MN-REACH Pilot

K. Nickels

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Who is Kevin Nickels

• Recovering Mechanical Engineer
• Systems oriented leader
• Value opportunities to positively impact the delivery of healthcare and creating value to all stakeholders
• Some areas of where I have helped along my journey
  – Nephrology/1st HF dialyzer (Cordis Dow)
  – Plasmapheresis – RA/MS (Cobe)
  – Cardiopulmonary – oxygenator (Scimed)
  – Cardiovascular – Angioplasty (SciMed)
  – Non-invasive spine (Kinesis Medical)
  – POS diagnostic (Rapid Diagnostek)
  – Tissue regeneration/healing (Celleration)
  – Venous Disease (Advance Vein Therapy)
  – Transdermal Drug Delivery (Rubigo Therapeutics)
  – Immunotherapy (CytoPherx)
  – Remote Cardiac Monitoring/mHealth (Preventice)
• Raised capital (~$100M) and/or monetized assets
  – Debt, Convertible Debt, Equity, Licensing and Grants
  – Angels, VC, Corporate, Government
• Today, finding a role in helping frustrated investors/Boards AND Founders with their startup
**Session 3: Commercialization Pathway**

| Objectives: | 1. Understand the difference between a product/service opportunity and a business opportunity  
|            | 2. Understand the pre-requisites and implications of different FDA and international regulatory approval paths  
|            | 3. Understand technology adoption and diffusion processes  
|            | 4. Determine if team’s technology should be licensed to an established firm or a startup  
|            | 5. Define the product *development* pathway (milestones, timeline) for team’s technology (based on hypothesized regulatory approach)  
|            | 6. Define product *adoption* pathway (timeline, sequencing of market segments, potential penetration rates) for team’s technology |

| Preparation: | Read: Diffusion of Innovation in Health Care (Cain & Mittman, 2002)  
|             | Read: *EITHER* FDA Regulation of Medical Devices (Johnson, 2012) *OR* How the FDA Approves Drugs (Thaul, 2012) |

| Content: | 1. Review what was learned from initial customer discovery activities, implications to value proposition hypotheses  
|          | 2. Aligning product development with the regulatory path  
|          | 3. Aligning product adoption with overall technology diffusion/ adoption factors  
|          | 4. Roles/dynamics of partners, licensees |

| Activities: | 1. Start commercialization research project plan  
|            | 2. Start product development plan/regulatory plan  
|            | 3. Start product adoption plan (including revisiting beachhead market, |

| Homework: | 1. Complete commercialization research project plan, product development plan, product adoption plan |
What many startups experience

What many of us were taught ...

All I Need to Do is Execute the Plan

What we know now...

Many business plans don’t survive first contact with Customers....Investors.... Or Exit Partners

...Leading to very frustrated Investors and exhausted/churned management teams
### Key Partners
- Curriculum development and instructional technology companies (The Learning House, Blackboard, University of Nebraska)
- Web-based curriculum software companies (School Software Group)
- Global Business Solutions
- Mayo Medical Ventures/ Mayo Medical Labs & Affiliated Practice Networks
- Marketing firms (education focused)
- Faculty/content experts
- Mayo Continuous Professional Development (CPD)
- Accreditors
- Certification bodies

### Key Activities
- Research potential market
- Curriculum design/redesign
- Pilot product with key learners/users
- Marketing/sales
- Delivery platform
- Contract development/legal process
- Consulting services

### Value Propositions
- Provide world class curriculum that is available to other institutions for education of allied health workers.
- Leverage Mayo Brand as the gold standard for professional development/continuing education resource for allied health professionals.
- Standardized curriculum will improve quality, decrease variation and lower costs.
- Quality of healthcare delivery impacts patient recovery/satisfaction, cost of providing care and is determining government funding; quality of education impacts the quality of care.
- Improve efficiency of curriculum development and dissemination of content. Education costs are unsustainable with each instructor creating their own curriculum and quality is variable.

### Customer Relationships
- Universities with Allied Health Sciences programs
- Medical institutions
- Students
- Faculty/Educators
- Professional associations
- Students and allied health professionals

### Customer Segments
- Potential students
  - Career seeking,
  - Un/under employed, career changers
- Universities
- Medical institutions
- Faculty
- Education administrators
- Clinic administrators
- Online curriculum companies
- Allied health professionals
- Government/ apprenticeships/ armed services

### Key Resources
- Instructional designers
- IT support
- Curriculum designers
- Content experts/educators
- Learning Management System platform
- Marketing consultants
- Customer service/support
- Pilot sites (University of Nebraska)

### Channels
- Software development
- Education trade shows/conferences
- Publishing companies
- Professional associations
- Web based advertising
- Traditional marketing measures
- Distribution methods: curriculum management system via the web
- National education organizations, certification bodies

### Cost Structure
- FTE
- Marketing
- IT support
- Software/hardware
  - Variable costs: system capacity, faculty capacity for interaction with students, tech support for students/faculty
  - Economies of scale: incremental costs for additional students are fairly low

### Revenue Streams
- Licensing agreements with customers
- Direct sales through software packages
- Web-based sales
- Partnership (professional associations, medical institutions, online education providers)
- Consulting on new program set up and program management
- Hosting the curriculum
- Customizing the curriculum
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### Customer Segment

- Potential students
- Career seeking
- Un/under employed, career advancers & career changers
- Universities
- Medical institutions
- Faculty
- Education administrators
- Clinic administrators
- Online curriculum companies
- Allied health professionals
- Government/apprenticeships/armed services
AFTER 8 weeks and 113 Interviews later...

**VALUE PROPOSITIONS**

- Increase Clinical Site Availability by 25%.

**CUSTOMER SEGMENT**

- Allied Health Administrators
- Allied Health Program Directors
Type of Market has a huge impact on multiple areas of your business

- **Market**
  - Market Size
  - Cost of Entry
  - Launch Type
  - Competitive Barriers
  - Positioning

- **Sales**
  - Sales Model
  - Margins
  - Sales Cycle
  - Chasm Width

- **Customers**
  - Needs
  - Adoption

- **Finance**
  - Ongoing Capital
  - Time to Profitability
What we wish about healthcare

- Simple needs
- Simple transactions
- Sweet, refreshing outcomes
Drivers in Life Science Acquisition Process

What we wish were drivers

1. Clinical utility
2. Medical need
3. Standard of care

What they actually are

- KOL opinions
- Reimbursement levels
- Publications (reviewed)

And Often get...

- Regulated speech
- Clinical trial results
- Industry practices
More startups fail from a lack of customers than from a failure of product development.
The Company

Background:
• 1999 Founded with $2M
• 2001 – Mgmt Team Fired by Series A Investor by inability to align and execute
• Feb’02 – New Mgmt team met with CMS and FDA to discuss clinical study to obtain reimbursement and market clearance

May’02 Presentation for Series B
June’15 Company Acquired by Aliqua Medical
Clinical Case Study – Wound Closure

Treatment standard of care (including PDGF)

Treatment standard of care **Plus** MUST Therapy (no PDGF)
Reimbursement Strategy

- Establish Clinical Efficacy and Pursue Dedicated CPT Code for wound healing
  - Educate CMS in the Value of Technology
  - Establish Clear Clinical Efficacy
  - Establish Compelling Value Proposition
  - Begin establishing support of Professional Organizations (Q3-4’02)
  - Request New CPT Code (Late 2003, pending initial FDA approval)
  - Apply for HCPC codes (Mar’04)

- Establish base of users with existing debridement CPT codes
  - Utilize CPT Codes for Clinician and other care providers
  - Pursue payment from Clinic Administrators for technology and disposables based upon Physician champions, clinical and economic data
**Company History**

- **April 1999**: Company Incorporated
- **July 2000**: $2.0M Series A Financing From Tyco Ventures
- **Aug 2003**: Patent Issued for Ultrasound Drug Delivery Device
- **Dec 2003**: Patent Issued for Ultrasonic Wound Treatment Device
- **June 2004**: FDA 510K Initial Clearance
- **June 2004**: $2.0M Series B-2 Financing Led By Affinity Capital
- **Aug 2004**: Initial Commercialization Team established
- **Dec 2004**: $2.5M Convertible Bridge financing led by Prism Fund
- **June 2005**: $300K in Sales for 1st Half and 2nd FDA Indication Approved
- **August 2005**: Diabetic Foot Study Peer-reviewed and Published in OWM
- **October 2005**: Completed $20.6M Series C Financing led by Triathlon Medical Ventures and Baird Venture partners
- **June 2006**: $6.8M Series B-1 Financing Lead By Affinity Capital
- **Thru a deNovo pathway after two NSE letters**
In March 2013, the AMA approved a CPT I code, 97610, for MIST Therapy effective January 1st, 2014. MIST Therapy Category I Code 97610 – Low-frequency, noncontact, nonthermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.

10 years later than what we understood …
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  - **Product Market Fit is critical to finance your Company and have a successful product**
  - Understand commercial risks and then, sourcing capital appropriately to manage those risks and timing dynamics critical to having a successful Company/Exit.
Thanks!

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