E4B Final Capstone: Executive Summary

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Innovation Title: *RhythmGuard*

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Innovation:

At *RhythmGuard* , our mission is to use innovative technology to improve the clinical monitoring of heart arrhythmias at every minute of each day to simplify anticoagulation management and improve patient outcomes.

Project Summary:

Current wearable heart-monitoring devices for home use are bulky, contain excessive wiring and do not provide real-time feedback for patients or clinicians, as they are only intended for initial diagnosis. In-hospital units that allow for real-time monitoring are also bulky, taking up valuable ward space, and contain numerous wires. At *RhythmGuard* our product allows for use of wireless wearable leads that integrate with ubiquitous technologies (example: smartphones) to allow for continuous ECG monitoring with single-use wearable technology slightly larger than standard wired ECG leads. The second component of our product is the proprietary software subscription that provides both the patient and healthcare provider a simple graphical user interface for real-time data analysis and alerts. The proprietary software contains ECG analysis algorithms allowing us to prioritize which arrhythmias need immediate provider review and can import the data into most electronic health record systems.

Management:

The technical team currently includes expertise in biomedical engineering, physiology, cardiology, orthopedic surgery and diagnostic/interventional radiology. The operational management team will be recruited and will include an accomplished systems integration expert from an outside industry (non-medical) and an expert at medical device marketing.

End-user Problem:

Approximately 6 million people in the U.S. have atrial fibrillation, including 9% of all people over 65. The prevalence is expected to increase as the population ages. The equipment needed for diagnosis of arrhythmias is bulky, expensive, must be returned by the patient, and does not provide real-time monitoring. Patients that need continuous monitoring without the need for defibrillation have no long-term wearable options and currently require surgical placement of a monitor. Use of real-time monitoring done in hospitals is labor intensive and expensive; atrial fibrillation patients cost on average $8,705 more than non-atrial fibrillation patients. The solution offered by *RhythmGuard* has hardware, software and a subscription monitoring service to address the end user needs in these three key markets.

Target Market:

The initial target market is comprised of patients that need continuous monitoring (such as a Medtronic implantable cardiac monitor), to assess medication efficacy, the potential cause of cryptogenic stroke, or the need for an implantable defibrillator. Of the nearly 700,000 ischemic strokes that occur in the US each year, roughly 30% (210,000 strokes/year) are cryptogenic, or from an unknown cause (Yaghi S. et al 2017). To eliminate atrial fibrillation as a potential cause of their ischemic episode and reduce the chances for future complications these patients require a tool to detect intermittent fibrillation. These patients would need to continuously obtain the disposable hardware components and require an indefinite subscription service for monitoring. This solution offers a lower risk (no device implantation), less expensive (disposable but high-sensitivity electrodes), and more convenient (on the person's smartphone device) solution than the current option of surgical placement of a cardiac monitor. Many patients in this target market currently have an implanted device with a limited lifespan and are no longer good candidates for surgical replacement. *RhythmGuard* offers an ideal solution for our initial target population that shows a strong interest among patients, providers and insurance companies. Additional medical markets related to diagnostic home use and hospital subscription services provide much larger end-target markets.

Customer Validation:

RhythmGuard has performed numerous interviews with patients, nurses, physicians, insurance representatives, and hospital managers. Patients in our initial target group are very excited to avoid surgery and maintain peace of mind with continuous monitoring. Insurance companies and health care providers have an interest in minimizing surgical complications. Due to the cost of surgery, complications and the limited lifespan of implantable units, insurance companies would pay a high price for this technology for this indication. The price they would pay for at home diagnosis would have to be competitive with current Holter monitors (approximately $250).

Technology Validation:

We can inexpensively produce a product that demonstrates the concept and function of our wireless disposable technology. As the product development milestones are met, clinical cardiologists, electrophysiologists and a diverse group of the general public will test our technology and make improvement recommendations. To recommend treatment modifications, the end product will need validation in a clinical trial to confirm efficacy in the most prescribed/recommended treatment groups. A clinical trial would not be necessary for the heart rhythm monitoring and notification service.

Sales/Marketing Strategy:

Product will initially be marketed to patients and providers as a way to avoid replacement of an implantable monitoring device. This could be used as a device to bridge patients that have non-functional devices or as a permanent solution to surgical replacement in patients with contraindications, or a desire to avoid surgery. Subsequent expansion will focus on home use as a replacement for holter monitors and the ability to outsource real-time monitoring for hospitals. The ultimate goal would be to market to any patient with atrial fibrillation as a means to monitor and offer improved treatment recommendations to better control their disease.

Business Model:

The business will generate revenue from two sources: hardware and subscription monitoring service. The hardware is made from inexpensive components that can be miniaturized and inexpensively mass produced. Initial hardware pricing can be high in our first target market. Unit production costs are low as they are targeted to home diagnostics and can be competitively priced with current Holter monitors. This will allow us to quickly recover the cost of development, have a high initial profit margin, and allow for lower pricing when a home market is pursued.

The software is a key component of the business offering an advantage over competitors in our model. The subscription software will initially have a low cost, and will be very profitable as the software will allow us to hire the minimum number of physicians needed as we sell subscriptions to ensure profitability at the earliest possible time and maximal profits at all time points as the company grows.

Competitors/alternative solutions:

Apple is the main competitor for a hardware and software solution. Our hardware would be designed to interact with their hardware as well as other common patient and hospital owned smart technologies. The service we are developing is different because it will provide a solution to interface technology with a qualified provider instead of bypassing the provider, which is a focus of companies like Apple. This means our technology could reach market sooner. In addition, the components of our software will be attractive to companies like Apple making purchase a likely exit strategy.

Another competitor is AliveCor, who offers a product that can monitor heart rhythm upon demand.

Competitive Advantage:

RhythmGuard offers a complete hardware/software service that will make diagnosis and monitoring easier and more cost effective at home and in hospitals through use of cost effective disposables that integrate with existing ubiquitous patient owned and hospital based technologies.

Ethical Risk Assessment:

The largest ethical risk is increased waste with the development of a disposable product. This is mitigated because the current non-disposable medical products have disposable components as a patient interface. In addition, a telemedicine program would reduce patient travel mitigating environmental impacts. Additional ethical concerns include data collection and management, which are also legally regulated via HIPAA.

Risk Assessment:

Risk factor	Risk mitigation strategy
Missing clinically significant arrhythmia	Software analysis reviewed by physician as part of business model for subscription service and software analysis that can assess appropriate use of hardware by patient
Product cost too high for disposable unit profitability	Design product with limited proprietary disposable parts while more expensive components can be purchased one time for long term use
Cost to employ physicians too high for subscription service profitability	Software designed to minimize the time needed for physician review of patient data, ability to hire physicians in different geographic locations
Difficulty selling our product in a medical market	There are numerous target markets within the medical field. However, interviews with additional potential customers identified animal and clinical researchers, athletes and athletic trainers as additional customer bases for our technology.
First mover	AliveCor has already gained some traction on the market for a mobile EKG product

Use of Funds:

Source of funds	Specific activity	Funds required	Deliverable	Delivery by
Initial funds				
Private (startup group)	Production of functional proof of concept hardware/software	2,000	Proof of concept hardware	One month
STTR Phase I vs. Angel Investor	First generation miniature hardware and software testing. Additional commercial development with new product. Refined calculation of commercialization costs and business model.	150,000	Functional scalable hardware and software	12 months following award
SBIR Phase II vs. Angel Investor vs. Venture Capital Investor	Generation of scalable hardware. Preclinical validation of product in all consumer groups: patients, clinicians, other end users/customers (insurance, coders using EMRs, etc). Refined calculation of commercialization costs and business model.	1,000,000	Final scalable product and user Interface. Revised business model incorporating relevant product and customer information.	24 months following award.
Total initial funds	1,152,000			
Subsequent funds	**Specific activity**	**Funds required**	**Funding source**	
Venture Capital	Clinical trials and Initial Approval	3,000,000	Private	
Venture Capital	Scaling up company and targeting new markets	TBD	Private	
Total subsequent funds	3,000,000 +			