



Pioneering science delivers vital medicines™

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# Biotechnology and Its Future in Algeria

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# Overview

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- Introduction of Amgen
- Value of Innovation
- Importance of Partnerships
- Keys to Success
- Conclusion



# Amgen: A Biotechnology Pioneer

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- Founded in 1980, Amgen was one of the first biotechnology companies to successfully discover, develop, and make protein-based medicines
- Today, we're leading the industry in its next wave of innovation by:
  - Developing therapies in multiple modalities
  - Driving cutting-edge research and development
  - Continuing to advance the science of biotechnological manufacturing



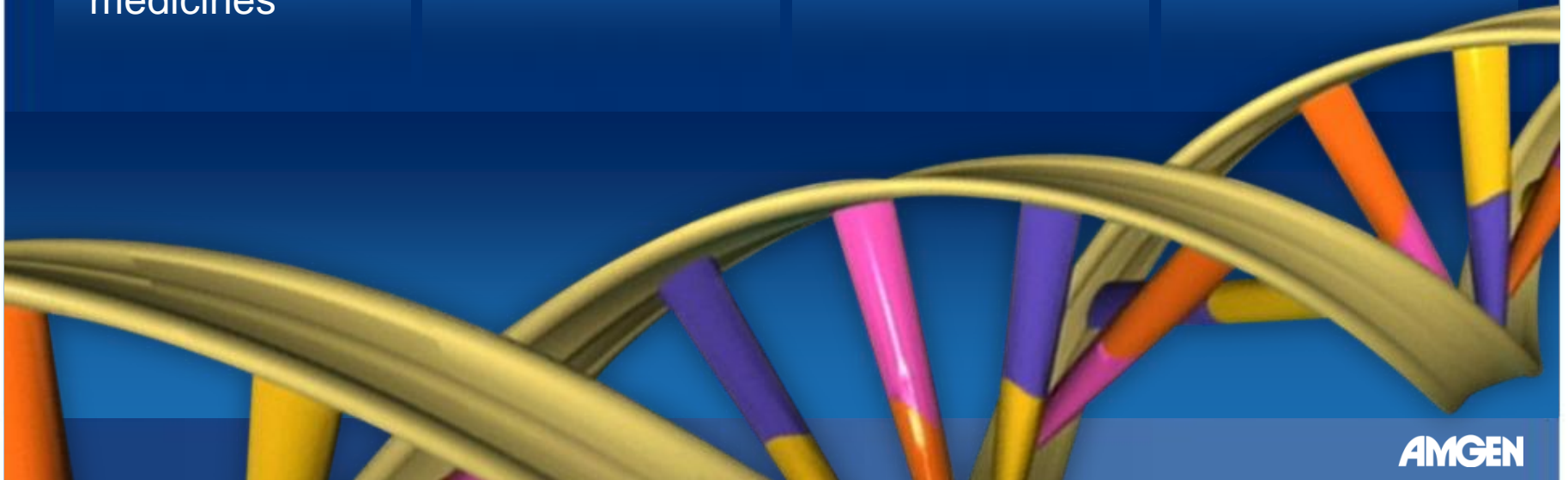
# Biotechnology Is the Future of Medicine....

Industry only  
~ 35 years old,  
yet already  
more than 500  
million people  
have been  
helped by  
biotechnology  
medicines

> 300  
biotechnology  
therapeutics  
available; many  
more awaiting  
regulatory  
approval

Thousands of  
new  
medicines in  
clinical trials;  
hundreds in  
late stage

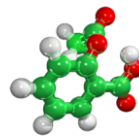
>50% of all  
therapies in  
development  
today are  
biotechnology  
medicines



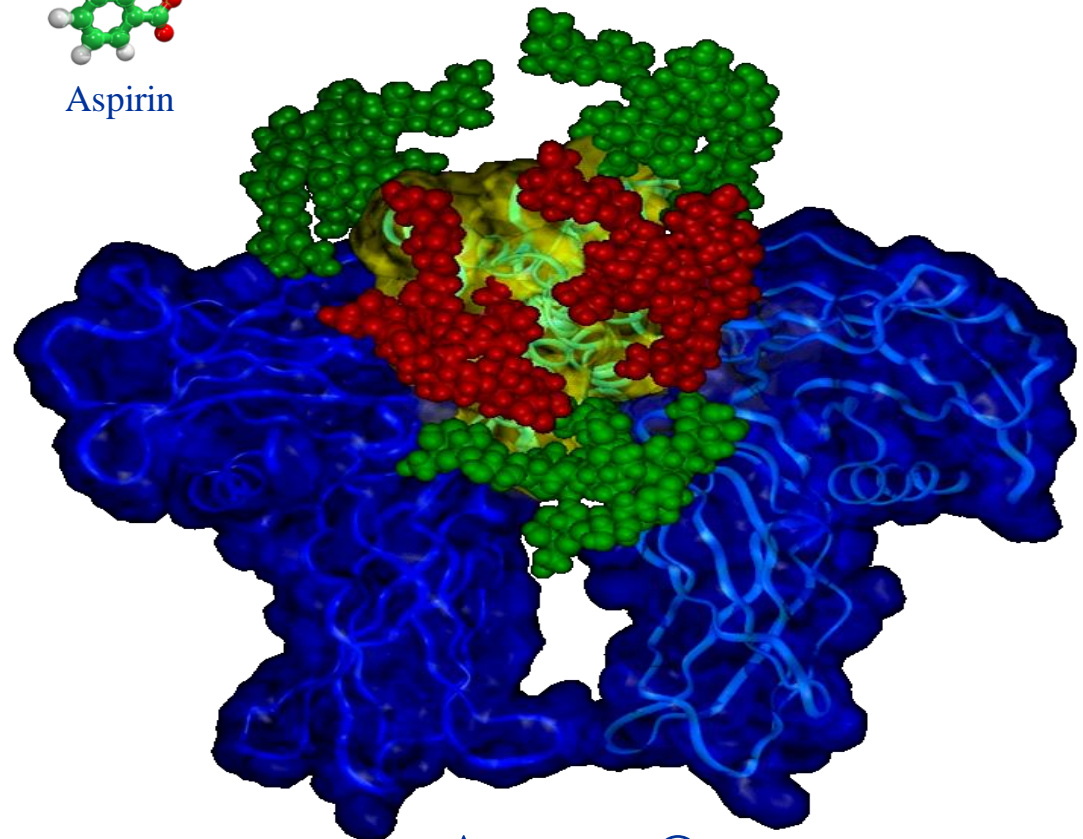
# Highly Complex Molecules...

## Biotech medicines

- Large numbers of molecular components
- Larger molecular size and weight
- Lack of exacting chemical specifications
- Derived from living organisms and therefore are difficult to produce and replicate
- Each cell line is unique



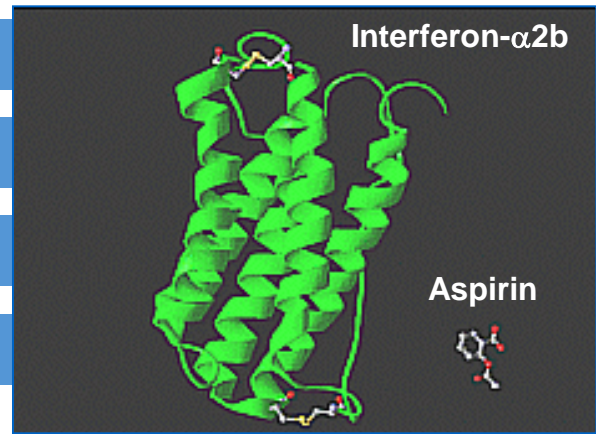
Aspirin



Aranesp®

# Biotech Drugs Differ From Chemical Drugs in Molecular Properties and Complexity of Manufacturing

		Biotech drugs	Chemical drugs
Properties	Size	Large	Small
	Structure	Complex	Simple
	Stability	Unstable	Stable
	Modification	Many options	Well-defined
Manufacturing		Unique line of living cells Impossible to ensure identical copy	Predictable chemical process Identical copy can be made
Characterization		Impossible due to a mixture of related molecules	Easy to characterize fully



Source: Graphic taken from 2000 Schering-Plough Research Institute/ EuropaBio <http://www.europabio.org>

# ...But Creating and Sustaining Biotechnology Innovation Is Difficult



Long product development cycles (10+ years)



High complexity; high risk of failure



Science and technology still evolving

# Getting Products to Patients Is Time-Consuming, Complex, and Expensive...

Clinical Trials



Manufacturing



Reimbursement



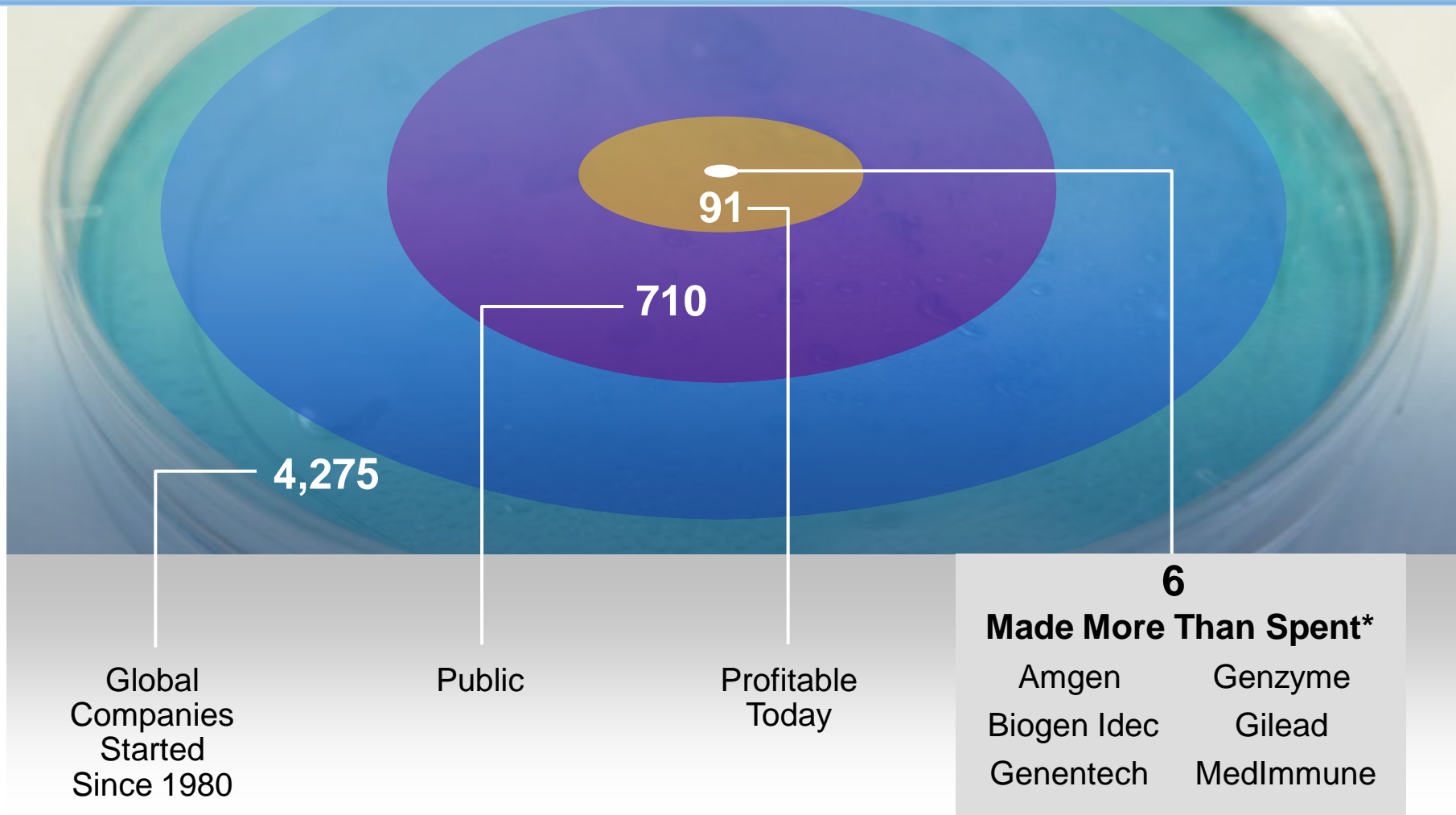
Approval



Competition

...but the chance to help millions makes it all worth it!

# Biotech is Promising – But it's Risky



\*As of 2006

# Value of Biotech Innovation

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- Biotech is using what we know about biology to improve the human condition.
- The value lies in its ability to create new jobs and fight serious diseases like cancer.
- Biotech medicines treat serious illness and allow patients to remain contributing members of their countries providing significant economic benefit.
- It is critical for governments to create policies that support the ecosystem of innovation and investments in R&D.



# Era of Unprecedented Advances in Medical Research

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## Understand the pieces

- Hardware of Life (20th Century) genes/proteins
- Software of Life (21st Century) – systems/network
  - “Genes ’r us”/ “biomarkers ’r us” / “algorithms ’r us”
  - Cost per bit of biological info rapidly decreasing (Moore’s law)

# Sequencing on the fast track

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- It took 13 years to sequence the first genome... now we sequence several human genomes every few days
- ...moving to \$1000/genome
- Personalized Medicine implications
  - Evidence based medicine
  - Advances in health information
  - Personalized, predictive, preventative & participatory medicine (P4)
  - Consumer Digital Health (but delivery system so flawed can't bring healthcare “advances” to market place)



...but will we be able to use this information?

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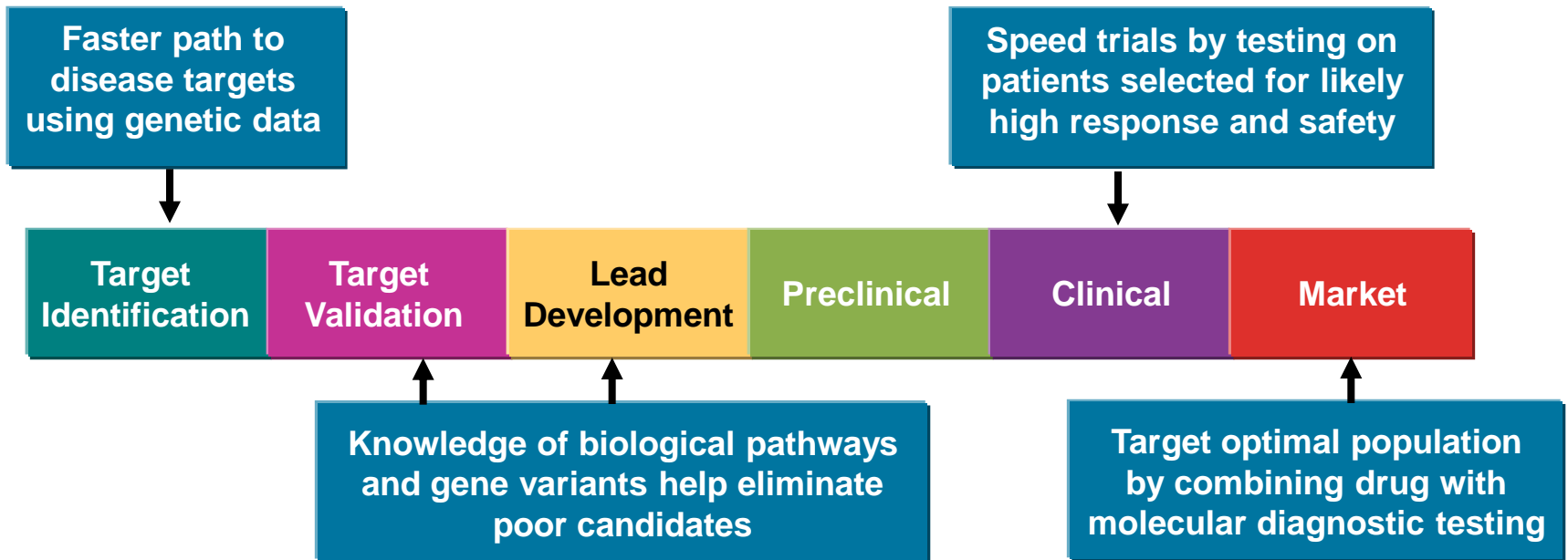


**"Here's my sequence..."**

*-New Yorker*

# Safer, More Effective Drugs

Identify disease targets, speed clinical trials, and advance more drugs that are safe and effective for specific populations



Source: Personalized Medicine Coalition

# What drives the movement for Personalized Medicine?

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**Technology...**  
but, more importantly...

**Consumer Demand for:**

**Safer, More Effective Drugs**

End of one-size-fits-all drugs. New drugs will be safe and effective for specific populations



**Faster Time to a Cure**

Using genomic information to find disease targets. Speedier clinical trials based on high responder population.



**Cost-Effective Healthcare**

Reduced costs, due to avoidance of futile treatments and improved clinical outcomes



# Personalized Medicine

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## Progressive Evolution Based on Increasingly Comprehensive Profiling of Disease Risk and Health Status



- Rational Rx based on profiling of underlying molecular pathology
- MDx and disease subtyping
  
- Rational Rx based on comprehensive molecular profiling of individuals
  - disease subtypes and optimum Rx
  - Rx AE risk
  - disease predisposition risk and mitigation
  
- Integrated framework of longitudinal data on individual health status
- Real time remote health status monitoring
- Transition to disease prediction and preemption

Source: George Poste

# Value of Biotech Innovation

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**Innovative medicines have added tremendous value to patients, the economy and society:**

- Innovation has transformed **treatment** outcomes, resulting in longer, healthier and more productive lives
- Innovation has driven real **financial gains** to society: more outpatient care, quicker recovery and fewer lost workdays
- New medicines provide **long-term benefits** to society, far outlasting patent protection

# Importance of Partnerships

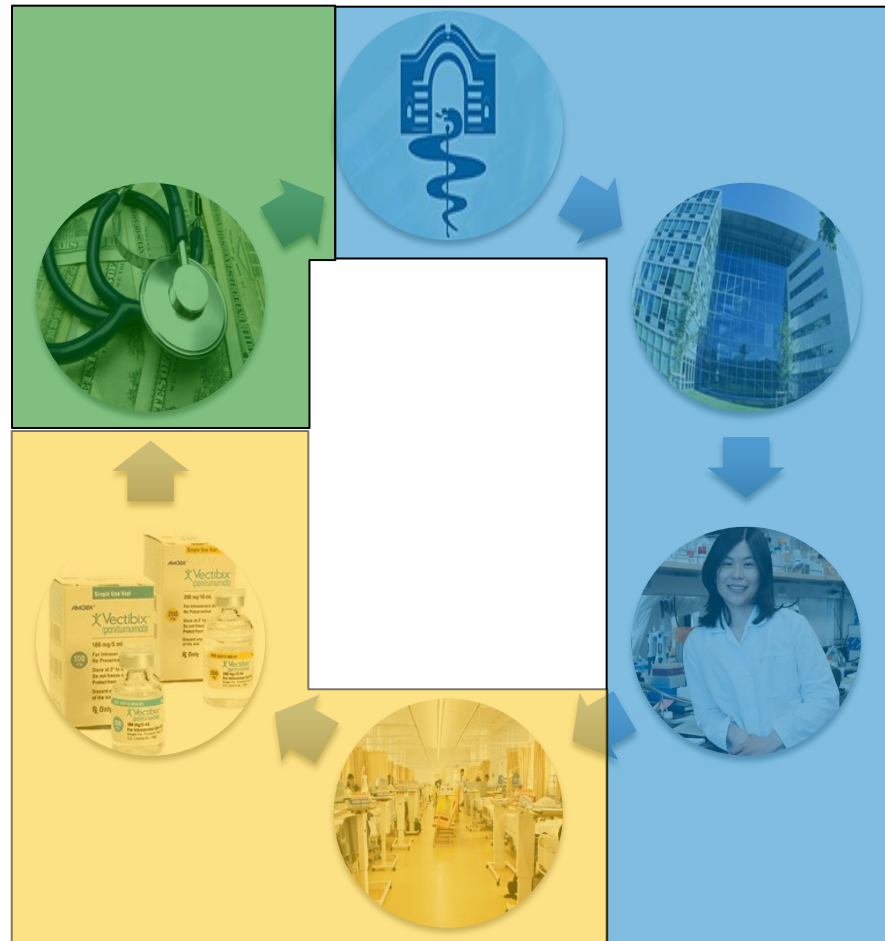
Academia

Reimbursement

Cluster

Regulatory approval

Start-up investment



Development / clinical trials

# Governments Are Often Inconsistent in Their Approach to Supporting Innovation

## Policies that Support Innovation and R&D Investment

- Market systems that embrace competition
- Intellectual property protection (patent and data exclusivity)
- Funding for R&D
- Favorable tax policy
- Market stability
- Orphan drug programs
- Transparent regulation

## Policies that Undermine Innovation and R&D Investment

- Cost-containment tools (including price controls)
- Antiquated tax policies
- Market uncertainty
- Value assessments that incorporate narrow value definition, low value thresholds, and delays in patient access

## Examples of Policies that “Bridge the Gap”

- Multi-dimensional, comprehensive assessment of value
- Support for decisions in the face of uncertainty

# Algeria is an Important Market to the Biotechnology Industry; it Can help to:-

Reach more patients

Diversify revenue base

Fuel long term growth  
and fund innovation



# And Algeria Can Attract Biotechnology investment

- **First – strong government policies that encourage investment.**
- **Second – strong protection of intellectual property rights.**
- **Third – an efficient, transparent and predictable regulatory system.**
- **Fourth – robust academic – industry collaborations.**
- **Fifth – reimbursement policies that value innovation**

