
# *Breaking down barriers…*
# *…building solutions*

**OECD Workshop on Knowledge Markets**
**16-17 October 2008**
**Washington, DC**

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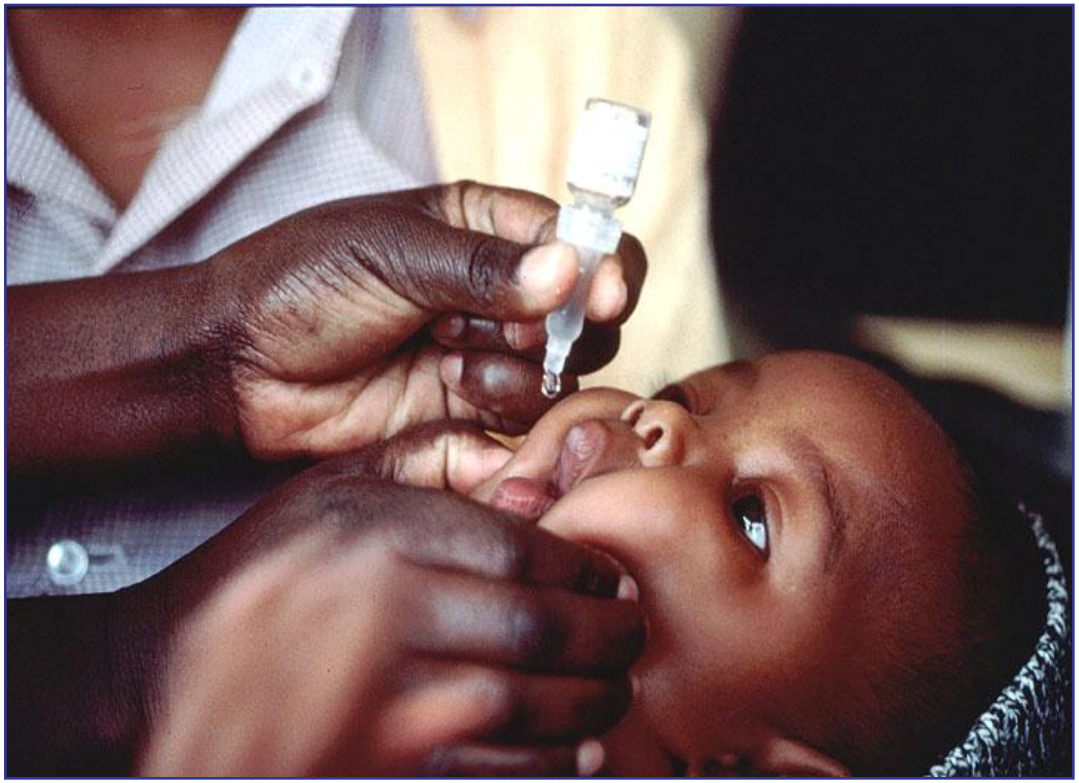
**Founder, Vice President of Strategy and Operations**

# BVGH Approach

***BVGH is harnessing the diverse resources of the biotech industry to create new medicines for neglected diseases of the developing world.***

**Our mission:**

- **To break down barriers that hinder product innovation for global health**
- **To catalyze R&D investment through market-based solutions.**



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# The Problem

***One billion*** **people across the globe have access to quality medical care and medicines.**

**The other *five and a half billion* don't.**

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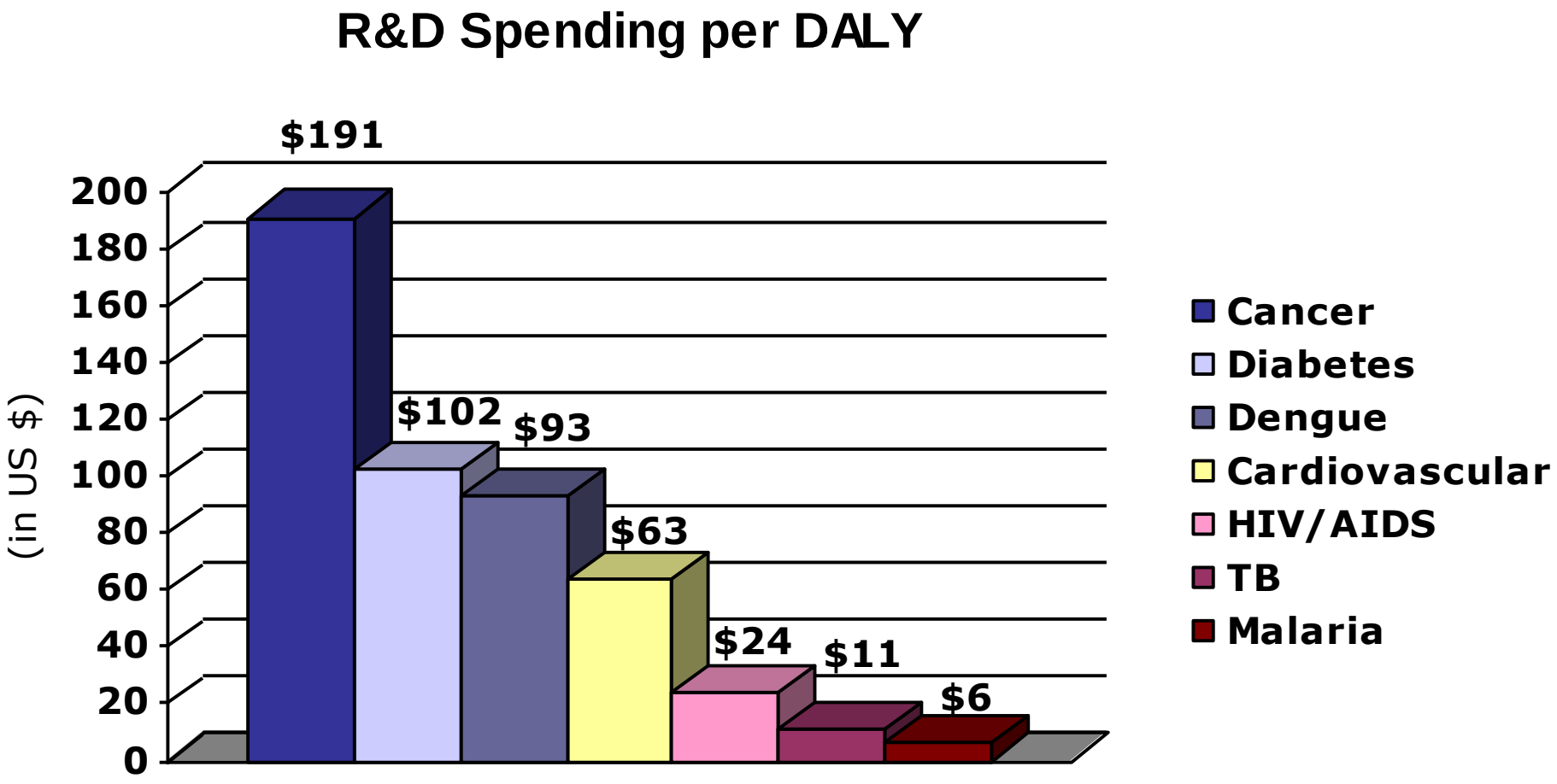
# Low R&D Funding for Neglected Diseases

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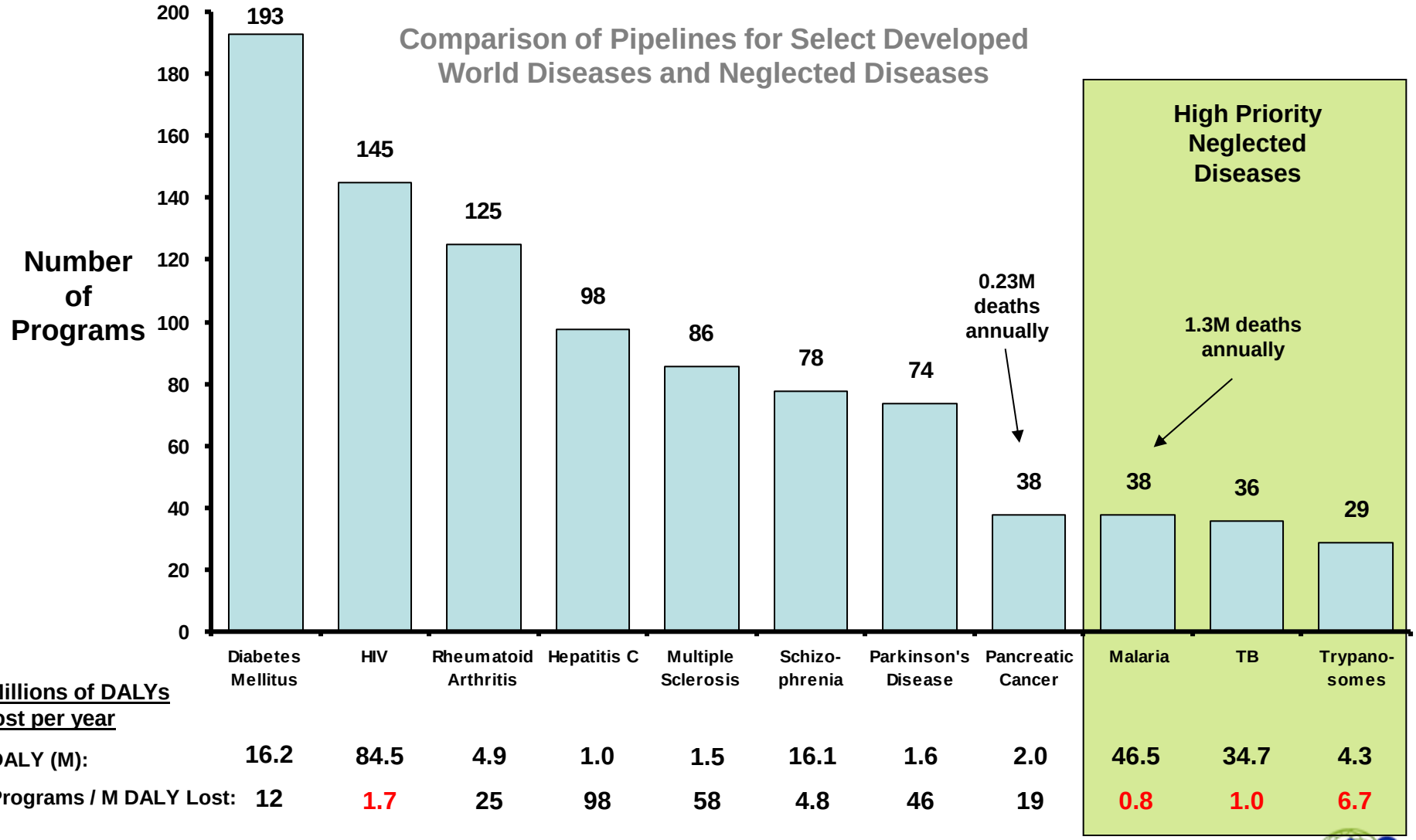
# And Pipeline Insufficient to Meet Need




| Millions of DALYs lost per year | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DALY (M): | 16.2 | 84.5 | 4.9 | 1.0 | 1.5 | 16.1 | 1.6 | 2.0 | 46.5 | 34.7 | 4.3 |
| Programs / M DALY Lost: | 12 | 1.7 | 25 | 98 | 58 | 4.8 | 46 | 19 | 0.8 | 1.0 | 6.7 |

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# What we need to do

- **Create entirely new vaccines, drugs and diagnostics for neglected tropical diseases**

- **Enlist the technology and leading biopharma innovators who have revolutionized health care for high-income populations**

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# Can biotech help build the pipeline of new medicines for neglected diseases?

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# BVGH Innovation Map Project

- **Goal**
  - **Map the capabilities of industry against unmet needs in NTDs**
- **Focus**
  - **Concentrated on therapeutics**
  - **Three pathogens: *P. falciparum*, *M. tuberculosis* & trypanosomes**
  - **Interviewed over 30 academics and 25 companies**


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# Innovation Map: Key Findings

1. Innovation gap in drug discovery for NTDs
2. Science sufficient to support discovery
3. Biotechs well positioned to lead discovery
4. Technologies and targets transferable
5. Substantial new investment required
6. Value justifies investment and risk-taking

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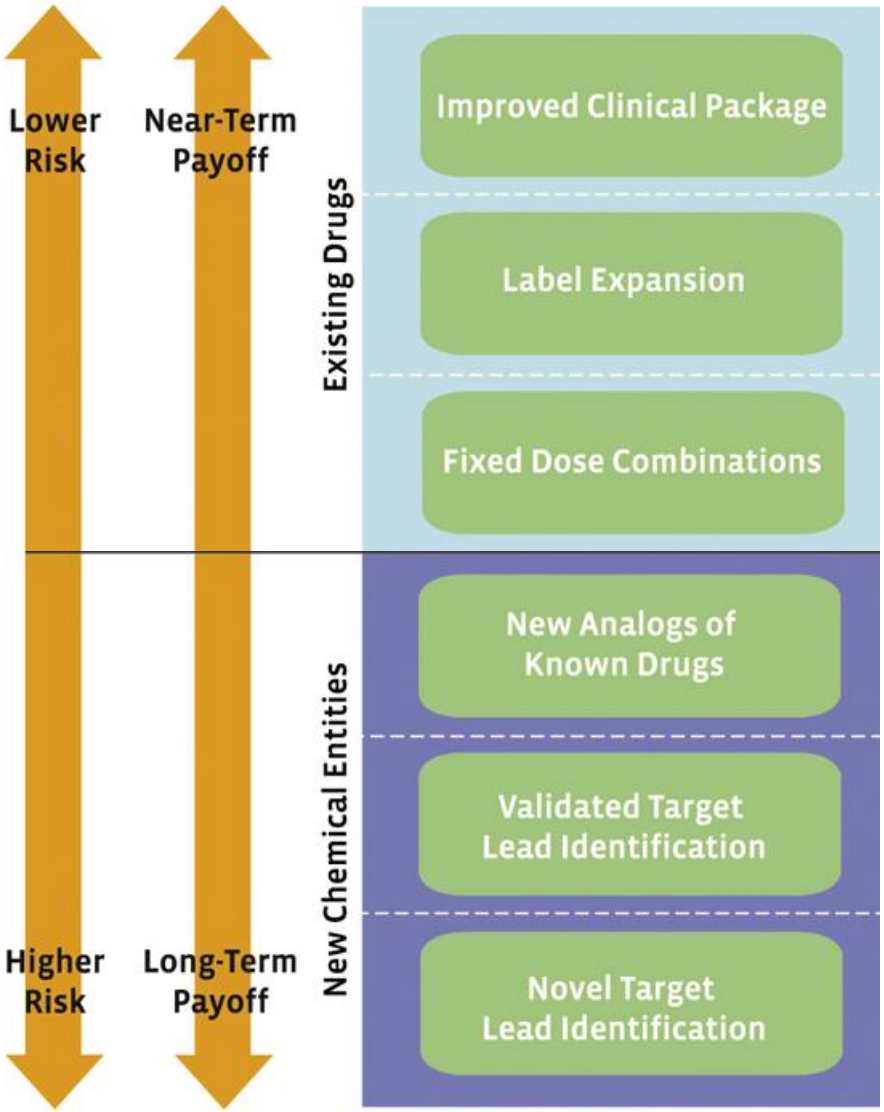
# Balancing risks and payoffs – old vs. new drugs




- Compounds with known PK and safety offer fastest market entry
- Existing molecules unlikely to achieve treatment goals
- Evolution of resistance necessitates NCEs
- NCEs that hit validated pathogen targets key to building pipeline
- Entails greater risk, cost and time

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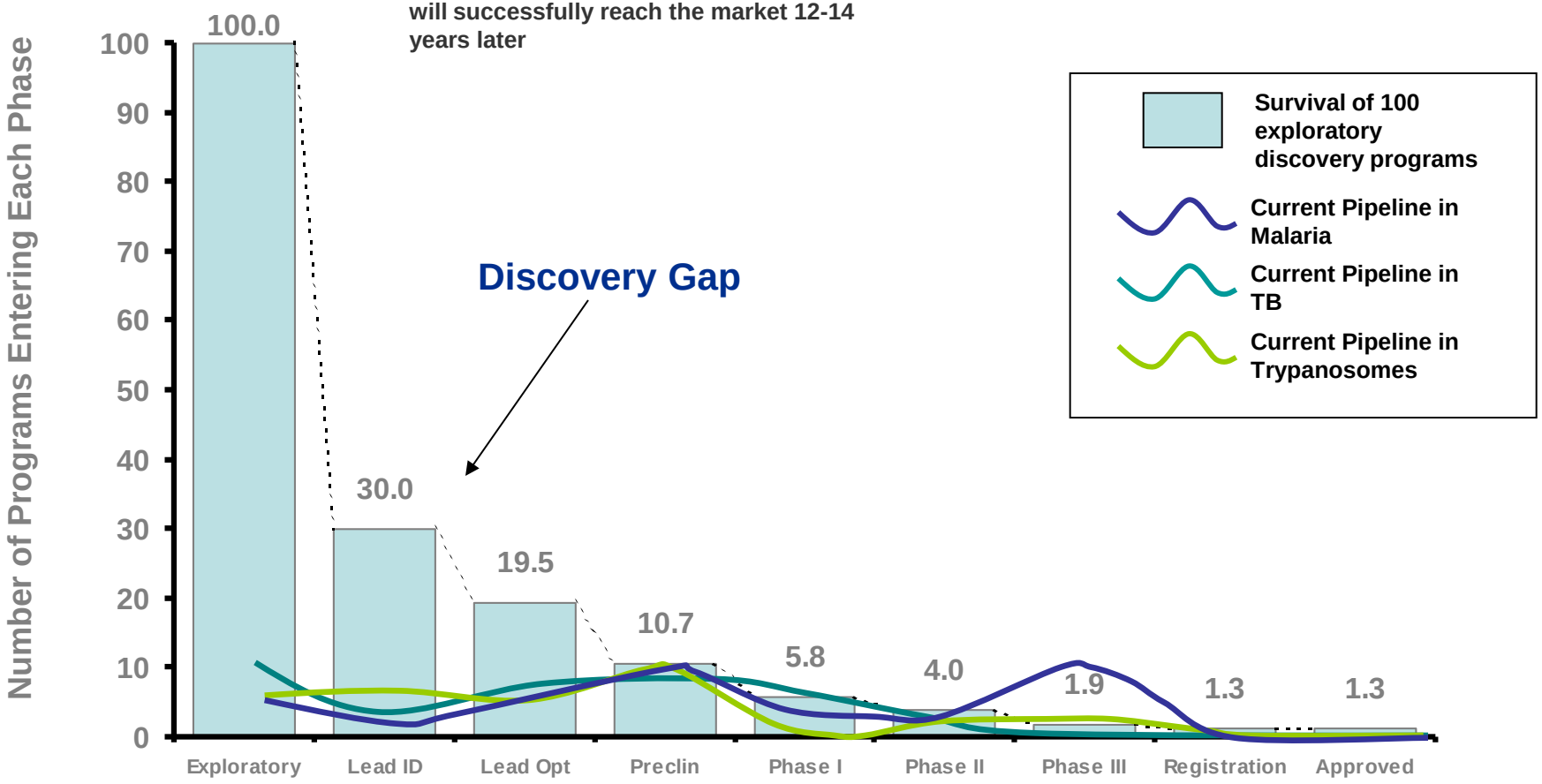
# 1 Innovation gap in drug discovery for NTDs

## Attrition Rates and Current Neglected Disease Pipelines

Out of 100 programs entering the screening phase of discovery, 1.3 drugs will successfully reach the market 12-14 years later




Source : BVGH/ L.E.K. Analysis

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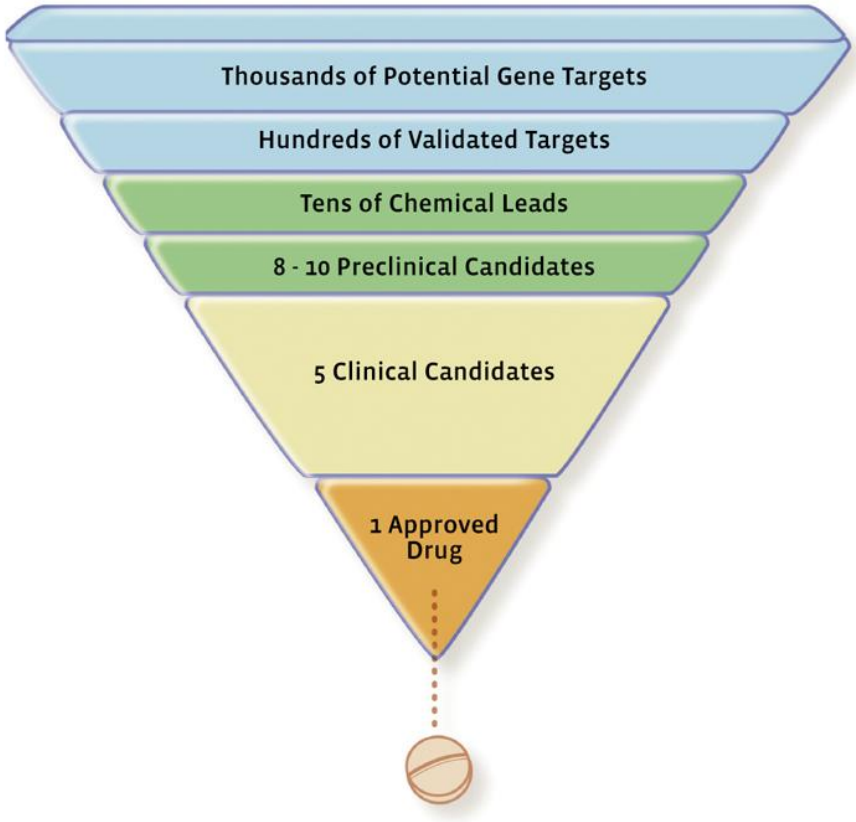
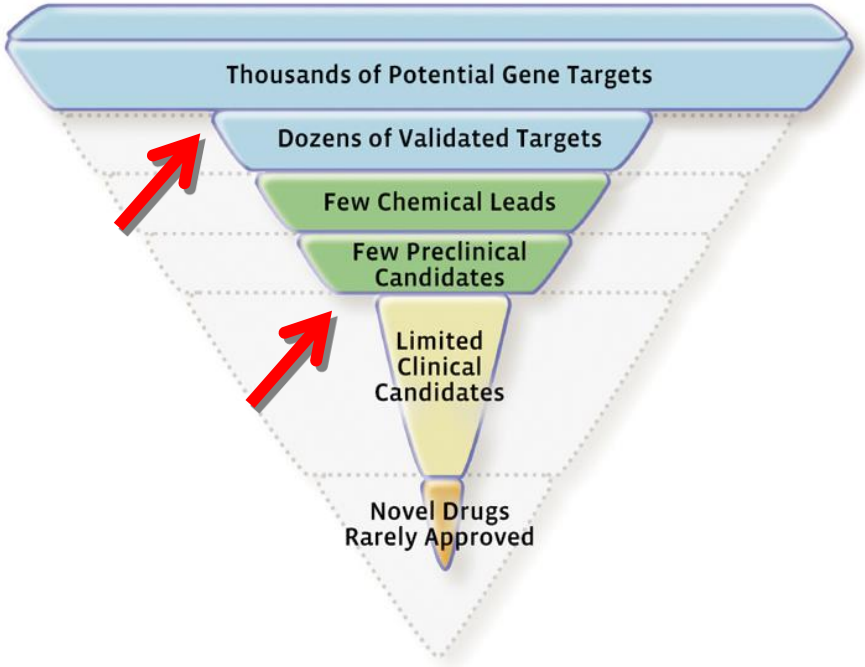
# Pipelines start with large numbers

## Developed World Diseases




## Neglected Diseases

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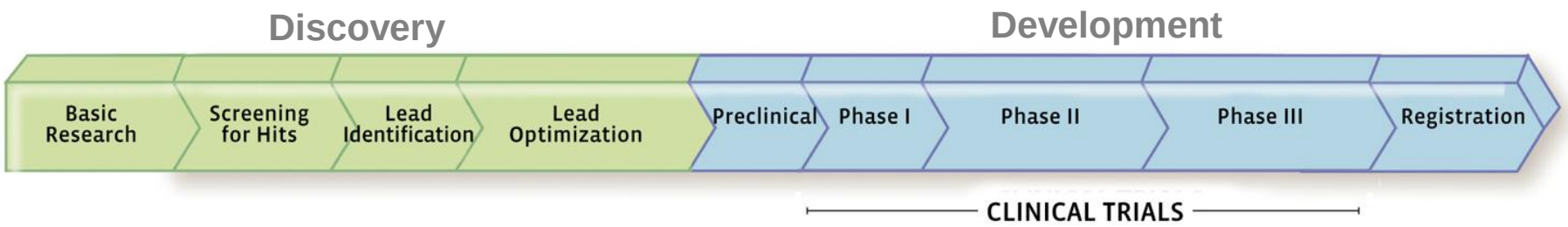
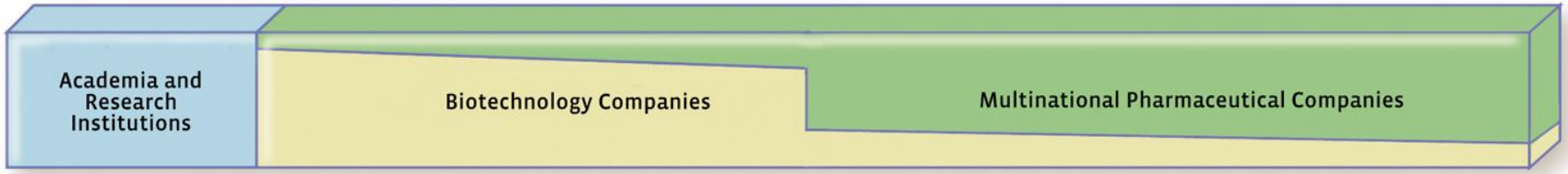
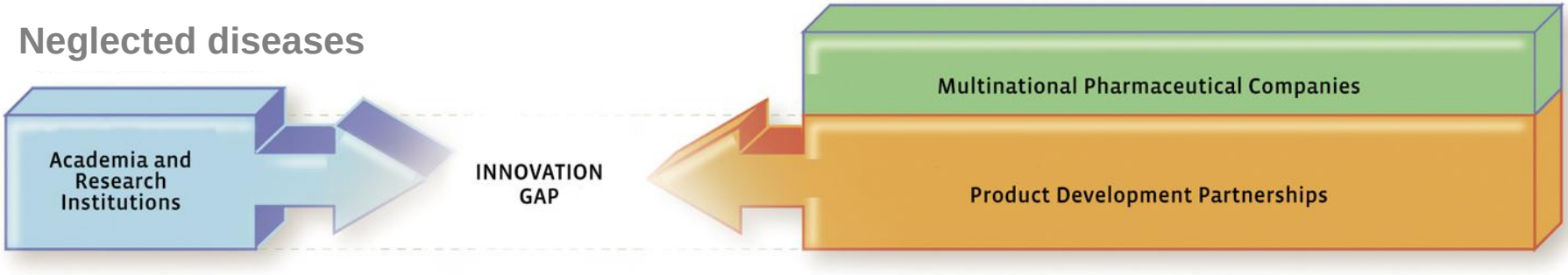
# Biotech missing from NTD R&D




## Diseases with a paying market




## Neglected diseases



# 2 Science is sufficient to support discovery

- **Essential discovery tools have been created for mycobacterium, plasmodium and tryps**
  - **Genomes for multiple species**
  - **Detailed understanding of metabolic pathways**
  - **Gene knockout technology**
  - **Whole-cell assay and biochemical screens**
  - **Adequate (but sub-optimal) animal models**
  - **Multiple validated targets**

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# 3 Biotechs well positioned to lead discovery

- **> 4000 firms globally**
  - India, China, Brazil, Singapore now emerging
- **Significant investments already**
  - > $400 billion invested since 1980
  - > $20 billion annual R&D expense
- **Not just large molecule drugs**
  - Started with large molecule drugs
  - since 2000, many small molecule drugs too
- **Today: biotech = engine of innovation for pharma**
  - > 2/3 of small molecule pipeline originated in biotech
  - Core innovators for new medicines

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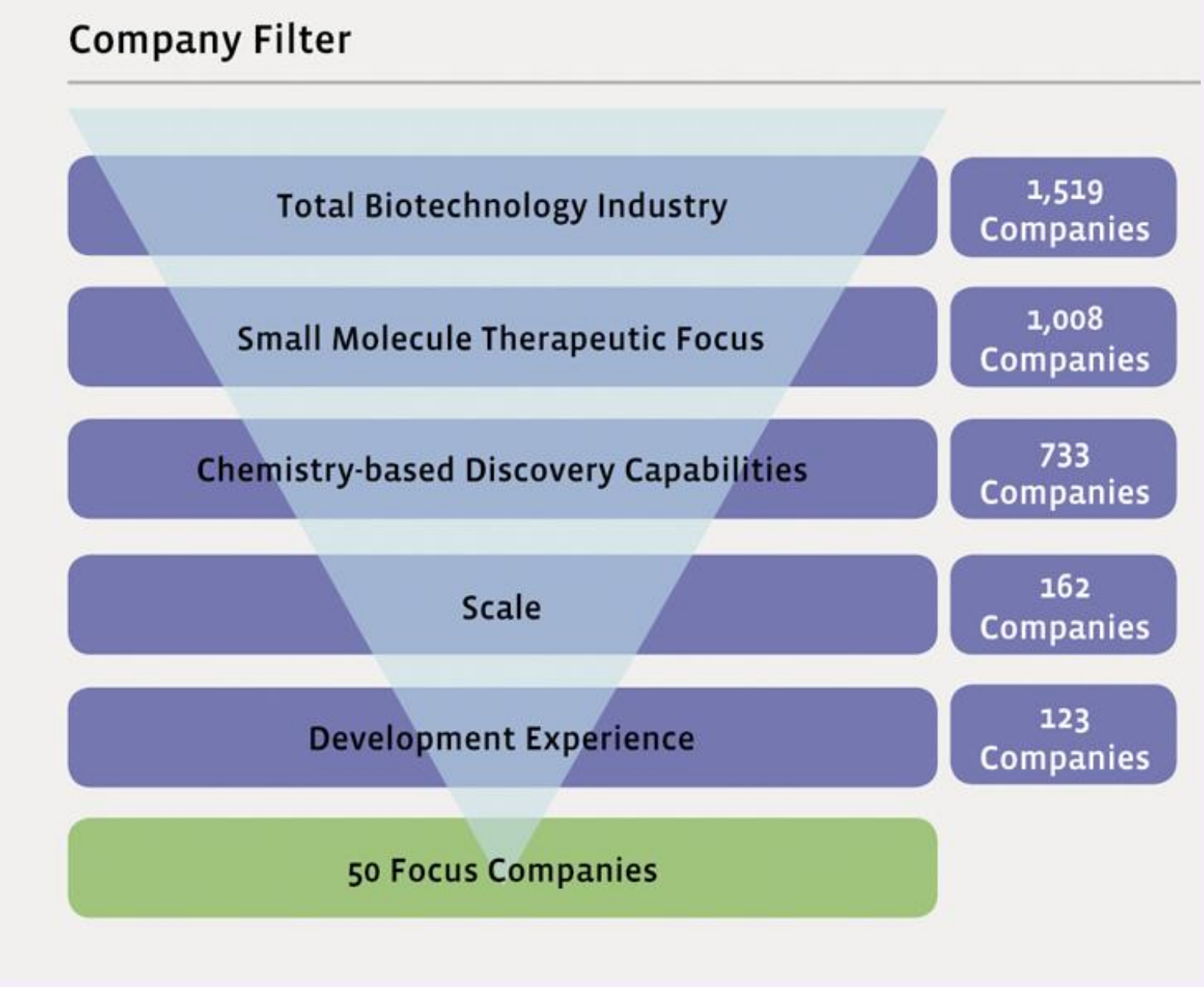
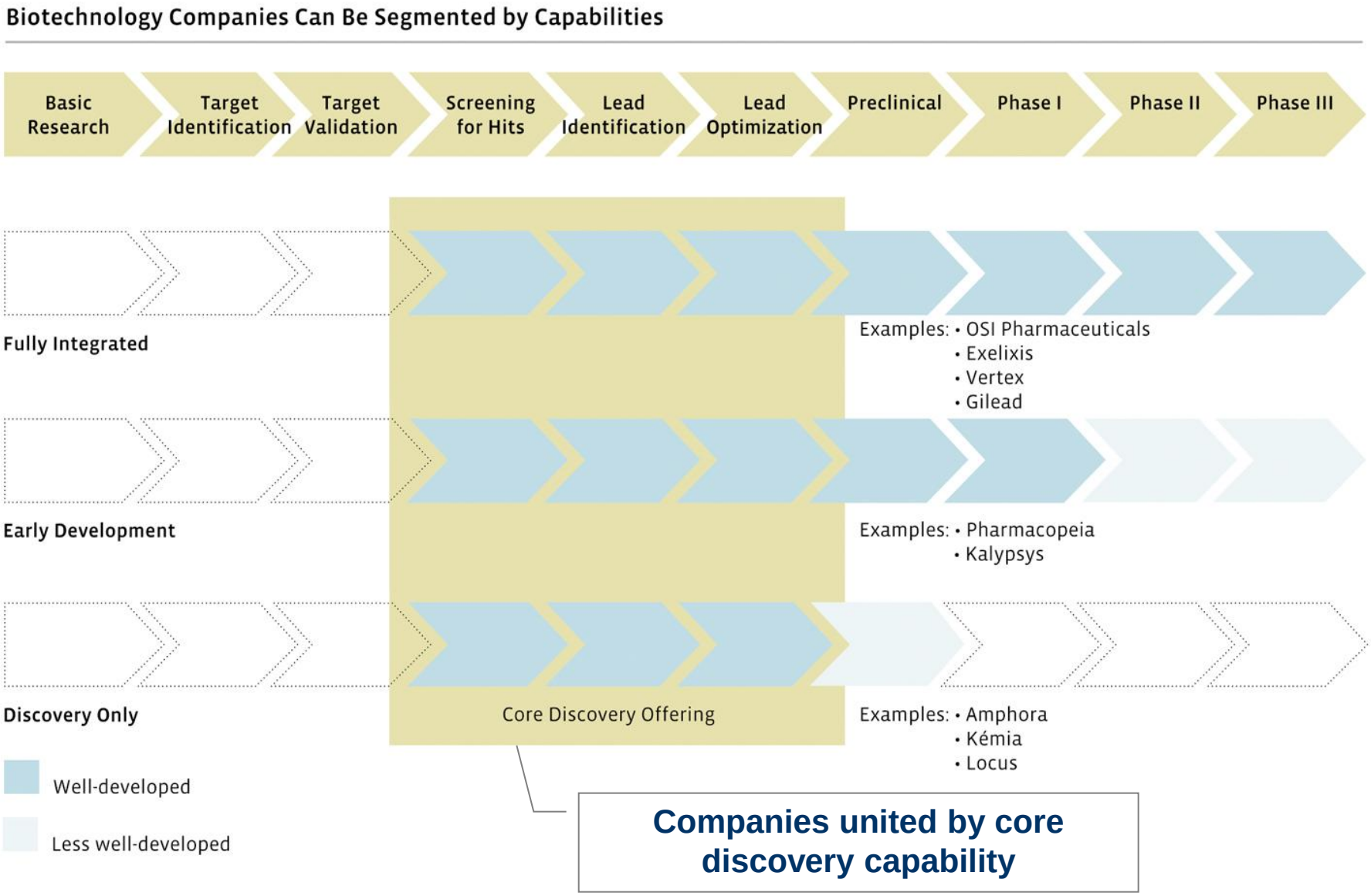
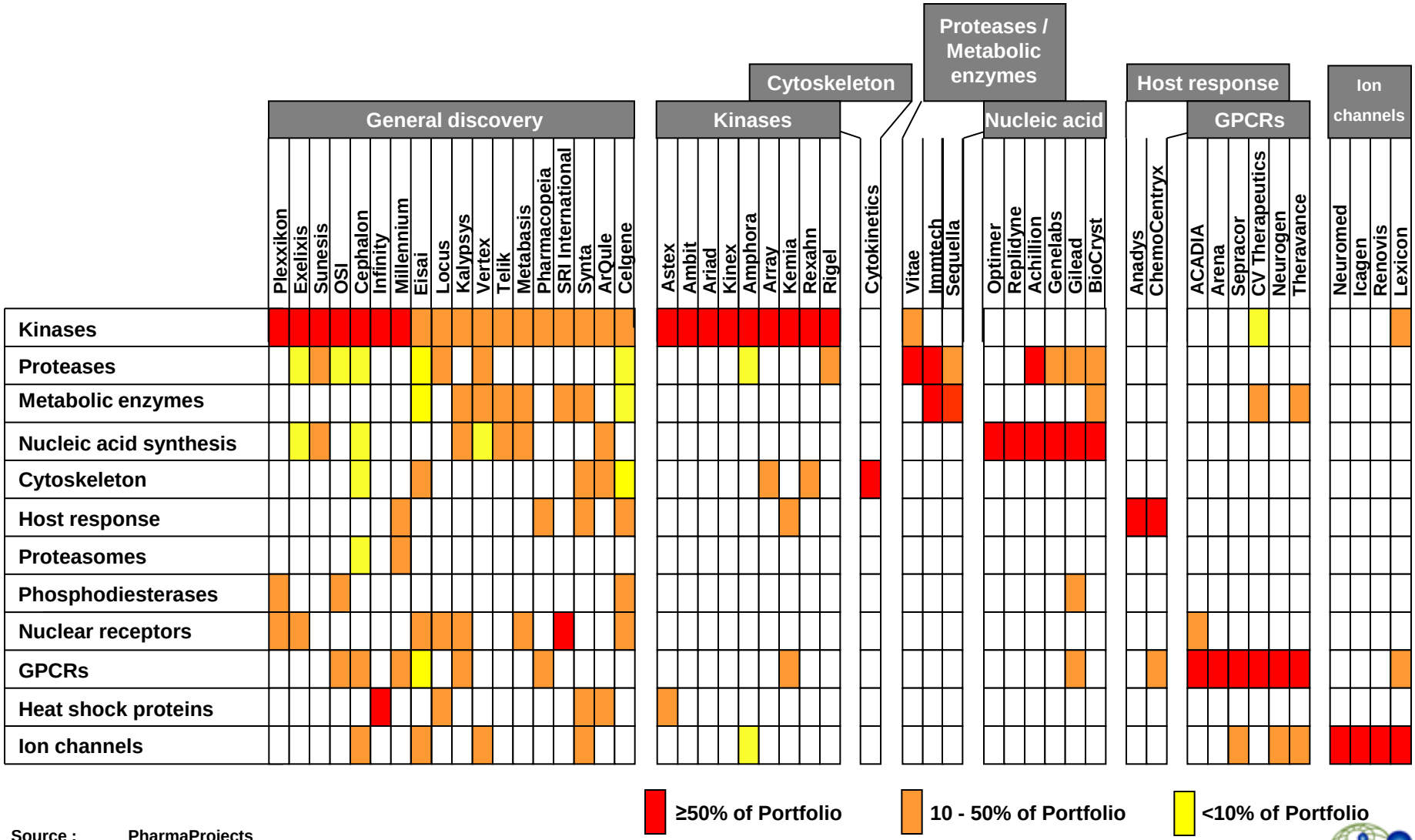
# Company selection process



# Wide range of size and capabilities



# Companies organized around targets




Source : PharmaProjects

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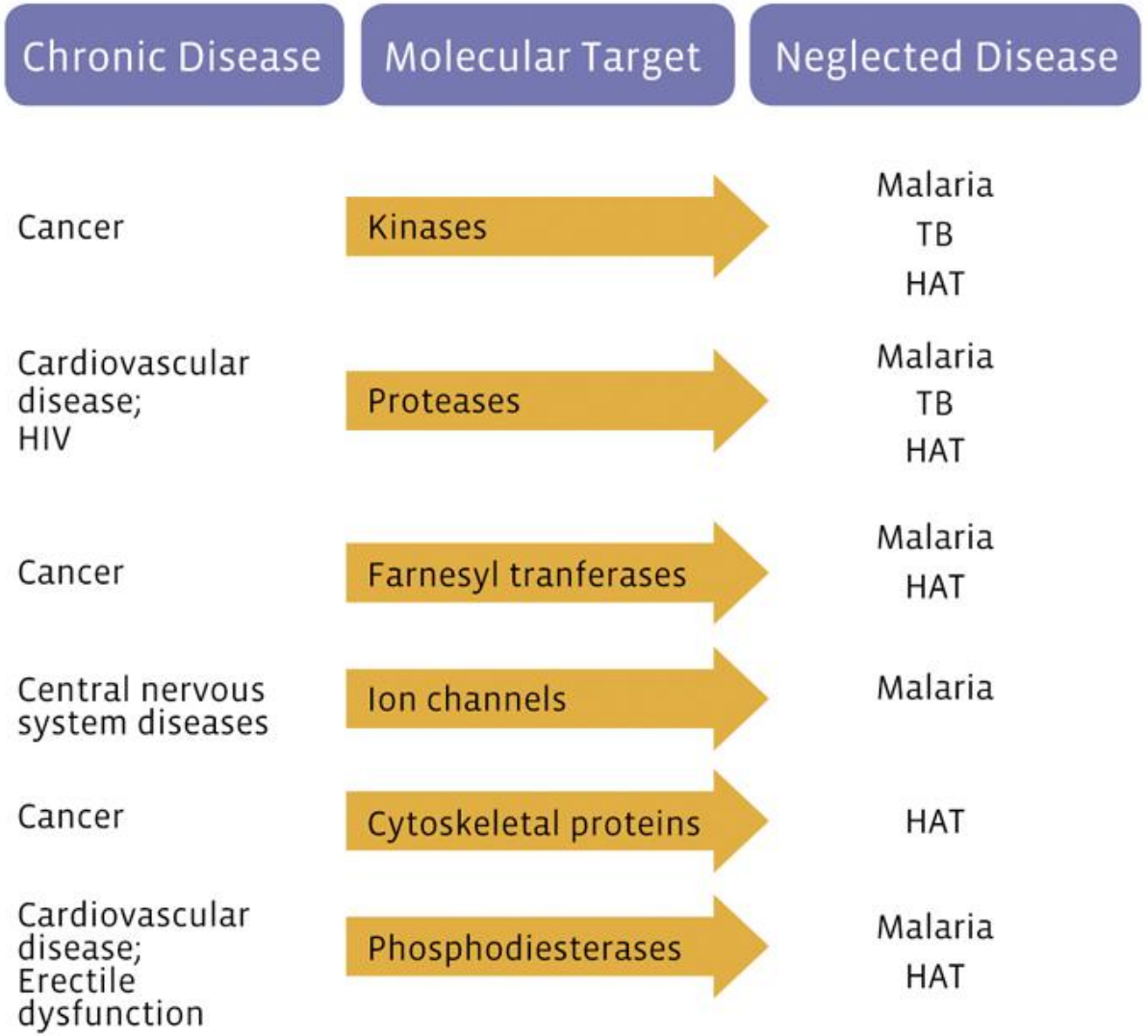
# 4 Technologies and targets are transferable

## Target Classes Are Transferable Across Diseases

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# Substantial new investment required

- **Opportunity:  Leverage $ billions of investment in biotech platforms**
- **Devote new funds to discovery R&D**
  - **Estimate $40m per year per disease for discovery**
  - **Goal is to build pipeline of one NDA every 3 years**

# Value justifies investment and risk-taking

- **NCEs essential to meet treatment goals**
- **Biotech assets can be leveraged to help build the pipeline and close the innovation gap**
- **New partnerships and incentives needed**
- **Success depends on dedicated, focused portfolio management**

# So how do we engage industry?

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# Barriers to biotech participation

- **Information**
  - **Unfamiliar with neglected diseases**
- **Funding**
  - **Skeptical of investor support for global health**
  - **Unable to access sufficient R&D funding**
  - **Concern about opportunity costs and focus**
- **Markets**
  - **Unsure of developing world markets**
  - **Disbelief that there's a profit to be made**

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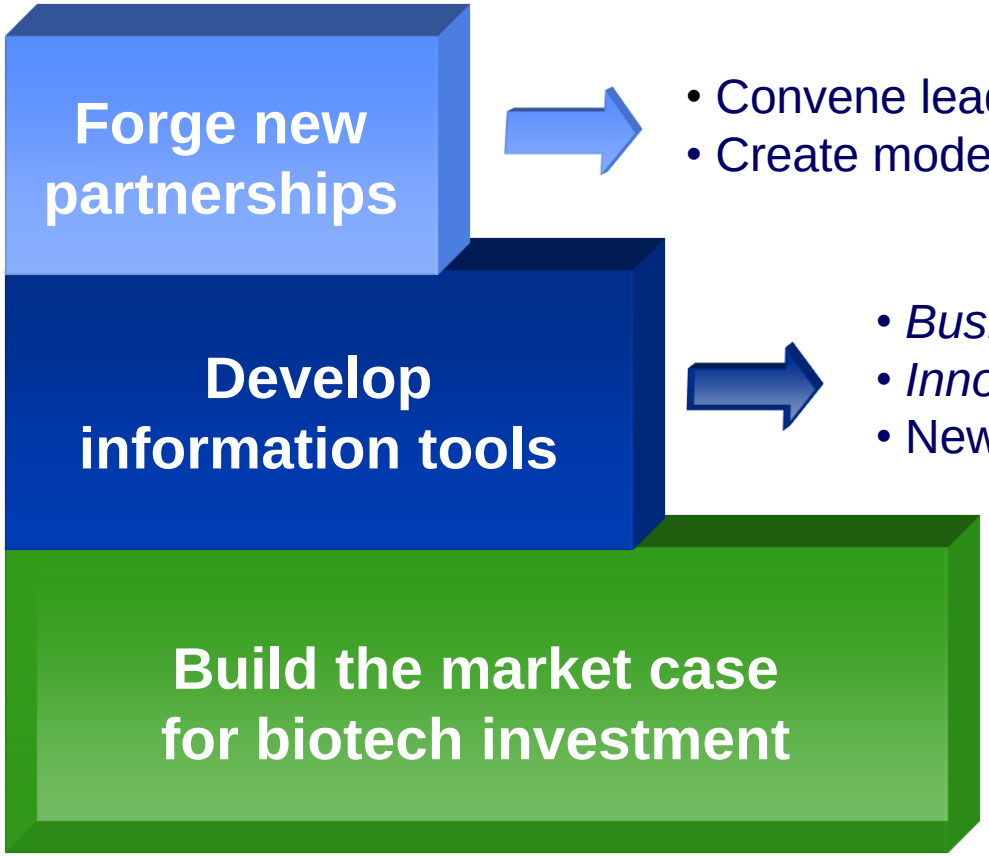
# BVGH Approach

## *Three Tiers of Support*




- Convene leaders in biotech and global health (PGH)
- Create model partnerships / attract funding

- *Business cases* to define markets
- *Innovation Maps* to guide initiatives
- New *business models* and *strategies*

- New *push + pull incentives*
- Donor demand for innovation

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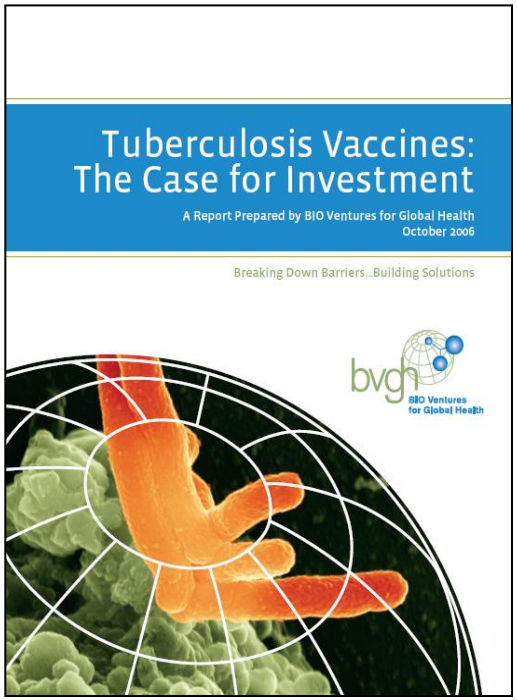
# Example of Impact: TB Vaccine Business Case




**Findings**

- Market will attract innovators ($450M – $1B/year)
- Lives saved justifies public sector investment
- Clinical trial risk is key hurdle
- Improved biomarkers key to shorter timelines

**Actions**

- Promoted findings with vaccine companies
- Promoted development of novel biomarkers
- Enhance developing world market

**Impact**

- Worked with 4 vx co. to evaluate opportunity
  - Brought potential partners together
  - 2 started new TB vaccine programs
- Formed TB biomarkers partnership

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# Partnering opportunities


- More than 500 attendees across all target sectors (biotech, pharma, PDPs, academics and investors)
- Innovator presentations
- Funder presentations
- Nearly 200 one-on-one partnering meetings

**Next PGH Forum: Fall 2009**

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***Building biotech solutions***
***for diseases of the developing world***

**www.bvgh.org**