CEO Update

Dear Shareholders and Prospective Investors,

Insitu Biologics had a very active Q4 of 2019 so I want to share some of our key accomplishments with you and give a few details on what Q1/Q2 of 2020 has in store for the Company.

We added several extremely important individuals to our team. Kay Warnott joined as our Vice President of Clinical. Kay is a critical care nurse/acute care nurse practitioner and has served in a variety of senior clinical roles at pain management companies, most recently at Sollis Therapeutics and Pacira Biosciences. We also added Rita Pendergrass as Director of Clinical Operations. Rita and Kay have worked together over the past 15 years in the pain management space. Together they form an incredible foundation for our clinical group as they have successfully executed multiple Phase I/II/III pain clinical trials and consistently brought those trials to completion under-budget and faster than planned. In addition, we added Dr. Lee Simon to our consulting team. Dr. Simon is the former Division Director of Analgesic, Anti-inflammatory and Ophthalmologic DP at the FDA (the same division of FDA that will be reviewing our clinical trial results and eventually deciding on approval of our New Drug Application).

Operationally, we have made significant progress towards the ability to manufacture clinical-grade product with our contract manufacturing partner, Lifecore Biomedical. As you may know, Lifecore has world renowned expertise in GMP-grade production of hyaluronic acid (a key ingredient in our lead product, Anestagel™) as well as being the contract manufacturer of choice for a number of companies in the pharmaceutical and biotech space.

We were originally planning to close our Reg A+ offering in 2019 but have continued to have interest from investors and requests to extend the offering, so our Reg A+ Tier II offering remains open for both accredited and non-accredited investors. You can still invest here.

Currently we are in communication with the FDA and have been pre-assigned an IND number. We are now submitting a request for a pre-IND meeting with the FDA and anticipate FDA will set a date for that meeting in the April/May timeframe. The result of that pre-IND meeting will be a more clear picture of what specific data FDA expects to see in our IND application and a confirmation by the FDA of our proposed Phase I-III clinical path forward.

We will also be adding several more key consultants and advisors to our team over the coming months to ensure we have all subject-matter areas covered. Insitu Biologics continues to make rapid progress towards our mission of providing patients and physicians with an opioid-free solution for post-operative pain. Thank you again for your financial support!

Sincerely,

Kevin Bassett
President and CEO