Disruptive technology for Bone and Soft Tissue healing analysis

Industry: *Primary:* Medical, Hospitals, Insurance Companies, Patients. *Secondary:* Research, Veterinarian, Dentistry, Training and Rehabilitation.

Problem: MSKI is the US's most significant proportion of healthcare expenditure, and X-rays account for over USD 100B annually of that expense. This procedure is qualitative by nature and has been shown to increase costs by over USD 16B because of diagnostic errors, leading to increased complications, expenditures, and permanent injury. Furthermore, X-rays expose the Patient to harmful radiation. Fractures occur more than once every second in the US (~22M a year), and each, on average, has four X-ray sessions with multiple (5-6) X-rays in each, and 12% of these require re-hospitalization due to misdiagnosis.

Solution: We use a wearable patch with embedded acoustic sensors and FDA-approved ultrasonic signals placed on the skin above a fracture site. This patch remotely sends acoustic data to our server, using AI/ML to provide the clinician with quantifiable/actionable data regarding the Patient's fracture healing. Our wearable sensor patch replaces multiple physician office visits that include multiple X-rays per visit. Orthoforge's solution continuously monitors and provides quantitative information on healing progress through telehealth, resulting in better outcomes, less radiation, significantly reduced costs, removing the primary cause of human error, and reducing the payer's liability. Future generations of the product will include the ability to aid the healing process, similar to current bone simulation devices.

Business Model: Our business model includes hardware, software, licensing and data sales. We sell the hardware through strategic partners and distributors with a 75% margin. The software will be sold directly to Patients, Payers, and Providers with a least 95% margin and licensed to other sectors like veterinary medicine and dentistry. The normalized data would be sold to payers/insurers, the Department of Defence, NSF/NRC, FDA/HC/NIH and Medical Corporations. Finally, we are planning to license our technology to secondary industries.

Market: Patients, payers, and providers are the targeted markets. A market survey (American Association of Orthopaedic Surgeons) was conducted, showing a 98% need for the technology. We will also develop or license the technology to other markets, such as veterinary medicine, dentistry, sports medicine, and research projects. The primary market is the US; however, there is interest worldwide.

Competitive Advantage: Currently, there is no other product in this marketplace. This technology will break the dependence on X-rays as the only solution for a fracture. It will also remove human error in X-ray interpretation while providing real-time data on the healing process. Orthoforge is the sole owner of patents in the US and EU, with continuations in process. The initial savings estimates for payers range from USD 8,000 (80%) to USD 9,000 (90%) per fracture, totalling USD 176B to USD 191B annually. It provides quantitative 3D information on the healing process rather than qualitative 2D X-rays, allowing doctors/clinicians to catch complications before they become more significant problems.

Team: Our team comprises public and private individuals with a proven track record of growing businesses and successful exits. Robust engineering, regulatory, and commercialization expertise with experience developing medical devices, receiving FDA approval, and launching in the marketplace. The team has worked on engineering and software development projects with NASA; The US and Canadian Military; US, Canadian, and International Governments at all levels; UN, NAFTA, and Olympic Secretariats; Fortune 50 Companies and pharmaceutical companies.

Regulatory Path: Our product has already undergone animal trials While we do not need FDA approval to use our solution, we have submitted to the FDA and have meeting April 20th.

Key Milestone: In 2024, the second-generation device and enhanced AI/ML Software will be completed, and sales will begin. In 2025, the development of the third generation of the patch will begin, which will include healing support.

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Driving Growth: The Advantages and Uptake of Industry Adoption

Benefits: Three main groups will benefit from our solution, and each will drive the adoption in their own way. The details of the benefits are shown below.

Patients	Payee Insurance Co.	Medical Professional
- Fewer office visits (~8 hours timesaving) - Less radiation, replacing X-rays with harmless sonar - The ability to monitor and view progress - Substantially less cost (if Patient pays - US payee) - Better medical outcomes	- Substantially less cost - More diagnostic certainty (further reducing costs) - The ability to aggregate data to see trends - The flexibility to use with any body type (Thin to Large) - Better medical outcomes	- Improved time efficiency and increased number of Patients - The ability to remotely monitor and view progress - The ability to catch issues/complications and quickly adjust the current care - Increased diagnostic certainty (quantitative 3D vs qualitative 2D X-rays-) - Telehealth billing - Can identify both edges of the fracture to about 0.1mm. - Better medical outcomes

Adoption: An anonymous American Association of Orthopedic Surgeons (AAOS) survey was conducted to identify potential customers/users' interest in this technology. At least 95% of respondents favoured remote monitoring, quantifying bone and soft tissues, and reducing radiation. Healthcare systems driven by private payers typically push products to clinicians who run their respective practices. In this case, the payers would significantly reduce their X-ray costs. At the same time, clinicians would have the ability to add revenue streams through remote monitoring and to increase clinical efficiencies. In the markets with national health programs, the main pressures are to reduce waitlists and to serve more Patients. While this solution is an adjunct to the initial X-ray, the plan is to replace all X-rays, becoming a standalone solution and creating a new standard of care.

Providers / Doctors	Payers / Government
- Have confidence in the value of this solution (Market Survey of the American Association of Orthopaedic Surgeons [AAOS]) 98% want a device that quantifies fracture healing progress, which would be valuable 95% want a device that quantifies soft tissue injury, which would be valuable - Catch issues/complications sooner - Improve Patient outcomes - Use a quantitative 3D healing process - Have more touchpoints with the Patient - Generate income through remote diagnostics - See more Patients	- Support Value-Based Medicine - Reduce a significant expenditure (Xray) - Realize $9.00 in savings per $1.00 spent - Support FAA / Health Canada's mandates for the reduction of harmful radiation - Use accepted technologies (Ultrasound and AI) - Reduce harmful effects - Reduce the opportunity for human error - Use existing Telehealth/Orthopaedic CPT Codes 93294, 93288 98975, 98980, 98977, 98981

Pre-FDA Approval: The solution is fit for human use, part of a bundled solution, and for use in physical therapy, sports medicine/training, veterinary clinics, or private clinics in the US and abroad.

Comparing Current Standards and Product Features: Bridging the Gap

Difference from Current Standard: Our solution provides quantifiable data instead of qualitative interpreted X-rays. This will revolutionize fracture healing by reducing the potential for human error, increasing health efficiencies, and providing a 3D result utilizing ultrasound acoustic waves. Unlike the 2D X-ray, the ultrasound wave "wraps" around and through the tissue and bone, giving the algorithm the needed data to provide the clinician with a 360-degree injury analysis. Where an X-ray (or multiple X-rays) provides an image of one singular cross-section, the data will provide the clinician with the necessary 360-degree information on the completeness of bone healing. Asymmetrical healing will no longer be a challenge for clinical professionals to assess and ultimately will allow the Patient to be confident that their bone is fully healed.

Core features:

- Customized wearable sensor patch for real-time monitoring
- Diagnosis-assisting software for accurate and efficient diagnosis
- Constant on-demand telemetry for remote monitoring and intervention
- An adjunct to the current standard of care, enhancing Patient outcomes

- 3D data for precise fracture analysis
- AI interpretation for continuous monitoring and early intervention
- Quick notification of possible complications.
- Seamless integration with existing processes and X-ray technology
- Patient and Clinician dashboard for monitoring healing progress and personalized Patient care

Additional features and functionality: Our platform solution provides an opportunity to add sensors to enable enhanced features. Compartmentalization is a concern with casts, which, due to swelling, may limit blood flow and oxygenation to the trauma site. This medical functionality can be complemented by other user interface features enabled by additional sensors. An accelerometer/gyrometer pair can be used to ensure Patient compliance, enhance the accuracy of the measurements, and provide feedback to the Patient. A temperature sensor can be used to identify infections reflected in high local temperatures.

Pressure Sensor: Able to track pressure inside the cast and alert of possible complications
Temperature Sensor: Able to track current heat around the fracture and alert of possible complications
Blood Oxygen Sensor: Able to track blood saturation levels and pulse and alert of any anomalies
Accelerometer/Gyrometer: Able to detect motion and orientation during measurements, enhancing precision

Detect mal-union and non-union: This is a key benefit of the solution, as healing complications can be identified quickly. Using this solution, you will get three data points to identify trends faster (in two weeks or less) than the current standard of care, which takes three months to identify a mal-union or non-union. This solution can identify and address a trend before it worsens.

Detect soft tissue damage: We have results demonstrating the progression of healing from hematoma to soft callus, hard callus, and hard bone. Our model and algorithms can identify each stage of healing from soft tissue to hard bone. This solution can potentially expand beyond bone fracture to other physical traumas (i.e., bone-to-muscle, bone-to-ligament, tendon, etc.). With adequate funding, we will start research to advance this expansion.

From Past to Future: Investment History, Capital Demands, and Compelling Reasons

Investments to date: USD 2M has been invested in developing the comprehensive hardware (electronics, mechanicals, transducers) and software (embedded through ML/AI). Below is a chart of the core developments.

- The hardware and software have gone through pre-clinical animal trials.
- Patents have been awarded in the US and EU.
- There are hardware and software development plans for the next phase, and strategic vendors have been selected.
- FDA pre-submission has been done and meeting booked

- The Human trial plan (if required) and partner selection (Henry Ford Health System) have been completed.
- Research grants have been submitted
- Research partnerships have been established
- Hardware partnerships have been formalized
- Graduate of the Johnson & Johnson Incubator

Capital requirements: The proposed investment will support the completion of the human trial, the FDA Submission and operations until cash flow is positive. We are also working on capital from other sources such as Research Grants ($10M+) and non-FDA-required sales (Licensing [Vet, Farm, Dentistry, Other Sectors], Partnerships [Studies], Companion Diagnostics, Sports Medicine/Training Efficiency).

Why now: The company's valuation is very favourable for investment now. The company has received interest from prominent players in the orthopaedic medical space who are looking for at least ten Patients to show efficacy. After we have achieved this, we will continue to dialogue with these companies, potentially leading to partnership or acquisition. There is minimal risk with the human trials as the make-up of a bone is the same between the test animals and humans. On completion of the Human Data, there is a possible exit via a purchase; we have identified several potential buyers and started a dialogue with them. It is anticipated that over the next two years, we will have made significant progress that will drive market interest, and the company should be cashflow positive by the end of 2024. On the first day of trading, we will have a market capitalization of CAD 16M, and based on comparables that are public and private with FDA approval, we could have a market capitalization of around CAD 160M. The full warrant as part of the QT Raise provides additional upside with no risk.

Growth: While the solution is initially focused on Long Bone fractures, our road map has expanded into Spine surgeries, other sectors such as Dentistry and Veterinarian and Companion diagnosis such as Medical Implantables. With Dentistry, the AI could be trained to identify cracks in teeth or changes from a baseline X-ray that require further investigation.
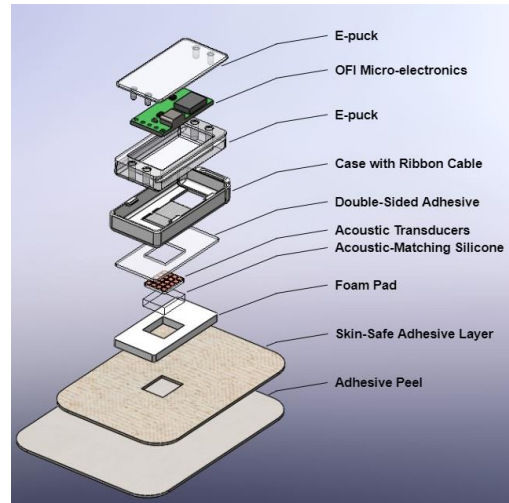
Strategic Vision: Navigating Market Opportunities, Revenue Models, and Projections

Market Opportunity: Fractures occur more than once every second in the US (~22M a year) at an average cost of CAD 10k per fracture, making the Total Addressable Market (TAM) CAD 220B. Initially, we are focusing on fractures involving long bones because of occurrence of this injury and easier penetration from utilizing clinical fixation. Based on this and our current business model, this would make our Serviceable Available Market (SAM) CAD 11B and our Serviceable Obtainable Market (SOM) CAD 1.7B. We have seen interest from Canada, the UK, the EU, and LATAM would expand this market opportunity.

Market Strategy: The Hardware will be sold through Strategic Partners such as Globus, NuVasive, Bioventus, DePuy Synthes, etc. These companies already have the sales and market infrastructure to sell to clinics and hospital systems. We will leverage their infrastructure and distribution channels; in return, they can mark-up and/or white-label our solution. The software will be sold directly to the providers and Patients via hardware activation.   As we build our database of normalized data, we would approach payers/insurers, the Department of Defence, NSF/NRC, FDA/HC/NIH, and Medical Corporations who find this information valuable.

Revenue Model: Hardware COGS is CAD 30; we would sell this to the Strategic Partners for CAD 125. The Strategic Partners would sell it to the end user with an MSRP of CAD 250. Our margin on the original sale is just over 75%, and the Strategic Partners' margin would be 100%. The software app would be sold to the Clinician for CAD 25 per month per Patient, with an average Patient on the system for three months. While optional, the Patient can also purchase the software app and view their health voyage for CAD 10 per month. Based on 100,000 Patients, the margins on the software would be over 95%. The revenue model around selling the normalized data is still to be worked out.

Revenue Projections: We project revenue of CAD 505M from our initial penetration based on key opinion leaders and their subsequent health systems. This is very conservative and does not consider the additional revenue streams listed below. We will be cashflow positive in 2024 and have an estimated net income of CAD 350M in 2028. A breakdown per year is shown in the chart below, along with our assumptions.
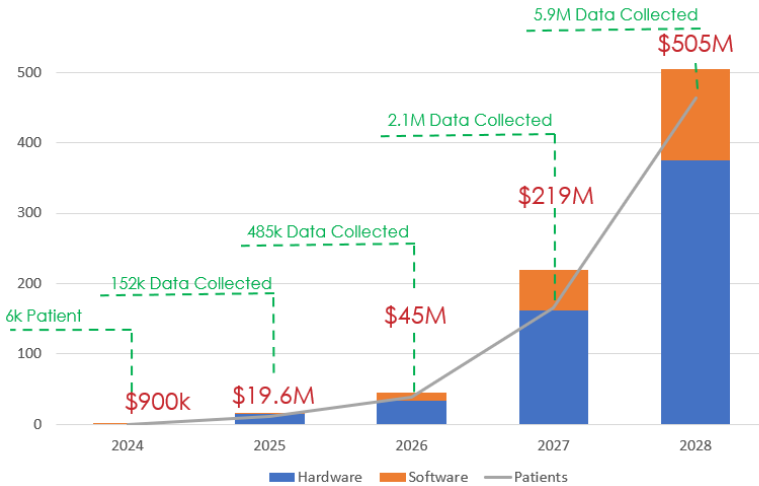
Investing Opportunity: We are offering 20M units at CAD 0.16 for a total of 3.2M, consisting of one common share and two warrants. One warrant is convertible to a ½ common share at $0.30, and the other warrant ½ common share at $0.60, which expire after three years. This opportunity is eligible for RRSP, RESP and TFSA accounts. For more information and to book a complete presentation, don't hesitate to contact us at paul@npn.ca.

We are also offering a debt/convert

- Minimum investment per person: $50k
- Interest: 12% per annum, paid annually
- Term: 3 years
- Convert: any outstanding balance plus accrued unpaid interest plus 10% into equity at $0.25/share or the previous close, whichever is higher