Team Name: Nanochon

Novel 3D Printed Joint Repair Scaffolds

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Team Name; Our team, **Nanochon,** is founded around a multi-disciplinary approach to tissue regeneration for joint recovery. We want to emphasize that the majority of the information in this executive summary is the product of market research, mentor guidance and networking achieved by participation in and successful completion of the NSF's I-corps entrepreneurial program. **Technology;** Our Product is a 3D patient specific regenerative device for joint repair, designed to re-grow both bone and cartilage inside a patient's body. The product consists of a 3D printed microstructure which is designed to promote both bone and cartilage growth simultaneously, and have greatly improved mechanical strength, specifically at the bone and cartilage interface (see figure).

Our product would offer a permanent solution to joint repair, whereas our competitors can only offer a prolonged period of restoration before the implant will fail or degrade, and need to be replaced again (for joint implants). From a biological standpoint, our unique nanomaterials and 3D printed design insure better control and localized development of a patient's own stem cells into mature tissue, as well as facilitating the device's eventual dissolve into the body. This will drastically limit complications which require costly corrective procedures and cause patients prolonged pain, discomfort, and loss of mobility.

Market; Total addressable market **(**TAM) estimate is currently $25 billion (internationally), based on a comprehensive report by the Integrated Healthcare Association (IHA). These IHA figures for the TAM are based on the annual value of all orthopedic implants. More realistically, our serviceable available market (SAM) and target market (TM) are estimated at $13 billion and $4 billion (international) respectively.

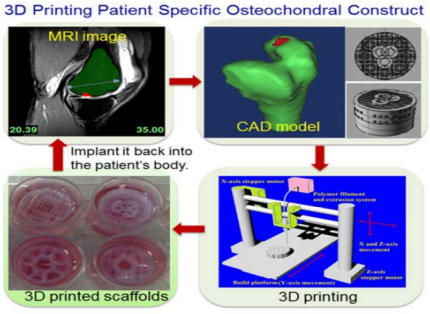
In this case, our customer ecosystem is slightly complicated. Our end users would be surgeons, but our actual customers would either be patients with various joint damages/diseases, health care providers or group purchasing organizations that supply hospitals, clinics, etc.

We would likely pursue a strategic partnership with a larger orthopedic company, when the time is right. Initially, we would rely on a website and try to advertise at trade shows and conferences (a model used successfully by other entrepreneurs in the tissue engineering space). We would heavily rely on a product sales revenue model. We would consider a licensing arrangement if it was beneficial and lucrative enough.

Commercialization Strategy; For focal defects, we are up against some products from large companies (such as Zimmer's Chondrofix product, or Arthrex's OATS), but these products are currently allograft based (cadaver tissue). There are some small startup operations, such as Cartiva, who make chondral and osteochondral devices out of biomaterials and synthetic polymeric materials are similar to our product but much more rudimentary, and do not claim to re-grow tissue. Rather, they are intended to be semi-permanent replacements for tissue loss alone. Our product also competes with injectable biologics, living cell treatments and polymer gels intended to cure and provide tissue infill. These products are widely used, but have highly variable results. In a broader sense, we are also competing against large orthopedic companies who make total joint replacements, since the types of injury we intend to repair with our products can lead to the need for a total joint reconstruction, if left untreated.

Customers (orthopedic surgeons and healthcare providers) we communicated with are very enthusiastic about this product. There are some barriers from regulatory agents (FDA, class III device and few or no predicate devices), high capital requirements to do regulatory validation and initial testing / product development, and potential technical difficulties in producing a complex synergistic product. Still, there have been successful startup ventures in innovative orthopedic products, and strategies to work around these hurdles (initially relying on grants (SBIR) and other non-diluted funding, pursuing European and international regulatory approval and conducting international sales, etc.)

The progression of funding (5 to 10 years) follows as 1) Seed funding and personal network (friends and family) funding ($100,000) 2) SBIR or non-diluted funding OR angel investment ($150,000 for phase I) 3) venture capital ($1 to $5 million) OR SBIR phase II ($1.5 million) OR large grant pursued with a partner organization or company (NIH, DOD or NSF grants, $2 to $5 million). These costs would eventually be followed by generation of product revenue, and eventual licensure or sale of the company / assets.



Figure; Flow chart of technology clinical use.