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Project Title: Ohio Orthopaedic Commercialization Center

Estimated State Funds to be Requested: \$25M

Ohio Orthopaedic Commercialization Center

Introduction: The Ohio Orthopaedic Commercialization Center (OOC) coalesces all the elements of orthopaedic product commercialization, creating in Ohio a unique ecosystem to bring orthopaedic products to the market. The foundation of the OOC is Cleveland Clinic's orthopaedic expertise in clinical patient care, IP creation, product development, preclinical and clinical testing, regulatory clearances, and Market Entry. With Cleveland Clinic as the foundation, combined with our collaborators, affiliates, investors and other partner groups, we will create the most comprehensive orthopaedic product environment in the **world**.

1. Stature and Resources:

The OOC includes world class resources to achieve the successful commercialization of orthopaedic products; combined, there is no other collection of resources, facilities, and expertise that is equal to OOC. Starting with the foundation of Cleveland Clinic:

- Clinical Care: Cleveland Clinic ranked #3 in USA in orthopaedic patient care.
- Healthcare commercialization: CC Innovations ranked in the top 5 in healthcare corporate venturing, and highest ranked hospital system in USA.
- Track record of commercialization:
 - o More than 200 orthopaedic products developed by Cleveland Clinic staff.
 - o Cleveland Clinic orthopaedic product licenses are returning >\$4M/year in license revenue to Ohio.
 - o Cleveland Clinic orthopaedic spin-offs have raised more than \$40M of investment into Ohio.
- Cleveland Clinic has world class R&D facilities leading to industry leading results:
 - o More than 150 peer reviewed orthopaedic publications each year.
 - o More than \$12M in sponsored R&D projects.

The current leading international location for orthopaedic products is Warsaw, IN, with 7000 direct jobs and \$11.3B revenue from orthopaedic products. Compared to Warsaw, the OOC has stronger manufacturing and engineering assets, and possesses features Warsaw is missing, such as:

- Sources of IP,
 - o Cleveland Clinic,
 - o Cleveland Clinic Alliance partners (Medstar, Notre Dame, etc.) and other partners,
- Clinical expertise,

- Preclinical and animal product development facilities.

With the impetus of a significant investment by the State of Ohio through the Technology Commercialization Center program, the OCCC will be able to secure major investments from academia, industry, and the clinical community to establish Ohio as the new world leader in orthopaedic product commercialization.

2. Scale and Opportunity:

Most of the elements of the OCCC already exist in Ohio; the OCCC will bind together these elements into a comprehensive commercialization environment.

A key element of the OCCC is that, of the \$43B orthopaedic implant market, it is estimated that more than 85% are products that are designated by the FDA as Class 1 or Class 2. These types of products do not require clinical studies to achieve FDA clearance, and as a result can transition from conception to Market Entry in a relatively short amount of time; 12-24 months is a typical product development cycle in the orthopaedic industry. Considering the State's stated desire that a successful TCC should achieve Market Entry in 2, 4, or 6 years, the natural time cycle of orthopaedic products allows multiple product cycles within the State's time horizon.

Another key element of the OCCC is that we are specifically building our commercialization strategy around collaborators that are long-standing, Ohio-based companies providing a solid foundation for retaining and growing jobs and wealth in Ohio. By contrast, New Companies based on IP can be relatively ethereal, and can easily be moved out of the State. As an example of the approach that will be employed by the OCCC, one of our collaborators is PCC Airfoils, one of the leading manufacturers of super-alloy investment castings. PCC's business is currently dominated by supplying to the aerospace industry, but like many Ohio manufacturing companies, they desire to expand their business into healthcare markets. PCC is an example of why Ohio is a good fit for orthopaedic products; because most hip and knee implants (US product sales of over \$12B/year) are produced by the exact same investment casting process that PCC uses to produce gas turbine airfoils. In fact, one of the largest orthopaedic product companies in the world, Stryker Orthopaedics, traces its history to one of PCC's main competitors, Howmet (through a spin-off Howmedica). PCC will be fundamental to the new company the OCCC will create to produce orthopaedic implants; the facilities and expertise that PCC will deploy to this project are rooted in Ohio.

Collaborators that are participating in the OCCC are:

- CCF Alliance partners:
 - o Notre Dame
 - o Medstar
 - o Long Island North Shore Jewish
 - o Others
- PCC Airfoils
- Bonutti Technologies

- NineSigma
- Private capital investors (specific names withheld for confidentiality)

3. Business Driven/Market Focus:

Cleveland Clinic continues to manage the previously funded OTF Mega-Center, the Global Cardiovascular Innovation Center (GCIC), and as a result is intimate with the detailed workings of that successful technology accelerator. Similar to the GCIC, the OOC will have a Commercial Advisory Board (CAB) and a Board of Directors (BOD). The CAB will be comprised of orthopaedic surgeons, orthopaedic industry leaders, and investors experienced in the orthopaedic market. Similar to the GCIC's CAB, the OOC will review product development projects and provide recommendations about project funding. In addition, the CAB will also be utilized to guide the overall scope of the OOC through specific activities to identify the most compelling market needs; the ones most promising to lead to new product opportunities and opportunities likely to lead to successful Ohio based companies. Similar to the BOD of the GCIC, the OOC BOD will oversee and guide the individual OOC elements.

The OOC will have an Executive Director, whose primary responsibility will be to execute the OOC's Mission: "to create the most comprehensive orthopaedic product commercialization environment in the world, with every investment of resources leading to sustainability". This Mission will be achieved through financial returns derived from successful commercialization projects and from future investments. This focus on sustainability from its genesis will require that the OOC stays responsive to market conditions.

The staff of the OOC will be comprised of orthopaedic experienced product development resources, who will guide projects and ensure that commercialization outcomes are achieved.

4. Service and Technology Acceleration Orientation:

Cleveland Clinic has already put in place a "mini" version of the OOC, which has delivered early positive results. In the middle of 2012 Cleveland Clinic formed its Center for Musculoskeletal Innovations (CMI), which is comprised of orthopaedic surgeons, product development, and business development experts. The CMI meets quarterly to review product development projects, to provide clinical and market direction to those projects. The CMI has hired an orthopaedic industry experienced product development engineer, using funds reinvested from previous orthopaedic commercialization projects. Since the formation of the CMI, the number of invention disclosures from the Orthopaedic Institute at Cleveland Clinic has increased by more than 35%, and the quality of the inventions is also improving. The CMI is validating that orthopaedic product development can lead to a sustainable commercialization environment. The TCC funds being requested to form the OOC will accelerate and expand this model to a sustainable critical mass, and to a level that can compete on a global scale.

Extending the lessons learned from the CMI and GCIC, the OOC will function:

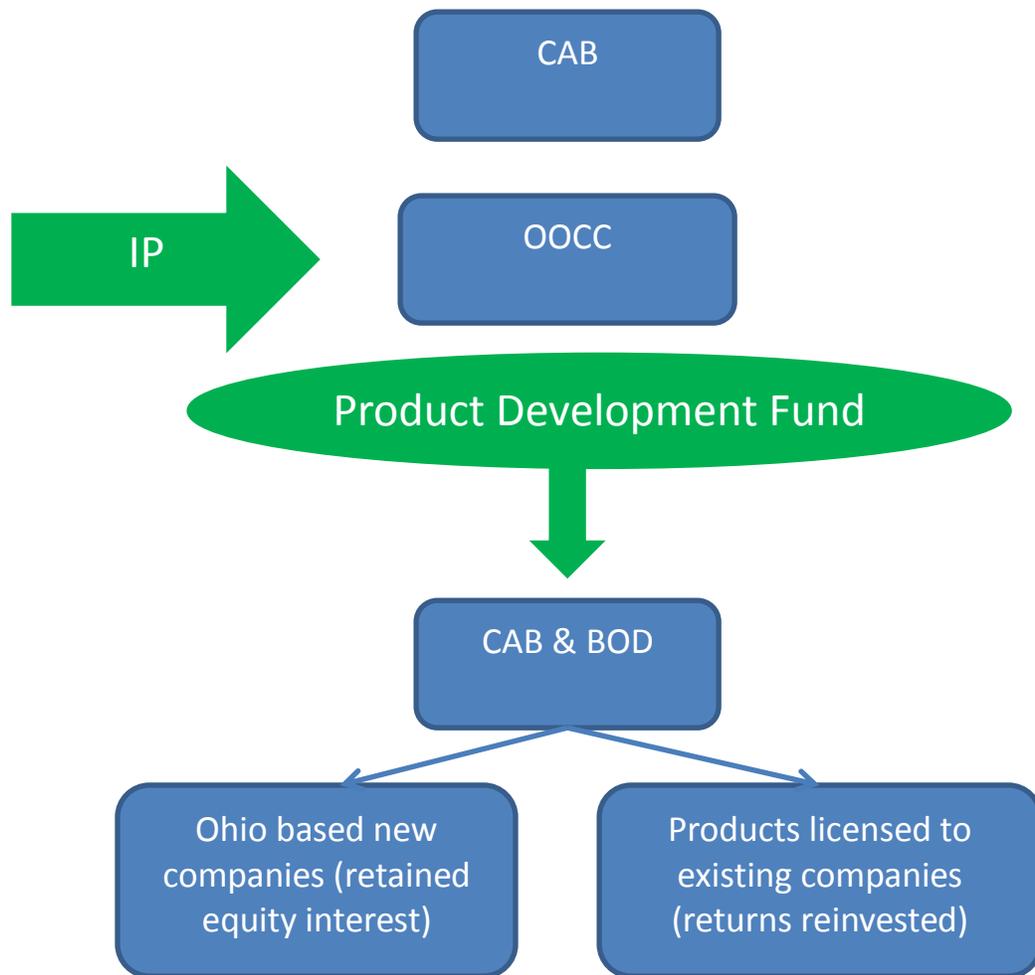
- CAB: Identify commercially promising market needs, ensuring a "market pull" approach.
- OOC: Acquire and develop IP related to the identified market needs; sources of IP are:

- Existing IP (sum of IP from Cleveland Clinic, Alliance partners, Collaborators)
- Structured invention – innovation group meetings convened around specific market needs. Cleveland Clinic’s recipe for Structured Invention is to bring together clinicians, engineers, patent attorneys, and business development experts to innovate around a specific market need.
- Open Innovation – The Open Innovation Intermediary, NineSigma, is a global open innovation leader. As a collaborator, NineSigma will proactively identify know-how and technology that aligns with the identified market needs through access to its global innovation network.
- OOC deploys TCC and matching funds to develop projects, to be ready for Market Entry.
- CAB & BOD: Direct projects to enter the market through either Ohio based new companies or licenses to existing companies. In either case, proceeds from these commercialization exits will be returned and reinvested to sustain and grow the OOC.

Based on current market assessments the OOC will start with the following list of targeted market needs, but this list will be adjusted by the CAB to remain current with market shifts:

- Adult reconstruction (more than \$13B of sales in 2012)
 - Implants
 - Instruments
- Extremities (\$1.3B sales in 2102)
- Spine (more than \$7B sales in 2012)
- Arthroscopy/Soft Tissue (more than \$4B sales in 2012, fastest growing segment at 8% YoY)
- Lower cost (generic) products (the healthcare industry is broadly feeling pressure to reduce costs; like the drug industry we will deliver low cost, high value products to the market)
- Custom products (advancements in imaging, computing, robotic, and manufacturing technologies are enabling patient specific products to enter the market – the challenge is to deliver patient specific solutions at low costs)
 - Implants
 - Instruments
 - Surgical plans/images
- Bone/tissue preserving products (as outcomes improve and life expectancies continue to grow, the need for products that preserve patient tissue become more important)
- Advanced technologies (MEMS, sensors, robotic, imaging; these technologies are coming into orthopaedics and are strengths for Ohio).

All of these market segments are dominated by products that can be commercialized in short timelines.



5. Validation and Sustainability:

As stated previously, the Mission of the OOCC is to become sustainable, with the Executive Director, BOD, and project management team focused on achieving this result. CCF has shown initial viability of the sustainable orthopaedic product development model through its CMI, which is already self-funding limited orthopaedic product development resources.

A key element of achieving sustainability is for the State funds deployed through the OOCC to be converted into “equity” that will generate returns and that will be re-invested in future OOCC projects. Creating new companies will be the most desired commercialization outlet for OOCC projects, because they have the double benefit of Ohio job creation and financial returns. However, even when the commercialization outlet requires licensing to an existing company, the OOCC will still “win” because proceeds from the license will be re-invested in the OOCC, leading to an expanding product development support structure. We expect to be able to complete multiple product development-launch cycles within the 4 year Term of the TCC.

The OCCC is responsive to the growing desire from Ohio's industrial base to grow in the Healthcare market. The OCCC will provide Ohio industrial companies the opportunity to participate directly in the healthcare market. These companies will anchor ortho new companies in Ohio.

6. Economic Impacts:

The OCCC is responsive to the State's desire for "short-, medium-, and long-term outcomes at intervals of 2, 4, and 6 years" because such a large amount of orthopaedic products are commercialized in short timelines. The OCCC will create high value jobs in multiple categories:

- New companies created in Ohio,
- Companies attracted to Ohio,
- Product development staff,
- Support for pre-clinical and clinical testing.