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INTRODUCTION

Good Morning. I am William D. Moeller, Chairman and President of American Biotech Laboratories of Alpine, Utah ("ABL"), a company which produces engineered, metallic silver, nano-sized particles in water-based products. Our engineered silver particles have performed far beyond anyone's expectations as anti-microbial agents, against a staggering variety of microbes such as malaria, flesheating bacteria (MRSA – Methicillin Resistant Staphylococcus aureus) and E.coli.

Whether used on surfaces as disinfectants or if taken internally as supplements, all of our ABL products are non-toxic and have no known adverse human side effects. Our products have surprised many experts in the medical and science worlds because of their ability to combat bacteria, yeast, and viruses. ABL products have been proven to destroy anthrax spores and bubonic plague bacteria on surfaces, to eliminate the malaria parasite in humans and a host of other beneficial results.

We have developed five products to date as well as several other new products currently in our product development pipeline. We manufacture all of our products in the United States. One product ASAP-AGX-32 (a water solution containing 32 ppm of our engineered silver nano-particles) has already been approved by the EPA as a surface disinfectant for hard, non-porous surfaces in commercial, residential, industrial, hospital and medical environments. Another product called Silgel is a non-toxic moisturizing gel, which utilizes our ASAP-AGX-32 as a raw material supply of silver particles. It is currently undergoing the final steps for FDA approval for the treatment of lacerations, first and second degree burns, abrasions, surgical wounds, skin ulcers etc. Several other new ABL products will soon warrant the filing of new FDA and/or USDA applications.

BACKGROUND

All my life I have been involved with the mining and processing of silver in Utah. I am Chairman of the Board of Clifton Mining, a Utah mining company holding several million ounces of silver reserves. My family and I are large stockholders in Clifton Mining. I have spent most of my life in Utah where my wife Jeneane and I raised our seven children together.

In the late 1990s, the price of silver reached a point where its mining and production costs were above its selling price. At that time, we needed to find an alternative use for silver that at least paid for removing the silver from the rock ore. We decided to devote some the resources of Clifton mining to try to create a new water-based product containing silver. Since ancient times it has been known that silver inherently possesses desirable antimicrobial and immune boosting properties. We planned to be the first to maximize those desirable effects of silver. We did our homework and found a plethora of colloidal silver products and devices littering the marketplace, most of which did not seem very sophisticated to us. Our analyses of various colloidal silver products (mainly dietary supplements) led us to the conclusion that these manufacturers lacked stature in the marketplace and the products produced were, at best, anecdotally effective.

In 1998 we created ABL with the idea of manufacturing high quality, standardized colloidal silver products. I talked all five of my sons into joining ABL in what we thought might be a nice family business. We worked hard inventing new methods to purify and standardize our silver products and, frankly, got a little lucky along the way because we ended up inventing and manufacturing something else all altogether.

Our initial discoveries are the subject of two issued US Patents: 6,214,299, which issued on April 10, 2001 and related US Patent 6,743,348, which issued on June 1, 2004 (See *Appendix 1*). Additional discoveries are contained in several other pending patent applications, most of which are not yet in the public domain.

Although ABL's initial products were referred to as "colloidal silver," we now know that our engineered particles are quite different. When most people use the phrase "colloidal silver," they mean ionic silver, silver salts or silver nitrate in a gelatin matrix. ABL's liquid products do not contain ionic silver, silver salts or silver nitrates. Rather, they contain engineered nano-sized particles of metallic silver dispersed in a matrix of pure water. Although these products are primarily water (99.999%)

because the actual silver concentration is so low. Their unique potency has been demonstrated by numerous laboratory (in vitro) and human (in vivo) tests carried out by ABL, at ABL's request, and in some of the most interesting cases, without ABL's involvement or even contemporaneous knowledge.

ABL's first three products that we manufactured were dietary supplements. These products have actual silver concentrations of 10 parts per million ("ppm"), 14 ppm and 22 ppm and are sold through a number of different outlets. For example, ASAP 10 (the 10 ppm product) is being sold through General Nutrition Center stores throughout the country under the name *Silver Biotics*. This 10 ppm of silver particles in purified water is colorless, tasteless, odorless and is non-toxic. Based on our knowledge of the engineering of the metallic silver particles, we estimate the actual shelf life of our products to be in excess of 10 years.

As demand for our products grew, we began distributing ASAP 10 worldwide. In short order, many different positive antidotal stories began to pour in from around the world. The interest in our product grows and certain private investors joined our core "family and friends" group. One user's experience led to an important event that would forever open our eyes to the power of our 10 ppm ASAP non-toxic liquid.

In 2001, twelve bottles of our 10 ppm ASAP product fell into the hands of a medical Doctor in Rwanda, Dr. Ewabuhihl Ezechias. One day I received a frantic telephone call from Dr. Ezechias' office that was in Rwanda caring for a group of very young children who were in the last stages of malaria about to die. Dr. Ezechias was looking for instructions on how to administer our ASAP 10 product to these desperately ill children. I suggested to the Doctor that he measure out a teaspoon or two to each of the children, two or three times a day and that he repeat the process until the children hopefully showed some improvement. He responded abruptly that there was no time for measuring anything – the situation was far too grave for "such niceties." All of these children had temperatures around 105 degrees, had not improved with conventional treatments and were all about to die. He asked me if he could simply put the water into their bottles. Knowing of its totally non-toxic properties and sensing his desperation, I assured him that it would not hurt the children.

Days later, Dr. Ezechias contacted and told me that he had put the ASAP 10 ppm water directly into the drinking water bottles of 11 of these children. All 11 of the young children who received the ASAP 10 ppm got better. A week later, the 11 left his clinic alive and healthy. Sadly, there were other children

who did not receive the ASAP treatment. Those children died in spite of receiving all the conventional treatments which Dr. Ezechias provided them. This affected me deeply and I realized that our ASAP 10 ppm had potent, positive effects on malaria patients. Besides the phone calls, we also received an indirect written communication from Rwanda which is included in *Appendix 2*.

Word spread quickly and soon scientists and medical doctors from around the world began to hear stories about ABL's silver products. One doctor from Mumbai, India, Dr. Dilip Mehta of Viridis BioPharma decided to check out the many stories. Without our knowledge, he began to test our products in a variety of different ways against several different micro-organisms. Dr. Mehta scientifically tested and compared our products with other silver-based products from around the world. Dr. Mehta concluded that no other product in the world had the biological efficacy of our non-toxic ASAP 10 ppm product. Traveling half-way around the world from India to Utah, Dr. Mehta unexpectedly showed up at our Alpine facility to begin a trusted and fruitful association advancing our knowledge and product base.

We also have met many important scientists along our journey, including Professor Rustum Roy who concurrently holds appointments with Pennsylvania State University, Arizona State University, and the University of Arizona. Professor Roy is a world leading materials scientist (please refer to www.rustumroy.com) whose initial interest was in determining and characterizing the physical properties of our water products. Because he was interested in water and its relationship to general health, Professor Roy wanted to correlate physical properties of ABL's water-based silver products with their superior biological performance. He found that our ASAP 10 and ASAP-AGX-32 water-based products are physically quite different in a number of inherent, measurable, physical properties from colloidal silver products. Professor Roy has now generated much data showing that our products are unique. Professor Roy has presented this data at several scientific conferences. Please see Professor Roy's letter in *Appendix 3*.

Professor Roy, in turn, introduced us to General Resonance, a cutting-edge science and technology company located in Maryland, whose work and expertise Professor Roy had scrutinized and tested at the Materials Research Laboratory at Penn State. ABL and General Resonance recognized their potential synergy and have formed a joint venture. The combination of General Resonance's fundamental understandings and its patented sciences and technologies with ABL's existing products and technologies promises to generate a long-lasting pipeline of new, more potent products with a

broader use spectrum (or even targeted specifically to particular diseases). Other joint ventures are likely. Clearly there has been much interest generated in ABL's new non-toxic products.

THE TECHNOLOGY

ABL manufactures its water-based products by controlling and delivering a few thousand Volts AC through highly purified silver electrodes in contact with the surface of high purity water. The silver in the electrodes is slowly dispersed into the water as metallic silver nano-sized particles. These engineered silver particles currently vary in size between about 10-50 nanometers in diameter, depending on the particular manufacturing conditions. Concentrations as low as 1-2 ppm have been shown to have efficacy against certain bacteria and viruses, however, the products being sold right now typically range in concentration of from 10 ppm – 32 ppm (i.e. ASAP 10 and AGX 32, both of which are greater than 99.999% pure water). These concentrations have been shown to kill or de-activate bacteria and viruses in a few minutes. *Appendix 4* shows in brief summary form certain in vitro results and data which demonstrate the broad spectrum efficacy of ABL silver-water solutions against a variety of microbes (and related human diseases).

The data in *Appendix 4* (along with other data not presented today) suggest that small amounts of selectively engineered silver particles can have dramatic anti-bacterial, anti-fungal, and anti-viral effects. Surface disinfectants (e.g., bleach) and most pharmaceutical products against these agents of disease function by various chemical reactions and are consumed and used up in the process. These agents that are consumed in this way must be replenished to remain effective. Our silver particles function differently and it is clear from ongoing research that our engineered silver particles are <u>not</u> consumed in chemical reactions the way other anti-microbial agents are. Rather, it appears that the silver particles function as catalysts, which promote certain lethal reactions in only unfriendly microbes (i.e., the destruction of bacteria, fungi and viruses). This is the same way platinum particles in an automobile's catalytic converter function. They promote lethal reactions in pollutants without being consumed in the process. We believe that this understanding is very important and partly explains the lack of any known negative biological side effects from the ABL products. If engineered properly, very small amounts of catalytic silver apparently can go a very long way.

MALARIA STUDIES

After ABL learned how the lives of the 11 young children in Rwanda were saved (discussed above)
ABL initiated contact with four different hospitals/clinics in Ghana. We shipped to these different medical facilities about 1000 of our 8 ounce bottles of ASAP 10. Obtaining good follow-up clinical data turned out to be quite difficult because once the patients felt better; they simply did not come back for further treatment and follow-up. For example, *Appendix 5* contains representative data from the Justub Clinic, run by Dr. Agnes Abraham, who reported after her first trials, that typically their patients return to the clinic only if they are still ill, which was not the case with their patients treated with the ASAP 10

Another preliminary trial occurred at the Air Force Hospital in Ghana where the Medical Officer in Charge was Dr. Evelyn Kwabiah. The five patients treated by Dr. Kwabiah all had positive outcomes (see *Appendix 6*). Dr. Kwabiah reported that patients with malaria who had received the ASAP 10: recovered faster than those receiving conventional treatments; recovered where conventional treatments had failed; or, that the ASAP 10 functioned as a prophylactic preventing the recurrence of malaria.

Ultimately, the success of ABL's ASAP 10 ppm against malaria gained such widespread acceptance in Ghana that the Food and Drugs Board of the Republic of Ghana issued a Certificate of Registration of a Drug for ABL's product (see *Appendix 7*).

Although we were receiving better clinical reporting, and Ghana had issued a Certificate of Registration, we still were not satisfied that the previous trials met the level of standardization we wanted to achieve. To obtain better data concerning ASAP 10's effectiveness against malaria, ABL (in cooperation with competent university medical professionals) designed a new protocol (see *Appendix 8*). The new protocol required that all Malaria patients be monitored for 15 days and were encouraged to return for follow-up testing and assessment with financial incentives (patients were paid a few dollars a day to come back and be monitored and tested). *Appendix 8* contains the study protocol, results, and one representative patient's chart. (An Executive Summary of these more reliably executed Malaria Studies in Ghana, supported by ABL, is shown in *Appendix 9*).

Study #3 listed in *Appendix 9* was the most reliable of the studies and used the protocol described in *Appendix 8*. The data showed that out of the 41 Malaria patients (ages 1-90 years) involved in the studies and receiving ASAP 10, all 41 people survived and there were no treatment failures. All

participating patients were deemed to have achieved full recovery in an average of 4.5 to 6.5 days, with recovery time differences probably being due in part to differences in total dosages. Clearly the data suggest that ABL's ASAP 10 ppm product, when administered in 2-3 teaspoon quantities 2-3 times per day (i.e., one ounce per day) reverses malaria and saves lives. The cost of this regimen in total is a few dollars and appears to be highly effective.

No undesirable or drug-like side effects were reported by any of the patients in any of these more rigorous studies. We believe that this was because the ASAP 10 ppm is primarily water with very small amounts of catalyst-like metallic silver particles therein,. This result is also quite different from all other known malaria treatments, which often involve quite uncomfortable side effects.

ABL has continued its efforts to determine the effectiveness of its ASAP 10 ppm product as an effective treatment against malaria. To that end, ABL sought the input of various malaria experts including that of Dr. Awa Marie Coll-Seck, Executive Secretary of the *Roll Back Malaria Partnership* hosted by the World Health Organization. Dr. Coll-Seck provided her comments which were instrumental in creating a proposed 660 patient study; initially to be performed in Senegal. This Protocol was just completed earlier this month, but has not yet been initiated. ABL hopes to be able to accomplish this or a similar study in the near future so that we can begin to have a larger impact on malaria worldwide.

TUBERCULOSIS

Preliminary data generated by two independent laboratories suggest an efficacy of ASAP 10 ppm and ASAP-AGX-32 against tuberculosis. But, because this data is new and not yet reviewed, we are reluctant to share any of the data at this time. However, we are encouraged by what we have seen.

OTHER PRODUCTS OF INTEREST

1. Surface Disinfectant.

ABL received EPA approval for ASAP-AGX-32 in 2003 (see *Appendix 10*). ABL also received a contract (Contract No. V797P-5762X) with the VA Hospitals, to use this product as a surface

disinfectant. *Appendix 11* shows data recently generated by an independent laboratory comparing AGX-32 to eight leading disinfectants for use against Methicillin resistant <u>Staphylococcus aureus</u> (MRSA). The data is reported two different ways: (1). "% **Effectiveness**," which compares how effective the leading disinfectant is compared to AGX-32 (e.g., "Phenol" is 40% as effective as AGX-32); and (2) "Coefficient," which shows the reverse or how much better AGX-32 is relative to the leading disinfectant (e.g., AGX-32 is 2.5 times more effective than Phenol). These data are very significant because AGX-32 is a non-toxic product, unlike most disinfectants, and yet functions as well or better than the other disinfectants. It can be used around hospitalized patients without any ill effects. Moreover, because the silver functions akin to a catalyst, it is not consumed in a chemical process and will continue to disinfect a surface until removed (e.g., by soap and water) from the surface on which it was applied.

2. Wound Care and Burn Care.

ABL has a 510(k) application pending with the FDA (see *Appendix 12*) for AGX SILGEL, a moisturizing gel containing ABL engineered silver particles. ABL expects the final animal study required for this FDA approval for wound care to be finished in June 2005. We anticipate that approval will be obtained for use of the SILGEL silver-gel product on: lacerations, abrasions, skin tears, leg and other surface ulcers, surgical wounds, first and second degree burns etc. The base material for manufacturing this product is ASAP-AGX-32 (a non-toxic precursor). This AGX SILGEL product is a broad spectrum, anti-microbial. SILGEL is not cytotoxic in studies performed to date (e.g., the gel has been proven to be non-toxic in the oral route, by mouse model studies up to 5000mg/kg of body weight). ABL's silver-gel provides moisture for wound healing and burn treatment, has no color or smell, requires no refrigeration and remains stable from 17-113 degrees Fahrenheit. In FDA approval comparison studies, AGX SILGEL was found to be over 10 times more effective in killing MRSA compared to a leading FDA approved silver-based product (at a challenge of about 10,000,000 bacteria/ml), even though the leading and approved product contains more than 300 times as much silver than AGX SILGEL.¹

¹ This product has not been offered for sale due to the pending FDA Application.

Dr. John A. Shaw, a practicing oncologist in Arizona, has recently been using AGX Silgel on an experimental basis to treat radiation burns from radiation therapy used for treating breast cancer. His reviewed work has been conducted at hospitals in Arizona. His initial findings are that the AGX Silgel promotes healing more effectively than other commercially available products. A letter from Dr. Shaw is included in *Appendix 13*.

GOVERNMENT ACTIVITIES OF INTEREST

ABL has initiated a number of recent US Government contacts, which have resulted in the testing of ASAP-AGX-32 and AGX Silgel products (or at least the desire to test). Many of these contacts have generated desirable data showing the efficacy of ABL's products for different uses. We have not offered these products for sale to the government yet.

Letters of support for ABL from Senator Orrin Hatch and Lt. General Paul K Carlton, Jr., addressed to The Honorable Tom Ridge, can be found in *Appendix 14*.

CONCLUDING STATEMENT

ABL has invented and patented a process and a product that should have wide applicability to a variety of bacterial, fungal and viral species. The production process is robust and can be quickly scaled-up to meet virtually any production demands. The ASAP 10 ppm product, in quantities of about 1 ounce per day, seems to eliminate the symptoms of malaria in human patients in about 4-6 days. Thus, one 8 ounce bottle of ABL's ASAP 10 ppm has been more than enough to eliminate the symptoms of malaria in each of the patients involved in the African studies. ABL is ready to make this product (or the process) available on a world-wide basis. We hope that the Committee will be sufficiently impressed to help us to help others.