The Evolution of a Point of Care Company

From R & D to Commercial Launch

Karen Hedine, President
Micronics, Inc. : Background

• Founded 1996
• Technology platform: laminar flow diffusion-based microfluidics (non-turbulent mixing)
• Key microfluidic differentiators at the time:
  • Use of thin film laminates versus silicone or glass
  • Early focus on diagnostic vs life science applications
• Company holds over 70 issued patents
  • Substantial expertise in sample prep, reagent integration, fully integrated disposables
In the beginning.....

- Investors had the vision for an IVD company
- Scientist / university had the technology
- Management team hired from large immunoassay-oriented companies

**Influencers**
- Microfluidics was a potential game changer
- *Lab on a card* rated one of the top 10 future technologies; IVD product applications TBD
Company Overview

Building value with emphasis on improving healthcare

1996 -
Advanced Patented Microfluidics Platform; venture backed; Series A-E

2002
Series A Recap

2004 -
Revenue generating customer services business / life science products

2005 - 2011
Peer Validated Technology:
- NIH
- CDC
- DOD
- Fortune 100 & Venture-Backed Clients

2008
Series B/C

Self-funded

2008
Series B/C

Today:
Acquired by Sony 2011
- IVD Products
- Custom Development

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Tipping Points That Lead to Business Transition

- Leadership Changes / Direction
- Recapitalization
- Freedom to Operate
- Post 9/11 & Other Drivers
- Funding
- The Future for POC
Leadership Changes / Direction

• 2001 - Change mutually motivated by investors and management

• **Core Strategy**
  • Management assumed certain risks in exchange for greater control
  • Business direction shifted to molecular diagnostics / POC
  • IP escalated as core asset
  • Exit plan / strategy outlined

• **Key Lessons Learned**
  • Importance of aligning technology with market opportunity
  • Industry experience / familiarity with commercialization hurdles / market
  • Board composition and support
  • Strategic execution on a plan: focus, focus, focus
Recapitalization as Part of Re-Direction

- Key questions:
  - Would company be able to attract necessary funding given current structure & needs?
  - Was the Exit Strategy clear & rewarding to key stakeholders?
  - How far would restructuring take the company; what more needed and when?
  - How to attract funding in down market(s)?
  - What trade offs would management / investors be willing to make?
Freedom to Operate

- Strategic IP plan implemented
- In line with business strategy / product plans
- Ability / opportunity to leverage as needed
- Competitive positioning
- In-versus out-license factor consideration

With internal business focus on POC IVD applications, needed to assess:
- System claims
- Reagent claims
- Intended applications
- Competition
- Market factors – time to market vs patent expiration dates
- Cost trade offs: trade secrets vs patent filings

FTO is a never ending process
Freedom to Operate

- IP assessment / plan deemed essential component of future success
  - Prosecution plan - when, where?
  - License considerations
    - Upfront fees
    - Royalties
    - Emerging market discounts
    - Government discounts
    - Deal timing vs product launch
    - Patent life

- **Core Strategy**
  - Negotiate global license rights, with lowest burden on COGS
    - Applicable to many of the target applications

- **Lessons Learned**
  - Since Micronics had solid IP estate, non-exclusive 3rd party licenses sufficient
After 9/11, demand for more specific and sensitive tests

Point of Information / Near Patient Point of Care paramount for many applications
- Private and public funding opportunities
- Diverse end users: public health, military, EDs...

Tests varied but shared common themes consistent with WHO’s ASSURED guidelines:
- Affordable
- Sensitive
- Specific
- User Friendly
- Rapid and Robust
- Equipment Free
- Deliverable to End Users
Other Drivers

- Disaster recovery
  - Emergency preparedness - Hurricane Katrina
  - Epidemics / outbreaks – H1N1
- Patient care outcomes – the impatient patient
  - New testing environments
    - Home INR testing
    - Accident scene blood gas testing
    - ED HIV testing
    - Emerging markets
- Regulatory changes
  - FDA – ease of waived testing requirements
  - Many POCT programs and POLS limit menus to waived tests
- Work force issues
  - National shortage of trained laboratory technologists

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Responding to Drivers

- Company well positioned:
  - Successful track record with DARPA
  - Demonstrated ability to simplify complex tests for ease of use
  - Advanced POC platforms responsive to broad set of emerging needs
  - Breadth of technology demonstrated
  - Held core IP or licenses to advance test development in fields responsive to market and central to business objectives

The two most important requirements for major success are:
first, being in the right place at the right time, and second, doing something about it.
- Ray Kroc
Funding The Technology

• Financing is time consuming and requires alignment of visionaries and adopters
• Read: Crossing the Chasm – Geoffrey Moore

• Company decided to pursue alternative means to fund core technology and specific tests / product feature advancements
  • Custom development for others /select out-licensing
  • Public / private funding / collaborations

Custom development for others /select out-licensing

• Provided the opportunity to work with established, experienced product-centric companies
  • Garnered insights into market trends, regulatory considerations, costs / timelines

• In return, customers obtained licenses to IP and /or expertise in solving product problems
Funding: Other

1. Federal Contracts/Grants
   - Applied as prime and as small business subcontractor
   - Performed scheduled tasks on schedule / budget

2. Foundation Funding
   - PNW consortium received the first Grand Challenge's in Global Health award from the Bill and Melinda Gates Foundation for the advancement of a POC device responsive to the needs of the developing world

   • Core Strategy
     - Retained all rights to its Background IP and any Derivatives developed under funding
     - Where possible, negotiated commercial rights to any product advanced under funding

   • Lessons Learned
     - Have a good contracts lawyer
     - Patenting before publishing
     - Manage contracts / subcontracts / FAR provisions carefully and actively
Vetted Technology

Contract /grant awards for Enteric Pathogens, Respiratory, HIV-MTCT, STDs

Collaboration for POC HIV – MTCT test

Contracts for development of ABORhCard and advancement of point of care molecular diagnostics for HIV, HBV, HCV

Grand Challenge in Global Health #14: the DxBox NAT / immuno “fever panel”

Subcontracts for advancement of CBW product applications: mass spec detection, sequencing
Funding the Future

• Core assets and proof of concepts well established
• Further funding needed to push products “over the wall”
• Infrastructure required to grow the company and product plan
  • Sales and Marketing
  • Systems Development
  • Clinical Trials/ Regulatory
  • Manufacturing

• Options weighed
  • Timing /Market Deal Trends
  • Business Growth Needs & Plans
  • Corporate “Fit”
  • Other Deal Terms
• Company became wholly owned subsidiary of global business with medical business growth strategy: synergistic support
The Future of POC

- Continues to represent one of the fastest growing segments of clinical laboratory market – estimated growth from 10-12% per annum
- New drivers continue to fuel growth
  - Technology advances – next gen sequencing, cloud computing, innovative solutions
  - Changes in the clinical environment that necessitate shorter hospital stays, improved patient turnaround time
  - Market demographics – expansion of healthcare infrastructure in emerging markets
  - Therapeutic advances developed in conjunction with diagnostic tests
  - Continued shift of some test to home care – e.g., self monitoring anti coagulation
  - Has applications in other markets (vet, food safety, environmental monitoring, bio threat, etc.)

Key influencers to consider
- Voice of the Customer
- Regulatory
- Competition
- Funding
- Distribution
- IP

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