# Advances in Biotech Innovation

AMIIF – Semana de Innovacion Mexico City March 30, 2017



### What is BIO

- World's Largest Biotechnology Organization
  - About 1000 members, from start ups to large MNCs
  - Most are small companies
  - Members from 35 countries
  - Host BIO International Convention annually c. 16,000 participants. June 19-22, San Diego
- Covers all three sectors or biotech: Biopharma, Agriculture, industrial/environmental. Common elements:
  - All three use same technologies
  - All involved in addressing some of the most important issues confronting mankind



#### **BIO's Mission**

#### Serve as Voice of Global Innovative Biotech Sector

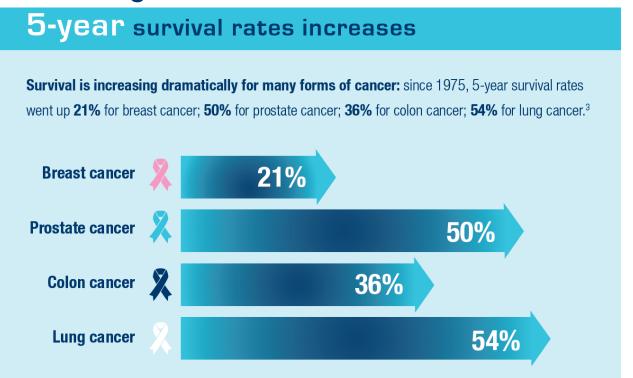
Define and advance policies best practices that promote global biotech innovation (regulatory, IP, financial)

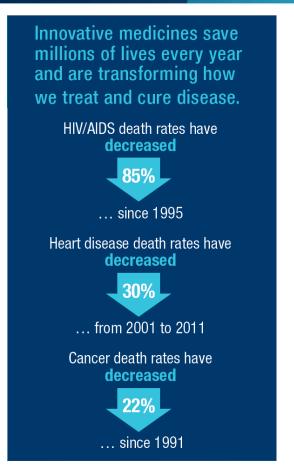
-Promote partnerships among parties engaged in biotech research and commercialization (the biotech "ecosystem")



## **Impact: Innovation Saves Lives**

#### www.bio.org/innovation







#### **Economic Benefits of Innovation**

■ In the United States, the Congressional Budget Office (CBO) credits each \$1 of additional spending on medicines with \$.20 reduction in other healthcare expenses.

REDUCING CANCER DEATH RATES BY 10%

WOULD SAVE CURRENT

AND FUTURE GENERATIONS

**APPROXIMATELY** 

\$4.4 TRILLION DOLLARS<sup>6</sup> Gains in cancer survival are worth nearly \$2 trillion,

with a majority of that savings going to patients, families and our economy as a whole.<sup>5</sup>

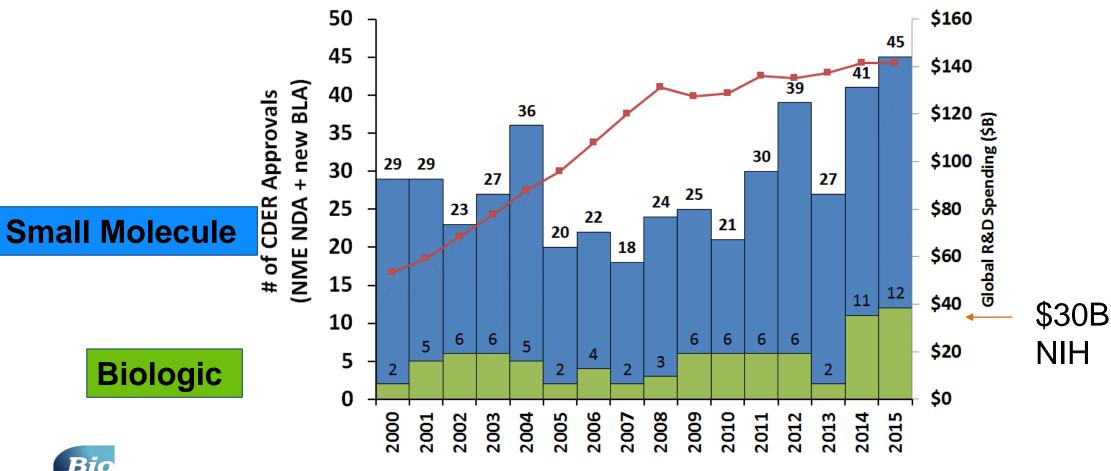


## Biotech on the Horizon: What's in the Pipeline?

Selected Diseases	Medicines in Development*
Cancers	1,813
Cardiovascular disorders	599
Diabetes	475
HIV/AIDS	159
Immunological disorders	1,120
Infectious diseases	1,256
Mental health disorders	511
Neurological disorders	1,329



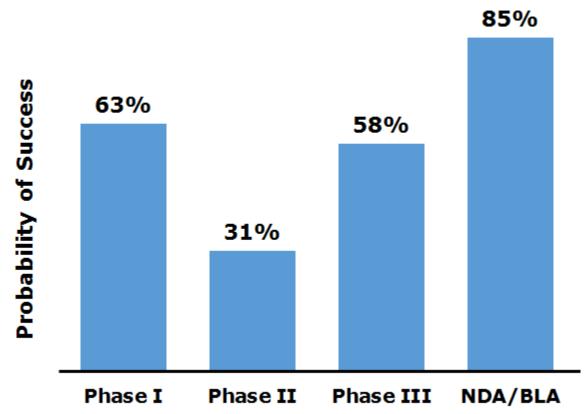
# **New Drug Approvals** (US FDA/CDER)





**Biologic** 

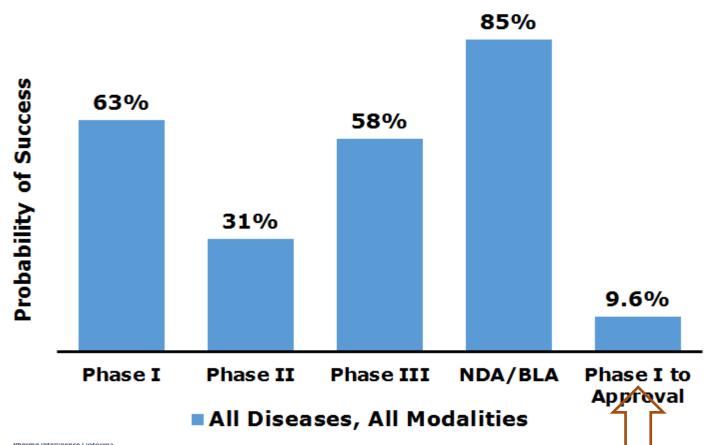
## **Clinical Phase Success Rates**





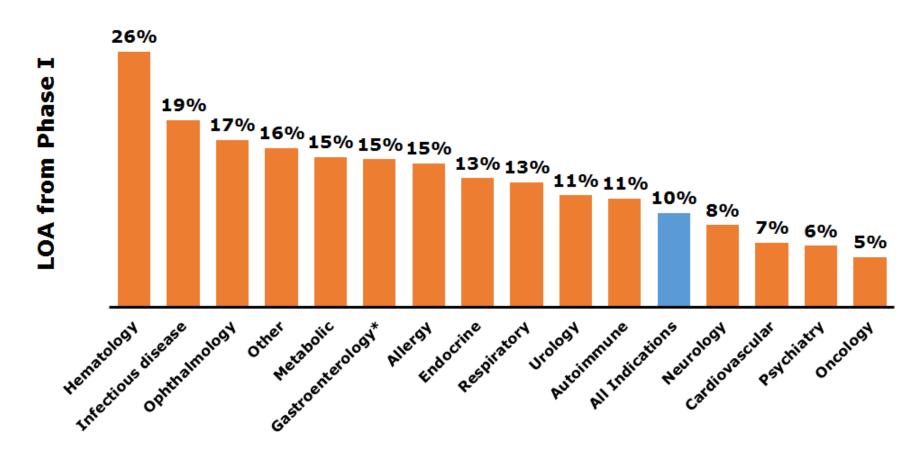


## **Phase Success Rates &** Likelihood of Approval from Phase I





# Likelihood of Approval from Phase I By Disease



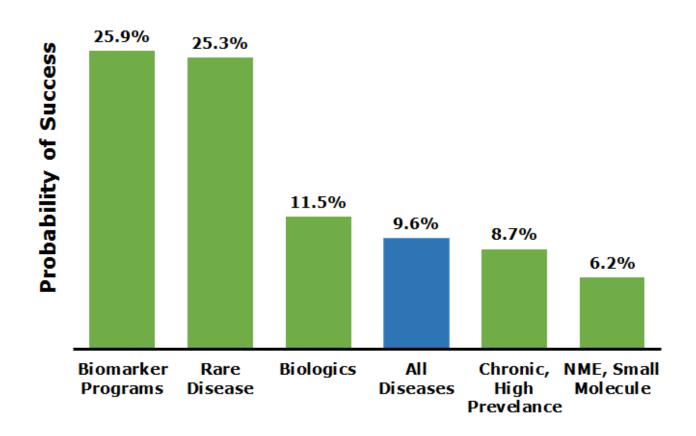






## **Success by Type of Product**

#### Likelihood of Approval from Phase I

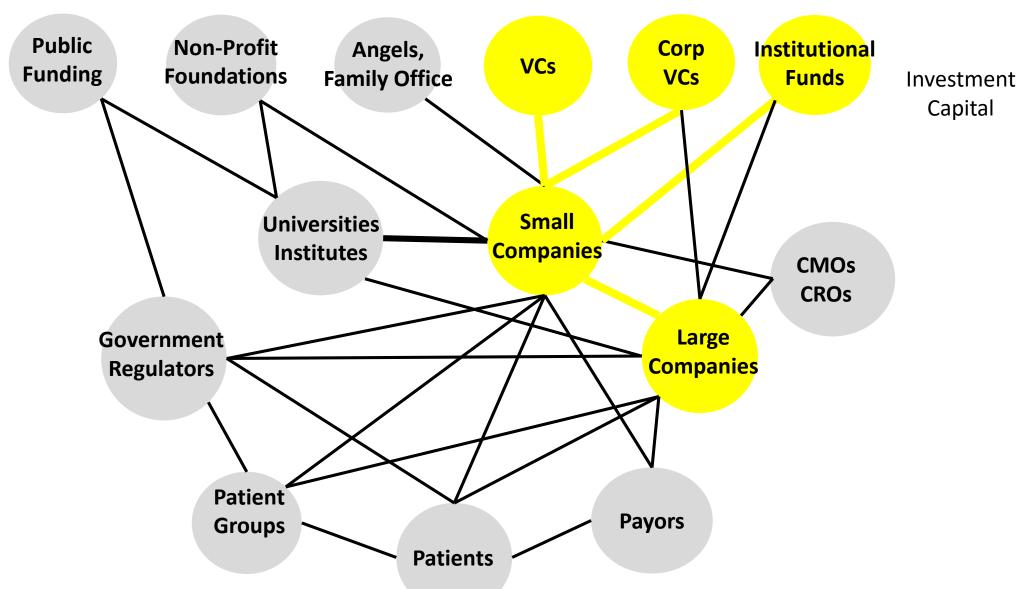








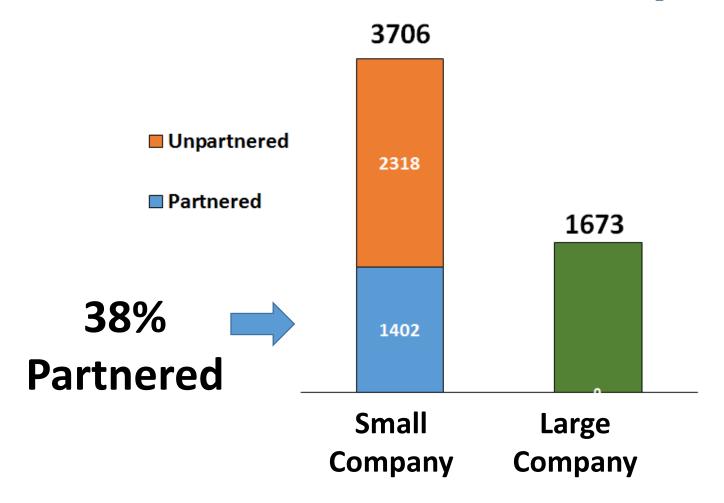
## **BioPharma Ecosystem**





## **Global BioPharma Pipeline**

- 5,393 clinical programs
- 70% from small companies





### **Financing Innovation**

**Angels, Incubators** 

**Family Offices** 

**Patient Groups /** Foundations/

**Gov SBIR/BARDA** 

Preclinical

**Venture Capital/Corporate VC** 

Phase I

**R&D Collaborations with Pharma/Biotech** 

**IPOs** 

**Follow-On Offerings** 

Phase III Market



Phase II

\$1.1 B\*\*

\$3.7 B

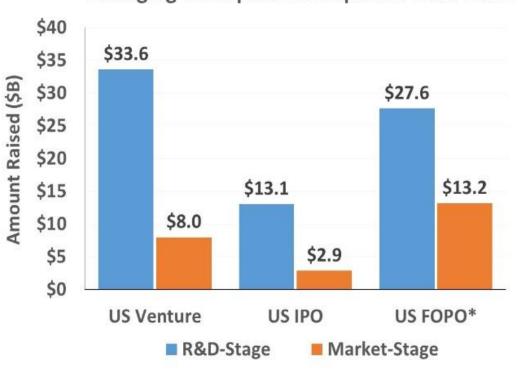
\$3.5 B

\$1.0 B

\$2.7 B

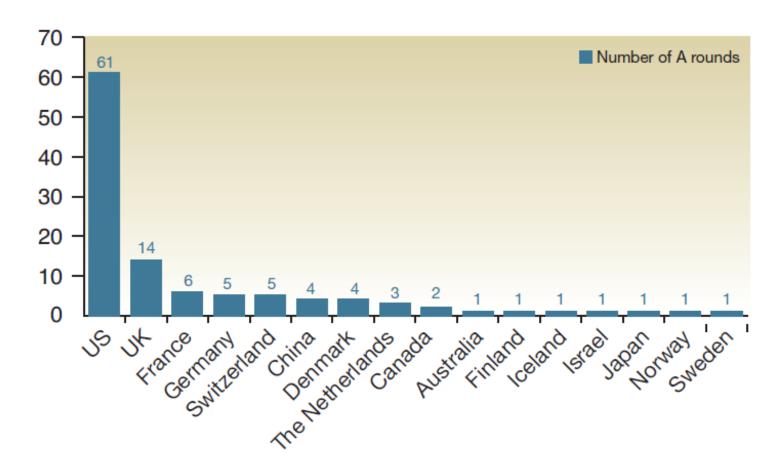
# US Investment into Biotech 2006-2015

US Investment for Emerging Therapeutic Companies 2006-2015



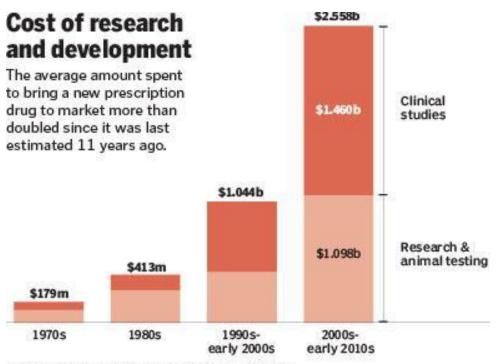


## **New Company Formation by Country**



**Figure 1** Number of startups by country in 2014. Source: BCIQ: BioCentury Online Intelligence.

#### **Cost of Innovation**



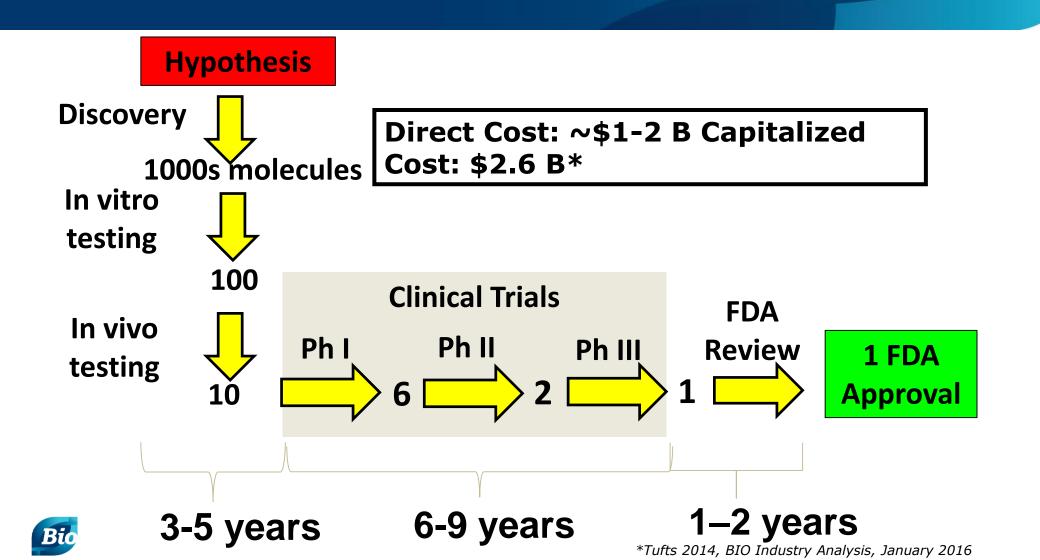


SOURCE: Tufts Center for the Study of Drug Development

DAVID BUTLER/GLOBE STAFF

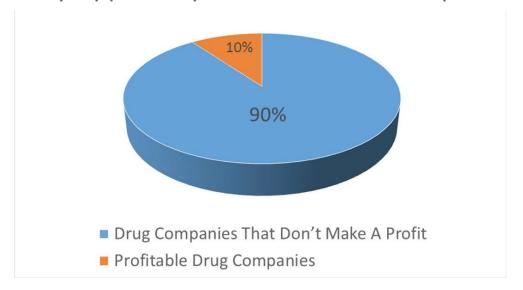


#### **Cost of Innovation**



#### **Cost of Innovation**

- Vast majority of the companies working on biotech innovations are small, pre-revenue enterprises that do not earn a profit.
- Only 2 of every 10 drugs on the market ever earn back enough money to match the costs of R&D and regulatory approval process before their patent expires





### **Some Key Questions**

- Can drug development be done more efficiently, i.e., faster, less costly and higher success rates?
  - Will require researchers, industry and governments working together to solve
- How will societies ensure that the incentives for innovation are sufficient? Can societies take a longer term view (the business model is long term) of the benefits
- Can the "start-up culture" of spreading risk among many small developers be replicated globally
  - Indeed, can the ecosystem of innovation become more globalized what policies will it take to advance that goal



# Thank you

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