Executive Summary

Mission Statement

Madorra is empowering women to live fuller, healthier lives. We are changing the paradigm for treating vaginal dryness by providing the first non-hormonal, non-invasive medical device, which treats a condition that has previously only been served by pharmaceuticals. We're giving postmenopausal women and breast cancer survivors the power to choose the non-hormonal treatment option they want.

The Problem

Decreasing estrogen levels, either from cancer treatment or menopause, disrupt vaginal blood flow and can induce vaginal dryness and atrophy. The most effective treatments for vaginal atrophy today utilize estrogen. However, given the increased rates of breast cancer associated with estrogen therapy, hormone-based treatments are contraindicated for breast cancer survivors. Additionally, many postmenopausal women are also reluctant to use estrogen-based treatments for vaginal atrophy, due to the risks of breast cancer and cardiovascular events. These women deserve a safe and effective treatment option.

Our Solution

Madorra's simple, easy-to-use, non-hormonal and non-invasive device will provide both immediate and long-term benefits and empower the millions of breast cancer survivors and post-menopausal women suffering from vaginal dryness to improve their sexual health and return to wellness.

Market Opportunity

Madorra's initial target market segment is the 1.4M breast cancer survivors in the US with vaginal atrophy, a $1.2B market opportunity growing at 6% per year. Breast cancer survivors represent a strong beachhead market, as they are an informed, activated population desperate for a solution. Subsequent market expansion will address the 9.6M post-menopausal women diagnosed with vaginal atrophy in the US, many of whom desire hormone-free therapy.

Revenue Potential

Madorra will reach revenues of over $150M in 5 years post-FDA clearance by capturing 5% of the breast cancer survivor market and 0.5% of the treatment-seeking, post-menopausal market.

Growth Highlights

- Acute Clinical Feasibility Study - Completed (2015) an IRB-approved, two-part (20 patient) study showing efficacy, safety and patient demand.
- Chronic Clinical Feasibility Study - Awarded IRB-approval and currently enrolling for a chronic study to show long-term efficacy of tissue revitalization and user compliance to at-home self-therapy.
- Product Development – Conducting patient interviews to inform product development decisions
- Financing – Fundraising for seed round of capital to reach key clinical milestone in 2016.

Company Description

Our Vision

Madorra strives to be the preeminent company serving cancer survivors and post-menopausal women's sexual wellness. Madorra will improve sexual wellness for breast cancer survivors and post-menopausal women by ushering in a new treatment paradigm for vaginal dryness and atrophy. The gentle therapy Madorra provides will revitalize tissue, treating vaginal atrophy without the use of hormones or worry of side effects. Madorra's simple device will be the preferred, oncologist- and gynecologist-recommended medical device to treat vaginal atrophy. The device's ease of use will empower the millions of women suffering from vaginal atrophy to reclaim their sexual wellness and extend their sexual health into the next chapter of their lives. Madorra will be a trustworthy brand that garners women's loyalty based on its mission to provide worry-free health solutions and curate clear, reputable healthcare information for cancer survivors and post-menopausal women.

The Problem

Breast cancer survivors are faced with a difficult reality after treatment: their sexual health has declined. Treatments for breast cancer interfere with the natural estrogenic stimulation of the vaginal tissues, causing vaginal dryness and atrophy. The tissue becomes thinned, dry, and inelastic, causing dyspareunia (pain with sex) and increased rates of infection. The effects of breast cancer treatment have limited survivors' capacity for intimacy, often leading to abstinence and strained relationships.

The most effective treatments for vaginal atrophy utilize estrogen, applied either locally or systemically. However, given the increased rates of breast cancer associated with estrogen therapy [Women's Health Initiative, 2002], estrogen treatments are contraindicated for survivors. Thus, while breast cancer survivors suffer disproportionately from vaginal atrophy, they lack any effective and safe treatment. Women who have endured difficult treatments and beaten cancer want to regain their quality of life and reclaim their femininity. This major unmet clinical need sparked the inspiration for the Madorra solution: the first, non-hormonal, non-invasive medical device to treat vaginal atrophy. Madorra's simple, easy-to-use device will empower the millions of breast cancer survivors and post-menopausal women suffering from vaginal dryness to improve their sexual health and return to wellness.

Our Customers

Our preliminary customers are the millions of breast cancer survivors that suffer from vaginal dryness and atrophy and have no viable solution aside from messy, ineffective over-the-counter products. We will then expand to the larger customer base of the tens-of-millions of postmenopausal women who suffer from vaginal dryness and atrophy. These women experience painful intercourse, chronic dryness and infections and must currently choose between topical lubricants or hormone-replacement therapy (HRT), which is associated with increased cardiovascular and cancer risks. Many women are seeking a hormone-free treatment (validated by our internal survey data) to this key quality of life concern.

Our Competitive Advantage

Madorra's competitive advantage includes intellectual property protection (retained top IP counsel verifies high patentability and freedom to operate, two applications filed with USPTO), technical expertise in medical device design/development, clinical science and non-invasive therapies, as well as

strong relationships with leading gynecologists focused on vaginal atrophy. Our competitive advantage will be further strengthened by FDA regulatory clearance (est. Q2, 2017). And most importantly, Madorra's unique device-based solution will disrupt a clinical space currently only served by the pharmaceutical industry.

Market Analysis

Market

The initial market segment for the Madorra solution is breast cancer survivors, as they currently have no safe treatment option for vaginal atrophy. Given recent emphasis on survivorship medicine and breast-cancer advocacy, this is an activated population with a significant patient pull for a non-estrogen treatment. The Madorra team has directly further validated this need with 70+ personal patient interviews with breast cancer survivors. The 1.4 million survivors with vaginal atrophy in the US today represent the initial addressable market [Breastcancer.org]. At $70/month, the median price of HRT treatments for postmenopausal women, the survivor market opportunity is $1.2B.

Based on cost of goods sold, the expected gross margins are 30% on the ~$200 reusable component, and 80% on the $70/month disposable component. Madorra will employ contract manufacturers to build the devices. Madorra's direct sales force will target the top 100 cancer centers in the US, calling on oncologists, gynecologists, survivorship physicians and nurse practitioners. Madorra will host educational seminars and have a presence on breast cancer advocacy platforms and at oncologic and gynecologic medical conferences. The device will ultimately be prescribed by a physician, and paid for out-of-pocket by the patient.

Once a strong base of breast cancer survivors has been established, Madorra will expand to serve the 9.6 million postmenopausal women in the US diagnosed with vaginal atrophy ($8B market opportunity). Expansion into the postmenopausal patient market will require an established distributor. Channels will focus on key-opinion-leaders (KOLs) in female sexual medicine and gynecologists active in the North American Menopause Society (NAMS).

With another 8.4M breast cancer survivors internationally, Madorra will then expand into the European and Australian markets. Madorra can capitalize on Osphena's® extensive marketing to raise awareness of vaginal atrophy and advertise online as a non-estrogen product, selling through physicians via a strong patient pull. The business model is highly scalable as the Madorra solution is adopted and revenue on disposables is achieved, increasing overall product margins. The entire market opportunity for treating vaginal atrophy worldwide is over $20B.

And lastly, after the initial FDA approval of the Madorra device as a prescription product, the company will pursue an over-the-counter approval from the FDA (and worldwide regulatory bodies) to increase access to Madorra's device and open up additional distribution models. Marketing efforts will scale in accordance with this new channel.

Market Validation

The design of the Madorra solution is based on insight garnered from more than 70 interviews with patients, key opinion-leading gynecologists and oncologists caring for women with vaginal atrophy, and local support groups including Bay Area Cancer Connections and Bay Area Young Survivors. Additionally,

Madorra has conducted an online survey of more than 100 women. The device has been designed to be discrete, easy to use, and non-penetrating, based on user feedback, and as such, it will fit seamlessly into women's lifestyles.

Since the mid 2000's, several large-scale surveys of postmenopausal women have explored the impact of vaginal atrophy on quality of life, and in 2013, the REVIVE study surveyed 3,046 postmenopausal US women to ascertain prevailing attitudes toward currently available treatments. Women noted that currently available treatments such as over-the-counter lubricants and moisturizers were troublesome due to their messiness and overall lack of efficacy. Prescription hormone replacement treatments on the other hand were concerning to women because of long-term safety concerns and risk of breast cancer. Hence there is abundant validation to support the fact that women prefer a safer, more effective treatment that offers greater comfort and convenience.

Our Competitive Landscape

Competition to our product is from either lubricants and moisturizers or estrogen-based treatments; yet neither of these categories sufficiently addresses the needs of our target market. Over-the-counter lubricants (e.g. K-Y jelly) and moisturizers (e.g. Replens) are non-hormonal gels and creams applied to the vaginal canal to alleviate dyspareunia and vaginal dryness. Insufficient symptom relief and inconvenience are most often cited as the major limitations of these products however. Hormonal treatments for vaginal atrophy include either systemic estrogen administered via pills or patches or local estrogen applied to the vagina via creams, tablets, or estrogen-eluting rings. These can be effective for some postmenopausal women, but are contraindicated for breast, ovarian, and endometrial cancer survivors because of the risk of cancer recurrence. The American College of Obstetrics and Gynecologists (ACOG) guidelines indicate non-hormonal methods should be considered first-line therapy due to a lack of data on the safety of hormonal treatments in breast cancer survivors. Hormonal therapies are also contraindicated for women with a history of stroke or myocardial infarction because of an increased risk of thromboembolic events [Women's Health Initiative, 2002]. In addition, many postmenopausal women are uncomfortable with estrogen therapies due to the publicized risks of cancer and thromboembolic events.

Two newer treatments for vaginal atrophy have recently emerged. First, the drug Osphena, which is a selective estrogen-receptor modulator, that acts on specific estrogen receptors but is not itself a hormone. Osphena is a daily pill approved for dyspareunia in postmenopausal women. Breast cancer survivors were not included in Osphena's clinical trials, and therefore the drug has a black box warning against its use in this population. The other new treatment is the MonaLisa Touch from DEKA Medical Lasers, marketed in the US by Cynosure. The MonaLisa Touch procedure uses a transvaginal, CO2 fractional laser to stimulate collagen production in the vaginal tissue over the course of three outpatient procedures. While early data from their first US clinical trial looks promising, the therapy has been slow to gain adoption because of its expense (as high as $3000/treatment), invasive nature, and lack of multi-year safety data.

Currently, there is no proven safe, non-invasive, and highly effective treatment for vaginal atrophy in breast cancer survivors. This creates an open opportunity for Madorra to market to an underserved and vocal patient population. While there are existing treatments for postmenopausal women, published reports and Madorra's internal survey data indicate that many postmenopausal women are wary of using estrogen and thus are seeking a more effective, non-hormonal therapy for vaginal atrophy.

Key Market Risks

Madorra's key market risks are 1) accessing patients and 2) ensuring patient compliance with therapy. To access breast cancer survivors, Madorra will benefit from strong breast-cancer advocacy groups and an increased awareness of survivor quality of life issues. Madorra will focus efforts not only on marketing to oncologists and gynecologists who will prescribe the Madorra device, but also on direct-to-patient marketing to induce patient pull for Madorra's treatment.

In the postmenopausal market, patient access will be more challenging. These women are a more dispersed population and can be seen by any gynecologist or primary care physician. In addition, Madorra faces direct competition with estrogen-based products and Osphena. However, internal surveys, patient interviews, and the large REVIVE survey recently conducted indicate many of these women do not want to use estrogen-based treatments. In fact, REVIVE found that 41% of postmenopausal women have long-term safety concerns with the use of hormones. Nonetheless, because the post-menopausal market is less concentrated, Madorra forecasts low penetration in this segment initially. Madorra will combat this by pursuing significant efforts in marketing and distribution to doctors and patients directly. The preliminary focus will be on physicians active in NAMS, female sexual health specialists, and general gynecologists, as they will prescribe the device. Limited direct-to-consumer marketing campaigns will also be utilized. In addition, Madorra will benefit from the recent "floats-all-boats" marketing pushes of Osphena and other estrogen products (in response to Osphena's market entry), which are increasing the societal dialogue about post-menopausal sexual health needs.

To address the second market risk of patient compliance, Madorra has cultivated (and will maintain) a culture of user-feedback to guide product design and use-experience decisions. Further, the team understands that patient compliance is a major challenge for all home-use therapies. Madorra's research has identified that behavior modification will rely on therapy ease-of-use and the patient's perception of device efficacy. With these criteria in mind, the Madorra device has been designed such that the form factor is lifestyle compatible, the device is extremely easy to use, and the therapy will provide noticeable symptom improvements after a few days' use.

Organization and Management

Legal Structure

Madorra Incorporated (Inc.) is a C-Corporation, registered in the state of Delaware, converted from a Limited Liability Company (LLC) as of December 2015.

Management

Holly Rockweiler, MS | Co-Founder and Chief Executive Officer (CEO)

Ryan Krone, MS, PhD | Co-Founder and Chief Technology Officer (CTO)

Jonathan Steinberger, MD | Co-Founder and Chief Medical Officer (CMO)

The Madorra team has industry experience in research, engineering, product development, strategic planning, and clinical medicine. All three co-founders are alumni of the Stanford Biodesign Fellowship for medical device innovation and entrepreneurship. Co-founder and CEO, Holly Rockweiler, MS, has experience in bioelectrical device development, user-centric design, and feasibility research from her prior work as a Research Scientist at Boston Scientific. She is dedicated full-time to Madorra and the development of this device. Co-founder and CTO, Ryan Krone, MS, PhD, has extensive hardware engineering and development expertise from his diverse work as a senior R&D engineer. He has worked with COR Innovations, LLC (a medical device startup), Abbott Vascular, and the Lawrence Livermore National Laboratory. He works with Holly in a full-time capacity at Madorra. The third co-founder and CMO, Jonathan Steinberger, MD, is an interventional radiologist with expertise in non-invasive therapies and breast cancer research, and he has market analysis and strategy skills from his work at consulting firm Easton Associates. He works with Madorra in an advisory role.

Table 1: Pro Forma Cap Table as of December, 2015

Name of Stockholder	Fully Diluted Percentage Ownership
Holly Rockweiler	47.21%
Ryan Krone	37.75%
Jonathan Steinberger	5.25%
Kathryn Olson	2.91%
Fogarty Institute for Innovation	3.88%
Option Pool	3.00%

Board of Directors

Holly Rockweiler and Ryan Krone are currently the sole, equal members of the Board of Directors.

Product and Services

The Product

Madorra is developing non-hormonal, non-invasive, wearable medical device to treat vaginal atrophy for breast cancer survivors and postmenopausal women. The device looks like a maxi pad or panty liner, and is worn in the underwear for daily treatments that are imperceptible to the user. Daily use augments natural body function by increasing vaginal blood flow, which brings about an increase in a

woman's own natural lubrication. With repeated use, tissue health is gradually replenished and vitality is restored.

The Madorra device takes advantage of the body's own mechanisms for vaginal lubrication: blood flow and transudate (extravascular fluid). In a healthy, estrogen-supported vaginal environment, the tissue is thick, lubricated, and elastic. When circulating estrogen decreases however, either naturally during menopause or artificially due to certain cancer treatments, blood flow to the vaginal tissue also decreases, causing a decline in tissue health. Rather than restoring the lost estrogen though, like currently available treatments do, the Madorra device harnesses proprietary energy modes and delivery mechanisms to increase blood flow to vaginal tissue deep within the body. Over time, repeated increases in local blood flow will stimulate thicker, more elastic, and better-lubricated vaginal tissue.

Design requirements for this wearable device are based on Madorra's extensive user research, involving more than 70 interviews with both patients and key-opinion-leading gynecologists and oncologists. The design has also been informed by Madorra's online survey of more than 100 women. Based on this research, the device has been designed to be non-penetrating, discreet, and easy-to-use, conferring strong therapeutic benefits while fitting effortlessly into a woman's lifestyle.

Research and Development Activities

Madorra recently completed a two-part acute feasibility clinical trial at Stanford University showing the safety, efficacy and demand for the technology and the device. Additionally, to show the chronic effects of frequent (daily) use of the device, enrollment in a longer-term (3 month) clinical trial began in December of 2015.

Product development activities began in earnest in December 2015. Currently women suffering from vaginal atrophy from natural estrogen reduction from menopause, or from treatments for breast cancer, are being interviewed to guide the development of a product that women want. These activities will lead to a design freeze of the device by mid-2016.

Intellectual Property

An extensive prior art search has been completed by the team to assess both freedom-to-operate (FTO) and patentability of our method and device in the United States. Consequently, Madorra has FTO on the use of the technology to increase blood flow. Further, our extensive search revealed no prior art covering the use of this technology to treat vaginal atrophy; therefore method claims are highly probable. In addition, as discussed above, the energy delivery to the vaginal canal from a completely external device presents unique challenges. The device has been designed to accomplish this safely via the specific disposable pad and closed-loop sensors. These aspects of the device have been designed specifically for application to the external genitalia and will ensure international patentability for the device.

Madorra has filed utility patent applications on the method of applying this technology to the vagina, the design of the disposable pad, and the device control and feedback mechanisms required for safe and effective use. As the device and therapy protocol are further developed, additional patent applications will be filed.

Marketing and Sales

Commercialization Approach

After FDA approval, Madorra will commercialize this technology by first focusing on breast cancer survivors. The prescription device will be sold through gynecologists and oncologists treating breast cancer survivors, calling on them through a direct sales approach. As the device will be initially paid for out-of-pocket, Madorra will focus sales online. Madorra will also leverage support from breast cancer support groups and foundations to increase awareness and target patients.

After gaining early traction in the breast cancer survivor market, Madorra will expand to the post-menopausal market. As this is a much more dispersed market, Madorra will use a distributor model to reach physicians specializing in female sexual function and those active in ACOG and NAMS. Initial revenue estimates assume 5% market share among breast cancer survivors by 5 years post-FDA clearance (2022), and a more conservative assumption of only 0.5% in the post-menopausal market. This financial model yields escalating revenue, meeting projections of over $150 million by 2022.

With the resources from early sales, Madorra will pursue two tactics to increase treatment accessibility for women in need. First, Madorra will work towards obtaining Medicare and private insurance reimbursement for the device, and second Madorra will pursue an over-the-counter designation.

Commercialization Plan

The Madorra team will follow a capital-efficient commercialization plan with sequential milestones targeted at risk reduction and value creation. Madorra is currently performing grant-funded clinical feasibility studies to eliminate any clinical risk to the project. The team's next step is to de-risk the technology by developing the therapy and generating system requirements. After completion of the feasibility studies and device development, Madorra will scale up product development and generate first generation prototypes. Once the product is developed, Madorra will raise money from angel and venture capitalist investors. This funding will be used to perform the pivotal clinical trial and receive FDA de novo 510(k) clearance for the Madorra device. Following product clearance, Series B funding from investors and strategic partnerships will be sought to build the sales and marketing engine needed to launch the product and positively impact the lives of patients suffering from vaginal atrophy.

Financial Projections

Product launch is targeted for Q2, 2018. Table 2 shows predicted market share for five years following product launch based on modest market share assumptions in the breast cancer survivor and postmenopausal markets. Conservatively, we predict over 160,000 customers, five years after product launch in the U.S., alone. Table 3 lists predicted revenue and cost-of-goods sold (COGS) for the reusable ('generator') and disposable based on the data in Table 2. We predict yearly revenue over $150M five years post launch with costs around $43M.

Table 2: Prospective Market Share

Year	2018	2019	2020	2021	2022	2023
Breast Cancer						
Breast Cancer Survivors with VA	1,493,167	1,586,334	1,679,501	1,772,668	1,865,835	1,959,002
Plus: New Survivors w VA	93,167	93,167	93,167	93,167	93,167	93,167
Total Breast Cancer Survivors with VA	**1,586,334**	**1,679,501**	**1,772,668**	**1,865,835**	**1,959,002**	**2,052,169**
Y/Y Change	*6.2%*	*5.9%*	*5.5%*	*5.3%*	*5.0%*	*4.8%*
Market Share						
Total Breast Cancer Survivors with VA	1,586,334	1,679,501	1,772,668	1,865,835	1,959,002	2,052,169
Net Market Share	0.00%	0.10%	0.50%	1.00%	2.00%	5.00%
Total BC Survivor Customers	**-**	**1,680**	**8,863**	**18,658**	**39,180**	**102,608**
Repeat BC Survivor Customers	-	-	1,680	8,863	18,658	39,180
New BC Survivor Customers	-	1,680	7,184	9,795	20,522	63,428
Postmenopausal						
Postmenopausal Women with VA	9,900,000	10,200,000	10,500,000	10,800,000	11,100,000	11,400,000
Plus: New Postmenopausal Women w VA	300,000	300,000	300,000	300,000	300,000	300,000
Total Postmenopausal with VA	**10,200,000**	**10,500,000**	**10,800,000**	**11,100,000**	**11,400,000**	**11,700,000**
Y/Y Change	*3.0%*	*2.9%*	*2.9%*	*2.8%*	*2.7%*	*2.6%*
Market Share						
Total Postmenopausal Women with VA	10,200,000	10,500,000	10,800,000	11,100,000	11,400,000	11,700,000
Net Market Share	0.00%	0.01%	0.05%	0.10%	0.20%	0.50%
Total Postmenopausal Customers	**-**	**1,050**	**5,400**	**11,100**	**22,800**	**58,500**
Repeat Postmenopausal Customers	-	-	1,050	5,400	11,100	22,800
New Postmenopausal Customers	-	1,050	4,350	5,700	11,700	35,700
Total Breast Cancer and Postmenopausal						
Total Customers	**-**	**2,730**	**14,263**	**29,758**	**61,980**	**161,108**
Total Repeat Customers	-	-	2,730	14,263	29,758	61,980
Total New Customers	-	2,730	11,534	15,495	32,222	99,128

Table 3: Prospective Revenue and COGS

Year	2018	2019	2020	2021	2022	2023
Revenue						
Generator						
New Customers	0	2,730	11,534	15,495	32,222	99,128
Units per Year	1	1	1	1	1	1
Total Generator Units	0	2,730	11,534	15,495	32,222	99,128
Y/Y Change	*n/a*	*n/a*	*322.6%*	*34.3%*	*107.9%*	*207.6%*
Revenue per Generator Unit	199	199	199	199	199	199
Generator Revenue	**0**	**543,171**	**2,295,234**	**3,083,507**	**6,412,116**	**19,726,554**
Y/Y Change	*n/a*	*n/a*	*322.6%*	*34.3%*	*107.9%*	*207.6%*
Disposable						
Total Customers	0	2,730	14,263	29,758	61,980	161,108
Units per Year	208	208	208	208	208	208
Total Disposable Units	0	567,736	2,966,775	6,189,737	12,891,848	33,510,558
Y/Y Change	*n/a*	*n/a*	*422.6%*	*108.6%*	*108.3%*	*159.9%*
Revenue per Disposable Unit	4.12	4.12	4.12	4.12	4.12	4.12
Disposable Revenue	**0**	**2,337,737**	**12,216,131**	**25,487,152**	**53,084,081**	**137,984,649**
Y/Y Change	*n/a*	*n/a*	*422.6%*	*108.6%*	*108.3%*	*159.9%*
Total Revenue	**0**	**2,880,908**	**14,511,365**	**28,570,659**	**59,496,198**	**157,711,203**
Y/Y Change	*n/a*	*n/a*	*403.7%*	*96.9%*	*108.2%*	*165.1%*
Cost of Goods Sold (COGS)						
Generator						
Generators	0	2,730	11,534	15,495	32,222	99,128
COGS per Generator Unit	0	200	130	120	100	80
Y/Y Change	*n/a*	*n/a*	*-35.0%*	*-7.7%*	*-16.7%*	*-20.0%*
Generator COGS	**0**	**545,900**	**1,499,399**	**1,859,401**	**3,222,169**	**7,930,273**
Y/Y Change	*n/a*	*n/a*	*174.7%*	*24.0%*	*73.3%*	*146.1%*
Gross Margin	*n/a*	*-0.5%*	*34.7%*	*39.7%*	*49.7%*	*59.8%*
Disposable						
Total Disposable Units	0	567,736	2,966,775	6,189,737	12,891,848	33,510,558
COGS per Disposable Unit	0.00	2.00	1.00	0.90	0.80	0.70
Y/Y Change	*n/a*	*n/a*	*-50.0%*	*-10.0%*	*-11.1%*	*-12.5%*
Disposable COGS	**0**	**1,135,472**	**2,966,775**	**5,570,763**	**10,313,479**	**23,457,390**
Y/Y Change	*n/a*	*n/a*	*161.3%*	*87.8%*	*85.1%*	*127.4%*
Gross Margin	*n/a*	*51.4%*	*75.7%*	*78.1%*	*80.6%*	*83.0%*
Total Product COGS	**0**	**1,681,373**	**4,466,174**	**7,430,164**	**13,535,648**	**31,387,663**
Y/Y Change	*n/a*	*n/a*	*165.6%*	*66.4%*	*82.2%*	*131.9%*
Gross Margin	*n/a*	*41.6%*	*69.2%*	*74.0%*	*77.2%*	*80.1%*
Other Cost of Sales						
Royalty Costs - 5.0% of Revenues	0	144,045	725,568	1,428,533	2,974,810	7,885,560
Excise Tax - 2.3% of Revenues	0	66,261	333,761	657,125	1,368,413	3,627,358
Total Other Cost of Sales	**0**	**210,306**	**1,059,330**	**2,085,658**	**4,343,222**	**11,512,918**
Total Cost of Sales	**0**	**1,891,679**	**5,525,503**	**9,515,822**	**17,878,870**	**42,900,581**
Y/Y Change	*n/a*	*n/a*	*192.1%*	*72.2%*	*87.9%*	*140.0%*
Gross Margin	*n/a*	*34.3%*	*61.9%*	*66.7%*	*69.9%*	*72.8%*

Funding Request

We are currently raising a seed round of $400,000 in capital to pay for engineering support, regulatory consulting, maintenance of intellectual property and product development activities until Q3, 2016. This seed round is in the form of a convertible note.

Following completion our on-going chronic clinical study and product development activities, we will raise a second seed round convertible note of $1.2M to support our pivotal study in Q4, 2016.

We will seek Series A funding of $5M to support regulatory approval and manufacturing development in 2017, with product launch targeted for Q2, 2018.