark Office

(USPTO). The first application was allowed by USPTO on August 2, 2017, and has just been approved to issue on September 5, 2017. The second Continuation Application was filed on August 3, 2017, and is currently under consideration by the USPTO. Upon allowance, these continuation applications should broaden the patent coverage to include a method of reducing the rate of hepatitis C recurrence in patients (including those patients also suffering from thrombocytopenia).

Interferon: We will continue to explore the modernization of interferon technology by researching new sources and types of interferon. This research will explore possibilities of new interferon production, preparation, and purification methods as well as new, more effective and efficient delivery methods. New proprietary processes will be investigated with the goal of producing a more efficacious and economical product. Additionally, ABI has a library of almost thirty years of scientific and clinical data on human and animal applications of low dose oral interferon.

Sjögren's Syndrome: We will investigate the availability of natural human and recombinant human interferon as well as natural and recombinant animal interferon. Once a new supply is located, we hope to begin by applying the technology to Sjögren's syndrome[2], an application we have previously studied and tested. In August 2003, we published the results of our Phase III clinical trial[3] where we continued to demonstrate the safety of low-dose oral interferon. We did not receive U.S. Food and Drug Administration (FDA) marketing approval because our study drug, low-dose oral interferon, did not perform statistically significantly better than the placebo with regard to stimulated whole saliva flow; however, aspects of the results were promising, as secondary endpoints were achieved, indicating a significant increase in unstimulated whole saliva flow at 24 weeks. The FDA requested we conduct another Phase III trial to more definitively demonstrate the efficacy of the treatment, but at that time we were unable to fund such a study. We intend to use our knowledge and experience gained in previous and new trials to develop this application to a much fuller and more beneficial extent. We believe there is, indeed, a demand for this treatment; national Sjögren's syndrome organizations have contacted us in the past, hoping that we will produce an interferon in quantities large enough for the several hundred thousand Sjögren's sufferers in the U.S. to benefit from the treatment. Another benefit to pursuing approval of treating Sjögren's syndrome with low-dose oral interferon is the status of Sjögren's as an "Orphan[4] Disease," a disease that affects a small percentage of the population. A disease that meets the FDA definition as an "Orphan Disease" is, by definition, treated with an "Orphan Drug". While the market for treatment of an "Orphan Disease" may be not be as large as its non-orphan counterpart, there can be significant benefits to the treatment sponsor (manufacturer), ABI. Benefits that can accrue to the Company could include: qualification for a seven-year FDA-administered market "Orphan Drug Exclusivity"; tax credits awarded the sponsor upon drug approval; FDA awarded research grants; and waiver of certain application fees that can have a very significant value. Applying our core technology to the treatment of Sjögren's syndrome could potentially be an opportunity to quick-start the oral interferon enterprise.

Influenza, Hepatitis C: Within the next couple of years, we will once again utilize the opportunities afforded by hepatitis C and influenza. Indeed, there are other treatments for hepatitis C which are very effective, but incredibly expensive. Influenza will continue to be

around for a long time; and because the virus mutates so easily and quickly, there will almost always be a strain of influenza to protect against, to fight, and to treat.

Animal applications: Within three years, we hope to investigate the use of interferon for treatment of animals. Application of low-dose oral interferon to animals is another area in which we have a great breadth and depth of experience. Over the years, ABI has conducted bovine, equine, feline, porcine, and mouse studies involving such indications as Bovine Respiratory Disease, Shipping Fever, Genetic Upregulation, Rotavirus, Diabetes, Influenza, Feline Leukemia, allergies, tumors, and many other conditions and diseases. We conducted a study several years ago to determine the impact of our low-dose oral interferon on the survival rate of piglets after weaning. Piglets receiving our interferon powder for three consecutive days after weaning had the highest survival rate, tracked through fifty-six days, of the four observed groups. Additionally, we have significant experience and an accumulation of data involving the production and application of bovine cytokines[5]. We have conducted numerous studies using bovine cytokines to treat both human and animal indications. Considering all of these important factors, we believe low-dose oral interferon should have a bright future in both human and animal applications because preparation and use are safe, economical, and easily administered.

MEDICAL DIVISION

Diabetes Management: The Medical Division has already begun operations by introducing on a trial basis an innovative, state-of-the-art technology into Taiwan and Hong Kong, and will endeavor to launch the technology in China, and the other Asian countries immediately. The technology is a unique, highly effective tool for diabetes management, which has already been commercialized in the U.S. by entities unrelated to ABI; ABI hopes to negotiate arrangements (by license, joint venture, or otherwise) leading to the introduction of this technology into Asian markets. As far as we have been able to determine, this procedure is the only safe and effective therapy for diabetes employing a U.S. FDA cleared device and procedure that slows, stops, or reverses many of the chronic complications of the disease. It is uniformly effective for treatment of both Type 1 and Type 2 diabetes and has shown to be effective in even the most impaired patients. The process has been developed over a period of twenty-seven years. During this time frame, fourteen clinical studies and sixty-five supportive studies and publications have been completed. The treatment has been medically administered over 200,000 times with no adverse reactions and requires no warnings of side effects. The cost of the treatment in the U.S. is covered by Medicare and most health insurance companies and appears to have the ability to reduce health care costs through its probable capacity to decrease the number and frequency of diabetes related emergency room (ER) visits, subsequent patient hospital admissions, and a reduction in the length of the hospital stays.

A Demo-Clinic was opened in Taiwan in May 2016, and continues to demonstrate the process and technology to patients and potential investors. The Taiwan clinic also teaches and trains medical personnel in the administration of the treatment. The ABI Medical Division is leading the effort to secure regulatory approval for large-scale deployment of the treatment in Taiwan. It is anticipated that three clinics will be opened by mid-2018 in Taiwan, and over the next approximately three years, the planned number of clinics in Taiwan will increase to ten. In February 2017, a clinic was opened in Hong Kong and is currently planning its first

expansion. Also in Hong Kong, a joint venture project is under negotiation. Plans are currently being made for clinic openings in China and Malaysia as well. Saturation of Taiwan, Hong Kong, China, Malaysia, and many other Asian countries will not only be a chosen strategy to increase Company value, but a primary goal.

Consumer Products Division: The Consumer Product Division is presently working on three major distribution ventures in Taiwan, Hong Kong, and China. First, this ABI division will offer a novel delivery system for nutraceuticals and food supplements such as Vitamin C, Glutathione, CoQ10, Curcumin/ Resveratrol, DHA, and a Multi-Vitamin. These products will employ a unique proprietary liposomal delivery system which ABI will endeavor to license for this purpose. Secondly, Consumer Products is importing to the Asian markets an exceptional natural resource product which can be modified for human, animal, or agricultural applications. Already, the Division has a distributor for Taiwan, Hong Kong, and China. This distributor is deeply involved in animal and crop research for the agricultural application of the product. The Company is currently negotiating a joint venture project with the producer of the product that will create opportunities for development of new products for new markets all around Asia. Finally, ABI in conjunction with Hidden Valley Herbs of Kentucky, which is owned and operated by ABI's Board of Directors member and Stockholder Paul Tibbits, will endeavor to enter the alternative medicine market through domestic and international distribution of natural Kentucky Wild Ginseng and other medicinal herbs. ABI will capitalize on the keen interest and high demand for Ginseng of this quality in the Asian markets.

Taiwan Office: We are evaluating the possible acquisition of ACTS Global Healthcare, Inc. (ACTS), a Taiwan Corporation (2013), to become our branch office in Taiwan and the marketing and distribution arm for ABI in the eastern hemisphere. Within a year we foresee the necessity of having offices in Hong Kong, China, and Malaysia.

Implementing all of our goals will require establishing multiple revenue streams. ABI will endeavor to evolve from one business unit with no commercialized products, to three business units with many products. We will strive to grow profitably and consistently over time by seeking joint venture opportunities with public and private companies.

Long term Goal: Ultimately, we want to create Company value and worth to the extent that we will be able to move ABI from the Over-the-Counter Bulletin Board market back to the NASDAQ, the Stock Exchange on which Amarillo Biosciences, Inc., AMAR, appeared when we originally became a public company in 1996. We recognize this is a long term goal.

Forward-Looking Statements: Certain statements made throughout this document are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 (the "Act"). Forward-looking statements include, without limitation, any statement that may predict, forecast, indicate or imply future results, performance, achievements, costs or expenses and may contain words such as "believe," "anticipate," "expect," "estimate," "project," "budget," or words or phrases of similar meaning. Forward-looking statements involve risks and uncertainties which may cause actual results to differ materially from those projected in the forward-looking statements.

Except for the historical information contained herein, the matters discussed in this letter are forward-looking statements that involve risks and uncertainties, including uncertainties related to product development, uncertainties related to the need for regulatory and other government approvals, dependence on proprietary technology, uncertainty of market acceptance of oral interferon or the Company's other product candidates (including geographic placement of products) and other risks detailed from time to time in the Company's filings with the Securities and Exchange Commission.

[1] Thrombocytopenia is a condition caused by abnormally low levels of platelets in the blood that seriously inhibit clotting and can result in significant and potentially dangerous blood loss. Thrombocytopenia can be caused by numerous diseases or by therapeutic treatment of various diseases and medications. Oral interferon has proven effective for the reduction of clotting inhibition. The high incidence of thrombocytopenia in society today generates a potentially strong and lucrative market demand for a safe, effective and cost efficient treatment like low dose oral interferon.

[2] Sjögren's syndrome is a chronic disorder of the immune system - a long-term autoimmune disease -- in which the patient's white blood cells attack the saliva and tear glands, leading to dry mouth and eyes because the body's tear and saliva production is reduced. (Medical News Today, July 19, 2017; www.medicalnewstoday.com/articles/233747.php)

[3] The study was conducted from October 19, 1998 to September 20, 2000, and was a randomized, double-blind, placebo-controlled, parallel group, phase 3 study. The group population was 497 eligible adults diagnosed with Sjögren's syndrome. (Arthritis & Rheumatism Vol. 49, No. 4, August 15, 2003, pp 585-593)

[4] Sjögren's syndrome can be found on the FDA list of orphan diseases at the following URL: https://rarediseases.info.nih.gov/diseases/fda-orphan-drugs/S

[5] In 2012 ABI granted to its founder, Dr Joseph M. Cummins, the right to pursue the development of bovine interferon alpha and other bovine protein extracts for his own benefit, or for the benefit of other persons or entities with whom he might be or become associated; without prejudice, however, to ABI's right to pursue the development of such products independently of Dr. Cummins, either alone, or in cooperation with other persons or entities.