

QB Sonic, Inc.

*Regenerating Tissue to
Maintain Bone Health*

Business Plan

November 2015

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Executive Summary

Company Overview

QB Sonic, Inc. (the “Company”) is a medical device company commercializing a non-invasive ultrasound stimulator for regenerating tissue. The Company is located next to Stony Brook University (“SBU”) in the Long Island High Technology Incubator (“LIHTI”) in order to collaborate with SBU’s Biomedical engineering lab. The Company has signed an option agreement with SBU to exclusively license the non-invasive ultrasound stimulator for regenerating tissue (“Technology”). The science behind the Technology has been researched and developed at SBU through grants totalling over \$2 million.

The Technology and Therapeutic Application

The Company is developing the non-invasive ultrasound stimulator for maintaining bone mass at the hip for the treatment of osteoporosis (“OP”). It comprises a hand-held controller unit and a wearable transducer unit. The transducer unit comprises a two-dimensional ultrasound array transducer that is held on the patient’s body at the hip with a wearable strap. The two-dimensional ultrasound array allows the ultrasound signal to be focused on the hips. The ultrasound signal emitted from the transducer unit is a dynamic low intensity pulsed ultrasound (“mLIPUS”), which enhances stem cell activation and provides cell differentiation to regenerate tissue. Proprietary software algorithms embedded in the controller unit generate the mLIPUS signal characteristics. The mLIPUS signal characteristics are tissue specific, i.e. bone regeneration has different mLIPUS signal characteristics than cartilage regeneration. The method of generating the tissue-specific mLIPUS signal characteristics is the subject of a provisional patent filed in March 2015.

The Market Potential

OP is characterized by the structural deterioration of bone tissue that silently progresses until a bone is fractured following a minimal trauma. OP typically occurs in people over 50, when older bone resorption is not balanced with new bone formation. OP causes 1.5 million fractures, including 350,000 hip fractures, each year in the United States. A 10% loss of bone mass at the femoral neck can result in a 2.5 times greater risk of hip fracture. This is the area of greatest concern because approximately 20 percent of hip fracture patients require long-term nursing home care, and only 40 percent fully regain their pre-fracture level of independence. Most importantly, hip fractures result in a 10 to 20 percent excess mortality within one year. The cost to the healthcare system has been estimated at \$17 billion for 2005 and due to the aging population is estimated to double or triple by 2040. OP is currently treated with medications that have side effects. The Company’s non-invasive ultrasound stimulator for regenerating tissue maintains bone mass and bone structure at the hips without side effects. OP affects 55% of Americans age 50 and above, of which 80% are women. In China, Europe, and the US, OP affects over 200, 80, and 50 million women, respectively.

The Company will market its products to doctors so that they can prescribe them to their patients. The patients will receive the Company's products from the Company's distributor. The patient's medical insurance company will pay for the Company's products. The Company anticipates that reimbursement codes will be available for the Company's products.

Founders

Sharon Barkume , J.D., M.B.A., has been involved in the management of a number of high-tech start-up companies including a ultrasound medical device company and a bio-imaging informatics company. Prior to receiving her MBA, Sharon was a patent attorney for an early-stage venture capital firm. Sharon has 17 years' experience as a patent agent/attorney. Prior to her patent law career, Sharon was a program manager and an electrical engineer for 7 years.

Yi-Xian Qin, Ph.D., Yi-Xian is a Professor of Biomedical Engineering and Orthopedics and the Director of the Orthopedic Bioengineering Research Laboratory at SBU. He is a world-renown researcher. For the past two decades, Yi-Xian's research has been focused on musculoskeletal tissue adaptation and regeneration through physical regulation.

Strategy

- Company will complete product development in 2018 and GLP animal testing in 2019.
- The Company will complete European first-in-man (FIM) trials in 2020 and pilot trials in 2021 for CE Mark approval in 2021. The Company anticipates entering into exclusive distribution agreements with qualified distributor in specific countries in Europe once clinical utility has been demonstrated for sales in Europe.
- The Company anticipates partnering with a major medical device company for performing pivotal trials in the US and applying for USFDA approval in 2022.
- The Company anticipates the major medical device company purchasing the Company's product for investor exit.

Key Financials

QB Sonic Summary Pro-Forma Financials (\$ in Thousands)						
	2016	2017	2018	2019	2020	2021
Sales Revenue from Distributer (50%)	\$-	\$-	\$-	\$-	\$-	\$18,000
Cost of Goods Sold	\$-	\$-	\$-	\$-	\$-	\$9,547
Licensing to SBU	\$3	\$10	\$10	\$-	\$-	\$900
Gross Margin						\$7,553
GM%						42%
Labor and Benefits	\$222	\$352	\$363	\$499	\$371	\$953
Clinical Trial Costs	\$-	\$-	\$100	\$-	\$500	\$1,000
All Other Non-Labor	\$303	\$402	\$369	\$315	\$418	\$1,198
Taxes Paid	\$-	\$-	\$-	\$-	\$-	\$1,541
Operating Income/(Loss)	\$(527)	\$(764)	\$(842)	\$(813)	\$(1,289)	\$2,862
Financing	\$625	\$2,200	\$-	\$4,000	\$-	\$-
Cash Balance	\$98	\$1,534	\$692	\$3,879	\$2,590	\$5,452

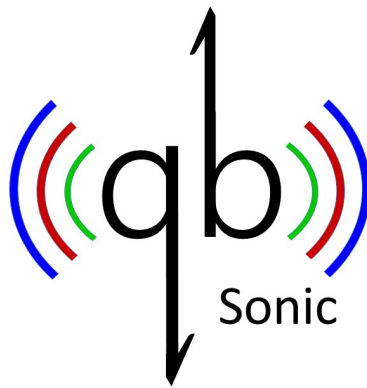
Funding Requirements

The Company is looking for a \$500,000 seed investment. This will provide funding for salaries, facilities, R&D costs, regulatory consultant fees, patent fees, licensing fees, quality system standards and legal fees. The milestones the Company expects to achieve with this funding includes:

- Sign license with SBU
- Complete R & D including animal and human testing
- Develop reimbursement/regulatory/marketing strategy
- Meeting with FDA
- Develop quality assurance strategy
- Select product development partners
- File international patent application

Investment Considerations

- Tissue regeneration is the next paradigm for healing the body
- Platform technology provides multiple products with software changes.
- Critical unmet clinical need: maintain bone mass at the hips without side effects
- Critical unmet clinical need: maintaining cartilage at the hips
- Safe and easy-to-use patient treatment
- Low technical risk and proven technology developed at Stony Brook University
- Tremendous target market for products
- Management team with strong technology background and the ability to obtain solid patents covering the Company's inventive technology



QB Sonic, Inc.

Detailed Business Plan

November 2015

The Company

QB Sonic, Inc. (the “Company”), founded in 2014, is a Delaware Corporation approved for operation in New York. The Company is a medical device company commercializing a non-invasive ultrasound stimulator for regenerating tissue developed at Stony Brook University (“SBU”). The Company has signed an option agreement with SBU to exclusively license pending patent applications, data, software, and know-how related to the non-invasive ultrasound stimulator for regenerating tissue (“Technology”). The science behind the Technology has been researched and developed through grants totalling over \$2 million from the NIH, the National Space Biomedical Research Institute, the US Army Medical Research, the Whitaker Foundation, and the New York Advanced Centers for Technology.

The founders of the Company are Sharon Barkume, J.D., M.B.A. and Yi-Xian Qin, Ph.D. Sharon Barkume will be responsible for performing the day-to-day management of the Company, developing the business strategy, securing intellectual property protection, and acquiring financing. Sharon has previous experience as an early employee with a start-up ultrasound medical device company, as a patent attorney for an early-stage venture capital firm, and as an attorney for various law firms. Prior to becoming a patent attorney, Sharon was an electrical engineer and a project manager for Eaton Corporation. Sharon’s experience and knowledge of patent law gives the Company a significant competitive advantage. Yi-Xian Qin will be responsible for overseeing the research and development of the technology. Yi-Xian is a world-recognized expert in musculoskeletal tissue adaption and regeneration with 20 years of experience in ultrasound technology development. He is the inventor of the Technology and has researched and developed the Technology at SBU since 1999. Yi-Xian’s experience and knowledge of musculoskeletal tissue adaption gives the Company a significant competitive advantage.

The Company is located in the Long Island High Technology Incubator (“LIHTI”) next to SBU. LIHTI rents office and lab space at reasonable fees to promote research collaborations between SBU’s scientists and technology companies commercializing their technology. The Company has received many benefits by being associated with SBU including participation in SBU’s Technology Innovation Boot Camp, Bio-Strategy meetings with the Center for Biotechnology, and various incubator programs. In addition, the Company has been accepted into New York state’s START-UP NY Program, giving the Company and its employees tax free benefits, including no income tax for ten years.

Additionally, the Company will hire bioengineers experienced in designing and testing ultrasonic medical devices and programmers experienced in programming and testing ultrasonic medical devices. The Company will also recruit a board of advisors that includes physicians, thought leaders, and business advisors with experience bringing medical devices to market. As needed, the Company will hire attorneys; a comptroller/book-keeper; a marketing/business development person;

and consultants for regulatory, clinical, QA, and reimbursement functions. Lastly, the Company will contract with outside organizations for manufacture, sales, distribution, and customer service.

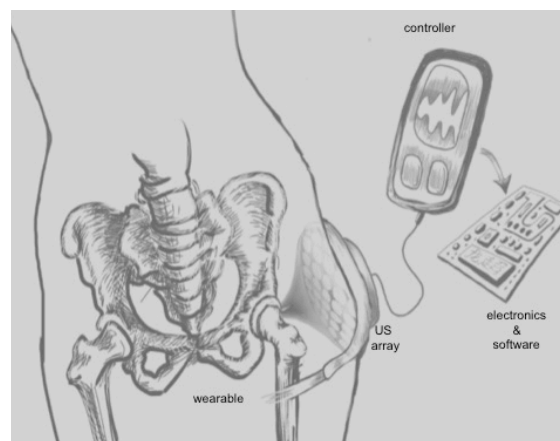
The Company is negotiating an agreement with Tsinghua Yuanxing (“TY”) to give TY the exclusive right to market, sell, and distribute the Company’s products in China. TY will provide an upfront payment and royalties to the Company for this exclusive right. TY will also pay the costs associated with manufacturing the products, clinical trials in China, and regulatory approval in China.

The Company’s mission is to develop innovative ultrasound technology that helps people prevent injury and promote healing so they can lead active and healthy lives. The Company’s values are:

- (1) quality – exceeding expectations;
- (2) innovation – pursue new creative ideas that have the potential to change the world;
- (3) discipline – push to get better everyday;
- (4) teamwork – work collaboratively to achieve a goal by being cooperative, contributing individual skills, and providing constructive feedback; and
- (5) Honesty – treat others, as you would want to be treated in order to create an environment of trust and support.

The Products and Therapeutic Applications

The Company is developing the non-invasive ultrasound stimulator for regenerating bone mass at the hip for the treatment of osteoporosis (“OP”). The product comprises a hand-held controller unit and a wearable transducer unit. The figure to the right conceptualizes the Company’s product. The transducer unit comprises a two-dimensional ultrasound array transducer that is held on the patient’s body at the hip with a wearable strap. The two-dimensional ultrasound array allows the ultrasound signal to be focused on the hips. The ultrasound signal emitted from the transducer unit is a dynamic low intensity pulsed ultrasound (“mLIPUS”), which enhances stem cell activation and provides mechanical loading for cell differentiation to regenerate tissue. Proprietary software algorithms embedded in the controller unit generate the signal characteristics necessary for each type of tissue stimulation. Accordingly, mLIPUS signal characteristics emitted from the transducer unit for bone



regeneration are different from mLIPUS signal characteristics emitted from the transducer unit for cartilage regeneration. The mLIPUS signal characteristics that are varied for the different tissues being regenerated include, the power, the frequency, the duration, and the sequence of phased array transducer element actuation. The sequence of phased array element actuation provides the mechanical forces necessary for stem cell activation and cell differentiation.

OP is characterized by the structural deterioration of bone tissue that silently progresses until a bone is fractured following a minimal trauma. Bone is comprised of trabecular bone and cortical bone. Trabecular bone is the sponge-like bone in the ends of long bones and vertebrae. Cortical bone is the hard outer shell of bones in the middle of long bones. Bone mass density ("BMD") is peaked between 18-25 years. BMD is determined by genetic factors, nutrition, endocrine status, physical activity, and health. Around the ages of 30–35, trabecular bone loss begins, causing an individual's BMD to decline and the microarchitecture of bone to be disrupted. The weaker spicules of trabecular bone begin to have micro-cracks, which are replaced by weaker bone during the aging process. Because osteoblasts (bone forming cells) and osteoclasts (bone resorption cells) inhabit the surface of bones, trabecular bone is more active, and is more subject to bone turnover and remodeling. OP occurs when older bone resorption is not balanced with new bone formation. Common osteoporotic fracture sites, wrist, hips, and spine, have a relatively high trabecular bone to cortical bone ratio and rely on trabecular bone for strength, so the intense remodeling causes these areas to degenerate most when the remodeling is imbalanced. This imbalance typically occurs with menopause and advancing age. Hormonal factors strongly determine the rate of bone resorption, explaining why women may lose as much as 50%, while men lose about 30%. Furthermore, a deficiency of calcium leads to impaired bone deposition and increased bone resorption.



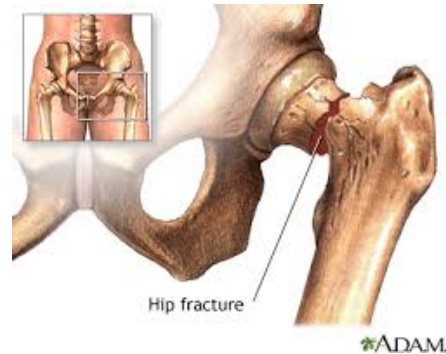
Diagnosis

Dual X-ray absorptiometry ("DEXA") is the most common technique for measuring BMD. Osteoporosis is clinically defined as a BMD T-score of -2.5 or more. Osteopenia, a precursor to osteoporosis, is clinically defined as a BMD T-score between -1.0 and -2.5. FRAX, a diagnostic tool that evaluates the 10-year probability of bone fracture risk, integrates BMD at the femoral neck and clinical risk factors to calculate the 10-year probability of hip fracture and the 10-year probability of a major OP fracture (clinical spine, forearm, hip or shoulder fracture). The clinical risk factors include age (65+ for women and 75+ for men), previous fragility fractures, glucocorticoid use, family history of hip fractures, low BMI, rheumatoid

arthritis, smoking and excessive alcohol intake.

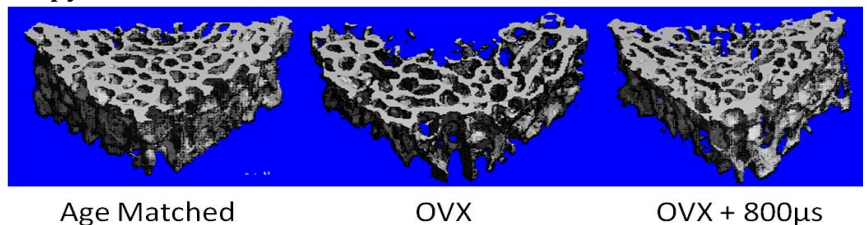
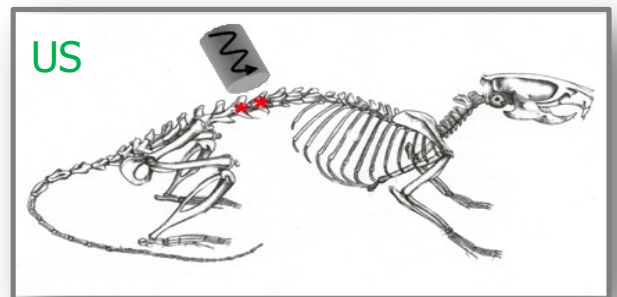
Outcomes

OP causes 1.5 million fractures, including 350,000 hip fractures, each year in the United States.¹ A 10% loss of bone mass at the femoral neck can result in a 2.5 times greater risk of hip fracture (shown at the right), while a 10% loss of bone mass in the vertebrae can result in a 2 times greater risk of vertebral fracture. The combined lifetime risk for hip, forearm and vertebral fractures is around 40%, equivalent to the risk for cardiovascular disease. Approximately 20% of hip fracture patients require long-term nursing home care, and only 40 percent fully regain their pre-fracture level of independence. Most importantly, hip fractures result in a 10 to 20 percent excess mortality within one year.² Low bone mass fractures cause 432,000 hospital admissions, 2.5 million medical office visits and 180,000 nursing home admissions annually in the U.S. The cost to the healthcare system has been estimated at \$17 billion for 2005 and due to the aging population is estimated to double or triple by 2040. Hip fractures account for 14 percent of incident fractures and account for 72% of costs.³



R&D

SBU has developed and tested a first-generation lab prototype and is currently testing a second-generation lab prototype. The first generation lab prototype contained a single transducer that was modified to provide mLIPUS. As shown to the right, the prototype was tested on the spine of three rats including: (1) a normal rat; (2) an OVX model rat that did not receive therapy; and (3) an OVX model rat that did receive therapy. An OVX model rat is a rat that has no ovaries, which simulates post-menopausal women with bone loss. The results of this testing are shown to the right.



¹ American Academy of Orthopaedic Surgeons website:
<http://www.aaos.org/about/papers/position/1113.asp>

² National Osteoporosis Foundation Clinician's Guide found at:
<http://nof.org/files/nof/public/content/file/344/upload/159.pdf>

³ American Academy of Orthopaedic Surgeons website:
<http://www.aaos.org/about/papers/position/1113.asp>

The second generation lab prototype currently being tested contains a 5 x 5 phased array transducer, shown to the right, that has been programmed to provide mLIPUS. The power, frequency, and duration of the mLIPUS for optimum activation of the body's biological mechanisms for bone regeneration will be confirmed with this prototype. The Company will need to convert the lab prototypes into a field prototype that is capable of focusing the mLIPUS into the hips. This field prototype will incorporate the phased array transducer into a wearable. In addition, the controller will be miniaturized and the software will be updated to focus on the hips.



The critical technical risks for this device is being able to position the probe and focus the mLIPUS to be targeted into the region of interest, i.e. the femoral neck. To mitigate this risk, the Company will design human anatomy-based templates that will be incorporated into the wearable and will perform human testing prior to completing product development.

The Market Potential

The Company will market the non-invasive ultrasound stimulator for maintaining bone health to people who are diagnosed with OP. Since OP affects 55% of Americans age 50 and above, of which 80% are women, the Company expects women over the age of 50 to be the target customer for the non-invasive ultrasound stimulator for maintaining bone health.

In China, Europe, and the US, OP affects over 200, 80, and 50 million women, respectively.⁴ OP fractures cause 432,000 hospital admissions, 2.5 million medical office visits and 180,000 nursing home admissions annually in the U.S. Hip fractures account for 14% of OP fractures and account for 72% of costs. The worldwide incidence of hip fracture in women is projected to increase by 240% by 2050.⁵

The Company will market the non-invasive ultrasound stimulator for maintaining bone health to doctors who diagnose and treat OP so that they will prescribe it to their patients. These doctors include rheumatologists, osteopaths, endocrinologists, oncologists, gynecologists, geriatricians, internists, and primary care physicians. The non-invasive ultrasound stimulator for maintaining bone health will be marketed to doctors through publications, trade shows, conferences, websites, and

⁴ International Osteoporosis Foundation Website: <http://www.iofbonehealth.org/facts-statistics>

⁵ American Academy of Orthopaedic Surgeons website:
<http://www.aaos.org/about/papers/position/1113.asp>

add campaigns to patients. The cost of the non-invasive ultrasound stimulator for maintaining bone health is expected to be \$2000. The Company feels this cost will allow easy adoption with a reasonable profit margin.

Competition

Although there are non-invasive ultrasound stimulators in the market for speeding fracture healing in the extremities and in the spine, there are no non-invasive ultrasound stimulators for maintaining bone health at the hip. Unlike the current medications for treating OP, the non-invasive ultrasound stimulator for maintaining bone health maintains BMD and bone structure in the hips without side effects. Surveyed rheumatologists, all currently prescribing medications for treating OP, are excited to have the non-invasive ultrasound stimulator for maintaining bone health as an alternative treatment because many of their patients do not want to take the medications or have taken the medications for a number of years and are worried about the long-term effects of the medications. In order to avoid fractures, identified OP patients are currently treated with medications that maintain or increase BMD. Unfortunately these medications have short-term and long-term side effects including osteonecrosis (bone death) of the jaw, atrial fibrillation, atypical fractures of the femur (thigh bone), stomach ulcers, severe pain (in joints, bone, muscle, jaw, back, chest, and eyes), gastrointestinal discomfort, swelling (face, hands, feet, tongue, and throat), headache, skin blisters, weakness, and irritation of the esophagus. Many people forego the use of medications because they are afraid of having these side effects. Even if the patient takes the medications, many practitioners recommend a drug holiday to avoid the long-term effects of the medications. There is currently no consensus on how long a patient can or should take the medications.

Competitive Advantage

The Company's clearest competitive advantage is that it can maintain bone health at the femoral neck (hips) without side effects.

Intellectual Property

IP will provide a significant competitive advantage for the Company. The Company has employed a world-renown scientific researcher and a patent attorney. The Company plans on exploiting this competitive advantage by creating an extensive patent portfolio. In addition, once the Company's products are offered for sale, the Company will invest in worldwide trademark protection. The Company's IP will significantly increase the value of the Company to a potential acquirer.

Patents

The Company has signed an option agreement with SBU to exclusively license the IP that covers the ultrasound stimulator. The Company has negotiated the terms of the exclusive license, which includes future IP developed at SBU from grants received by the Company. The Company has performed additional patent searches and will file an additional provisional patent application by the end of 2015. The Company will take over patent prosecution of all patent applications from SBU.

The pending provisional patent application was filed on March 9, 2015. It describes the inventive methods for promoting cell growth. The Company will submit an international PCT application based on this provisional application. During the national stage filings, the Company will file applications in the US, the EU, China and Japan. The Company will consider also filing applications in Canada, Korea, Australia, India, Israel, and South Africa.

Trade Secrets

The Company has created a trade secret policy and has/will put confidentiality agreements in place with all employees. Non-disclosure agreements have been used in all sensitive conversations outside the company.

Trademarks

The Company has applied for federal trademark protection for its name “QB Sonic.” The Company will file additional trademark applications for its logo and product names prior to the sale of its products.

Freedom to Operate

The Company has performed a freedom-to-operate analysis for bone stimulators and believes that it will not infringe any patent rights because the use of ultrasound for bone stimulation has been in the public domain since 2014 when patents owned by Exogen (now Bioventus) expired.

Regulatory Strategy

The Company will contract with a regulatory consultant to provide regulatory affairs interface. The Company will seek guidance from the USFDA by filing Pre-IND/IDE briefing documents prior to product development and testing.

The Company will leverage data obtained from studies performed in Europe for CE Mark and USFDA submissions. The Company will gain EU regulatory approval through the CE mark and commercializing in the EU market before applying for USFDA clearance because of the following reasons:

- It will require a smaller number of patients

- Post Market data can be collected in a Registry rather than a clinical trial with Registry costs that are much lower than clinical trial costs
- Data collected in the registry is less stringent than a clinical trial
- Products can be sold for Registry data collection, but cannot be sold for clinical trials in the US
- The Company can collect data for papers, abstracts, and presentations to support a broader product launch in the US
- The Company can use EU clients for marketing purposes in the US.

The Company believes that regulatory approval for maintaining bone health can be achieved through the new USFDA *de novo* pathway because (1) they are a novel devices with new intended uses; (2) they present a moderate or low risk profile; and (3) no predicates exist with the same intended uses. The Company will use the USFDA pre-submission program to receive feedback from the FDA regarding the *de novo* pathway and the necessary studies needed for *de novo* clearance. The Company expects the USFDA *de novo* pathway to take approximately one year.

This regulatory strategy is helpful to the Company for several reasons: (1) it provides early clinical data that will be used in subsequent regulatory clearances; (2) it provides the Company with user feedback on device performance and adoption prior to seeking subsequent regulatory clearances; and (3) it provides a revenue stream for the Company while seeking subsequent regulatory clearance.

Clinical Studies

The Company will contract with a clinical consultant to provide a clinical strategy, clinical research, biostatistics, and data management.

The Company expects FIM trial to be conducted in Europe. The focus of the clinical trial will be acute safety. If the clinical results indicate adequate safety, pilot trials will be initiated to achieve CE Mark. If the clinical results from the pilot trial in Europe indicate adequate safety, pivotal trials will be initiated in the US.

The Company anticipates that the regulatory approval agencies will require the Company to continue collecting clinical data on the use and performance of its devices after approval is received.

Manufacture, Quality Assurance, and Customer Service

The Company does not plan to manufacture its products. The Company will develop OEM supplier agreements with appropriate ISO-qualified manufactures for the ultrasound transducers, electronic circuit boards, housing, and the wearables. The Company anticipates that TY will produce the housings, packaging, and instruction manual

The Company will contract with a quality consultant that has experience in developing Quality Assurance Systems. The Company will use a web-based document management system for collecting, monitoring, maintaining, reviewing, and signing-off clinical study data that supports clinical trials. The Quality System will include vendor visits on a regular basis and will ensure adherence to ISO standards for conformity and traceability of sourced material.

The Company anticipates that the ultrasound transducers will require a maintenance schedule to ensure proper energy levels. In addition, the controller may require service. TY will provide customer service to its customers in China. Prior to commercialization in Europe and the US, the Company will outsource customer service activities.

Reimbursement

Costs associated with fractures due to bone deterioration, especially hip fractures that require nursing home stays, are a substantial burden to the health care system. Similarly, costs associated with reduction of pain due to joint deterioration, especially joint replacement surgeries, are a substantial burden to the health care system. Since bone and joint deterioration occur in people over 40, and more typically in people over 50, payment of these costs are likely to come from Medicare or Medicaid. Presently Medicare reimburses osteoporosis medications, bone growth stimulators for delayed-union fractures. There is a shift in the U.S. to prevent health issues. The Company feels that these factors will be beneficial to receiving reimbursement coverage for its products.

The Company will hire a reimbursement consultant with expertise in the reimbursement policies of European nations and the US. The consultant will assess the reimbursement landscape, perform market research with payer decision makers, evaluate strategic options, determine evidence needed (clinical and economic endpoints) needed to support reimbursement, and prepare a reimbursement dossier.

Sales and Marketing

The Company anticipates entering into exclusive distribution agreements with qualified distributor in specific countries in Europe once clinical utility has been demonstrated in Europe.

The Company anticipates that TY will market, sell, distribute, and service the Company's products in China. The Company will receive a royalty for each product sold by TY. TY has a direct sales force of 30 people and agreements with 30 different distributors throughout China.

The Company will seek to raise additional funding through a partnership with a large US company for the marketing, distribution, and sales of its products in the US.

The Company will market its product to doctors so that the doctor can prescribe it to patients. The Company anticipates that sales will proceed as follows:

	2021	2022	2023	2024	2025
Number of salespersons	5	10	25	40	60
Number of new doctors prescribing	250	500	1,250	2,000	3,000
Total number of doctors prescribing	250	750	2,000	4,000	7,000
Bone stimulators sold	18,000	54,000	144,000	288,000	504,000
Revenue (M)	18.00	54.00	144.00	288.00	504.00
Revenue from sublicensing (M)	-	-	10.80	32.40	54.00
EBIT (M)	6.82	23.23	77.17	166.46	289.47

Exit Strategy

After commercialization in Europe, the Company will seek out a strategic US partner for commercialization in the US with plans for later acquisition. Possible strategic partners include Medtronic, J&J, GE Medical, KCI, Stryker, and St. Jude Medical.

In March of 2015, St. Jude Medical acquired Spinal Modulation for their neuro-stimulator system for \$175 Million. Spinal Modulation had achieved CE Mark for the system, shown European sales, finished USFDA trials, and applied for PMA approval in the US.

Management Team

Board of Directors & Management

Sharon Barkume , J.D., M.B.A.

CEO

After receiving her MBA with a concentration in innovation, Sharon has been involved in the management of a number of high-tech start-up companies including a bio-imaging informatics company and an ultrasound medical device company. Prior to receiving her MBA, Sharon was a patent attorney for an early-stage venture capital firm. Sharon has 17 years' experience as a patent agent/attorney. Prior to her patent law career, Sharon was a program manager and an electrical engineer for 7 years building detection systems for satellites. Sharon will generate the business strategy, perform fundraising efforts, oversee legal matters, negotiate IP licenses, manage additional IP acquisition, recruit company personnel, and oversee company operations and business development.

Yi-Xian Qin, Ph.D.

CTO

Yi-Xian is a Professor of Biomedical Engineering and Orthopedics and the Director of the Orthopedic Bioengineering Research Laboratory at SBU. For the past two decades, Yi-Xian's research has been focused on musculoskeletal tissue adaptation and regeneration through physical regulation and characterization of bone quality, particularly in mechanism and mitigation of bone loss, orthopedic implant fixation, bone fluid flow controlled bone remodeling and cellular activities, promotion of fracture healing and regeneration with functional physical stimulation, and ultrasonic diagnostics and therapeutics for bone quality assessment and regulation of bone mass. Yi-Xian will oversee the Company's research, design, development, pre-clinical testing, and vendor selection.

Engineering

Brian Guo, Ph.D. is a biomedical engineer with a focus on providing medical ultrasound/optical imaging systems, acoustic therapeutic systems, 3D imaging algorithms, and motion control solutions. Brian has 17 years' experience in high-speed digital design, analog/digital design, imaging system simulation and development, SCH/PCB design and debug. In ultrasound medical devices, Brian has 8 years' experience in design & development of neuro-stimulators, 3D medical ultrasound imaging, photo-acoustic imaging and diffusive optical imaging. Brian has previously worked with SBU to develop the prototypes for the bone stimulator and the bone scanner.

Yong Zou has a master's degree in computer science and geophysics and more than 15 years of engineering and project management experience in emerging medical

device companies. He is an expert in the design and development of hardware and software for ultrasonic medical devices. He has extensive expertise in software verification, validation and development life cycle management. He brings broad knowledge in risk management, quality assurance, regulatory compliance, pre-clinical studies, and clinical studies.

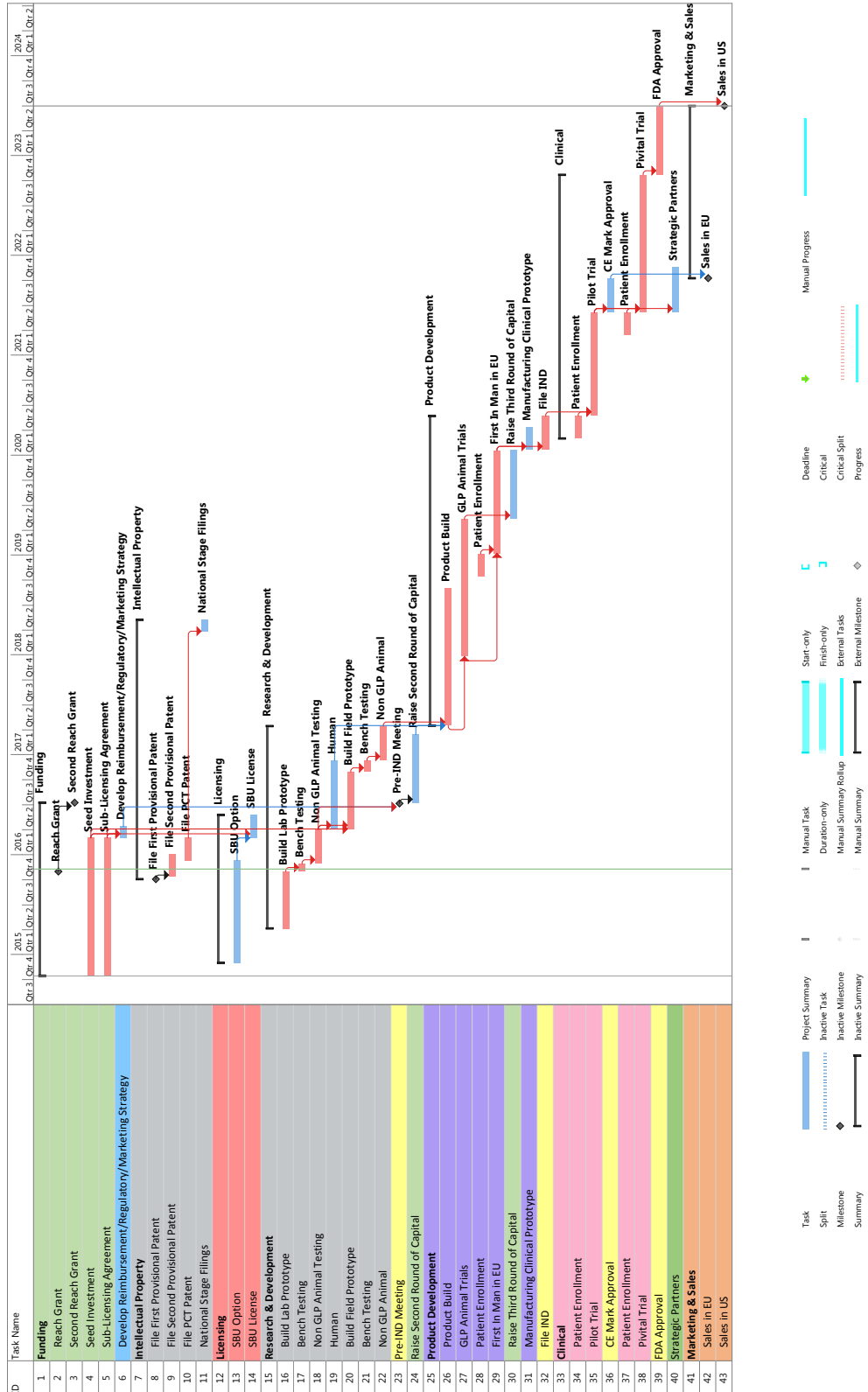
Scientific Advisory Board

Marie Gelato, M.D., Ph.D. is a Distinguished Service Professor of Medicine, Division of Endocrinology. She is the Program Director of SBU's Master's degree in Clinical Research and SBU's NIH funded GCRC for 16 years and continues to direct the institutional Clinical Research Center. She has over 20 years' experience doing investigator initiated patient oriented research. She is presently the lead diabetologist of an NIH multicentre clinical trial to assess the role of periodontitis on glucose control in patients with Type 2 diabetes mellitus. She has published over 100 journal articles. She was a member of the FDA Advisory Panel for Endocrine and Metabolic Drugs and still serves as an ad hoc member. Dr. Gelato has collaborated with Dr. Qin for 5 years.

Clinical Consultant

Donna-Bea Tillman, M.P.A., Ph.D. has over 17 years of experience with the Food and Drug Administration, Center for Devices and Radiological Health, including six years as the Director of the Office of Device Evaluation (ODE). She is an expert in the regulation of medical device software. She also spent two years leading medical device regulatory affairs for Microsoft's Health Solutions Group.

Timeline & Strategy



Financials

	2015				2016				2017				2018				2019				2020	2021	Total
	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4					
Revenues																							
Founder start up funding (K)	12000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	\$ 12,000		
Grants awarded (K)	0	0	0	0	25000	0	0	0	200000	0	0	0	0	0	0	0	0	0	0	0	\$ 225,000		
Private sector funding (TY) (K)	0	0	0	200000	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0	\$ 200,000		
VC funding	0	0	0	500000	0	0	200000	0	0	0	0	0	0	0	0	0	0	0	0	0	\$ 6,500,000		
Total Revenues Available =	12000	0	0	700000	0	25000	0	200000	0	200000	0	0	0	0	0	0	0	4000000	0	0	\$ 6,837,000		
Expenses																					\$ -		
Carry over (start up expenses)	\$3,716																				\$ -		
Salary	\$ -	\$ -	\$ -	\$ 61,375	\$ 53,375	\$ 53,375	\$ 117,476	\$ 117,476	\$ 117,476	\$ 117,476	\$ 121,001	\$ 121,001	\$ 121,001	\$ 121,001	\$ 124,631	\$ 124,631	\$ 124,631	\$ 124,631	\$ 124,631	\$ 371,423	\$ 502,566		
LHIT incubator space rent	\$1,396	\$1,286	\$1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 1,286	\$ 5,145	\$ 34,839		
All insurance	\$ 300	\$ -	\$ 210	\$ -	\$ 1,545	\$ 1,245	\$ 1,455	\$ 1,249	\$ 1,549	\$ 1,459	\$ 1,249	\$ 1,552	\$ 1,252	\$ 1,335	\$ 1,125	\$ 3,925	\$ 3,625	\$ 3,635	\$ 4,350	\$ 14,350	\$ 56,858		
Business expenses	\$ 24	\$ 54	\$ 113	\$ 3,149	\$ 2,904	\$ 904	\$ 963	\$ 4,174	\$ 929	\$ 988	\$ 6,674	\$ 929	\$ 929	\$ 988	\$ 5,174	\$ 929	\$ 929	\$ 929	\$ 8,223	\$ 8,323	\$ 49,158		
Travel	\$ -	\$ -	\$ -	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 25,000	\$ 25,000	\$ 146,000		
Conferences & trade shows	\$ -	\$ -	\$ -	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 1,000	\$ 4,000	\$ 4,000	\$ 24,000		
Legal expenses	\$ -	\$ -	\$ 200	\$ 16,000	\$ 15,800	\$ 2,200	\$ 15,000	\$ -	\$ 2,000	\$ -	\$ 15,000	\$ -	\$ 200	\$ -	\$ 62,000	\$ -	\$ 47,200	\$ -	\$ 26,500	\$ 87,200	\$ 985,400		
R&D costs	\$ -	\$ -	\$ -	\$ -	\$ 22,000	\$ 132,000	\$ 22,000	\$ 22,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 198,000		
Outsource regulatory affairs	\$ -	\$ -	\$ -	\$ -	\$ 2,500	\$ 12,500	\$ 2,500	\$ 2,500	\$ 2,500	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 45,000	\$ -	\$ 10,000	\$ 77,500		
Outsource clinical prototype development	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 60,500	\$ 27,500	\$ 49,500	\$ 27,500	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 242,000		
Outsource GTP animal testing	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ 6,000	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 54,000		
Outsource clinical trials	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 100,000	\$ -	\$ -	\$ -	\$ -	\$ 500,000	\$ 1,000,000		
Production for trials & final marketing	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ 130,000	\$ 260,000	\$ 1,020,000	\$ 1,496,000		
Followup outsourced studies	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -		
Licensing fees to SBU	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -	\$ -		
Total Expenses	\$5,436	\$1,340	\$1,809	\$88,810	\$106,410	\$210,510	\$109,579	\$222,185	\$166,240	\$183,440	\$176,709	\$192,709	\$165,468	\$163,468	\$139,216	\$184,971	\$137,471	\$339,181	\$1,275,341	\$2,685,484	\$6,855,388		
Cash Flow (K)	\$6,564	\$5,224	\$3,415	\$614,605	\$508,194	\$322,884	\$213,105	\$1990,920	\$1,824,680	\$1,841,240	\$1,664,531	\$1,471,821	\$1,306,353	\$1,142,885	\$943,275	\$704,059	\$519,089	\$381,618	\$4,042,437	\$2,707,066	\$1,612		