The Business of Bioscience

What Goes Into Making a Biotechnology Product?

Craig Shimasaki
BioSource Consulting Group
January 15, 2010
UC Davis Biotechnology

Overview

• Brief overview of biotech industry
• Characteristics of successful Biotech Entrepreneurs
• Considering starting a biotech company? What are the steps involved
• Preparing yourself for future career as biotech entrepreneur
Some Biotechnology Industry Statistics

- Started in 1976 with the cloning of human DNA into bacteria
- Created over 200 new therapies and vaccines
  - Cancer, diabetes, heart disease, AIDS, multiple sclerosis, Alzheimer's, arthritis
- Over 400 biotech drugs in clinical trials, more than 200 diseases
- Over 1,500 U.S. biotech companies, 350 publicly traded companies
- Worldwide more than 4,400 biotech companies
- Over 300,000 biotech industry employees worldwide
- 30 years ago there were no more than 5 companies
- In 2008, over $13 billion was raised by U.S. biotechnology companies

Types of Biotechnology Products

- Human Healthcare Products
  - Drugs, diagnostics, medical devices, genetic testing, vaccines, biologics
- Animal Healthcare Products
  - Veterinary drugs, diagnostics, vaccines
- Food & Agriculture Products
  - Genetically engineered animals, crops, vaccines
- Industrial & Environmental Products
  - Biofuel production, industrial enzymes, clean up products
Five Essential Facets to building Biotechnology Locally

• Availability of venture capital
• Proximity to high-caliber academic and research institutions
• Ready reserve of talented scientific workforce
• Presence of specialized laboratory space
• Availability of seasoned entrepreneurs

Why is the Biotech Industry Unique?

• Different from all other industries and businesses
  – Melding of science + business – creates a business of scientific uncertainty
• Different from IT and other high tech industries
  – Higher development costs
  – Longer development times
• Must reach three different customer markets
  – Patient, Physician, Payor
• One of the most highly regulated industries
Drug Discovery Timeline and Costs

**General Timeframe for Biotech Product Development**

<table>
<thead>
<tr>
<th></th>
<th>Applied Research</th>
<th>Dev</th>
<th>Clinical</th>
<th>Regulatory</th>
<th>Mfg</th>
<th>Marketing</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Therapeutic</strong></td>
<td>1 to 2 years</td>
<td>2 to 4 years</td>
<td>2 – 4 years</td>
<td>2 – 4 years</td>
<td>1 – 2 years</td>
<td>Patent life remaining</td>
</tr>
<tr>
<td><strong>Diagnostic</strong></td>
<td>0.5 – 1 year</td>
<td>1 to 2 years</td>
<td>1 – 2 years</td>
<td>0.5 – 1 year</td>
<td>0.5 – 1 year</td>
<td>Patent life remaining</td>
</tr>
</tbody>
</table>

**Total Product Development time**
- Therapeutic: 12-15 years
- Diagnostics: 5 to 7 years

**Average Cost of Product Development**
- Therapeutic: $350 million to $1.2 Billion
- Diagnostics: $25 million to $125 million

Source: PhRMA, based on data from Center for the Study of Drug Development, Tufts University
Characteristics Successful Biotech Entrepreneurs Have In Common

Biotech Entrepreneur Characteristics

- Passion and Vision
- Ability to speak two languages
- Multi-disciplined translator
- Learns new skills quickly
- Aware of “Unknown-Unknowns” syndrome
- Persistence
- Effective negotiator
- Good business sense
- Creative problem solver
Successful Entrepreneurs
Learn to be Great Leaders

• Leading is not knowing it all
• Leading is not dictatorship
• “Leading is enabling a team of highly talented individuals with shared core values to see, understand and reach the vision you draw for them”

What are the Backgrounds of a Biotech Entrepreneur?

• Scientist/Physician/BioEngineer from a university, non-profit research foundation or institute
• Scientist/Physician/BioEngineer from the biotech or pharmaceutical industry
• Businessperson such as former executives in venture capital, pharmaceutical or life science industry
• Core group of individuals spun off from another life science organization such as a pharmaceutical company
When starting a Biotech Company, what do you do first?

Overview of Steps

- Start with an innovative breakthrough discovery!
- Search for a commercial product idea from this discovery with a true market need
- License the technology under favorable conditions for development and financing
- Find a great attorney
- Protect intellectual property with good patent strategy
- Select the right business model
- Legally establish the business
Overview of Steps (con’t)

• Work as a virtual company as long as possible
• Identify and verify your marketing strategy
• Outline the product development path and make significant progress
• Write your business plan
• Raise plenty of capital and frequently
• Hire the best you can find
• Look for alliances and partnerships
• Focus on the regulatory and clinical phase early
• Develop a corporate culture of innovation
• Evaluate progress, make adjustments, execute

Product Development Pipeline
Three Simultaneous Development Programs

- Product Development (R&D)
- Corporate Development (Business and Financing)
- Market Development

Product Development Path

- Translational vs Academic Research
- Little R, Big D
- Identify and meet Product Development Milestones
- It's about creating value
- Value increases as risk is reduced
- Recognize scientific uncertainty
Corporate Development Path

- Identify corporate, patent, securities attorney
- Secure intellectual property, form strategy
- Set up a business legal structure
- Constitute Board, Advisory board
- Draft agreements – CDA, Non-compete, Invention Disclosure and Employment
- Issue founders stock, stock options, vesting
- Close financing rounds, terms and timetable
- Raising capital and from whom: when and how much

Market Development Path

- Most misunderstood and underappreciated “science” of biotech business development
- Develop a good marketing strategy
- Validate the market
  - Primary and Secondary market research
- Watch to be sure the science converges with the market need
Who Will You Work With? A Biotech Dream Team

Components of Biotech Success

- Operational Execution
  - Management Experience, Staffing
  - Technology, IP Protection and Regulatory

- Financing and Funding
- Market Development Proper Segmentation, Positioning
Reasons for Biotech Company Failures

Poor planning, Poor execution of the plan
• Running out of money
• Inability to raise more money
• Failure in clinical trials, no capital to continue operations
• Limited market for the product
• Technology failure, no capital to change development strategy

How can I prepare for a future as a Biotech Entrepreneur?
The path of a biotech entrepreneur is not so straightforward

Preparing Yourself for a Career as a Biotech Entrepreneur

- Get excellent education and training
- Have an inquisitive mind (life-long learner)
  - Especially about things outside your area of expertise/experience
- Read lots of books
- First job in the biotech sector of your interest
  - Understand what best practices look like
  - While there learn as much in your discipline and other functions as possible
- Attend many forums, interact and listen to others in the industry
Preparing Yourself for a Career as a Biotech Entrepreneur

• Learn about businesses – spend a portion of your reading about business and business strategy
  – Business Week, Wall Street Journal, business books written by CEOs and former CEOs
• Understand the “whys” of business
  – know the consequences
  – think of better ways to solve the same business problems
• Consider MBA or additional business training
• Technically trained individuals have the capability to be superior business leaders

Final Tips

• Be…rather than perform
• Learn to see what others don’t
• Intently plan and prepare, but be aware of opportunities
  – “Louis Pasteur “chance favors the prepared mind”
• Learn to enjoy the ride because “tomorrow” never comes
• Dream Big