Cambridge Orthopaedic Labs: US regulatory update

From: David W. Anderson

All:

It is with great pleasure that I can report that the first 510K submission to the FDA for the PolyArmour Non-Invasive External Wrist Fixator was submitted to the Agency today.

In this comprehensive report, the COL team and our consultants have compiled a comprehensive set of data that included but was not limited to:

- Pre-clinical data
- Clinical data sets
- Biocompatibility testing

Clearance times for 510k's are unpredictable, but we have provided the Agency with a document that should (and I emphasize should) move through to clearance on a timely pathway. With this submission made, we can now start the process of obtaining clearance to sell the PolyArmour technology in the UK and EU. That process should result in clearance in 2023.

This submission starts the final clock for launch of the PolyArmour product in the US. In preparation for that launch, our contract manufacturer will make the first production run of the product in July. This run will provide us with samples for the sales team, product for a post-clearance case series at several major institutions and provide product for initial sales.

Our professional sales organization, which we began recruiting in March, will launch PolyArmour in the US in 2022.

The next steps are critical to our commercial success, but I want to thank Sally Maher and Dr. Bajwa for their critical assistance with the data and the submission that significantly enhanced the quality of our document.

If you have any questions, please do not hesitate to contact me by email or phone at any time. I will have additional updates in my Q2 shareholder update in about 4 weeks.

All the best and thanks for your support.

Sincerely,

David W. Anderson, CEO

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