Malignext Targeting Technologies

TARGETING A CURE THROUGH INNOVATION

VISION

- Approximately 30-40% of surgeries to remove non-palpable cancers of the breast fail to achieve a negative or clear cancer free margin. These surgeries that fail to achieve a negative margin result in a second surgery, a re-excision.
- Malignext's technology aims to reduce this rate to 10-15%.

Market Size

- In the US, there are 60,000 cases of Ductal Carcinoma In Situ (DCIS) diagnosed each year. 80% of these cannot be felt on physical exam (non-palpable).
- There are approximately 50,000 cases of stage 1 Invasive Ductal Carcinoma diagnosed per year, many of which are non-palpable.
- Malignext's technology and technique can be used both for biopsies of non-palpable, suspicious mammographic lesions, and for lumpectomy in the setting of non-palpable cancers.
- The cost associated with re-excision breast surgery in the United States is estimated at $450,000,000 per year in the United States alone.

The Problem

- The current standard of care for biopsy and/or excision of non-palpable lesions of the breast, wire localization, uses 2-D imaging to target a 3-D lesion.
- Using this technique, non-palpable breast cancers are two times more likely to require reoperation compared with breast cancers that the surgeon can feel on physical exam.

The Problem – other costs

- Re-excision surgery results in:
  - Emotional distress
  - Delays in adjuvant chemotherapy and radiation
  - Poor cosmetic outcome
  - Delayed recovery
  - Adverse socioeconomic effect secondary to delay in return to work
  - Burden to healthcare system secondary to increase costs and decreased productivity

The Fix

- Malignext's technology employs a technique similar to wire localization, but makes the targeted area easier for the surgeon to find by creating a 3-D target.
- Under x-ray guidance a thermosensitive polymer is injected to the area of the lesion. At body temperature, the liquid that is injected becomes a dense gel ball which can be felt in the breast tissue, giving the surgeon a 3-dimensional target.
- Improved targeting will result in increased success of first cancer operations, thereby reducing need for and costs of additional surgery.

Traction

- Malignext was selected as project for the Capstone class at the Texas A&M University school of Bio-Medical Engineering.
- Malignext was designated as a new and emerging technology by the state of Washington and accepted as a client by SIRTI (The Spokane Intercollegiate Research and Technology Institute).
- Malignext accomplished preliminary bench research through collaboration with animal physiologists at Washington State University.

More Traction

- Malignext has been awarded three grants from the Pacific Northwest National Laboratory in Richland, Washington, through the TAP (Technology Assistance Program).
- Malignext has applied for patent protection
- Malignext was selected to be a poster presenter at the 2014 LSINW (Life Science Innovation Northwest) Convention.

Most Traction

- Malignext has won $250,000 Life Science Discovery Fund Grant. Most of this research will be done at PNNL as well as Washington State University. This grant has over 40 milestones for us to achieve. Through this grant we will have achieved “Proof of Concept”
- After Malignext won the LSDF Grant, PNNL awarded an extra $20,000 for additional gel related research

Business Model

- Malignext is a C corporation.
- Current work is aimed at identifying the safest and most effective polymer for our device and technique.
- We anticipate pursuing biocompatibility testing, animal efficacy testing and bench testing that will be necessary to gain FDA approval.
- After achieving the above, Malignext would consider selling or licensing to a company that is better suited to manufacture, market and distribute our product.

Who we are

- Jamie Khaw, MD. Dr. Khaw is a Board Certified general surgeon practicing in Portland, Oregon. She graduated from Albany Medical College in 2000 and completed her internship and residency for general surgery at the hospital of St. Raphael, a Yale-New Haven affiliate, in 2005. She is certified through the American Board of Surgery. Dr. Khaw has extensive experience with surgeries and treatments related to breast cancer. She enjoys living in the Northwest with her husband and three children.

- Jarrett LeClaire. Jarrett LeClaire is the other partner in Malignext. After 8 months of marriage, his wife, Ilene was diagnosed with breast cancer. Shortly thereafter, Ilene underwent a mastectomy to remove her tumor and because a negative margin was not obtained had to have a second surgery. Jarrett learned that the re-excision rate was between 30-40% and decided that was a massive problem on many levels and a solution was needed. Through a nurse that worked with Jamie and was an integral member of Ilene's treatment team, Jarrett and Jamie were introduced. They both decided that a solution was needed and Malignext was formed soon after. During the day Jarrett works as a sales engineer primarily in very high heat industries with a focus on manufacturing for the aerospace industry.

Who we are continued

- Barbara Terasevich PhD. Barbara is our chief research scientist. She operates the Terasecich lab at PNNL and has a reputation worldwide as a leading material scientist/polymer chemist.
- Catherine Unruh. Catherine is a product development and program management professional with over 18 years in the medical device industry leading cross functional teams to develop well over 20 medical device product lines including several for breast cancer and reconstructive surgery. Catherine will ensure that all FDA regulatory requirements are satisfied while ensuring the finished product provides value to the customer. Catherine has an M.S. in Engineering Management from Drexel University and a B.S. in Bio-medical Engineering from Rensselar Polytechnic institute.

Who we are continued

- Melissa Sherman, Ph.D.. Director of Technology and Business Development at IP Group plc. IP Group is a leading UK intellectual property commercialization company, developing technology innovations primarily from it's research intensive partner universities. The group offers more than traditional venture capital, providing it's companies with access to business building expertise, networks, recruitment and business support. Melissa's responsibility includes building partnerships with universities to identify, foster, invest and commercialize innovative technology. The IP group has approximately $1.5 billion in assets

Financing

- Malignext is seeking funding for further research, patent protection and reaching benchmarks necessary for FDA approval.
- The estimated cost to get us through FDA approval is between 5 and 7 million dollars.
- Our immediate goal is to raise $1.5 million in order to perfect our polymer gel, gain patent protection and get to the first order of patient trials

The Real Reason