A Primer for budding entrepreneurs: *I think I have a great idea, now what?*

- Background on Confluent
- The Primer...
- Discussion
Company Overview

- Platform technology of “in situ polymerized” biomaterials and delivery devices
- Targeting large potential markets in biosurgery, specifically: Adhesion Barriers and Sealants
- First to market products
- Products commercially available

Confluent’s vision is to be the leading developer of products for unmet needs associated with surgical sealing and adhesion prevention
Proprietary "Reversible" Hydrogel Technology

LIQUID

Water Soluble PEG Reactive End Groups

Hydrolyzable Segments

When mixed, the liquids crosslink to form an absorbable hydrogel

 compañia de asistencia médica

GEL

Amino acid with Reactive End Groups

Reaction (~2 sec)

(> 90% water)

Segments Hydrolyze

LIQUID

Amino acid with Reacted End Groups cleared by kidneys

Absorption (4-8 weeks)

Water Soluble PEG cleared by kidneys
DuraSeal: Broad applicability and dual benefit

**Sealant** > Cranial, Spine, Vascular, Thoracic

**Adhesion Barrier** > Cranial, Spine, Cardiac

**Significant revenue opportunity:**
$1,372 billion initial target opportunity for Confluent

- Spine: $358
- Neuro: $304
- Thoracic: $148
- Vascular: $371
- Cardiac: $191
DuraSeal – Mechanism of Action

Intended Use:
• Duraseal is intended for use as an adjunct to sutured cranial dural repair to provide watertight closure.

When applied, DuraSeal:
• Rapidly diffuses into tissue crevices and crosslinks
• Interlocks within tissue crevices resulting in excellent tissue adherence
• Blue colorant allows for visualization of gel coverage and thickness
DuraSeal – Mechanism of Action

DuraSeal can withstand elevated CSF pressures due to:

- Strong tissue adherence
- High cohesive strength
- Biomimetic elasticity
DuraSeal – Mechanism of Action

Post operative attributes:

• Separates dura from the bone flap preserving the tissue plane

• May facilitate subsequent re-operation
DuraSeal – Mechanism of Action

Biocompatible absorption:

- Water soluble linkages hydrolyze over 4 to 8 weeks
- Water soluble PEG molecules are liberated and cleared via the kidneys
DuraSeal – Mechanism of Action

DuraSeal Benefits for cranial surgeries:

• Creates an immediate watertight seal
• Blue colorant allows for visualization of gel coverage and thickness
• Reduces postoperative CSF leaks
• Safely absorbs after the body has naturally healed
• Easily prepared in 2 minutes
<table>
<thead>
<tr>
<th>Event</th>
<th>Quarter</th>
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<tbody>
<tr>
<td>DuraSeal begins EU commercial sales</td>
<td>Q4 ’03</td>
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<tr>
<td>DuraSeal PMA filed</td>
<td>Q2 ’04</td>
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<tr>
<td>FDA approval and U.S. Launch of DuraSeal</td>
<td>Q2 ’05</td>
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<tr>
<td>DuraSeal Spinal clinical trial begins</td>
<td>Q3 ’05</td>
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<tr>
<td>DuraSeal reaches $1.5 MM/month sales</td>
<td>Q4 ’05</td>
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<tr>
<td>Confluent acquired by Covidien for $245MM</td>
<td>Q2 ’06</td>
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Product Roadmap and Strategy

Overall Market Opportunity Size

Time

Combination Products
DuraSeal with antibiotics and analgesics

Adhesion Prevention and Sealing
SprayGel and DuraSeal

Surgical Sealing
DuraSeal
Financial Overview

Products commercially available

Exceeded forecast for 2005 by 25%

Profitable by 2006

Revenue ($ millions)

A Primer for budding entrepreneurs: *I think I have a great idea, now what?*
Considerations

- Evaluating the idea (critique, refine..)
- People
- Business plan and process
- Funding
Evaluating the idea: Real, Win, Worth
Evaluating the idea: *Real, Win, Worth*

**REAL**
- Does your product serve an unmet or an underserved need?
- What is the potential impact? Can it save lives?
- Are you in a dynamic field (cardiology, spine..)?
- Is this a technology platform or a product idea?
- Are your customers known to be early adopters?
- Is the problem a widely acknowledged one?

Net net: Solve a problem, solve a BIG problem, solve a known problem!
Evaluating the idea: *Real, Win, Worth*

**WIN**

- How elegant and differentiated is your solution?
- What is your “unfair advantage”?
- Is the product VERY easy to use?
- Is it cheaper, better, AND faster than BASE (Best Available Substitute)?
- Do physicians, patients, and payers ALL win?
- What are the barriers to entry (IP, regulatory)?
- Is this a 510K or a PMA product? Is this a drug or a biologic?
- Can your product kill a patient?
- What is the regulatory pathway/risk?
- How easy is it to demonstrate product efficacy/value proposition?

**Net net:** Solve the problem elegantly and completely. Dominate the hill rather than share the mountain!
Evaluating the idea: *Real, Win, Worth*

**WORTH**

- Is this a market development or a market replacement effort?
- How fragmented is the customer base? (How many and where)?
- How big is the existing vs potential market?
- Is this a disposable or a capital good?
- What kind of pricing?
- What is the “go to market” strategy? (DSO, distributors, corporate partners)?
- What is the time to market in the U.S.?
- What are the margins likely to be?
- Do you need to vertically integrate manufacturing or can it (at least initially) be outsourced?

Net net: Look for 70%+ gross margins, >$250 unit pricing for disposables, over $100MM existing and over $500MM potential market and a concentrated customer base!
People

Management and Employees
• Don’t hire everyone in your image
• Start with people you know, respect, and have proven successful
• A first time entrepreneur should consider having a partner/mentor
• Look for people with both large and small company experience
• All employees should be preferably “full time” so interests are aligned
• Consider deferring some salary for additional stock incentive
• Don’t hire too many academics, look for industry experience
• Don’t over-hire

Board and Advisors
• Have a board evenly stacked with insiders, independents, and investors
• Get physician customer and key opinion leaders involved early
Business Plan

Key Elements
• Executive summary- 5-7 page summary of the investment opportunity
• Market Opportunity
• Technology and Product
• Competition
• Clinical/Regulatory Strategy
• Marketing and Distribution Strategy
• Schedule of milestones
• People (Key employees, board)
• Financials (Budget, revenue forecast) for 3 yrs
• Limit full plan to <35 pages and have lots of charts, figures, and pictures
Business Plan

Process

• Find a good lawyer, who is versed in venture financings
• Clean house (Secure all the IP, contracts, agreements, financials, references)
• Consider having a product demonstration, if applicable
• Have physicians handy who are familiar with the product/technology
• Be prepared for a 6 month process where you have to speak to 50-75 groups
• Try to generate 2 competing term sheets, but don’t let them collude
Funding - Seed Stage

• Invest some of your own money, but NOT all your savings
• Consider “friends and family” for seed investment, but with caveats
• Consider physicians/customers as source of seed capital
• Seed investment can be raised as a “convertible note”
Funding - Series A (Institutional Round)

• Raise sufficient funds to reach a meaningful milestone
• Get at least one professional deep pocketed investor to value and invest
• Do reference checks on the investors prior to taking their money
• Do not fixate only on the highest valuation
• Find the right VCs through mutually trusted references
• Generate two competitive term sheets at a minimum
• Never stop generating leads until you have signed a term sheet
• Preferably combine the two competing sheets and get the “best of both worlds”
Funding - Series A (Negotiations)

- Set valuations not only for this round but for future anticipated financings, to prevent future “down rounds”
- Don’t be resistant to taking more money than you need
- Pay attention to
  - Liquidation preferences
  - Negative covenants
  - Voting rights
  - Board participation
  - Anti-dilution provisions
- Cap expenses
Caveats

• Every situation is unique
• Don’t be discouraged, everything takes longer and more money than planned!
• Remember…The only real protection for a start up is EXECUTION
• My views are more applicable to medical device deals
• Forming a company is not the only way to execute on an idea
  – License to established entities
  – Bootstrap and sell a product idea
• If you passionately believe in your idea, do something about it!
Thank You!