



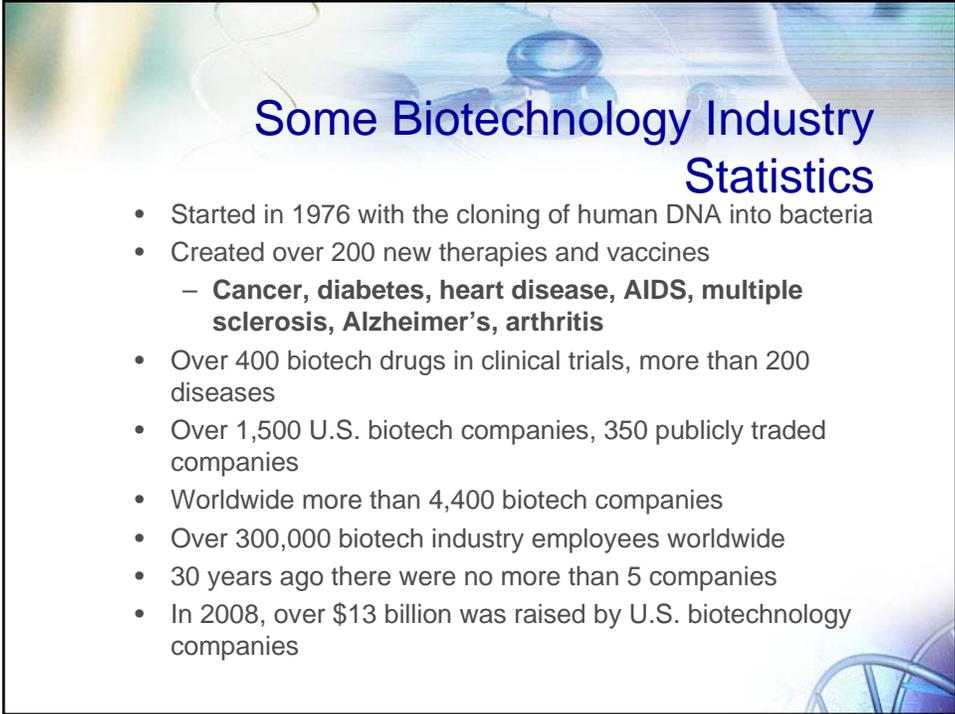
The Business of Bioscience

What Goes Into Making a Biotechnology
Product?

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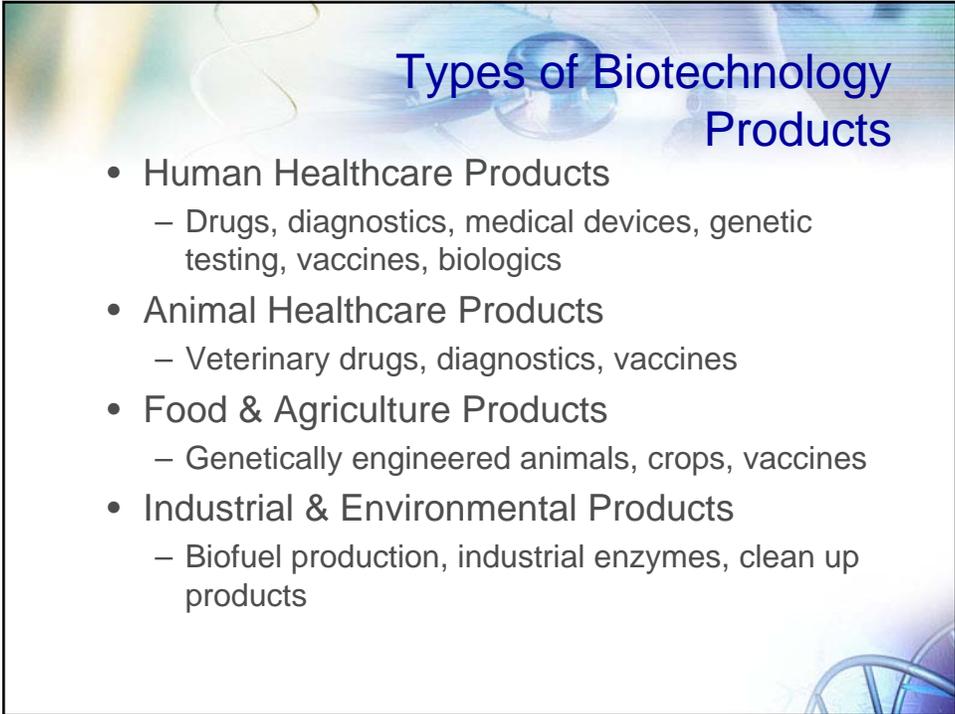
Overview

- 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



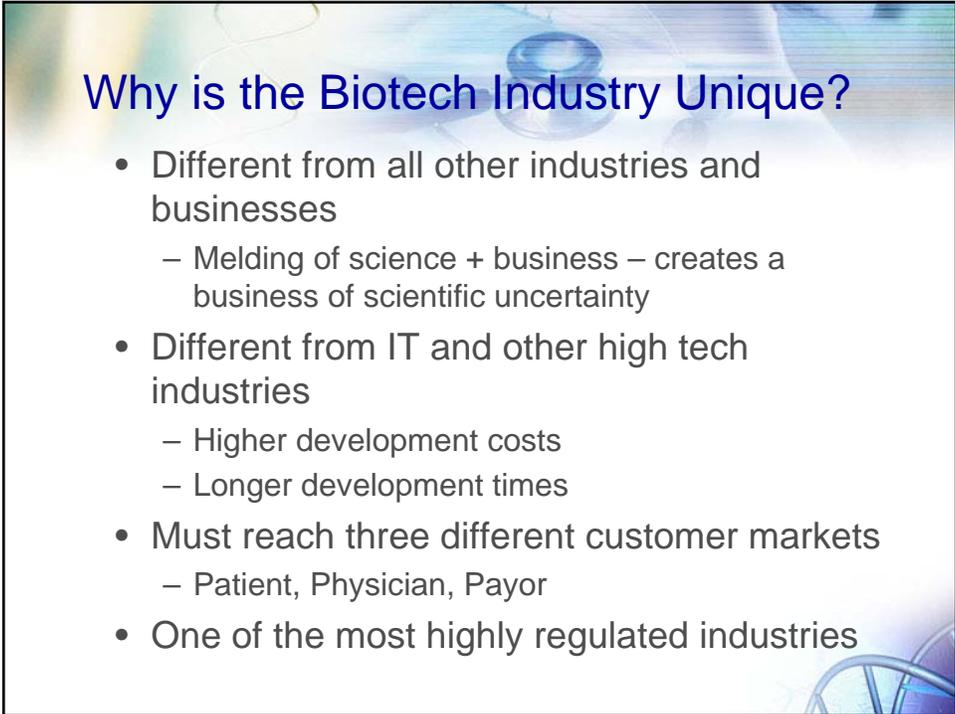
Types of Biotechnology Products

- 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

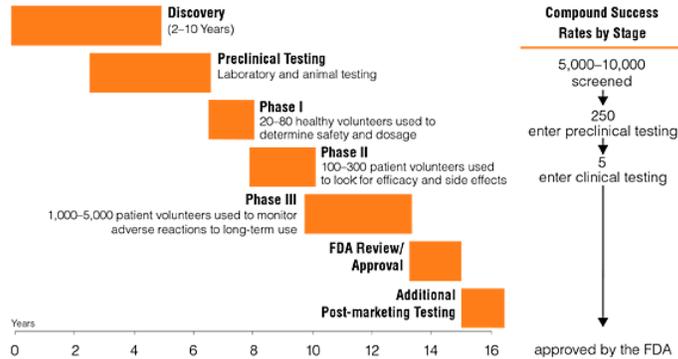
- Availability of venture capital
- Proximity to high-caliber academic and research institutions
- Ready reserve of talented scientific workforce
- Presence of specialized laboratory space
- Availability of seasoned entrepreneurs



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



Source: PhRMA, based on data from Center for the Study of Drug Development, Tufts University

General Timeframe for Biotech Product Development

| | Applied Research | Dev | Clinical | Regulatory | Mfg | Marketing |
|-------------|------------------|--------------|-------------|--------------|--------------|-----------------------|
| Therapeutic | 1 to 2 year | 2 to 4 years | 2 - 4 years | 2 - 4 years | 1 - 2 years | Patent life remaining |
| Diagnostic | 0.5 - 1 year | 1 to 2 years | 1 - 2 years | 0.5 - 1 year | 0.5 - 1 year | Patent life remaining |

Total Product Development time

Therapeutic: 12-15 years

Diagnostics: 5 to 7 years

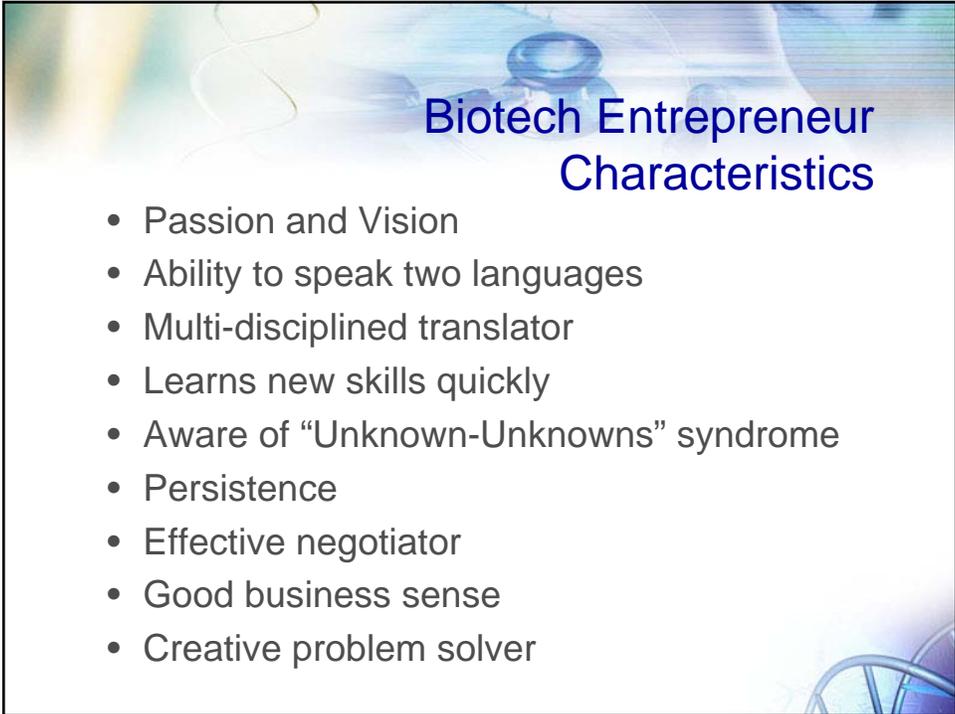
Average Cost of Product Development

Therapeutic: \$350 million to \$1.2 Billion

Diagnostics: \$25 million to \$125 million



Characteristics Successful Biotech Entrepreneurs Have In Common



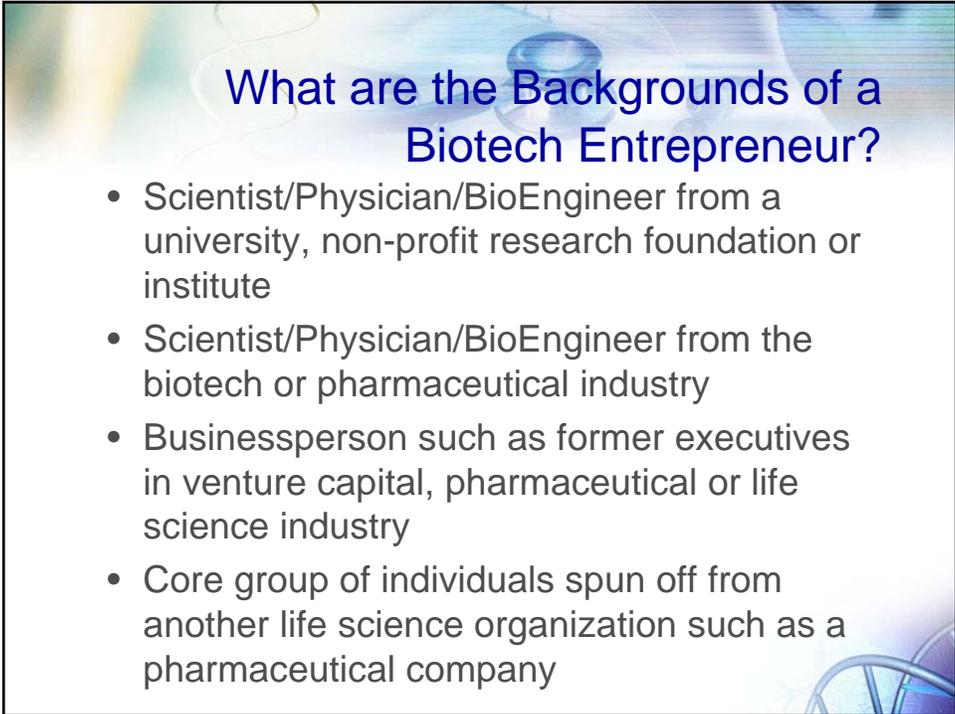
Biotech Entrepreneur Characteristics

- 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?

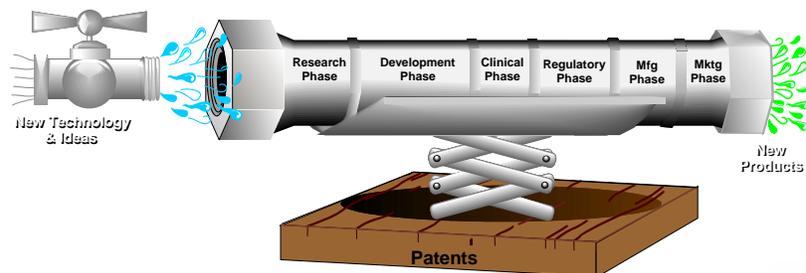
Overview of Steps

- 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
- Its about creating value
- Value increases as risk is reduced
- Recognize scientific uncertainty



Corporate Development Path

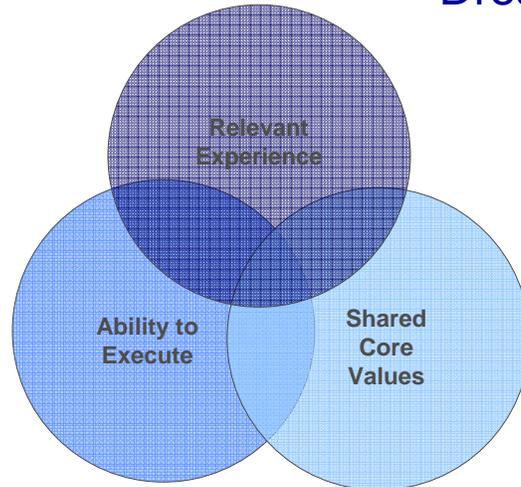
- Identify corporate, patent, securities attorney
- Secure intellectual property, form strategy
- Set up a business legal structure
- Constitute Board, Advisory board
- Draft agreements – CDA, Non-compete, Invention Disclosure and Employment
- Issue founders stock, stock options, vesting
- Close financing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



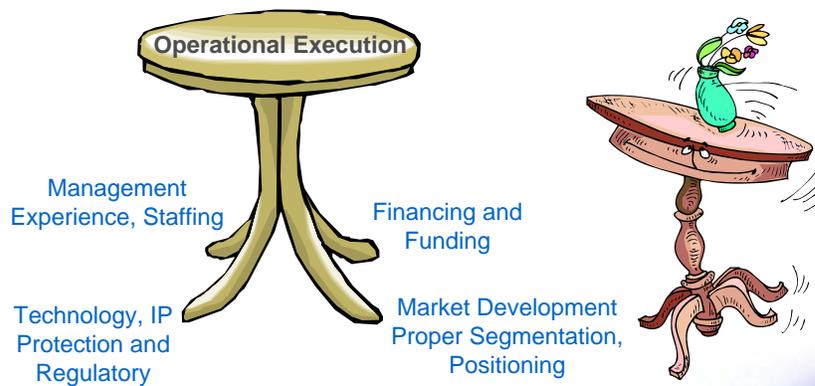
Market Development Path

- 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





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?

Road to Being 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

