



## Next-Generation Bone Fracture Healing

More than half a million people a year end up with delayed or non-union bone fractures. These are fractures that haven't healed after 90 days of fixation. This end state is usually caused by poor vascularity, due to conditions like osteoporosis, diabetes, cardiovascular disease, or even just advanced age. In fact, 40% of Americans suffer from one of these conditions.

These patients are all headed towards expensive and risky surgeries, which everyone wants to avoid: patients, providers, and most of all, payors. If you end up with one of these delayed or non-union fractures, the chances are good that your orthopedist will prescribe the use of bone growth stimulation (BGS) device. This is a \$1.4 billion serviceable obtainable market, however all the products in this space are extremely lackluster. There has been no BGS technological advancement in more than 30 years. Some devices on the market have extremely low (60-70%) success rates. Some devices require up to 24 hours of usage per day, which patients hate. And no product on the market today provides any kind of feedback on usage or healing.

Until now. Sonogen has developed a new BGS device based on safe and effective Low-Intensity Pulsed Ultrasound (LIPUS) that disrupts the industry standard in several ways. It delivers a patent-pending signal that's extremely rich in acoustic shear wave content, which we've proven heals 30% faster than any current device. In addition, the device has sensors that allow the monitoring of device usage and bone healing, and includes all the telehealth technology necessary for remote patient monitoring.

Here's how it works. When an orthopedist determines that a patient's fracture isn't healing they prescribe the device. It's sent to the patient's home, and they use it for just 20 minutes per day. After treatment, they return the device to its charging cradle, we capture the treatment data off the device and send it to our HIPAA-secured cloud. We then make the analyzed data available to web and mobile applications.

Sonogen has assembled an extremely capable team of engineers and biophysicists, including Alan Winder, a world-renowned expert in the area of acoustics. He was on the original engineering team that brought the Exogen device to market in the early 1990s. This device was the world's first ultrasonic BGS device, and currently owns a third of the total BGS market in the United States. And while this device does stimulate blood flow and bone regeneration, it's decades old and hasn't changed significantly in all that time. Our device further maximizes patient compliance through usage and healing feedback, which is a meaningful market discriminator for all constituents. We've also assembled a world-class business and medical advisory board of key opinion leaders, representing several top-level medical institutions.

Sonogen has four worldwide PCT patents pending, as well as trade secrets that cover its fracture healing assessment algorithm. We have developed a working device prototype, and completed animal studies that demonstrate our system's superiority. We will commercialize first by showing substantial equivalence to the Exogen device, which avoids the need for clinical trials and also allows us to inherit Exogen's entire label. We will use a pharmaceutical sales model, bolstered with aggressive medical education and social media marketing, using pre-existing CPT codes. Upon market entry, we will begin conducting human clinical trials to collect data on fracture healing, to demonstrate superior healing effectiveness, and to test additional applications such as spinal fusion healing. Our goal is to ultimately expand our label to at least include all fresh fractures at risk, a \$3.6 billion serviceable addressable market.

Sonogen recently won a \$50k non-dilutive USDoD grant to support our device commercialization efforts. In parallel, we are working to close a \$1.2M seed raise to complete our device design, build and testing, and achieve FDA regulatory approval in 18 months. We have secured a lead investor, and negotiated terms (convertible note, \$5M cap, 20% discount, 8% interest rate). Sonogen also qualifies for the Maryland Biotechnology Incentive Tax Credit, which will return up to 50% of investments to qualified investors.

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