VibroniX

Saving Lives Through Label-free Imaging.

Business Plan

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1. Business Summary

Vibronix was founded by Dr. Ji-Xin Cheng and Dr. Pu Wang aiming to development advanced imaging and sensing technologies for disease treatment and diagnosis. We are currently commercializing an intraoperative breast cancer assessment tools, named MarginPAT, to help remove the tumor within one surgical operation and thus eliminate the risk of 2nd surgical operation.

2. Product Summary

2.1 Problem

Each year in the United States, there are ~240,000 new breast cancer cases, 70% of which are eligible and undergo breast-conserving surgery, or lumpectomy. A breast cancer diagnosis and the following treatment often forces women to leave their jobs, especially among ethnic minorities, with 32% of women quitting work after diagnosis. Young women and mothers who are survivors of breast cancer continue to have psychological and physical symptoms for years after the disease, affecting relationships with their spouses and children. After the operation, histopathology is often performed to check whether the excised tumor specimen is surrounded by a sufficient amount of normal tissue, so called clear or negative margins. In the standard of care, it takes 1 week to obtain such histology information. If, however, a positive margin is identified, a second operation will be performed to prevent cancer recurrence. Currently, the reoperation rate is 25%. This results in the problem of:

- Additional cost for the second or even third surgical operation to the provider and payer,
- Emotional distress and physical pain for the patients, and
- Unnecessary mastectomy because of patients' fear for the second operation and the following cosmetic surgery.

Arming surgeons with more effective tools for removing cancerous tissue during lumpectomy will reduce the need for 2nd surgeries, increasing the likelihood of treatment success and reducing the trauma experienced by breast cancer patients and their families. To effectively reduce the re-operation rate, an intraoperative margin assessment tool with **high speed** and **high diagnostic accuracy** is needed.

2.2 Solution

Vibronix' intraoperative imaging tool, MarginPAT, based on Vibronix' patent-pending technology, provides rapid assessment of cancerous tumors during the initial surgery. It is faster and more accurate than any competing product or technology available today, and will significantly reduce or eliminate the need for 2nd lumpectomy procedures. MarginPAT utilizes photoacoustic tomography and ultrasound imaging, to provide rapid imaging for surgeons that is accurate and

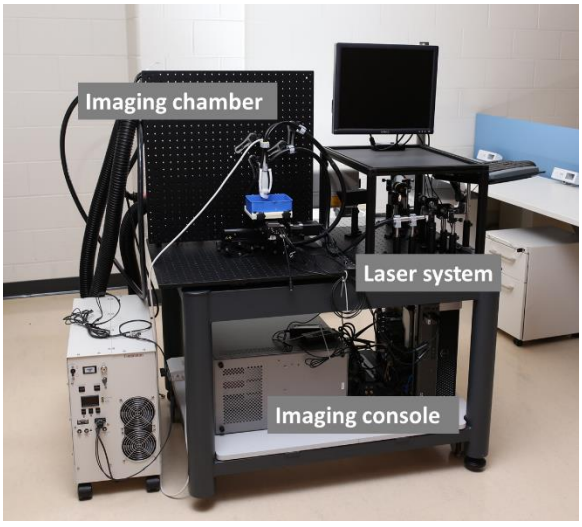


Figure 1: MarginPAT product

tissue-specific. MarginPAT system (**Fig. 1**), consisting of an imaging acquisition console (high-frequency ultrasound machine), a laser system, and an imaging chamber, provides:

- **High sensitivity** in cancer detection, representing the gold standard in histology,
- **Short procedure time** (<4 min) that allows the surgeon to clear the cancer residue during the first surgical operation, and
- **Multi-modality** in tumor diagnosis in pre-operation and wire-localization in the operation.

Our pre-clinical test suggests a 100% sensitivity and 85% specificity in breast cancer margin assessment compared to gold standard histology (Published). This pilot system is currently in use in the IU Health under clinical validation (pilot trial) to evaluate sensitivity and specificity.

2.3 Competitive comparison

Cytological examination and frozen section are widely applied clinically, but they suffer from long procedure time and low sensitivity **(70%)**; Radio frequency spectroscopy reduces the procedure time, but still suffers from the sensitivity (**70%**) and specificity (**68%**) due to the lack of chemical selectivity; Optical coherence tomography (OCT) have improved the sensitivity and specificity. But the penetration depth is limited (**less than 1 mm**), impractical to assess the whole tissue, and the image interpretation is subjective and has **large variation** (**Sensitivity range from 33.3-91.7%, Specificity range from 47.4-97.4 %**). (**Fig. 2**) Compared with the competing technologies, MarginPAT gains advantages by having multiple contrasts at the same time, which greatly boosts up the sensitivity and specificity. By appropriate imaging processing method, MarginPAT can obtain the information that covers traditional ultrasound, RF-spectroscopy and x-ray, which are all considered single contrast systems. Therefore MarginPAT has 1) **Close to 100% sensitivity and 85% specificity; 2) Shortest procedure time (3 min to cover 40 cm^2 tissue); 3) Sufficient sensing depth (3 mm); 4) Has the ability to perform traditional ultrasound imaging for other breast surgery procedures.** Owing to this competitive edge, the specific value proposition of the MarginPAT system is listed below:

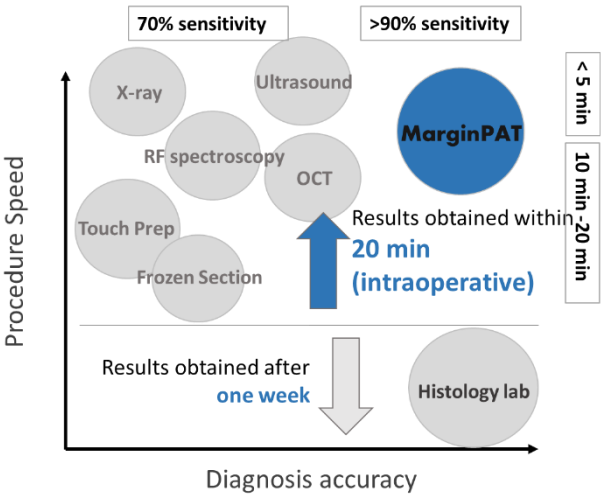


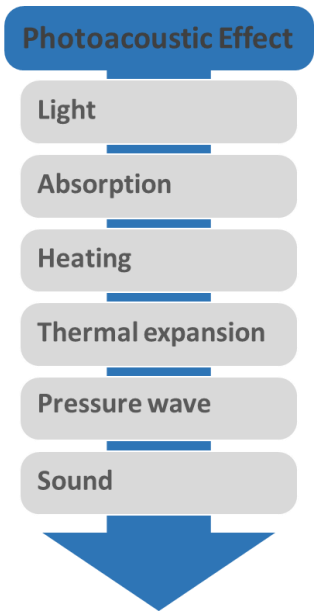
Figure 2: Competing technologies for MarginPAT

We sell MarginPAT to hospitals and cancer centers. Our customer has a problem and it is that it usually takes one week to know if there is any cancer residue after breast-conserving surgery, which leads to an average 25% high re-operation rate. We solve this problem by providing 3D margin compositional information of the excised tissue within several minutes, which will potentially reduce the re-operation rate down to zero.

2.4 Technology

Mechanism of MarginPAT Technology: MarginPAT is based on dual-mode photoacoustic/ultrasound technology. It can differentiate between normal and cancerous tissue

based on the tissue optical absorption property, tissue density and tissue acoustic impedance. In this technology, the photoacoustic mode is used to measure the tissue optical absorption, while the ultrasound mode with radio-frequency spectral analysis is used to measure the tissue density and acoustic impedance. The photoacoustic effect is a light-to-sound conversion phenomenon that occurs in the samples irradiated by a pulsed laser. When specific molecules (eg: fat or hemoglobin) absorb specific laser emission, the light energy is partially converted to heat, which induces a local thermal expansion. This thermal expansion then creates a pressure wave (sound wave) that is detectable by an ultrasound transducer. Therefore, we can reconstruct images of different chemical components with different laser excitation. In the meantime, the traditional ultrasound imaging can be performed. By analyzing the frequency of the ultrasound signal, we can obtain further data about different tissue-specific features, such as calcification, fibrosis of tissue, and breast lesions. With such comprehensive tissue-specific contrast, we can classify the cancer and non-cancer tissue with high sensitivity and specificity using multivariate data analysis methods (**Fig. 3).**



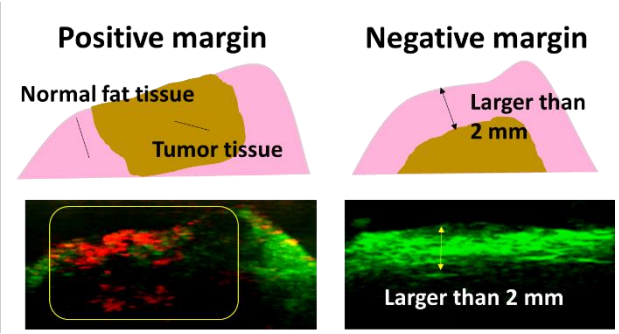


Figure 3: Typical images of positive and negative margin of the recessed tumor tissue

Ultrafast 3D Margin Evaluation: MarginPAT can perform 3D margin assessment of the excised tumor tissue within 4 min. It not only provides the doctor with information of margin status, but also helps to the doctor to locate the tumor residue within the surgical cavity by viewing the 3D imaging of the excised tissue. **3D images of our recent clinical data located in Appendix A.**

2.5 Fulfillment

The potential medical procedure of MarginPAT is illustrated in **Fig 4**. This procedure can be performed in the same operation room during the lumpectomy. The excised tissue will be cleaned with saline and moved to the imaging chamber of MarginPAT. MarginPAT will automatically scan the entire sample and output a result. The whole procedure takes **only 4 minutes**. Our algorithm will provide a cancer score map of the surface of the excised tissue. The surgeon will use this image to make a judgment of whether and where to remove additional tissue. Meanwhile, MarginPAT covers all the traditional ultrasound functions, such as ultrasonography and Doppler ultrasound. Thus, it can be applied in other occasions with lumpectomy, such as pre-operation diagnosis and wire-localization in operation, providing an overwhelming advantage to all the competitors.

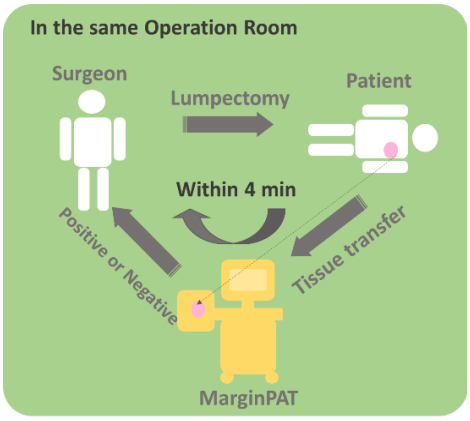


Figure 4: Operation procedure for MarginPAT

2.6 Future product

The representative clinical data shown in **Appendix A** confirms good correlation with pathology report. Our early study proved that MarginPAT is a transformative technology that have the potential to improve the clinical practice.

The 2nd version prototype design is shown in **Fig. 5**, which will reach design freeze when it is built. This design will meet the user needs and economic for manufacturing.

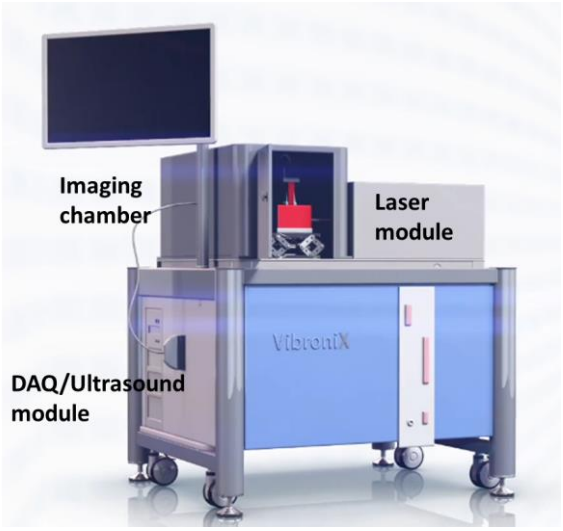


Figure 5: The 2nd version MarginPAT product

2.7 IP Management

In protecting our intellectual property (IP), Vibronix has filed three patents applications to protect:

1) **Performing photoacoustic imaging with the laser wavelength higher than 1100 nm,**
2) **Manufacturing and using a compact high-efficient laser for photoacoustic imaging of fat, and**
3) **Ultrasound/photoacoustic dual-modality imaging system and algorithm on the basis of frequency-domain analysis.**

These three patents will block potential competitors from 1) commercializing a photoacoustic imaging system using molecular vibration as a contrast mechanism to visualize fat; 2) using Raman laser system for photoacoustic imaging; and 3) manufacturing ultrasound/photoacoustic dual-modality imaging system based on frequency-domain analysis and classification algorithm.

Facts about MarginPAT

- Finished the prototype
- Under clinical validation with IU Health
- 100% sensitivity and 85% specificity

Facts about IP

- 2 patent applications
- Exclusive license from Purdue

With worldwide market potential, Vibronix will convert PCT applications in major markets such as U.S., Japan, China and the European Union as the market directs. Vibronix will have 3 further IPs to protect the cartridge design, the algorithm and system architecture. All of the additional three IPs will be filed to U.S., E.U., China, and Japan.

Status of Vibronix' Current Patent Applications:

1. Patent application 1 "**Bond-Selective Vibrational Photoacoustic Imaging System and Method**"
   - Provisional filing: 8/2010; Conversion to full application: 8/2011; Published: 8/2012
2. Patent application 2 "**Raman Laser for Vibration-Based Photoacoustic Endoscopy and Tomography**" (converted to PCT)
   - Provisional filling: 1/ 2013; Conversion to full application: 1/ 2014 Published: 7/2014
3. Patent application 3 "**Method and Device for *In Situ* Cancer Margin Detection**"
   - Provisional filing: 10/2015

License agreement: Vibronix has exclusively licensed the patent applications from Purdue Research Foundation (PRF). [1]

3. Market Summary

3.1 Market analysis

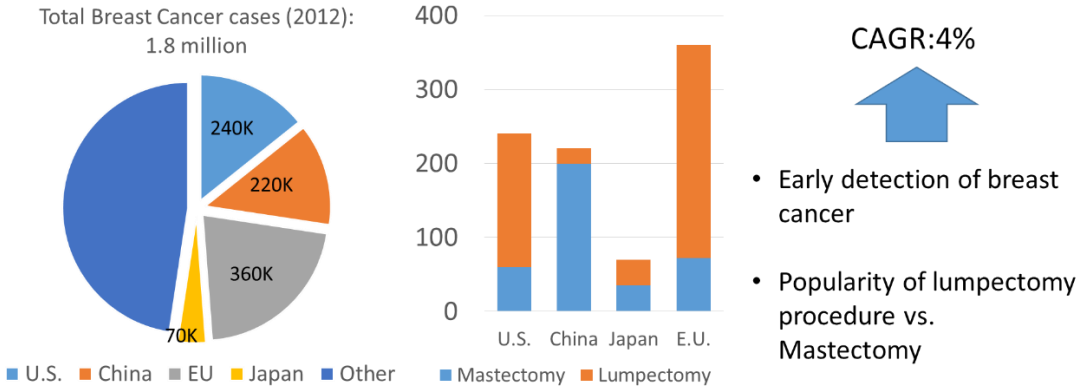


Figure 6: The total number of breast cancer cases and the number of lumpectomy surgeries in each region (thousands)

There are 1.8 million breast cancer cases globally with a CAGR of 4% to 2030. The major geographic market are U.S., China, E.U. and Japan. However, not all breast cancer cases are eligible for lumpectomy. The current breast tumor early screening helped U.S. and E.U. to detect early breast cancer. It results high lumpectomy rate in those two regions. In Japan, the lumpectomy rate is ~50%. However, In China, the rate is as low as 5%. The growth of the market is due to early screening and growing popularity of lumpectomy over mastectomy (**Fig. 6**).

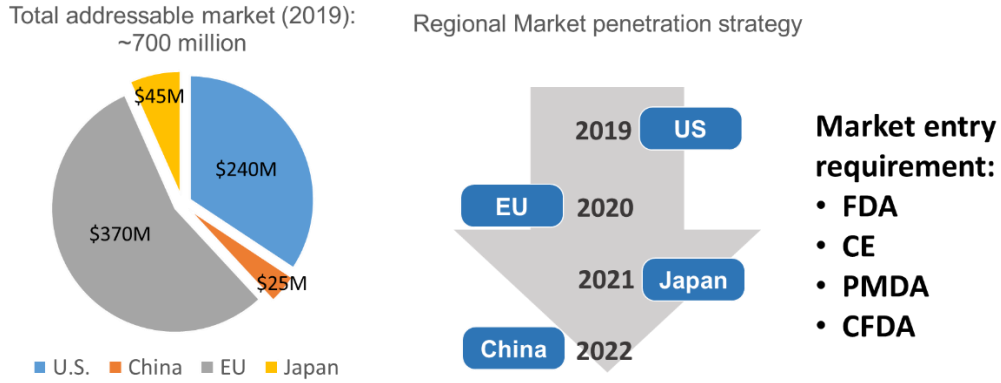


Figure 7: The total addressable market in different region, and the market entry requirement

The total available market on 2019 can be estimated to be around **$700 million** based on the potential number of lumpectomy cases and the cost to perform MarginPAT procedure (~$1,000). The U.S. market is estimated to be around **$240 million**. The major market entry requirement for

[1] The PRF offers an Express Start-up License, an exclusive license with non-negotiable pre-set terms, to Purdue innovators for a fast track to commercialization. This license cannot be sub-licensed within 2 years. For each Annual Period, the LICENSEE shall pay PRF earned royalties. Detailed information of the express start-up license from PRF can be found in the following link: http://otc-prf.org/express-license

those region are regulatory approval. Although E.U. is the largest market, Vibronix still aims to enter U.S. first as we have better connections and opinion leaders in U.S. We will sequentially enter E.U., Japan, and China when obtaining the market approval (**Fig. 7**).

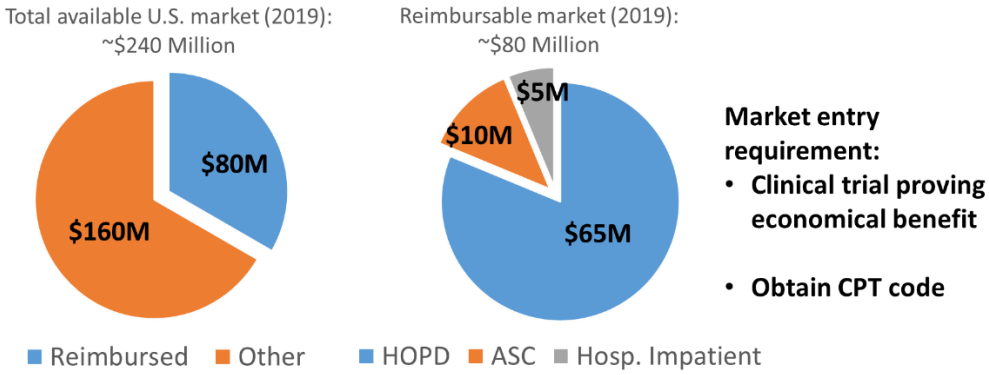


Figure 8: The reimbursement landscape in U.S.

U.S market is segmented by the reimbursement status. Currently there are ~80,000 reimbursed lumpectomy procedures in the U.S.[2], with which the MarginPAT can be bundled immediately after market approval. In those reimbursed cases, 80% are reimbursed in hospital outpatient department, ~15% reimbursed in ambulatory surgical center, and 5% reimbursed in hospital impatient. As the hospital outpatient department pays the most (2 times more than ASC), we consider HOPC as our major customers when entering the market. To further penetrate the reminder market in U.S. ($160M), we need to establish a specific CPT code for MarginPAT system. Clinical trials are needed to obtain data that proves economic benefit and advantages over existing techniques (**Fig. 8**).

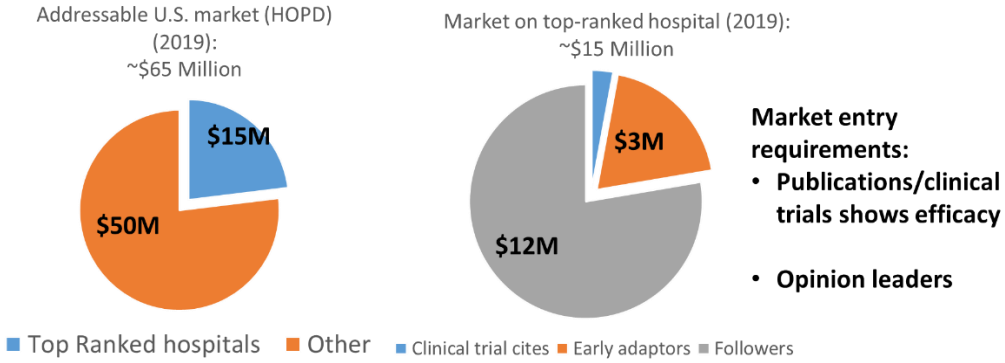


Figure 9: The market segmented by the adaptability of new technologies.

To further breakdown the market, the major market Vibronix will target in the first 3 years are the so called “top 100 hospitals”. Those hospital has large number of lumpectomy cases (IU Health Simon Cancer center, who is ranked 47th, has ~150 lumpectomy cases) and the doctor are more willing to adapt new technologies. Within those hospitals, there are “early adaptors (~$3M)” and “followers (~$12M)”. The early adaptors are the first 10-20 hospitals with opinion leaders that eager for new technologies. Those market can be obtained if we have prestigious publications

[2] The reimburse assessment is available.

and clinical trials with appealing efficacy data. With the advocates from the opinion leaders in the early adaptor, the market of the followers can be obtained (**Fig. 9**).

3.2 Competitions

Surgical margin assessment is a competitive area and multiple procedures and technologies are applied in this field. To effectively reduce the re-operation rate, an intraoperative margin assessment tool with the following major criteria is needed (*User needs based on surgeon interviews*):

1) High sensitivity: closely associate with the histology result;
2) High speed: less than **20 min** to obtain the result;
3) Deep tissue sensing: able to sense more than **2 mm** depth of the tissue;
4) Large sampling area: able to adapt to the entire tissue surface **(~40 cm^2)**;

	Sensitivity	Specificity	Resolution	Procedure time	Sensing depth
Cytological examination	Fair	Fair	Good	Fair	Poor
Frozen section	Poor	Good	Good	Fair	Poor
Radio frequency spectroscopy	Poor	Poor	Fair	Fair	Good
Optical coherence tomography	Fair	Fair	Good	Fair	Fair
Raman Spectroscopy	Good	Good	Fair	Poor	Fair
Diffuse reflectance imaging	Fair	Poor	Fair	Fair	Poor
MarginPAT	Good	Good	Fair	Good	Good

Good Fair Poor

Direct competitors:

Cytological examination and frozen section could be clinically applied with cytology expertise and frozen section equipment availability. During frozen section analysis, the specimen is frozen, sliced, and analyzed microscopically during the surgery. However, this procedure takes **30 min** and the result shows low sensitivity **(70%)** owning to the sampling method. Cytological examination is based on the histological characteristics of the cell surface of malignant cells, which sticks to glass surfaces, whereas benign mammary fat tissue does not. By placing a glass slide against boarders of the excised specimen and then examining it later histologically, margin status could be obtained. However, cytological examination can only see the tissue's surface and do not provide margin width and multi-focality information. Furthermore, 85% and 72% of 351 surgeons interviewed in a survey by University of California San Diego never used cytological examination or frozen section analysis in their procedures. The adoption rates of these two techniques are very low in real clinic practice.

Radio frequency spectroscopy utilized the different RF response from cancer and non-cancer tissue to differentiate the margin status. It is a hand-held device that exam the tissue point-by-point by surgeon. It usually takes the surgeon **20 min** to scan and record the spectra at the desired locations (**Fig. 10**). However, even though it reduces

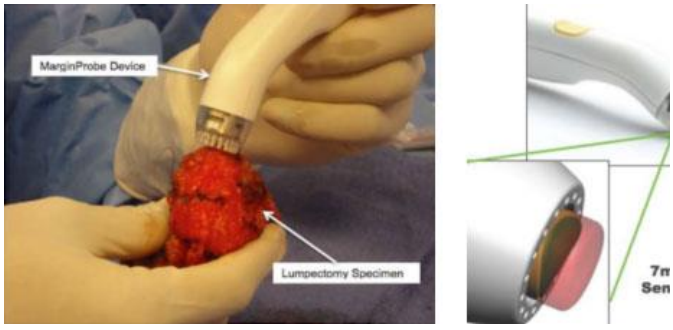


Figure 10: MarginProbe from DuneMedical.

the procedure time, but still suffers from the low sensitivity (**71%**) and specificity (**68%**) due to the lack of chemical selectivity. Although FDA approved, multiple doctors reported that this procedure does not statistically significantly reduce the reoperation rate. (*Current product: MarginProbe, by Dune Medical*)

About Dune Medical:
Dune Medical Device is founded in 2002. It raised 2 rounds with total $26.5M (from Crunchbase). MarginProbe went through a 300-patient randomized trial to prove 56% reduction of reoperation rate. It goes to market after a PMA route (details can be found in FDA.org). About 60 surgeons are using MarginProbe nationwide in the U.S. It is currently on the market with one-time charge of $20,000 to institutions and costs $1,000 for each non-reusable probe. MarginProbe gets $900 reimbursement per procedure (can be found in reimbursement landscaping report), and it is reimbursed in Germany now. Some doctors reported to use CPT 19499 to get reimbursed in U.S. (can be found in reimbursement landscaping report). According to the interview, the doctors and payers think that the 56% reduction rate does not justify the high cost of the procedure in U.S

Intraoperative x-ray is routinely used in lumpectomy and it provides fast whole tissue assessment (result comes in **1 min**). If micro-calcifications occur close to the edges of the specimen, the surgeon may decide to shave the associated cavity edges to remove any residual malignant disease (**Fig.11**). However, the use of radiographic X-ray mammography is limited due to limitations in detecting small, non-calcified lesions. Therefore, it has very low sensitivity (~**50%**) and specificity (**~77%**). (*Current product: Trident System, by Hologic*)

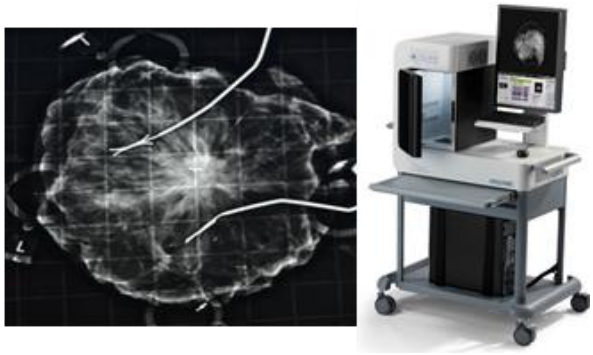


Figure 11: Trident from Hologic.

About Trident System:
Trident System is priced at ~$90,000. The system goes to market through 510(k) pathway.

Optical coherence tomography utilizes the echo of light from tissue to determine the margin status. The product is a hand-held device that exams the tissue by surgeon. It provide a 2D image for every scan by the surgeon. The reader subjectively decides the margin status based on the facts that: Low sparse scattering, which forms a relatively uniform “honeycomb" structure, is characteristic of normal adipose (fatty) tissue. Banded and fibrous structures indicate normal stromal tissue and collagen. Heterogeneous dense, high-scattering patterns and irregular disruption in the structure indicate tissue that is suspicious for malignancy (**Fig. 12**). OCT have improved the sensitivity and specificity. But the penetration depth is limited (**less than 1 mm**), it is impractical to assess the whole tissue, and the image interpretation is subjective and has **large variation according to different readers**

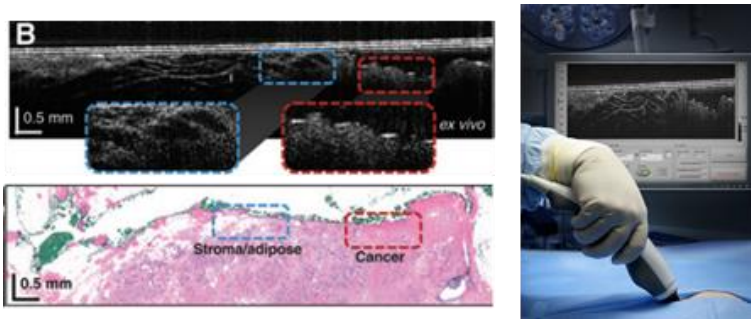


Figure 12: Foresee from Diagnostic Photonics.

(**Sensitivity range from 33.3-91.7%, Specificity range from 47.4-97.4%**). (*Current product: Foresee System, by Diagnostic Photonics*)

About Diagnostic Photonics:
Diagnostic Photonics was founded 2008. They raised about $1.6M. The system goes to market through 510(k) pathway.

Indirect competitors:
Emerging optical technologies, including diffuse reflectance imaging, and spatial offset Raman spectroscopy, have improved the sensitivity and specificity but still suffered from their long procedure time (**~10 fold longer than MarginPAT**), shallow tissue penetration (**less than 1 mm in dense tissue**), or not being able to assess the entire tumor tissue.
Near infrared fluorescence imaging and Cherenkov Luminescence Imaging technology has been reported for in vivo breast tumor removal. However, it requires exogenous labels to specific cancer target, which raises the issues of labeling efficiency, toxicity, and regulatory burden (**Fig. 13**). (*Current product: LightPath System, by LightPoint Medical*)

Figure 13: LightPath from LightPoint Medical.

2.4 Competitive advantage

Compared with the competing technologies, MarginPAT has

1) **Close to 100% sensitivity**
2) **Shortest procedure time (4 min to cover 40 cm^2 tissue)**
3) **Able to cover the entire excised tissue**
4) **Sufficient sensing depth (3 mm)**
5) **Has the ability to perform traditional ultrasound imaging for other breast surgery procedures.**

"The MarginPAT system naturally fits in the medical practice in lumpectomy. If the clinical study suggests a high reduction rate of reoperation, MarginPAT will definitely be a routine test in lumpectomy procedure." **- Linda. K. Han. MD, Director of Breast Surgery, Simon Cancer Center, IU Health**

MarginPAT gain advantages by having multiple contrasts at the same time, which greatly boost up the sensitivity and specificity. By appropriate imaging processing method, MarginPAT can obtain the information that covers traditional ultrasound, RF-spectroscopy and x-ray, which are all considered single contrast systems. Owing to the competitive edge, t**he MarginPAT system will effectively reduce the re-operation rate after lumpectomy to ~0% with minimal additional procedure time in the operation suite.**

4. Strategies Summary

4.1 Regulatory and compliance

MarginPAT system is an intraoperative diagnosis device. There are predicated system which have the same intent of use such as table top x-ray system --- Trident system from Hologic. We will be Class II device and goes through 510(K) process (Trident system went through 510(k) as well). Our regulation strategy is that:

1) Discussion that the differences between the MarginPAT and predicated systems do not raise new questions of safety; and

2) The valid scientific data demonstrating that the MarginPAT is at least as effective as the predicated systems.

Vibronix is expected to get market approval for MarginPAT in the second half of 2017.

The Design Control implementation strategy and Quality System Initiation Strategy is available (provided by Pearl Pathways).

Pearl Pathways™ Accelerating product development

Pearl is a medical research organization providing expertise in regulatory and compliance service to medical device companies. We partnered with Pearl in regulatory affair.

4.2 Reimbursement strategy

The core of the reimbursement plan is to design the product not only for the clinical benefit but also for the economic benefit. Vibronix will consult MEDIClever, a reimbursement consulting company, to create a detailed reimbursement assessment and strategy. Vibronix will integrate this strategy throughout the product development and clinical trials. Vibronix and MEDIClever will carefully design a clinical trial that could prove the economic benefit of the MarginPAT product to obtain new codes of reimbursement.

MEDIClever Reimbursement Consultants

Mediclever is a reimbursement consulting company that help life science companies to facilitate the process of getting reimbursement coverage. Vibronix partner with Mediclever in developing reimbursement strategy.

Based on current assessment, the competing technologies has been reported to be bundled with **CPT 19301**, or direct with **CPT 19499** as unlisted. Both procedure mapped to **APC 0028** which is **a ~$1000 payment[3].** MarginPAT will get paid in the same way before specific code is developed. Noticeably, as MarginPAT system has the ability to perform ultrasound, it can be applied in ultrasound-guided wire localization procedure during lumpectomy (**CPT 19084**), which is a **~$700** payment. **The reimbursement landscaping report is available upon request.**

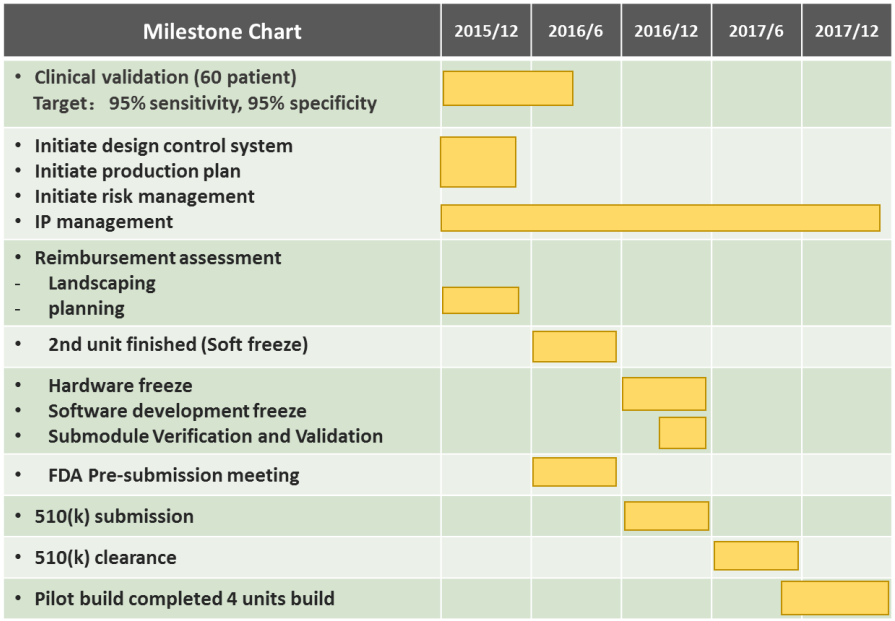
4.3 Go-to-market strategy

Vibronix will go through the development phase and then submit the 510(k) application for market approval. Vibronix will then go to market based on the market analysis (**Section 3.1**).

Product development phase

During the first 3 months, Vibronix will initiate a design control system with collaboration with *Product Realization Group, LLC (secured partnership)*. We will also initiate document control and risk management within the first 3 month. The brief development plan is listed below (The detail roadmap is available upon request). During this phase, Vibronix will conduct a clinical validation study in the collaboration with *Purdue University and Indiana University School of Medicine (secured partner)*. The test goal are: 1) Match the user needs, (compact, hazard free, laser protection, short procedure time); 2) **Able to reach 95% sensitivity and 95% specificity in comparison with histopathology.** If this sensitivity can be achieved, we can relatively reduce the reoperation rate 95% (e.g.: a hospital which has a reoperation rate of 20% can reduce the reoperation rate to 1%). Vibronix is working with *Mediclever, LLC (secured partner)* in reimbursement landscaping and planning. Within 6 month, Vibronix will obtain the information such as reimbursement mechanism, decision makers and strategy, value story, economic model,

[3] APC 0028 has a total payment of $2168. However, this procedure has 'T' indicator, which means that the second procedure will have 50% discount.



and the feedback from decision makers. We will implement the feedback to our design, and make sure the R&D line up with the reimbursement strategy. Vibronix is working with *Pearl Pathway, LLC (secured partnership)* in regulatory issue. We will initiate a pre-submission meeting in about 9 month to further determine the classification of the MarginPAT system. Vibronix will work on software architecture in house. We will launch the first version of our analytical software in 9-12 month. We will finalize the user needs, design input and the R&D plan by next February.

Vibronix will finish the second unit with soft freeze by June 2016. We have secured our laser development partner, Nanjing Institute of Advanced Laser Technology (NIALT) in China to develop and build a low-cost, reliable compact laser source for MarginPAT. In this prototype, we will implement the newly developed laser subsystem co-developed with NIALT that meet the quality and safety standard from FDA. We will send this system for multiple standard test to ensure the quality of the build. This is a key milestone towards the commercialization of the MarginPAT system.

Vibronix will outsource the research through contract with Purdue University for testing and feedback. We will further engineer the second unit till hard freeze by the end of 2016. After we freeze the design, we will submit the testing document along with the efficacy data to FDA for 510(k) clearance. In the meantime, more clinical studies will be performed to prove the economic benefit for obtaining the reimbursement code. **We expected to receive the market approval from FDA in the middle of 2017. We will then produce 4 more units for multisite clinical trial to establish reimbursement code.** Vibronix will engage manufacturing partners during this stage as well. The manufacturing protocol and procedure will be developed as well.

PURDUE UNIVERSITY

Vibronix is a Purdue-Spinoff company and still working closely with Purdue in research and development. Vibronix leverages the state-of-the-art engineering facilities at Purdue through contractual service.

Indiana University Health

Vibronix partners with IU Health and Simon cancer center to conducting clinical validation study. IU Health is the largest care provider in the state of Indiana and have excellent track records in healthcare innovation.

NIALT 中国科学院上海光学精密机械研究所 南京先进激光技术研究院

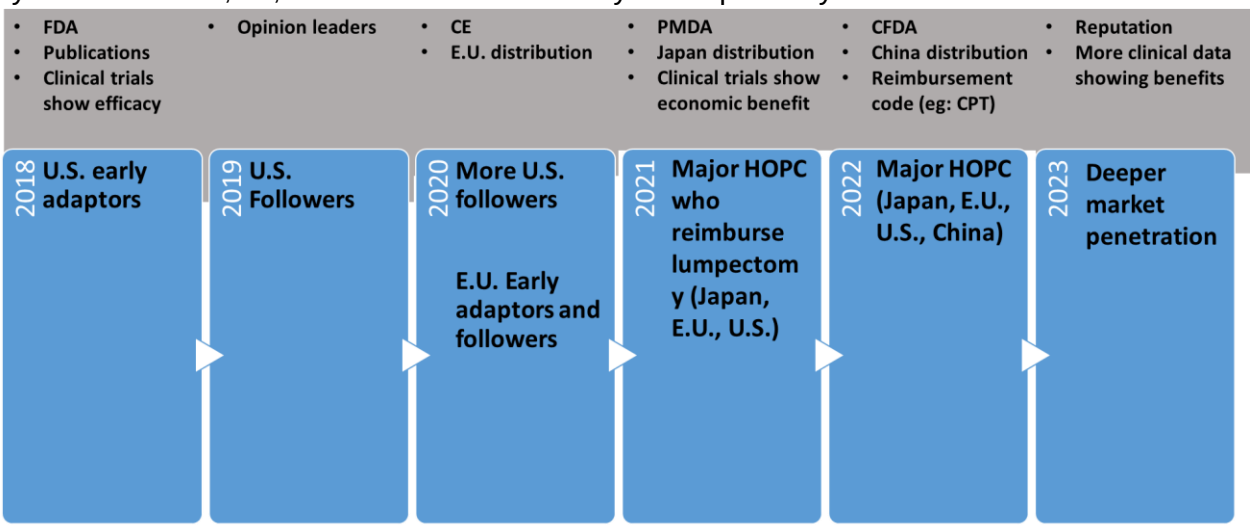
NIALT is the subsidiary institute of Chinese Academy of Science. It is one of the best laser development service provider in the world. Vibronix partners with NIALT in laser source development and potential manufacturing.

Product Realization Group®

PRG is a company providing development and prototyping service. It has costumers from various industries including medical devices (INTUTIVE surgical, Boston Scientific etc.). PRG serves as our development partner and quality control manager.

Go-To-Market phase

Vibronix will start to manufacture and sell the MarginPAT system on 2018. Vibronix will apply the **direct sales model**. Vibronix will use the option pool to recruit a VP of Sales on 2018 to lead the sales of U.S. market. Vibronix will have a 7 people sales team by 2020 to cover the initial market. According to the market analysis (**Section 2.1**), we will engage the early adaptors with the publication and appealing clinical data (~$3M available market). Once we get support from those early adaptors and opinion leaders, Vibronix will attract the followers in the highly reputed hospital in the U.S. (~$15M available market) on 2019. With CE mark and E.U. distribution set up, we will enter the E.U. market on 2020. With PMDA approval and Japanese market set up, we will enter the Japanese market (~$45M). By that time, with the clinical data that prove the economic benefit, the available is further opened up to major hospital outpatient center that reimburse lumpectomy in U.S., E.U., and Japan on 2021. Vibronix will enter the Chinese market in the year of 2022. By that time, we expect to obtain specific reimbursement code in U.S., E.U., and Japan. Much deeper market penetration is expected. Based on the above market analysis, Vibronix should have system sales of 7, 40, and 120 in the first three year respectively.



4.4 Business model

There will be two revenue sources:

1) The sales of the MarginPAT system as capital equipment at lower price,
2) The recurrent sales from the special sample cartridge.

Vibronix will profit from the revenue of the service and upgrade, fiber bundle, and sample cartridge. The estimated system price and COGS are listed below:

Price:

MarginPAT system: $90,000; Sample cartridge：$300.

Cost: (detail cost information is under confidential agreement with partners/vendors, only the total cost is provided)

MarginPAT system cost (Imaging console + Laser system + Imaging chamber) - $50,000; Sample cartridge：$35; Annual service and upgrade $5,000.

The cost of the MarginPAT system (laser, console and chamber) is justified by the quotes from vendors and licensing agreement from partners (available when signing the NDA). The cost of the sample cartridge is estimated via material cost, processing cost and packaging cost at a

volume of larger than 10,000 pieces. The annual service fee include one person travel, flash lamp fee, and overhead.

The MarginPAT system will become obsolete after 5 years.

5. Management Team Summary

Vibronix was co-founded in 2013 by Dr. Ji-Xin Cheng and Dr. Pu Wang. Vibronix' executive team represents qualified experts in product development and management.

Dr. Ji-Xin Cheng, Co-founder, CSO: Dr. Cheng is a professor in the Weldon School of Biomedical engineering at Purdue University, and is a leading expert in developing optical imaging tools and novel nanotechnologies for biological and medical applications. Dr. Cheng has published over 150 peer-reviewed articles and has established worldwide fame in his field. Dr. Cheng is the co-founder and president of Vibronix. He will oversee the project, apply for government grants, and provide expert advice in R&D.

Dr. Pu Wang, Co-founder, CTO: Pu Wang graduate from Weldon School of Biomedical engineering at Purdue University with expertise in the development of biomedical imaging devices. He has published many peer-review articles in top journals such as *Nature Photonics, Science Advances, Physical Review letters Angewandte Chemie etc*. Dr. Wang is the co-founder and Chief Technology Officer of Vibronix. He will lead the technology development and is also responsible for fundraising.

Adam Beal, Head of Finance, Adam Beal joined Vibronix in 2015, and is a 2nd year MBA student at Purdue University. He received his BS in Microbiology from Colorado State University and has founded several companies, with over $3M in career sales. He is responsible for financial projections, business planning, business development and strategy.

Dr. Eric Chan, Head of Product Development: Dr. Chan is a Purdue alumni. He has 22 years of increasing responsibility in medical device senior management roles, building product development teams emphasizing fast-paced development through entire product life cycles, ensuring delivery of clinically effective, market-focused evolutionary and revolutionary products that are compliant with domestic and international regulatory requirements. He envisioned, developed, managed, and implemented R&D activities leading to successful commercialization of products integrating hardware, disposables, and software, with in-house staff, as well as outside consultants and OEM vendors.

Dr. Geetha Rao, Ph.D MBA, Head of Quality and Compliance: Dr. Rao has MIT PhD and a Stanford MBA. She is an experienced entrepreneur, executive, and strategic advisor to medical device, healthcare, and philanthropic organizations, addressing issues for high-risk technologies, including medical devices, health IT, and connected health systems. Particular focus on operational excellence and quality management that meets best-in-class, international standards. Internationally recognized expert in risk management and served on several international policy making bodies.

Dr. Mike Keer, Operation Management: Dr. Keer graduated from Northwestern University. He has over 20 years of leadership in bringing new high technology hardware products to market. He specialized in new product development and introduction, Product Lifecycle Management (PLM), regulatory compliance, strategic planning, marketing, business development, finance, personnel development, project management, process optimization, and making connections. He is also the Mentor for Stanford University's Product Realization Lab, Lemnos Labs, Wearable World, and instructor for New Product Introduction.

Rui Li, Hardware Development and Medical coordinate. Rui Li is a PhD candidate from Weldon School of Biomedical engineering at Purdue University with expertise in the laser development and photoacoustic imaging system development.

Lu Lan, Software development: Lu Lan is a PhD student from Weldon School of Biomedical engineering at Purdue University with expertise in the signal processing, parallel computation, software development and photoacoustic imaging system development.

Advisory council

The management team is coached by a qualified Advisory Council, which guides Vibronix' business development and product development.

Dr. Timothy Peoples: Tim Peoples is the Entrepreneur in Residence and the Regulatory Affairs Officer for the Purdue Foundry. His expertise includes regulatory affairs, startup companies, entrepreneurship and life sciences. At the Foundry, he utilizes that expertise to work closely with startups in the life sciences, medical device and chemistry industries, helping locate and execute regulations faced by many entrepreneurs in those fields. Prior to his position at the Foundry, Peoples was the Director of the Purdue Technology Center in West Lafayette and the director of the Purdue Research Park Entrepreneurship Academy. He also has been involved in formation of three startup companies and was an executive for a large multinational corporation.

Dr. Linda K. Han, MD, Dr. Han has over 20 years medical practice in Breast cancer surgery. She is the Professor of Surgical Oncology in IU School of Medicine, Director of Breast Cancer Surgery, IU Health Simon Cancer Center. She help Vibronix in clinical validation.

Todd M Wallach, MBA, MSE, MB. Mr. Wallach has over 30 years of experience in life sciences, technology, systems, business development, strategic, operating and commercial planning, intellectual property licensing, finance and operations. He is a successful life sciences entrepreneur and seasoned senior executive in Biotechnology, Pharmaceuticals and Devices/Diagnostics, and has started and built companies with total market capitalization of >$1B, managed P&Ls of over $50M and raised over $75M in capital. Mr. Wallach is currently CEO and President of Evogen Inc., a commercial stage biothreat detection and diagnostics company. Mr. Wallach was formerly Chairman, CEO and a member of the founding management team of Molecular Detection Inc., a commercial stage molecular diagnostics company.

6. Financial Plan Summary

6.1 Secured Funding and Fundraising plan

Vibronix has secured **~$350,000 funds** from an STTR grant (~$200,000), a state grant from Indiana (~$50,000), and multiple business plan competitions and awards (~$50,000). Vibronix won 1st place in BMEidea 2015, 2nd place LES Foundation Business Plan Competition, 2nd place in Burton D Morgan Business Plan Competition, Global Action Challenge finalist, MIT-CHIEF China trip, NCIIA/VentureWell Phase II grant.

Vibronix plans to have three major rounds of fundraising to push the product through 510(k) approval and achieve initiate sales:

1) Round A has three sub-rounds: **By March 2016**, Vibronix needs **$400,000** to build the second unit and reach soft freeze. The major milestones are the development and testing of the laser subsystem and development of the sample cartridge. The laser system design is one of the most essential parts towards the FDA approval. **By June 2016**, Vibronix needs **$600,000** to develop the MarginPAT system and reach a hard design freeze; **By Sept 2016**, we need **$1,000,000** to test, and certify the MarginPAT system; submit 510(k); and receive 510(k) clearance on July 2017. The budget breakdown is shown in **Appendix B**. The detail R&D budget till the end of 2017 is available upon request.
2) Round B will open after the 510(k) clearance to raise ~**$1.6M** to support more clinical study to obtain CPT code in U.S.
3) Round C will open at the mid of 2018 to raise **~$3M** to setup the direct sales and initial COGS.

6.2 Financial forecast

The Pro-forma income statement is listed in next page.

The statement is based on the assumptions listed below:

1) MarginPAT system is cleared for sale on 2018.
2) Cost and price are listed in **Section 4.4**.
3) The average patient flow for each customer is 100 patient/year.
4) The number of customers is estimated to be 7, 40, and 120 in the first 3 years.
5) The operating expenses, indirect COGS are estimated base on the companies at the same size and the method to deliver the system.

6.3 Exit strategy

Vibronix expect a strategic acquisition by a major ultrasound manufacturing company. The average acquisition time for a cancer diagnosis device company is ~5-6 years. Therefore, the acquisition is likely to happen during the Phase II, described in **Section 4.3.**

Vibronix Corporation

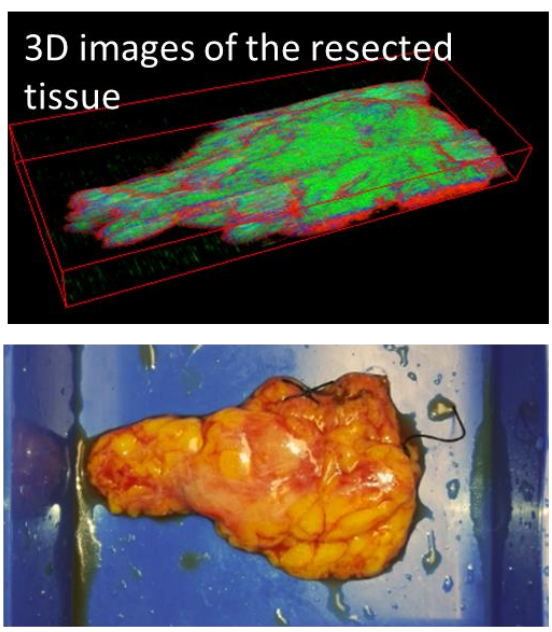
Annual Summary
Operating Plan Model

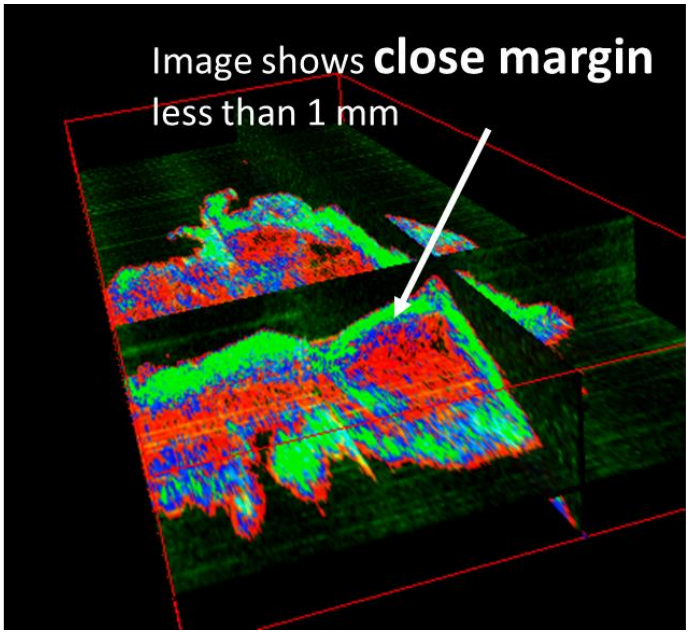
	2016	2017	2018	2019	2020
Income Statement:					
Instruments	$0	$0	$630,000	$3,600,000	$11,340,000
Disposables	$0	$0	$69,667	$754,676	$3,100,032
Other:	-	-	-	-	-
Revenue	$0	$0	$699,667	$4,354,676	$14,440,032
Cost of Goods Sold:					
Direct COGS:					
Instruments	$0	$0	$350,000	$2,000,000	$6,300,000
Disposables	$0	$0	$8,155	$88,340	$362,880
Total Direct COGS:	$0	$0	$358,155	$2,088,340	$6,662,880
Indirect COGS:					
Shipping	$0	$0	$9,450	$54,000	$170,100
Scrapped Inventory	$0	$0	$1,575	$9,000	$28,350
Mfg & Warehouse Supplies	$0	$0	$1,575	$9,000	$28,350
Warranty Expense	$0	$0	$1,575	$9,000	$28,350
Warranty Shipping Exp	$0	$0	$1,575	$9,000	$28,350
Operations	$12,200	$203,023	$500,251	$369,347	$372,916
Total Ind COGS:	$12,200	$203,023	$516,001	$459,347	$656,416
Total COGS	$12,200	$203,023	$874,156	$2,547,687	$7,319,296
Gross Margin	($12,200)	($203,023)	($174,489)	$1,806,989	$7,120,736
Gross Margin %	-	-	-24.9%	41.5%	49.3%
Operating Expenses					
Research & Development	$569,245	$1,209,883	$1,194,762	$843,774	$844,511
Marketing	$10,400	$146,726	$183,756	$354,896	$466,190
Sales	$0	$137,772	$260,840	$466,831	$651,044
Gen & Admin	$145,709	$405,234	$689,662	$747,978	$801,728
Total Operating Expenses	$725,354	$1,899,614	$2,329,021	$2,413,478	$2,763,473
Operating Income	($737,554)	($2,102,637)	($2,503,510)	($606,489)	$4,357,263
Other Expense (Income)					
Interest Income	$0	$0	$0	$0	$0
Interest Expense	$0	$0	$0	$0	$0
Other Expense (Income)	$0	$0	$0	$0	$0
Total Other Expense	$0	$0	$0	$0	$0
Profit Before Taxes	($737,554)	($2,102,637)	($2,503,510)	($606,489)	$4,357,263
PBT as a % of Sales:	-	-	-357.8%	-13.9%	30.2%
EBITDA	($735,610)	($2,080,458)	($2,454,789)	($542,837)	$4,428,761
EBITDA as % of Sales:	0.0%	0.0%	-350.9%	-12.5%	30.7%
Revenue Per Employee	$0	$0	$69,967	$334,975	$1,031,431
Total Cash Balance	($650,460)	($2,728,094)	($5,250,787)	($6,388,441)	($3,315,883)
Change		($2,077,634)	($2,522,693)	($1,137,655)	$3,072,559
Capital Spending	$20,000	$135,000	$42,500	$47,500	$2,500
Headcount	3	9	10	13	14
PBT Check	$ -	$ -	$ -	$ -	$ -
Cash Check	$ -	$ -	$ -	$ -	$ -
Total Dept. Expense		$ 2,102,637	$ 3,203,177	$ 4,961,165	$ 10,082,769

7. Supplementary Information

Appendix A:

The example of 3D MarginPAT images acquired in our recent clinical trial at IU Health. (Patient: 68 year-old white women, under bilateral partial mastectomy, **diagnosed with invasive ductal carcinoma, pathology report shows negative but close margin (<1 mm)**)





The 3D image from MarginPAT using the described methods published in Li et al., Biomedical Express (2015) shows the topographic structure that is correlated to the photograph of the specimen. Green color indicated the normal tissue. Red color indicated the high chance of tumor (blood ambiguity will be further eliminated in the manuscript under preparation, data is not shown here). The orthoslice view shows that an invasive tumor mass that is ~0.3 mm to the surface was identified, which is well correlated with the pathology report.

Appendix B: Brief Budget Justification of the Series A Financing

The budget for the Series A is to finish the 2nd prototype and to submit 510(k).

Contractual research at Purdue University	Vibronix will contract Purdue University to leverage its ability in research and clinical study, system testing, and new product validation.	$200,000
R&D of the laser	Vibronix will partner with NIALT for laser development and pilot production of 3 units.	$250,000
R&D of the data acquisition module/ultrasound system	Vibronix will collaborating ultrasound system design companies, hardware development companies to develop the DAQ system of MarginPAT. Vibronix will budget 1 hardware engineers in house ($180,000 total cost with supplies). Vibronix will budget 400 hour consulting effort for $180/hr for electronics design. Vibronix will have 3 pilot units ($120,000 each).	$600,000
Software/UI development	Vibronix will budget 1 imaging processing software engineer and 1 UI designer (ultrasound specific) for software design ($200,000 total cost with supplies)	$200,000
Regulatory and compliance	Vibronix will partner with PRG and Pearl Pathway for regulatory and quality compliance services.	$350,000
Reimbursement development	Vibronix will continue partner with Mediclever in Phase II for reimbursement development, including communicating with payors, hospital, and opinion leaders and strategy in other countries.	$100,000
IP development	Multiple patent applications during the Phase II development stage. 3 patents will be nationalized to multiple country.	$300,000
System testing	Vibronix will pay 3rd party testing service for device testing	$100,000
General and administrative expenses	Salary for CTO, COO and potential CEO. ($60,000 each). Other administrative expenses including rent, travel, accounting, legal services ($100,000).	$280,000