

## SCIENTIFIC DETAILS

### Objective

Complete the development and commercialization of a Robotic Surgical Assist Arm (RSAA) for use in orthopaedic surgical procedures based on intellectual property previously disclosed to UCLA.

### The Clinical Need

In orthopaedic surgery, common types of procedures include fixation of bone and soft tissues as well as reconstruction of degenerated or damaged bone and soft-tissues. Currently, surgical manipulation of these bones and soft tissues is accomplished with the application of manual force either directly on tissue or through devices that transmit forces to the tissue including pins, screws, bolts, straps, and clamps.



### The Solution

I have identified a novel potential application of robot-assisted surgery for orthopaedic fracture management. Specifically, I have developed a Robotic Surgical Assist Arm (RSAA) for fracture reduction that is simple to operate, inexpensive, and overcomes the difficulty surgeons face in precisely positioning unstable bone fragments during surgery.

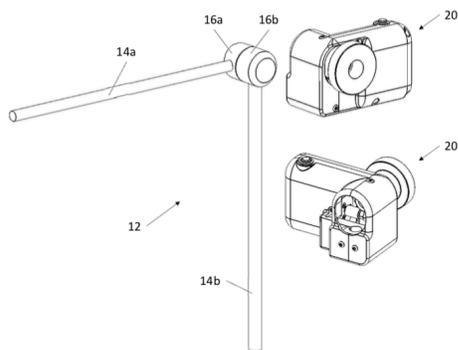
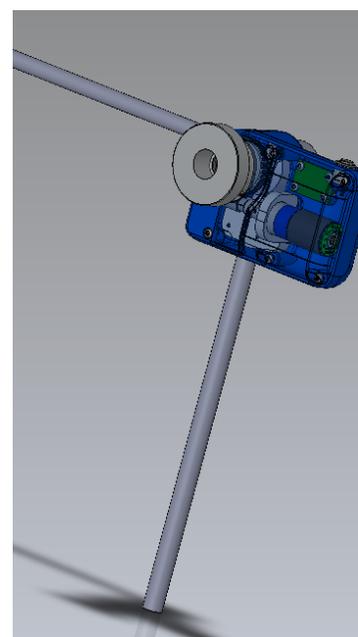


Figure 1



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## UCLA INNOVATION FUND PROPOSAL

### The Market

The mechanical arm market estimated size is 9,000 hospital customers in the United States. My goal is to capture 1% of the total U.S. market within one year of product launch with a 3-year goal of 5% and a 10-year goal of 10%. Target Customers, Customer Needs, and the Relevant Market Size are described in more detail in the End User portion of this application.

### Intellectual Property

The UCLA Technology Development Group has submitted a patent application for this “Multi-Component System for Manipulation of Bone and Soft Tissues” under UC. Case No. UC-2015-900-1-LA. and Patent Application Serial No. 15/810,450.

### R & D Strategy

My goal is to found NewCo Medical (NCM) as a dynamic medical device innovator, developing unique medical device IP into functional products helping physicians achieve better surgical outcomes. NCM will license and develop the Robotic Surgical Assist Arm (RSAA) based on the patent filed by UCLA. NCM will oversee the R&D and manufacturing of the RSAA and accessories. I have previously worked on the prototype with Axxess Surgical Innovations, which is a leader in the creation of advanced solutions that anticipate and meet the needs of the market. The plan would be to contract their U.S. based state-of-the-art manufacturing facility to create a contemporary design geared to achieve optimum surgical results.

### Funding Requirements/Use of Funds

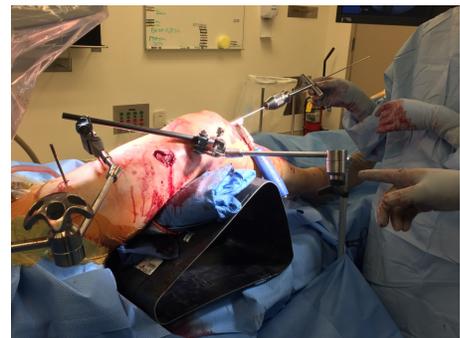
My plan is to fund the development of this project through the UCLA innovation fund. I estimate that the cost of development will be \$200,000. I plan an aggressive timeline to begin marketing and sales six quarters after project launch. Specific milestones are listed in detail in the Proposed Development Milestones portion of this application.

### Regulatory Strategy

Based on an initial analysis, the RSAA is anticipated to be an FDA Class 1 510(k) Exempt device under FDA Product Code FWZ. If this is adjusted and the product becomes an FDA Class 2 product, then the financial estimate and timeline would need to be adjusted.

### Clinical Studies

I plan to perform clinical studies of the RSAA at UCLA. I have received approval for use of the non-motorized version and this has been tested as proof-of-concept under UCLA IRB#16-001873. I will apply for an amendment to test the final motorized production prototype to allow further demonstration of the utility of the RSAA.



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## COMPANY NAME

### Reimbursement

The pricing structure has not been finalized but will be based one-time sales of the arm and recurring sales of disposable accessory drapes. I estimate that the RSAA List Price will be approximately \$12,000. The drape will be priced between \$150-250.

### Business Model

#### Distribution Plan

My plan is to sell and market the RSAA through an independent distribution network which will be given exclusive geographical territories. Additionally, there is a need to partner with OEM companies. These companies will add the RSAA or an iteration of the device as part of their portfolio.

#### Operations Plan

My plan is to use Axxess's resources to market and sell the RSAA and accessories. This will be finalized when the product is going through testing. The most critical operational department will need to be regulatory and quality assurance (RAQA). I will begin developing the products utilizing the Axxess QMS, manufacturing and engineering services.

### Financial Information

#### Revenue Model

I previously examined the market size in an article that we published looking at orthopaedic trauma incidence. I used the data from that study to roughly estimate the incidence of relevant lower extremity trauma cases in California that would be potential candidates for this device. This averages around 12,500 cases annually in California. Extrapolating from California representing approximately 1/8 of the U.S. population, the initial market would be in the area of 100,000 cases annually nationwide. I am not aware of any directly competing device in the trauma space at this time. I envision this device has potential use in a variety of orthopaedic procedures beyond trauma as well as in other surgical specialties.

### Exit Scenarios

I would like to develop the RSAA and bring it to market. After a few years of market penetration, my goal is to either sell the product line or the IP to one of our OEM partners.

### Management Team

The management team will consist of myself supervising Axxess Surgical personnel and is discussed further in the Key Personnel section of this application.

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