April 20, 2021

Dear Investor:

I am pleased to report that **3DBio has successfully received approval of its Investigational New Drug (IND) application from the FDA**. This approval clears the way for 3DBio to commence human clinical trials for the microtia living ear implant, and ushers in an important next chapter as 3DBio is now a clinical-stage company. This IND approval is the first of its kind granted by the FDA and we believe makes 3DBio the first and only clinical-stage bioprinting company, ever.

We are currently preparing two clinical trial sites (one in Los Angeles and one in Texas), and continue to work with other prominent surgeons in New York and elsewhere. We are fortunate to be working with the top ear reconstruction surgeons in the world.

This journey has not been easy, and it has taken longer than we expected when we initiated operations about five years ago. The several dozen technical hurdles we overcame represent significant competitive barriers. Some of these problems were considered to be the seminal “unsolved” challenges within tissue engineering and regenerative medicine, including issues related to achieving cell quantities for full-scale body parts, preserving key rheological and biological bio-ink properties while overlaying FDA cGMP process requirements, developing the first cGMP aseptic bioprinter for therapeutics manufacturing, and more. We also had to navigate uncharted regulatory and clinical territory as this was the first product of its kind; related to this was the development of a comprehensive Quality Assurance and Quality Control framework that required the development and qualification of many novel in-process and release assays.

We didn’t start out thinking we would need to become multiple companies under one roof: a cGMP collagen bio-ink manufacturer, a cGMP cell process manufacturer, a manufacturer of cGMP-grade bioprinters, a cGMP manufacturer of an implantable device adjunct (our “Overshell Technology”). What we learned, however, is that given the novelty of this technology we needed to vertically integrate in order to control all aspects of the production process. This vertical integration now provides 3DBio an unparalleled advantage in the field.

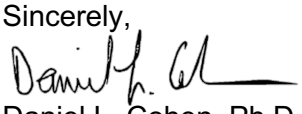
In addition to initiating clinical trials for our ear program shortly, and accelerating our next three programs (annular repair, whole intervertebral disc, nose cartilage), we are also broadening our horizons and charting a course towards other indications (e.g., rotator cuff, organ replacement). We have a clear path towards these additional indications with compelling strategies for expanded capabilities including vascularity and nerves.

We are now raising a bridge round to fund us toward clinical trials, and are beginning to explore a Series B. We are also focused on expanding the team as we transition to a clinical-phase company. Recent key hires include three additional Quality Team members (two joining from Novartis and one from GE): Director of Quality, QC Manager, and QA Specialist.

We have also completed the spin-out of American PAPR, now called Paladin Protective Equipment, with 3DBio retaining a minority ownership interest. As a reminder, when COVID hit the U.S., we rapidly developed and received approval from the CDC/NIOSH (achieving a perfect score upon NIOSH inspection) to commercialize our Powered Air-Purifying Respirators. As one of only a dozen approved manufacturers, Paladin has a bright future. At the helm is Paladin’s new CEO, Giles Kyser, a retired Marine Colonel and former AirBoss executive.

Thank you for your support on this journey, we greatly appreciate it.

Sincerely,



Daniel L. Cohen, Ph.D.
CEO and Co-Founder