Innovations in Spirometry

ENPRO 357

Business Plan Presentation

Autumn 2001
The #3 cause of death in the US

26 Million diagnosed asthmatics

COPD (Chronic Obstructive Pulmonary Disorder)

Diseases often monitored at home using peak flow meters
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Spirometer:
An instrument for measuring the volume of air entering and leaving the lungs.
Clinical Spirometers

$2000 and up

Operated by trained medical personnel

Require a PC to operate

Require calibration on a daily basis
Home Spirometers

- Less accurate
- Only perform one test
- Don’t perform FEV1, which is preferred by physicians
- Patient responsible for recording data
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Home Device with Near Clinical Accuracy

Device capable of performing multiple tests, including FEV1

Affordable for home use

Does not require calibration

Logs test results automatically

background  issues

technology  customers

financials  future

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Technology

Fluidic Oscillator
Electronics package

Benefits

Affordability
Accuracy
Versatility
Automatic Diary

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fluidic oscillator
30 million Americans with chronic lung diseases

Target asthma patients first
- Youth (under 18)
- Women
- African Americans

Insurance companies, physicians
Need clinical evidence to prove benefits
Percentage Distribution of Asthma
By Sex, Age, Race and Geographic Region, 1998

SEX

Male
4,550,372
42.9%

Female
6,062,684
57.1%

AGE

Asthma
10,613,056
Conditions

5-17 years
2,894,220
27.2%

18-44 years
3,817,945
36.0%

45-64 years
2,081,312
19.4%

Age 65+
924,618
8.7%

RACE

Other
889,854
8.4%

Black
1,679,906
15.8%

White
8,351,811
78.7%

GEOGRAPHIC REGION

Northeast
2,177,833
20.6%

South
3,774,017
35.6%

West
2,230,046
21.0%

Midwest
2,431,160
22.9%

Monitor disease accurately
Low cost/ no cost to patient
Physician recommended
Improve diagnostic ability
Reduce hospitalization
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First must pass ATS 1994 standards
Gain IRB approval and obtain IDE
Four stages of clinical trials
FDA Approval
Market device to asthma patients
Collect long-term use data to convince insurance companies of benefits
Either license technology or become an LLC to manufacture and market product.

Focus primarily on asthma patients.

Convince insurance companies of benefits for asthma patients.

Use clinical trial data and expert panels.

Spirometer will be ~$200.

Not as expensive as a diagnostic spirometer, more accurate than a Peak Flow Meter.

Possibility of bundling with software.

Market to physicians as compatible with current technology.
Lung disease patients

- 26 million people with asthma
- 3.0 million with emphysema
- 8.9 million with chronic bronchitis
- 10.6 million with COPD

If we capture 15% of the asthma market with one product per customer:

- 1.59 million people
- $318 million in sales

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Polarized market

Peak Flow Meter Makers ($6 to $30):
- Ferraris, Nellcor Puritan Bennett, Respironics, Spirometrics

Spirometer Makers (> $2000):
- Nellcor, QRS, Schiller, Micro Medical, PDS, Spirometrics

Our product is a niche product, accurate monitoring device at low cost ($200)

Competitors unable to develop our technology

Clinical trials key to prove benefits
• Profit Margins
  – Standard medical device profit margins (4-4000%)
  – 200%

• Retail Cost per Unit: $200
Budget for Autumn 2001
funded through generous support of
Irving and Sylvia Footlik

Phase III Budget
Spring 2002 – License Agreement
## Budget Phase III: Research and Development Continuation

This budget contains provisions to complete the research and development of the spirometer. Research and development will take place concomitant with patent application and identification and recruitment of strategic partner relationships. It is expected that development will require major investments in personnel, materials, and equipment. Below is a detailed breakdown of the expected costs:

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<th>Item</th>
<th>Size</th>
<th>Model</th>
<th>Rate</th>
<th>Cost</th>
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<td>$75/hour</td>
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<td>2 weeks, 1 person)</td>
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Research & Development

- Subcontract Electronics  
  Spring 2002

- Finalize sensor selection & oscillator design  
  Spring 2002

- Proof-of-concept Clinical Trials  
  Summer 2002
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Business Development

- Patent Application  
  Winter 2002
- Patent Approval  
  Autumn 2003
- Identification of Strategic Partners  
  Summer 2002
- License Agreement  
  Autumn 2003
• **Hurdles to Overcome**
  - FDA Approval
    - Minor issue to obtain permission for clinical trials

• **One major risk: patentability**
  - Identify alternate strategies for protecting intellectual property

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**Autumn 2001**
• Humanitarian Benefits

• Capitalist Benefits
   - Existing Market
   - Ease of Use
   - Retail Price
   - Low Risk

Return on Investment!
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