EXECUTIVE SUMMARY

Contact:
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Funding Stage: Preclinical

Capital Seeking: $500k-$2M

Winner:

Connecticut Angel Investment Forum "Life Science Favorite" and "Tech Company to Watch" at the 2014 CT Innovation Summit, NSF SBIR Phase I, CTNext's EIA awards, and others.

Intellectual Property:

Device to Treat Incontinence, US Application 14/678,058, Apr 2014 & International PCT/US2015/025500.

Overview

Urinary incontinence is a widely prevalent condition, affecting 1 in 3 women. Although a very private concern, it has far-reaching physical, psychological, social, and economic implications, with annual costs to the US healthcare system approaching $25 billion. Elidah is developing a non-surgical treatment for mildly to moderately symptomatic incontinence sufferers. Through this wearable therapeutic device, Elidah will improve the quality of life and reduce the need for surgery for tens of millions of women.

The Need

Stress urinary incontinence (SUI) is the involuntary loss of urine usually due to weakened pelvic floor muscles and resulting from a variety of factors including child-bearing, athletic pursuits, trauma, and aging. This loss of urine often occurs when physical exertion (e.g. sneezing, jumping) increases intra-abdominal pressure. There are no medications that address SUI, and while surgery can provide relief, it is painful, expensive, and not without problems. Although active muscle contraction (i.e. Kegel exercises) and/or intravaginal electrical muscle stimulation (EMS) have proven clinically successfully, these exercises are difficult to perform and use of intravaginal probes presents psychological and physical barriers, and thus both options have poor adoption and compliance, leading two thirds of affected women to quietly suffer without effective treatment. It's clear that, from the patient's perspective, available treatment options are woefully inadequate.

The Innovation and Product

Recent clinical reports demonstrate that a pattern of surface electrodes placed proximate the perineal region are as effective as intravaginal electrodes at retraining the pelvic floor muscles, by stimulating both the muscles directly and indirectly through the pudendal nerves. Building on this discovery, Elidah is developing an EMS device that eliminates the intravaginal probe.

This wearable therapeutic device is discretely worn over the patient's absorbent pad and under the clothing. Low intensity therapy is comfortably administered in short 10-20 minute sessions, multiple times during the day and while the patient goes about normal activity. The device is comprised of a credit-card-sized signal generator and a disposable electrode component. It is programmed through a docking station and/or mobile app, and usage data is optionally transmitted to a physician, a practice shown to significantly increase patient compliance.

The Target Market

Elidah's fully developed device will enter a market with substantial commercial opportunity. US sales for non-surgical therapeutic incontinence products exceeds $300 million (2007) and the global market is $1.6 billion (2011). The market opportunity for the device is even greater considering that 2/3 of suffers currently forego treatment. It is these tens of millions of women that this technology has the opportunity to benefit most. Further, development success in this space is likely to extend to parallel markets including male urinary incontinence (a leading complication following prostate surgery) and fecal incontinence, greatly expanding Elidah's market opportunity.

Current treatment solutions include use of intravaginal probes (InTone device, InControl Medical) which many women are resistant to use; instead, choosing to quietly suffer with their symptoms. In customer surveys, 70% of woman preferred Elidah's proposed treatment to intravaginal stimulation. Patient resistance to use of intravaginal devices has also been validated by Elidah's medical

Regulatory

The product is an FDA Class II device requiring a 510(k). Performance requirements are well defined by FDA guidance documents, suggesting a relatively clear regulatory pathway. Further, the FDA has identified this as a Nonsignificant Risk Device, allowing clinical evaluation with only local IRB approval (i.e. prior to FDA review). This allows Elidah to expedite both the collection of clinical data and regulatory clearance of the device.

Business Model and Planning

- **Market Validation and Marketing** – In an effort to validate assumptions regarding market and product needs, Elidah has conducted numerous interviews with both patients and clinicians. Results from these in person and anonymous interviews support the end user dislike/disinterest in current treatment options and the users' willingness to use Elidah's proposed therapeutic solution. In marketing the product, Elidah will pursue both salesperson-to-physician and direct to consumer strategies.
- **Reimbursement and Revenue** – At least three insurance reimbursement codes already exist, providing an immediate and sizeable revenue model. A competitive device lists its product near $800 and realizes reimbursements in excess of $500. In addition to the base device, the disposable electrode presents the opportunity for reoccurring revenue.
- **Funding and Timeline** – A staged development strategy focuses immediate effort on design, fabrication and clinical assessment of the electrode component. Then, the signal generator will be designed and packaged in a wearable form factor. The FDA cleared device will be in clinical use in 2016, with broad commercial launch (supported by clinical data) in 2017.

Team

Gloria Kolb and Eric Kolb are medical device engineers and entrepreneurs, each with almost 20 years of product development experience and each having led development efforts from concept generation through clinical use and commercialization. They have demonstrated innovative thinking with a combined 35 medical device patents. The team has specific expertise with urological devices and wearable therapeutic technologies, and relevant expertise with mechanical engineering, biomedical engineering, biomaterials, regulatory, quality systems, intellectual property, project management and entrepreneurship. Further, Elidah's team includes an electrical engineer, and clinical advisors with expertise in gynecology, urogynecology, urology, physical therapy and clinical research, including individuals from Yale Medical Center and Danbury Hospital. Elidah has teamed up with Womens Health USA for clinical studies.