Case Study:
Strategic Review of
Soft Tissue Regeneration’s Opportunities
in the Surgical Mesh for Breast Reconstruction Market
Case Study

Case Overview

- Client wanted to leverage platform biodegradable synthetic mesh technology used in ACL repair for new use in breast reconstruction (>\$300M market) and expand product pipeline
- Strong competitive market existed for synthetic meshes and surgeon loyalty to biological mesh category

- We engaged diverse team of Yale PhD candidates (Biomedical Engineering, Pharmacology, Biophysics, Astrophysics)
- Completed comprehensive market/competitor analysis, analyzed costs to get to market, end user (surgeon) interviews, marketing model and business model optimization
- Recommended client pursue this market based on strong growth potential to maintain strong pipeline based on rigorous quantitative/qualitative analyses

- Based on our work, our client had the confidence to pursue new product space based on existing technology
- Considered recommendations for preclinical model, and began strategic discussion with Board of Directors
- Client recently secured \$4.7M in funding from investors
Trends in breast reconstruction

Overall increase in total reconstructions
Positive trend in use of tissue expander and implant (TE/I)
Negative trend in flap surgeries

Case Study
Market Overview

Breast reconstruction market rapidly changing

- 78,832 in 2000 to 96,277 in 2011 → 2% CAGR
- 250,000 masectomies/year in US
- Diverse surgical needs
- Patient-driven shift toward masectomies will drive the growth of US breast reconstruction market
- **45 to 65 percent** of women who inherit a BRCA1/BRCA2 mutation will develop breast cancer by age 70²
- Cost and complications of flap surgery tending toward implants
- Immediate reconstruction option increasing significantly¹

Market Breakdown

- US market opportunity: over $300 million
- Procedures: 100,000*
- Avg. revenue/procedure: $3000
- ADM rapid growth: 60% of share
- Growth of synthetic mesh: two competitor companies

Case Study
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Costs to get to market, timeline, regulatory hurdles

Initial investment and development costs

Revenue from 2020 onward

<table>
<thead>
<tr>
<th>Type of Barrier</th>
<th>Description</th>
<th>Difficulty</th>
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<tbody>
<tr>
<td>R&amp;D</td>
<td>Clinical data needed to establish safety/efficacy (FDA) vs. clinical superiority (reimbursement)</td>
<td>High</td>
</tr>
<tr>
<td>Reimbursement</td>
<td>Currently no reimbursement coding for resorbable, synthetic meshes</td>
<td>Medium</td>
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<tr>
<td>FDA</td>
<td>510(k) premarket approval due to “substantial equivalence” to existing product</td>
<td>Low</td>
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Preclinical Studies

Clinical Trials

Sales/Operations

Phase

Preclinical Testing

Clinical Trials 1-3 Years

FDA Approval 9-12 Months

Sales, marketing, distribution

Revenue

Year

2014

2015-2017

2017

2018-2019

2020 Onwards
Marketing Strategy to Key Stakeholders

Communications strategy needs to address:

**Product**
- Build product brand
- Emphasize strengths and benefits
- Market the ‘ease of use’ and ‘cost’ differentiator

**Publicize**
- Engage KOL, respected surgeons/scientists in regenerative medicine
- Target key peer-reviewed journals and leading national conferences
- Run ads in medical journals

**Direct Contact**
- Utilize expansive sales force
- Develop surgical training tools for variety of learning styles (e.g. in-person, videos, continuing education)

Key stakeholders:
- Surgeon
- FDA
- Hospital purchasing
- Insurance
- Patient

Decision power levels:
- High decision power
- Medium decision power
- Low decision power