Leveraging Consulting to Build a Bionic Technology Company

Robert Horst
Tibion Corporation
Email: bob@tibion.com
Web: www.tibion.com

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Outline

• Iterating to find and perfect the right technologies
• Building prototypes for early market feedback
• Addressing medical device challenges
  – reimbursement
  – quality systems
  – FDA clearances
• Meeting VC investment objectives
• Market focus and clinical validation
• Lessons learned
The Plan (in 2002)

- Create active orthotic products to augment and rehabilitate muscle function
  - Enhance quality of life for the mobility impaired
  - Promote effective recovery and rehabilitation regimens
  - Address multiple musculo-skeletal pathologies

- Create revolutionary new technology

- Drive creation and ownership of a new active orthotics industry
Target Market Areas (2002)

Market Segments

Impaired Mobility
- ALS
- Cerebral Palsy
- Multiple Sclerosis
- Muscular Dystrophy
- Osteoarthritis
- Parkinson’s
- Polio
- Spina Bifida
- Stroke

Rehabilitation
- Surgical Recovery
- Mobility Assist / Ambulation
- ROM / Muscle Strengthening
- Monitoring / Feedback

Exercise
- Weight Training
- Resistive Force Training
- Performance Assistance
- Monitoring / Feedback
Market

795,000 strokes per year
  - Every 40 seconds, a stroke occurs

635,000
  - Survive and require therapy
    (Conroy, Topics in Stroke Rehab)

400,000
  - Enter rehab hospitals (IRF) or skilled nursing facilities (SNF) for therapy
    (Conroy, Topics in Stroke Rehab)

$7.6 billion/year on post-stroke rehab
  - (Agency for Health Care Policy and Research)
Stroke in the U.S. – Chronic

- 6.5 million people living with stroke (AHA)
- 50% are stroke survivors that still have gait impairments (Visiten, Stroke Journal)
- 3M+ chronic stroke survivors who would benefit from Bionic Leg Therapy
The Plan

- Novel idea
- Working Technology
- FDA Clearance
- First Patient Success
- First Sale
- Scalable Revenue Plan
- Funding for Growth
Key Technologies

- Actuator
- Battery
- Embedded Software
- Orthosis
- Electronics
- Control Panel
- Bluetooth
- Sensors

Tibion Bionic Technologies
Move... yourself.

Wednesday, October 19, 11
**Tibion Technology Overview**

- Efficient transfer of force to body
- Continuously variable transmission actuator
- Integrated electronics board with high current motor drivers that do not interfere with low voltage biomechanical sensors
- Charging and switching electronics for high-current Lithium Ion batteries
- Custom motor controller using a field programmable gate array to
- Real-time software system including sensor acquisition, motor control and user interfaces
- High-level software algorithms to address various patient needs
- Algorithms for transparent assistance
- Wireless data access
PowerKnee Mechanical Prototype

- Uses DC motor and 380:1 reduction gear to provide assistance.
- Control electronics is embedded microprocessor plus motor controller.
- Allows Tibion to:
  - Determine force requirements
  - Optimize control algorithms
  - Evaluate effectiveness of assistance
- Is much bulkier than final product
  - Motor/gearing is much heavier and larger than electrostatic motor
- Cannot replicate some uses of final product due to lack of free movement mode.
Actuator Development

- Much more difficult than we ever imagined
- Designed and/or prototyped 9 ideas before finding one that met all requirements

1. Linear Electrostatic
2. Rotary Electrostatic
3. Harmonic Rotary Electrostatic
4. Hybrid Electrostatic/Magnetic A
5. Hybrid Electrostatic/Magnetic B
6. Hybrid Electrostatic/Magnetic C
7. Single belted CVT (continuously variable transmission) A
8. Single belted CVT B
9. Dual belted CVT

- Final approach
  - Electronically variable CVT
Electronics

◆ Control Board
  ◆ ARM7 Processor
  ◆ Custom FPGA motor controller
  ◆ Battery charger
  ◆ Sensor Interfaces
    ◆ Current/voltage/temperature
    ◆ Force sensor
    ◆ Position sensors
◆ User Interface Board
  ◆ Display processor (ARM7)
  ◆ 128 x 128 RGB Organic LED display
  ◆ Speaker for audible alarms
Electronics Evolution

Off-the-shelf processor and motor controller boards

Custom motor controller prototype

Integrated processor and motor controllers

Reduced size with integrated processor, motor controllers and sensor interfaces
Live Data Utility

- PC application interfaced to PowerKnee via Serial Port or Bluetooth
- Observation of selected configuration information and live sensor data
- Setting of configuration parameters
- Recording min and max values of selected parameters
- Error logging
- Capture of traces for export to Excel graphs and later analysis
Tibion Bionic Leg Evolution
Stroke Rehabilitation Today

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Related Products

Exoskeletons under development in US, Israel, Japan
  - Not therapeutic, not for rehab
  - Not intention based

Movement governed by:
  - Position control and/or EMG feedback

Essentially, “Vertical Wheelchairs”
The Future of Medical Robotics
How Bionic Leg works

• Sensors in shoe detect weight distribution
• Sensors in knee orthosis
  – *Detect knee angle*
  – *Detect intended movement*
• Therapist programs Bionic Leg computer
  – *Patient weight*
  – *Start force*
  – *Assistance/resistance*
  – *Assist extension limit*
Bionic Leg: Transforms post-stroke gait recovery

- Wearable robotic device equalizes affected, unaffected legs
Bionic Leg Therapy

- Progressive Functional Mobility Training
  - Sit to Stand, Transfers
  - Pre-gait & Static Balance
  - Progressive Gait and Stair Training
    Over-ground & Treadmill

- Interactive Intervention
  - Therapist driven modulation
  - Positive feedback: i.e. weight bearing thru limb leads to desired assistance
Tibion Access Plan

Allows rapid implementation of latest rehabilitation technology

Avoid large capital investments

Always have cutting edge equipment through regular upgrades

Avoid obsolescence

<table>
<thead>
<tr>
<th>Access Plan (12 month contract)</th>
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<tbody>
<tr>
<td>TBL</td>
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<tr>
<td>Training &amp; Consumables</td>
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Compatible/compliant with CMS

- Medicare Part A, Part B pay for the therapy the Bionic Leg enables – no special codes, no extra paperwork
- Bionic Leg persuades
  - Patients to come back for more rehab sessions than conventional therapy
  - Private insurers to pick Bionic Leg providers, extend therapy past normal limits
  - SNF patients to pay for extra days
Timeline

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>2001</td>
<td>Begin Research Research</td>
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<tr>
<td></td>
<td>5/27/01</td>
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<tr>
<td>2002</td>
<td>Tibion Incorporated</td>
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<tr>
<td>2003</td>
<td>Win Business Competition</td>
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<tr>
<td>2004</td>
<td>Series A $3.5M</td>
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<td>2005</td>
<td>First Neuro Patient</td>
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<td>2006</td>
<td>First Sale (Whittier) $10.2M</td>
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<tr>
<td>2007</td>
<td>Series B</td>
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<td>2008</td>
<td>$L</td>
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<td>2009</td>
<td>$</td>
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<td>2010</td>
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<td>2011</td>
<td>$FP</td>
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Key to Crisis

M - Financial Meltdown
$ - Out of money
? - New invention needed
L - Leadership change
F - FDA Audit
P - Production Problem

Major Activities

Research  Technology Dev  Design  Quality  Mfg/Sales

VC Presentations

Major Questions

Meet req for force, size, weight?
Can we find investors?
Will it help patients?
Can we sell any?
Is it a business?
Lessons Learned

• Start a company for the right reasons
  – To do exciting work
  – To make a contribution
  – Not to get rich (there are easier ways like the lottery)
• Consulting as an alternative to seed funding
  – Support yourself with consulting
  – Spend remaining waking hours at startup
• Must be the right kind of startup
  – Not for companies in competitive space (too slow)
  – Best for companies with unproven technology or market
• Time management is difficult
  – Initially hard to get enough consulting work to survive
  – Later hard to turn down work to build the startup.