Enhanced Mechanical and Cytocompatibility Properties of Novel 3D Printed Osteochondral Scaffolds

SEAS R&D Showcase; Entrepreneurial Prize Executive Summary

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.

o What is your product or service?

Our Product is a 3D patient specific regenerative device for joint repair, designed to regrow both bone and cartilage inside a patient’s body.

o What is your estimate of the total available market annually, and how did you calculate it?

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 SAM and TM are estimated at $13 billion and $4 billion (international) respectively.

o Who would your customers be?

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.

o How will you find and sell to them?

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).

o What is your revenue model?

We would heavily rely on a product sales revenue model. We would consider a licensing arrangement if it was beneficial and lucrative enough.

o What are the incumbent competing products or services?

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 autograft based (cadaver tissue). There are some small start up 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.

Why would customers buy your product or service over incumbent offerings?

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.

What are the potential barriers to success?

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 start up 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.)

How much money do you need and how will you get it?

The progression of funding (5 to 10 yrs) 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 R01 or NSF grant, $2 to $5 million).

These costs would eventually be followed by generation of product revenue, and eventual licensure or sale of the company / assets.