



December 18, 2020

Greetings Insitu Biologics Shareholders,

Our entire Team would like to wish each of you and your families a Happy Holidays and best wishes for the New Year! We hope you are safe and continue to remain so as this pandemic enters what is hopefully its final phase here in the US and across the world.

First, a big thank you to everyone who joined the voting trust. Over 85% of you opted into the trust which brings our shareholders-of-record down to 68 from more than 450. Our investment banker had an initial goal for us to get to “double digits” and you blew past that goal! This puts us in an improved position from a capital structure standpoint to raise the large amounts of capital necessary to conduct our clinical trials. So, congratulations to the trust members – you’ve made Insitu Biologics stronger! *[Note: if you initially opted out of the trust, but would now like to join, please contact stephanie.klein@insitubiologics.com before Dec. 31.]*

Second, as many of you know, we have a close relationship with LifeCore Biomedical as our development and manufacturing partner. We also sub-license a robust portfolio of Cleveland Clinic Foundation hydrogel patents through our agreement with LifeCore. We recently worked with the LifeCore team to better align the terms of our license agreement – both with respect to our pain management focus as well as the payment schedule, which will now coincide with the timing of our planned rounds of fundraising. Our signed agreement runs through 2029, which assures we continue to remain partnered with a world-class pharmaceutical products manufacturer.

Third, our Engineering and Operations teams have been working diligently on our new formulation featuring ropivacaine as the active pharmaceutical ingredient (API). Over the past few months, robust in-house bench testing as well as evaluation through our pharmacokinetic and animal test partners has culminated in an extensive set of animal studies being conducted this December and January. These studies will focus on the API release characteristics of our formulation. We are very optimistic about the prospect of reaching the performance requirements necessary to satisfy our customers (patients and physicians) as well as the safety requirements necessary to satisfy the FDA. We expect the results of these studies in early Q1 of next year.

Despite the challenges of 2020, this was an incredible year for Insitu Biologics, resulting in several key accomplishments that promise to deliver an even better 2021. We look forward to finalizing our formulation and pre-clinical testing as we progress our product towards human clinical trials. We are eternally grateful for our good fortune and for your involvement as financial supporters of this enterprise. So, thank you and God bless you and your families as we head into an exciting 2021!

Best regards,

Kevin Bassett
President and CEO
Insitu Biologics, Inc.