**SFB 2021 Business Plan Competition-CellField Technologies LLC**

Ram Saraswat, Scott Wood.
South Dakota School of Mines).

**Team Name:** Our team name is CellField Technologies with team members, Dr. Scott Wood, professor with the Nanoscience and Nanoengineering department at South Dakota School of Mines and Technology, and his doctoral student Ram Saraswat. CellField Technologies was incorporated in March 2020 by Dr. Wood as a South Dakota LLC.

**Technology:** CellField Technologies LLC is working to develop and commercialize a novel modular cell culture platform for preclinical testing of bio/pharmaceutical treatments of joint diseases such as osteoarthritis (OA). No disease-modifying OA drugs (DMOADs) have ever been approved by the FDA for the treatment of OA. This is, in large part, because many aspects of OA pathogenesis remain poorly understood due to the inability of previous pre-clinical models to properly mimic the various intricacies of human OA pathogenesis. Synovial joints are complex multi-tissue organs, and thus, recent approaches study of the joint as an organ have emerged to examine OA pathogenesis within the context of the paracrine interactions between the various cell types of the joint.

We are developing a technology enables that paracrine signaling between discrete cultures of cells from various tissues of the joint and uses topographical cues rather than growth factors to regulate and maintain physiological phenotypes of those cells, thus minimizing off-target effects. We recently validated the industry need for such a system by interviewing pharmaceutical scientists and executives involved in the development and testing of DMOADs as part of our NSF I-Corps participation in Summer 2020. During our I-Corps interviews, we repeatedly heard our potential customers express intense desire for the availability of a "joint on a chip" that could be used to test drug efficacy while simultaneously i) enabling paracrine crosstalk between cells in different articular joint tissues, ii) replicating the structure of human articular cartilage, iii) decreasing experimental variability, and iv) enabling the modeling of multiple OA pathogenesis pathways. While we recognize that we are not the first to design a joint on a chip, we believe our unique approach will enable us to be the first to market in commercializing such a technology and will enable us to meet each of market needs described above.

**Market:** Based on our recent NSF I-Corps interviews with over 120 scientists from the pharmaceutical industry, we learned that pharmaceutical companies contract the vast majority of their preclinical research needs out to contract research organizations (CROs). Thus, we plan to operate as a CRO, providing research services for a fee to bio/pharmaceutical companies needing early *in vitro* preclinical data for investigational drugs to treat joint arthropathies such as OA. We will initially service a small segment of the growing Global Healthcare CRO market, projected at $62.1B by 2027, with 6.6% CAGR. We expect our serviceable obtainable market (SOM) to be the overlap between the *in vitro* and arthropathy (i.e., joint disease) segments of the preclinical CRO market (valued at $4.1B in 2020 with 8.3% CAGR). Our initial primary customer segment will be scientists trying to develop DMOADs. We expect to develop secondary customer segments focused on other joint diseases or non-pharmaceutical OA treatments as we grow. Our I-Corps efforts also brought us to the realization that we will be dealing with a re-segmented market scenario. This is because the global OA therapeutics market ($6.1B, 8.1% CAGR in 2019) is currently comprised primarily of analgesics and dietary supplements that do little-to-nothing to slow or reverse OA. By contrast, the global joint replacement market, currently serviced by medical device companies and orthopedic surgical hospitals, is much larger ($19B, 5.1 CAGR in 2018). We believe that our preclinical contract research services will enable our customers, the bio/pharmaceutical companies, to develop the first-ever DMOADs, thus leading to restructuring and explosive growth of the OA therapeutics market at the expense of the joint replacement market.

**Commercialization Strategy:** Our long-term commercialization strategy is to address four key barriers to the development of DMOADs in order to deliver data of the highest possible quality and reproducibility. This begins with producing an easy-to-use, modular joint-on-a-chip system that can be used to model the joint as an organ while facilitating the use of a wide variety of analytical techniques. By modeling our system on human anatomy and utilizing it with human cells, we expect to be able to replicate the onset and development of OA in humans more accurately than small animal models. We are currently investigating the ability of our *in vitro* cartilage model technology to facilitate re-differentiation of primary human articular chondrocytes which have lost their phenotype due to expansion. Success here will enable us to develop a biobank of cells from many human donors belonging to a wide variety of healthy and at-risk groups which we can use to replicate the clinical variability present within the population in a repeatable and predictable manner. We expect this 'repeatable variability' to increase the value of our modular joint-on-a-chip system for early phase *in vitro* contract research services.

We are currently working to optimize the design of the 3D printed components of our joint on a chip prototype. We next plan to de-risk our technology by validating that we can co-culture cells from the bone, cartilage, and synovium for up to 30 days while maintaining the viability, physiological morphology, and expression of key phenotypic markers for each. The research data obtained through using our Joint on Chip prototype will be sold for a fee. Once the technical workflow of the "Joint on Chip" prototype has been established, then a detailed budget sheet calculation will be pursued to optimize the profits.