Vagus Nerve Stimulation for the Treatment of Atrial Fibrillation

Team 20, Lessons Learned
101 Interviews
IRL 4
Founders (Rosellini/Spitaels) who have raised >$50M and wasted >$10M in VC funding on advanced implants with no market need. **DESPERATE FOR REPEATABLE PROCESS TO PROVE UNMET NEED**

- Added preclinical/clinical founders (Bates/Duke) to solidify clinical approach and translate technology with 7 publications, >100 canines, and n=20 clinical patients

- **We assumed that because neurostimulation companies weren’t studying Atrial Fibrillation we were wrong to pursue it**
What we missed

• Atrial fibrillation (AF) affects **3 million** Americans with more than 529,000 hospitalizations.

• Prevalence is expected to double by 2020.

• Total annual treatment costs are estimated to be **$6.65 billion**, including **$3 billion** for hospitalizations directly related to AF diagnoses, **$1.95 billion** for inpatient management of AF.

• Comorbid diagnosis of stroke increased the cost to **$12 billion** in 2006, primarily because of the costs of rehabilitation, long-term care, and lost income (shameless plug for Microtransponder, Inc.)
Key Personnel

Will Rosellini  CEO

- 6 advanced degrees: JD, MBA, MS Neuroscience, MS Comp Biology, MS Reg Science
- Founder/CEO returned $40M to investors
  - LTG-DSS (exit, reverse merger, 2012)
  - Sarif Biomed (acquired by MARA 2013)
  - Microtransponder (IPO plans in 2016)

Mark C. Bates, MD  Founder/IE

- Cardiovascular intervention opinion leader having performed or supervised 1000s of cases and published > 100 manuscripts.
- Innovation expert with over 60 issued or pending US patents
- Founder of multiple medical start-ups generating 5 acquisitions by large device companies and 1 merger.

Austin Duke  CSO and Founder

- PhD in Biomedical Engineering
- Expertise in biomedical engineering, biomedical optics, neuromodulation
- Work featured in Nature Photonics and Journal of Neural Engineering
- 7+ Years in preclinical/clinical R&D
- Principal investigator for US and international grants

12/10/2014
First BMC – 11 Interviews

- **Key Partners**
  - Manufacturer
  - Software Firm
  - Regulatory Counsel
  - Distributor
  - Non-dilutive Financing
- **Key Activities**
  - Prove Clinical Outcomes
  - Demonstrate Cost Efficacy
- **Value Proposition**
  - Treatment for Refractory Pts
  - <AF Burden
  - >NSR
  - Identify responders first
  - Simpler data presentation
- **Customer Relationships**
  - Journals
  - Conferences
  - Physician Advocates
- **Customer Segments**
  - Cardiac EPs
  - Med Device companies
  - Patients with advanced AF/HF
  - Patients with co-morbidities
- **Cost Structure**
  - Device COGS
    - Manufacturer
    - Clinical Trial
    - Distributor
    - Labor
- **Revenue Streams**
  - Device Sales
    - IP License
    - SW License
    - Reimbursement for Data

- **Hard to treat & Study**

12/10/2014
What We Did

We “got out of the building”, talked to Physicians and Patients, asked some wrong questions

- Q: Would patients with AF take an implant?
  - A: Yes – much trust in doctor’s advice

- Q: We think early-stage AF is adequately treated, but it would be cool to treat patients that also have HF, right?
  - A: Right, there are no treatments for those patients.
# Updated BMC – 30 Interviews

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*12/10/2014*
Talked to many physicians and Cardiovascular Device Execs, but asked more **wrong** questions

- Q: If we solved advanced AF that would be pretty cool, right?
  - A: Yes! Absolutely! Nothing has advanced in 30 years.

- Q: What are the most important outcomes to show/measure in a clinical study?
  - A1: Must be improvement in AF burden!
  - A2: Must be improvement in symptoms!
Updated BMC – 60 Interviews

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What We Did, Finally

Attended conferences, talked to more physicians/execs, and asked the right questions

- Q: If we gave you a device that treated patients with early-stage AF, would that be a big deal?
  - A: Yes! As many as 25% of my patients don’t respond to therapy or aren’t eligible for competing therapies

- Q: If we give you clinical data and IP, do you care if we don’t have a device?
  - A: Not at all. Don’t spend $ on a device. We already have them
Updated BMC – 100 Interviews

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Key Activities
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- IP
- Neurostimulator

Value Proposition
- Treatment for Refractory Pts
- AF Burden <50%
- NSR >90%
- Symptoms <50%
- KOLs

Customer Relationships
- Journals
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- Indirect Distribution
- KOLs
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Customer Segments
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12/10/2014
Here’s where we are:

- Received NIH and EU Contracts totaling >$7M to develop approach for a number of autonomic disorders.
- Acquired Synaptix, SA and repurposed CE Marked IPG for use as a Vagus Nerve Stimulator
- Completed >100 KOL interviews to confirm clinical approach
- EC/CA approval for 10 patient, 2 site feasibility study

☐ Cuff lead to begin MRI compatibility testing
☐ Phase II SBIR submission in Q3 2014
  ☐ Phase 1 Preclinical Data + EU Clinical Data

☐ Need $1.5M A round to match $5M BioWin award to fund GMP device for follow-on 20 patient study
Investment Readiness Level

Plausible exit
Cash to exit
Unit economics Validated
Reimbursement
Regulatory
Intellectual Property
Attractive solution & ID of MVP
Compelling clinical need + large mkt
Effective team?
**First BMC – 11 Interviews**

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**Key Resources**
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- Neurostimulator

**Indirect Distribution**
- KOLs
- Conferences

**Channels**
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**12/10/2014**