

January 4, 2017



Oragenics Shareholder Update

Advances Drug Development Programs Focused on Conditions with Significant Unmet Medical Needs

TAMPA, Fla.--(BUSINESS WIRE)-- Oragenics, Inc. (NYSE MKT:OGEN.BC), a clinical stage biotechnology company advancing lantibiotics to treat serious bacterial infections and biotherapeutics to treat oral mucositis (OM), today issued a shareholder update from CEO Alan Joslyn outlining the Company's vision and strategic growth strategy and highlights the significant accomplishments in 2016.

Dear Shareholders:

As we begin a new year, I wanted to provide an update on the Company's strategic vision and accompanying action plan that will fuel our future growth and drive shareholder value. With the significant accomplishments from last year and as we look ahead, we are quickly preparing to advance our lead drug candidate, AG013, for the treatment of oral mucositis to a Phase 2 clinical trial in addition to completing the work necessary to file an Investigational New Drug (IND) application for the lantibiotic OG716 for the treatment of *Clostridium difficile* in 2017. Both programs, if successful, would yield first in class therapeutics for oral mucositis and *C. difficile*, respectively. We also look forward to additional opportunities to expand our clinical development programs through strategic collaborations and partnerships that will further strengthen our pipeline.

2016 was a transformative year for Oragenics, in which we completed several near-term objectives and continued to build a solid foundation for long-term growth. We have established ourselves as a leading clinical-stage biotechnology company dedicated to developing novel bio-therapeutics for serious unmet medical needs, and have spent the past year significantly advancing our pipeline. We received Fast Track Designation for our lead candidate AG013 for oral mucositis and completed the selection process for our second generation lantibiotic, OG716. Earlier in the year, we also successfully divested the Company's oral probiotics business to ProBiora Health in a favorable transaction, allowing us to focus exclusively on the development of novel biotherapeutics and antibiotics.

AG013 for Oral Mucositis is Phase 2 Ready

Oral mucositis is one of the most debilitating side effects of chemoradiation therapy, occurring in up to 80% of patients with head and neck cancer. Patients suffer from painful inflammation and mucosal ulceration in the lining of the oral cavity, throat and esophagus. There are currently no commercially available treatment options addressing the underlying condition in this cancer population.

AG013 is an ActoBiotics™ therapeutic candidate formulated as a convenient oral rinsing

solution and designed by our partner Intrexon Corporation (NYSE:XON) to deliver the therapeutic molecule Trefoil Factor 1 (TFF1) to the mucosal tissues in the oral cavity. Trefoil Factors are a class of peptides involved in the protection of gastrointestinal tissues against mucosal damage and play an important role in subsequent repair.

Following our Type C meeting with the U.S. Food and Drug Administration (FDA) in August 2016, they provided us with helpful guidance on the manufacturing process for AG013 as well as matters that will help us achieve a successful Phase 2 clinical trial.

Another key accomplishment this year was the FDA Fast Track designation we received for AG013 in November of 2016, which further validates our science as well as highlights the serious need for a treatment for oral mucositis. This designation will allow us more frequent interactions with the FDA and potentially shorter review times as we advance the clinical development program for AG013.

We are well prepared for our Phase 2 trial after we successfully manufactured AG013 clinical trial material and we look forward to the ability to submit our IND-amendment to the FDA in early 2017, and then treat our first patient shortly thereafter. The Clinical Research Organization that will be overseeing management of the AG013 Phase 2 clinical trial has been selected and I am pleased to note that they are already actively recruiting well-established centers in both the United States and Europe to participate in the study.

Lantibiotic Program for Serious Bacterial Infections Preparing for IND

Clostridium difficile (*C. difficile*) is a bacterial infection that most commonly affects older adults in hospital and long-term care facilities after they receive an antibiotic administration, although there is an increasing rate of infection in younger and healthier populations. *C. difficile* is now associated with nearly 500,000 infections annually in the U.S., resulting in 29,000 deaths in the United States alone. Certain strains, including NAP-1, have seen a 400% increase in deaths since 2000. We are addressing this severe unmet medical need by developing a lantibiotic against *C. difficile* with our partner Intrexon.

Through our Exclusive Channel Collaboration (ECC) with Intrexon, we have created an extensive library of potential second generation lantibiotic homologs to MU1140, a lantibiotic peptide targeting the bacterial cell wall component called lipid II. We know the lantibiotic class is effective in treating gram(+) infections including serious methicillin resistant *Staphylococcus aureus* (MRSA) and Vancomycin Resistant Enterococci (VRE) and we intend to identify lantibiotics from our library that possess the best physical chemical and microbiological profiles to treat serious bacterial infections.

To that end, during the summer of 2016 we completed a series of *in vivo* animal studies which led us to select OG716 as a second generation MU1140 homolog for advancement into FDA IND-enabling studies for the treatment of *C. difficile* infections. OG716 has distinct physical chemical advantages over predecessor compounds while also possessing enhanced intellectual property protections. These advantages include improved stability of OG716 in gastric and small intestinal fluids thereby negating the need for special drug formulations to selectively deliver the compound to the large intestine at the site of infection.

One of the most significant challenges to advancing lantibiotics into successful therapeutics to treat widespread serious bacterial infections has been the inability to manufacture

sufficient quantities in a cost effective manner. Through our collaboration with Intrexon, however, we have been able to enhance yields multiple fold during our fermentation and purification process, thereby enabling us to generate quantities sufficient to proceed with further development.

We have successfully transitioned manufacturing of OG716 to an external contract manufacturer, which has allowed us to begin the process of manufacturing sufficient amounts of OG716 to initiate our toxicology program. The first toxicology study is underway and after completing the additional work, we look forward to being able to file the IND for OG716 in 2017.

Key Executive Appointment

In June of 2016, I joined Oragenics as President and Chief Executive Officer and a member of the Board of Directors. I have extensive drug development experience along with experience as a CEO at a number of private biotechnology companies and I look forward to helping lead Oragenics to success.

Sale of Oral Probiotics Business/Financing

In June of 2016, we sold our oral probiotics business to our former Board member Christine Koski, for \$1.7MM. While we were able to monetize this business, the sale of the business has enabled Oragenics to focus solely on research and development of treatments for unmet medical needs.

In addition to the money raised from the sale of the oral probiotic business, we raised \$4.9MM in an offering in June 2016. We plan to raise additional capital as necessary to continue advancing our product portfolio through upcoming milestones.

Looking Ahead

We are very excited about the path forward for Oragenics. We believe our new strategic focus as a clinical stage development company for the treatment of unmet medical needs will enable the company to create a high value niche in the healthcare space while also bringing relief to patients who currently lack sufficient treatment for their conditions.

Both our Biotherapeutics and Lantibiotics programs, if successful, would yield first in class therapeutics for oral mucositis and *C. difficile*, respectively. While concentrating on the successful development of AG013 and OG716, we also look forward to enhancing our pipeline with additional promising product candidates and partnerships where strategic interests are aligned.

Overall, we are pleased with our recent performance and anticipate the continued achievement of our goals and objectives in 2017. Most importantly, we would like to thank our loyal shareholders for their continued support.

With Best Wishes,

Alan F. Joslyn, Ph.D.
President and CEO

About Oragenics, Inc.

We are focused on becoming the world leader in novel antibiotics against infectious disease and on developing effective treatments for oral mucositis. Oragenics, Inc. has established two exclusive worldwide channel collaborations with Intrexon Corporation, a synthetic biology company. The collaborations allow Oragenics access to Intrexon's proprietary technologies toward the goal of accelerating the development of much needed new antibiotics that can work against resistant strains of bacteria and the development of biotherapeutics for oral mucositis and other diseases and conditions of the oral cavity, throat, and esophagus.

For more information about Oragenics, www.oralgenics.com

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