Sonogen

Contact Information:
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Total Raise:
- $2.0 million ($1.1M closed)

Lead Investor:
- Old Line Capital Partners
  www.oldlinecap.com

Timeline:
- FDA submission by 1Q25, approval by 3Q2025

TRL-5 Technology:
- Engineering prototype
- POC animal study
- Four patents pending

Development Partners:
- Industrial Design
  RPM Tech
- Transducer Design
  Blatek Industries
- Software Development
  Prolucid
- Regulatory Support
  Prime Path MedTech

Sonogen is a Qualified Maryland Biotech Company

Investors in this round receive a 33-50% rebate from the state of Maryland.

Summary

Sonogen Medical seeks firms looking to syndicate with our lead investor for a **$2.0 million** seed raise. These funds will allow us to complete an **18-month program** to commercialize an innovative bone growth stimulation device with built-in usage and healing monitoring, based on proven patent-pending technology with validated freedom to operate.

Problem

Roughly 8% of the seven (7) million extremity bone breaks per year in the United States (560,000 patients) fail to heal on their own, usually due to vascular insufficiency. The medical devices available in the **bone growth stimulation space** are antiquated, unreliable, hard to use, and provide no feedback on the fracture healing process. This costs patients **$1 billion per year** in lost wages, and payors **$12 billion per year** in unnecessary surgeries.

Solution

Sonogen's device delivers an ultrasonic shear wave signal that has been proven in IEEE peer-reviewed animal trials to **heal 30% faster** than the current standard of care in this space (Bioventus EXOGEN), which a member of our scientific team helped design. Our device is also specifically designed to maximize patient compliance through **fracture healing monitoring and usage feedback**, and is fully mobile app and telehealth enabled.

Market Size

The total addressable market (TAM) for fresh fractures is **$21 billion per year** in the USA alone, and $525 billion worldwide. The service obtainable market (SOM) for delayed and nonunion fractures is **$1.7 billion per year** in the USA, growing at a CAGR of 5.5%. Sonogen has a clear path to market leadership.

Regulatory Pathway

We will initially pursue a validated **device equivalence** pathway using the EXOGEN device as a predicate. We will pursue human clinical trials after FDA submission. Note that our device leverages existing US CPT reimbursement codes for diagnostics, therapeutics, and telehealth medicine.

Intellectual Property

We have submitted a comprehensive set of four worldwide **PCT patent applications**, and completed the national filings in five key regions (US,EU,BR,IS,JP). We intend to keep our Fracture Healing Assessment algorithm proprietary, as a **trade secret**.