



Biotechnology

Challenges and Opportunities in Biotechnology

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Outlines

- *Background*
- *Challenges*
- *Strategies*
- *Vision*
- *Opportunities*

Biotechnology

Any technological application that uses biological systems, dead organisms, or derivatives thereof, to make or modify products or processes for specific use.”

From: United Nations [Convention on Biological Diversity](#)

Challenges In Biotech

- *Average time to develop new drug: 15 years*
- *Costs to develop new drug: \$800M-\$1.5B*
- *Biotech industry has lost \$45B in 30 years.*

Challenges For Biotech Funding Angel Investors/Venture Capitalists

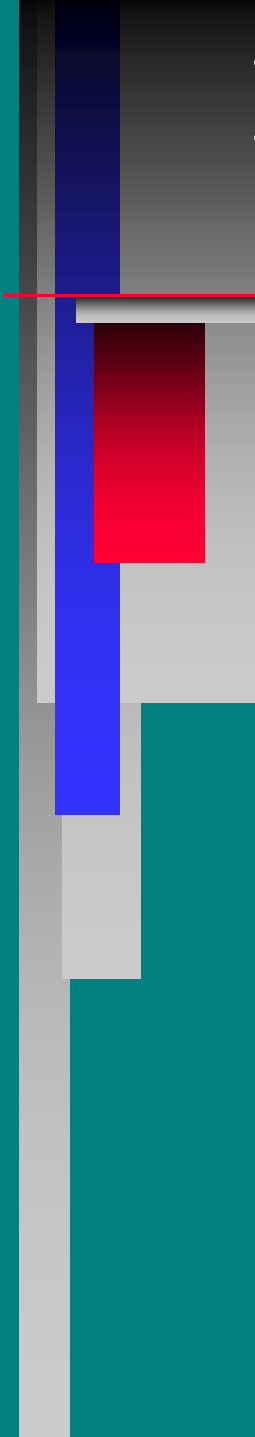
Thousands of proposals are received each year

A few hundred are read or looked at

10-20 are researched & considered

A handful are selected to receive financing

Drug Development Chance of Success

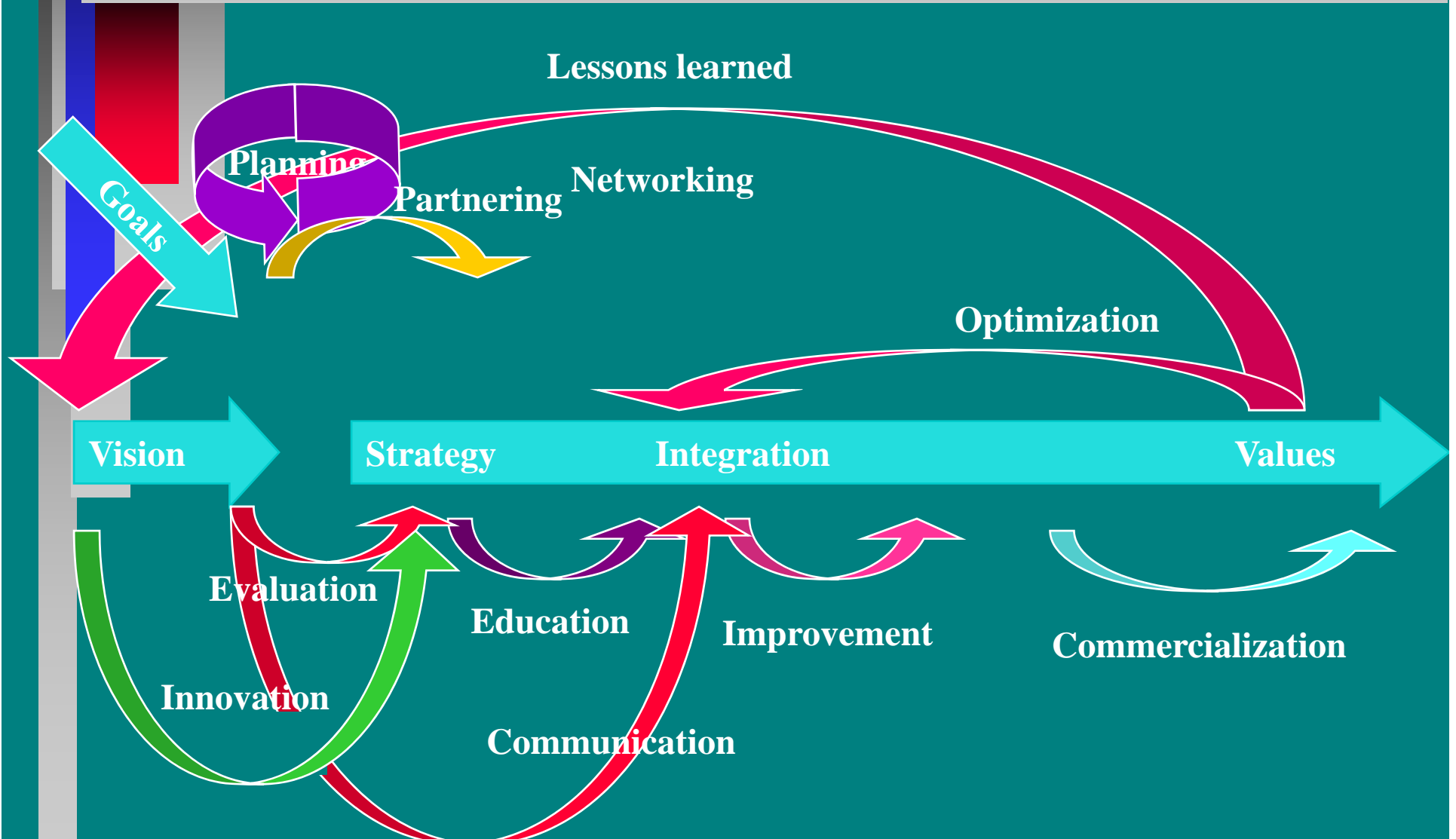


<i>Preclinical-</i>	<i>3%</i>
<i>Phase I-</i>	<i>21%,</i>
<i>Phase II-</i>	<i>49%</i>
<i>Phase III-</i>	<i>74%</i>

Common Mistakes In Biotech Idea To Marketplace

- *Often rely on the science & technology to tell the story and lack of a thorough understanding of the need of their product*
- *Fail to view marketing as real work*
- *Lack of cohesive planning and communication from idea to product launch*

Critical Paths to Create a Value-targeted Business



Critical Elements To Create Value- targeted Business

- *Establish clear vision*
- *Communicate goals*
- *Coordinate cross-functional teams*
- *Allocate resources to maximize return on investment*
- *Target the marketplace*

The Challenges

- *Strategy*
- *Vision*
- *Capital*
- *Marketplace*
- *Regulation*
- *Innovation*

“Dynamic Times Necessitate Dynamic Strategies”

*“Yet many people still cling to basic premises
and static skill levels of the comfortable
past while they are dragged forcibly into the
volatile future”*

--William Boast



Top 10 Biotechnology Companies

REVENUE (\$ IN BILLIONS)

Companies	2008	2007
Amgen, Inc	15.3	14.7
Genetech, Inc	13.4	11.7
Gilead Sciences	5.4	4.2
UCB SA	5.3	5.3
Genzyme Corp	4.6	3.8
Biogen Idec, Inc	4.1	3.2
CSL Ltd	3.6	3.1
Celgene Corp	2.2	1.4
Cephalon Inc.	2.2	1.4
Actelion Ltd	1.4	1.2

Source: Med Ad News, June 2009

Top 10 Biotechnology Companies

RESEARCH & DEVELOPMENT EXPENSES

Companies	2008	2007
Amgen	3.3 billion	3.2 billion
Genetech Inc	2.8 billion	2.4 billion
Genzyme Corp	1.3 billion	737,685,000
UCB SA	1.1 billion	1.1billion
Biogen Idec Inc	1.1 billion	925,164,000
Celgene Corp	931,218,000	400,456,000
Gilead Sciences Inc	721,768,000	591,026,000
Vertex Pharmaceuticals Inc	516,292,000	518,677,000
Cephalon Inc.	362,208,000	369,115,000
Actelion Ltd	346,274,038	270,097,078

Source: Med Ad News, June, 2009

Strategy

“Don’t hunt a lone antelope, because lone antelopes tend to attract lone lions”

-- Mr. Niyikiza

Dr. Niyikiza received his Doctorate and Masters degrees from Indiana University and a Masters from the African Institute of Statistics and Applied Economics in Kigali, Rwanda.

Strategy

Dr. Clet Niyikiza experience couples a leading knowledge of oncology drug development with a passion for systems approaches to medicine which make him an excellent leader for our teams working on a pipeline of very exciting oncology therapeutics. A mathematician by training. Dr. Niyikiza used a systems biology approach to identify the previously unknown role of a blood marker which was causing life-threatening toxicities for one of the therapies. The discovery allowed for the successful development of the therapeutic for multiple indications in cancer and was featured on the front page of the The Wall Street Journal in 2004.

Myriad Factors That Lead To a Successful Hunt

Wind speed

Wind direction

Grass Conditions

Presence of predators

Second Chances; Lilly Drugs Arising From Earlier Failures

DRUG	STATUS	HISTORY
STRATTERA	Marketed for ADHD	Failed In Depression
EVISTA	Marketed for Osteoporosis	Failed for Birth Control
ALIMTA	Marketed for Mesothelioma	Trial had been stopped
CYMBALTA	Reviewed by FDA for Depression	Failed at lower dose

Strategy

"The Network Biology approach of understanding the intricate underlying mechanisms of a disease first and then designing a drug based on those complexities has the potential to be hugely beneficial to patients," says Dr. Niyikiza”

The Challenges

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Doing the Arithmetic: A Growth Pattern for Amgen

<i>First year</i>	<i>1975</i>	<i>\$1M</i>
<i>Next 5 years</i>	<i>1980</i>	<i>\$10M</i>
<i>Next 5 years</i>	<i>1985</i>	<i>\$100M</i>
<i>Next 5 years</i>	<i>1990</i>	<i>\$ 1 Billion</i>
<i>Next 5 years</i>	<i>1995</i>	<i>\$10 Billion</i>

Amgen valuation is \$61.39 Billion on September 28, 2009.

*Source: Wall Street Journal, August 31, 2001, and Med News September 2003

Creating a Top-Tier Company

(The Rathmann model)

Vision: 10X Valuation Growth in 5 years

- *Create good business models*
- *Maintain Marketplace focus*
- *Innovate*
- *Expand intellectual property*
- *Focus on value chain*
- *Ensure sufficient liquidity*

Keys to Optimize the Product Development

- *Improve Project Selection*
- *Improve Predictability of Outcome*
- *Increase Safety*
- *Lower Cost*
- *Shorten Time to Market*

Technology-Driven Value

Research Development

Commercialization

Idea

Pre- clinical
& Clinical

FDA
Approval

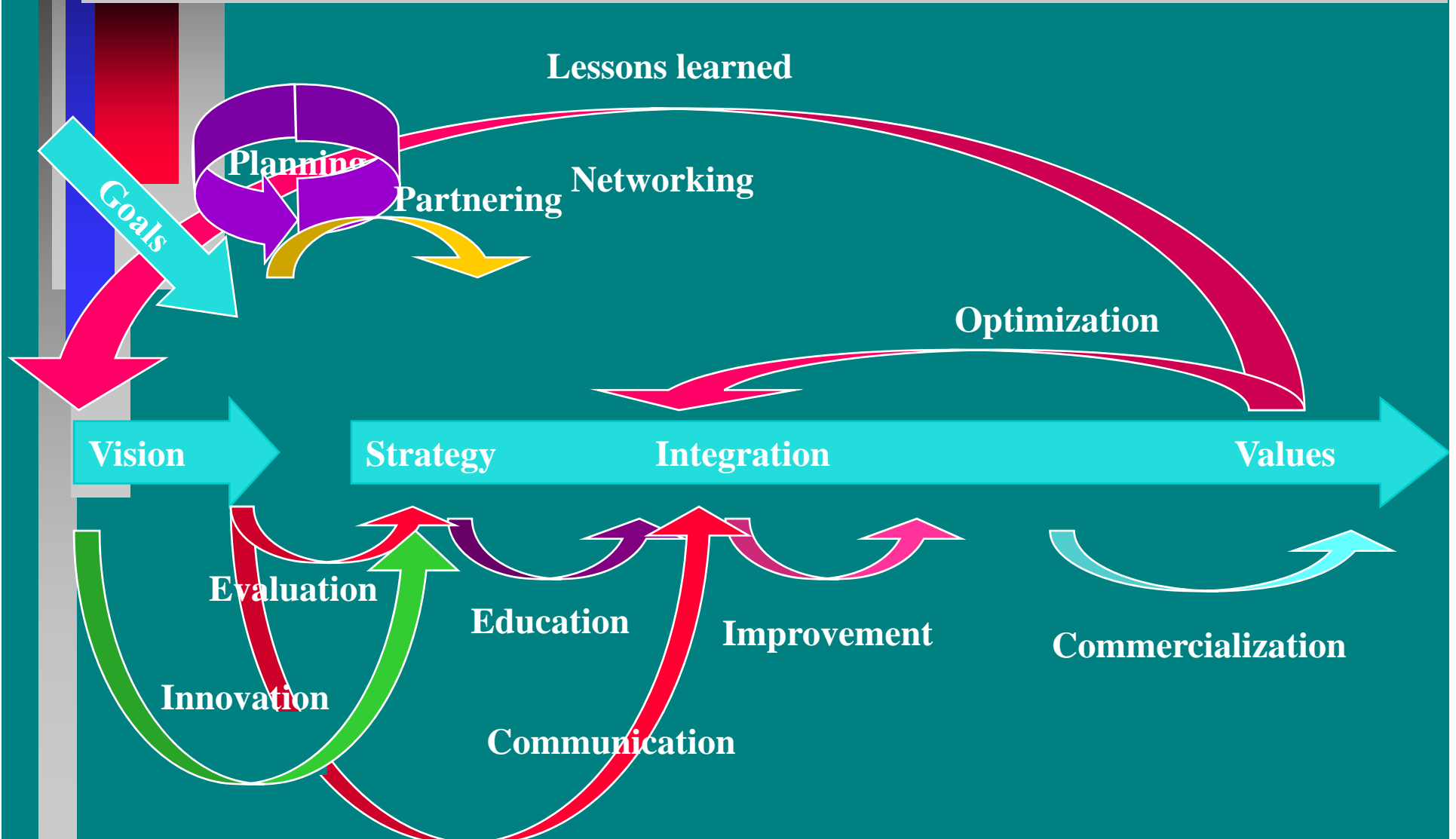
Market Launch

- Lengthy time of development therapeutics (up to 15 yrs)
- Expensive (800 million to 1.5 billion dollars)

The Challenges

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- *Regulation*
- *Innovation*

Critical Paths to Create a Value-targeted Business



Lessons Learned

Understand place on the value chain
-management and investment

Strengthen intellectual property
-intellectual capital and infrastructure

Safeguard regulation and clinical testing
-safety and credibility of product lines

Have a long-term financing plan
-staying power to accomplish mission

Summary

- *Develop dynamic strategies*
- *Define vision*
- *Identify expertise of partner(s)*
- *Build team which understands the R&D and market's needs and wants*
- *Understand value chain*
- *Develop intellectual property*

A New Hope





登鶴雀樓

白日依山盡
黃河入海流
欲窮千里目
更上一層樓

王之煥

CLIMBING HUAN-QUE TOWER

Wong Zhi-Huan

The sun sets behind the mountains,
And the golden river surges toward the sea;
To widen your view far into the distance,
You have to climb up one more flight of stairs.