

**THE ECONOMICS OF MICROBICIDES
DEVELOPMENT**

MICROBICIDES 2002

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MICROBICIDE INITIATIVE

Microbicide initiative goal

**To mobilize
the international
community (public and
private sectors)
to develop and deliver
effective microbicides as
rapidly as possible**

Participant institutions

Agency for International Development (U.S.)
Alliance for Microbicide Development
Biosyn, Inc.
Centers for Disease Control (U.S.)
CONRAD/GMP
Department for International Development (U.K.)
EPIcyte Pharmaceuticals
Family Health International
Glaxo SmithKline
International Center for Research on Women
International Family Health
International Working Group on Microbicides
Moriah Fund
National Institutes of Health (U.S.)
PATH
Population Council
Rockefeller Foundation
South African Medical Research Council/Univ. of
Natal
SSL International
U.K. Medical Research Council
World Bank

FIVE WORKING GROUPS

Advocacy

- To identify gaps in advocacy and resource mobilization and create a strategy to fill these gaps

Access

- To plan efforts to ensure equitable access to microbicide products (prior to launch)

Science

- To survey microbicide R&D, identify intellectual or resource gaps, and specify how to fill

Mechanism

- To identify new capabilities to support and speed product development
- To design these new capabilities and/or mechanisms

Pharmaco-economics

- To estimate the market potential, returns to investment and public benefits of microbicides

We will speak about two areas today

AGENDA

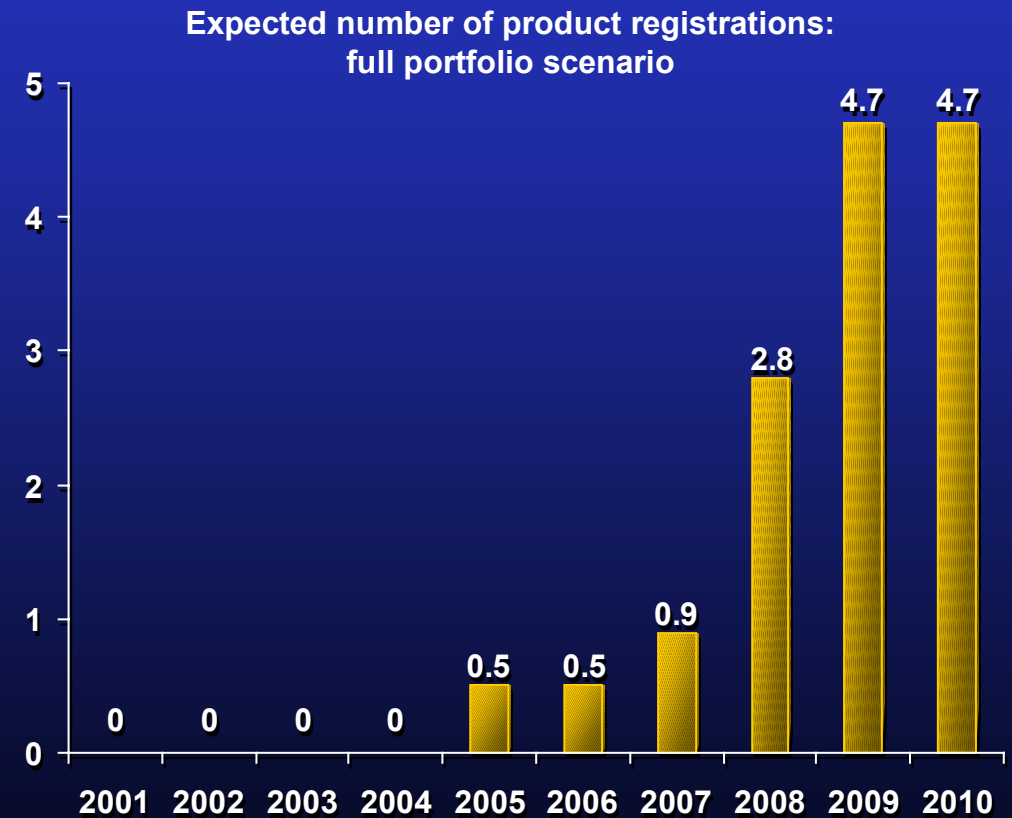
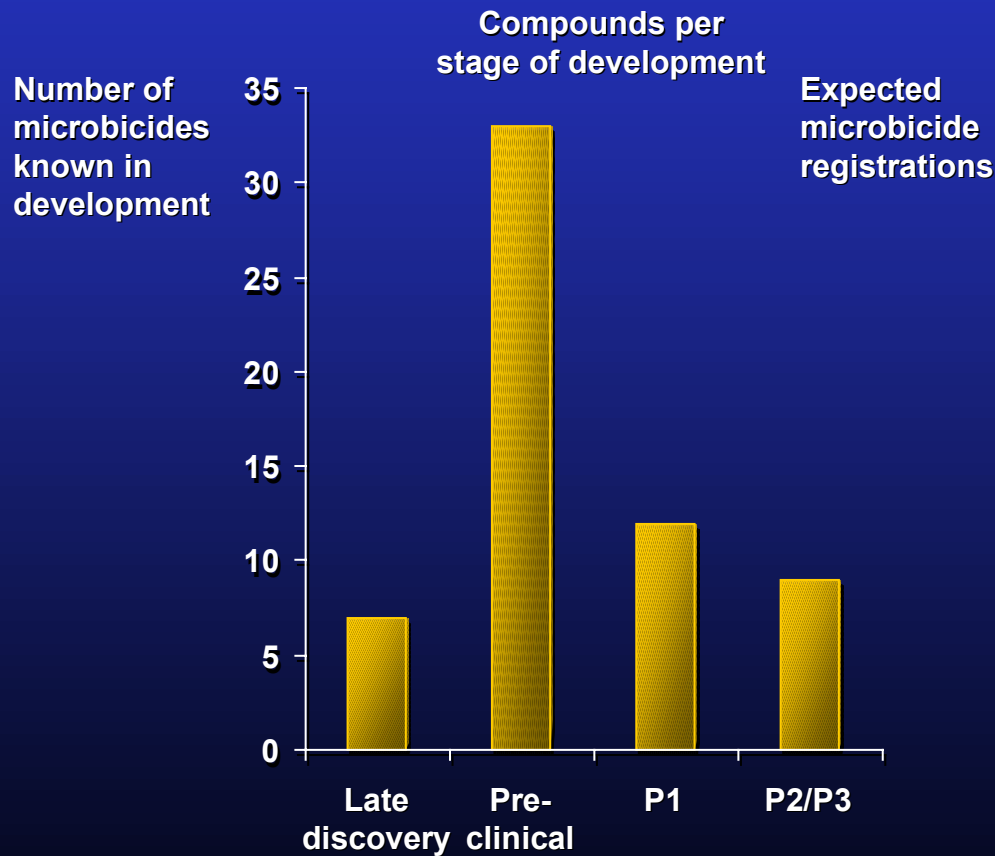
The cost : complexity of development

The potential : pharmaco-economics results

DEVELOPMENT EFFORTS PROMISING...

Relatively Full Pipeline...

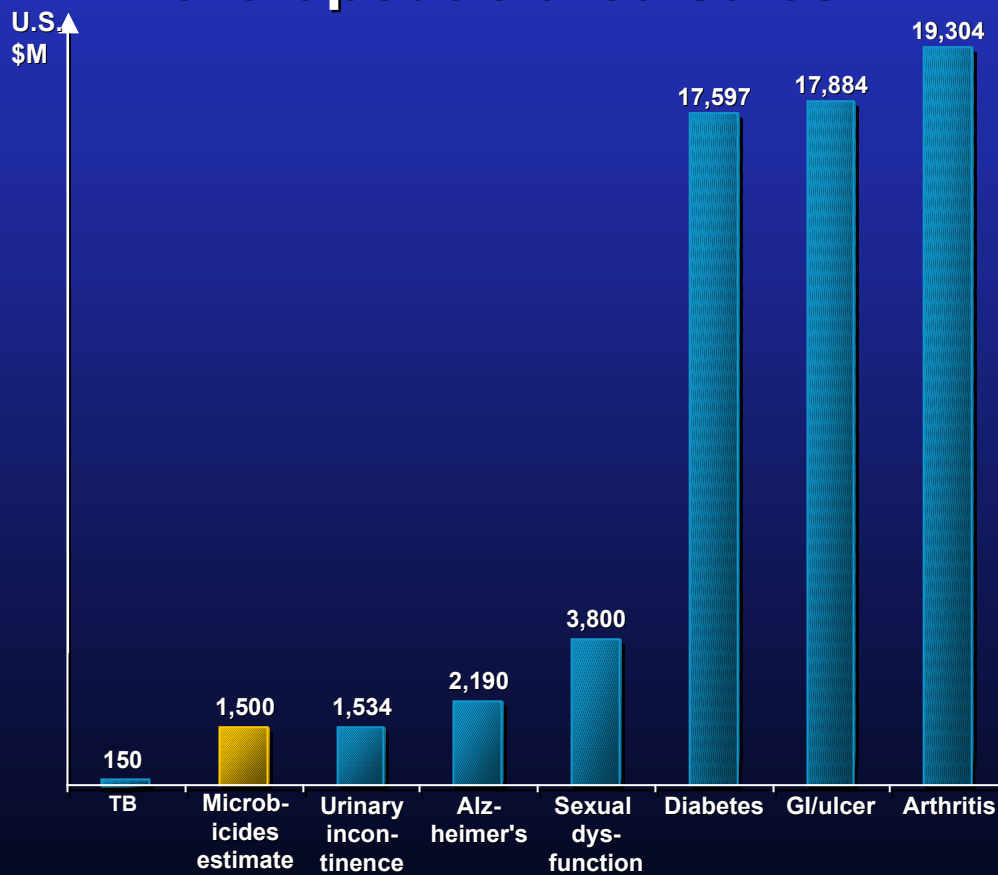
...May Produce a Product in 5 to 10 Years
(If All Products Developed On Schedule)



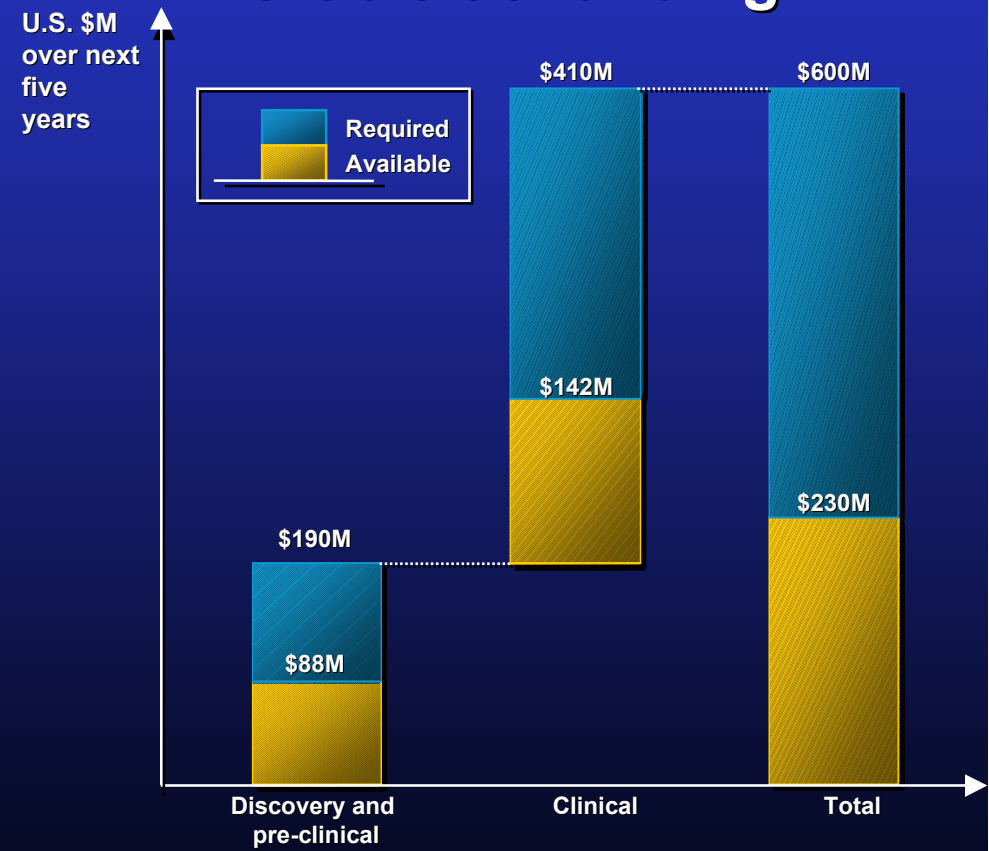
Source: Alliance for microbicide development; BCG probabilistic model

...BUT, DESPITE MARKET POTENTIAL, RESOURCES CURRENTLY INADEQUATE

Projected annual therapeutic area sales



Required vs. available microbicide funding



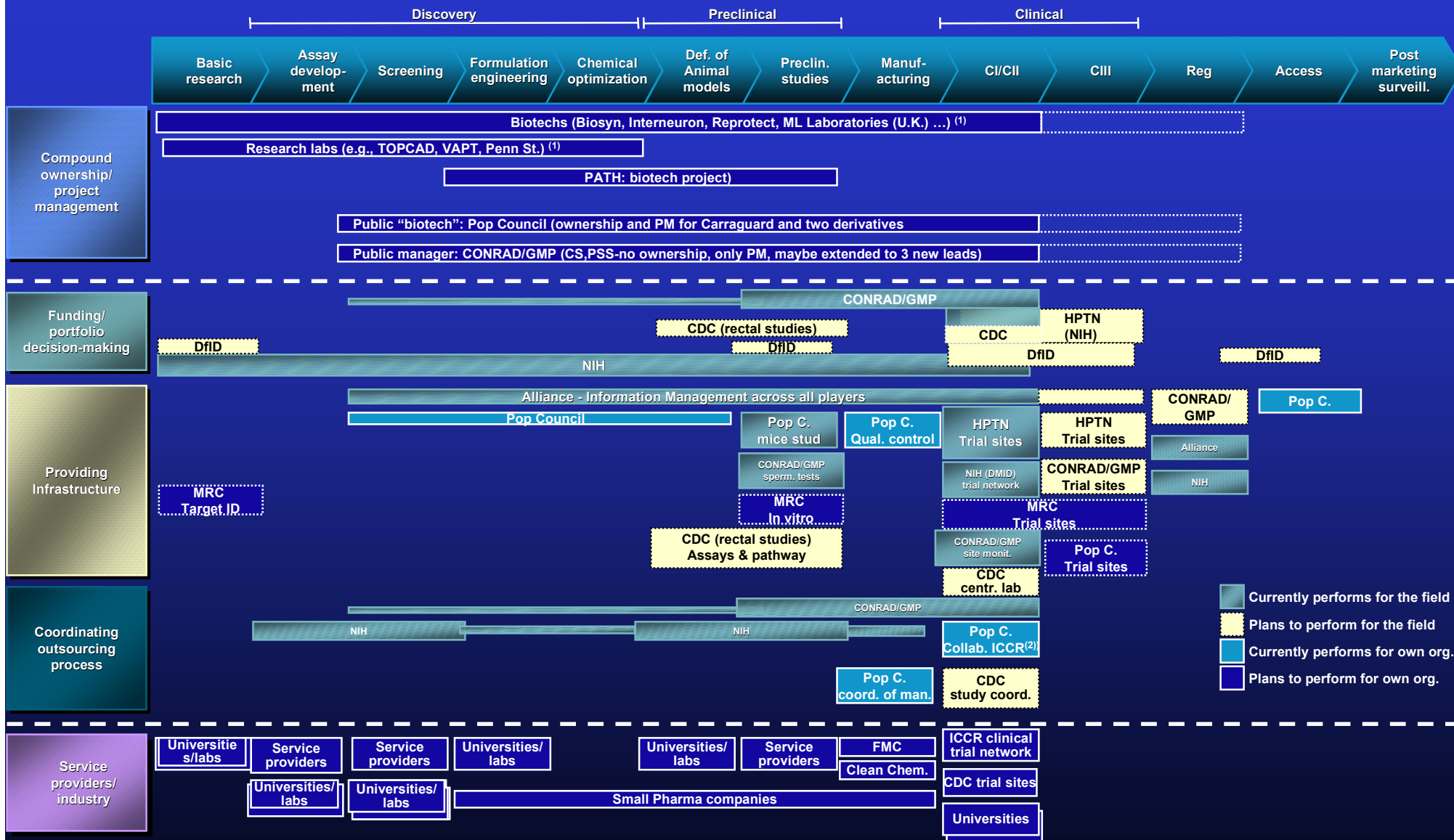
Source: SG Cowen; Pharmaco-economics team analysis; BCG probabilistic portfolio model; BCG interviews

MANY PLAYERS– MANY ROLES

	<u>Academic</u>	<u>Non-profit</u>	<u>Gov't</u>	<u>Biotechs</u>	<u>Pharma</u>
Project mgmt	✓	✓		✓	
Decision-making		✓	✓		
Infrastructure		✓	✓		
Coordination		✓	✓		

✓ = institutions involved in role

MICROBICIDE PRODUCT DEVELOPMENT MAP

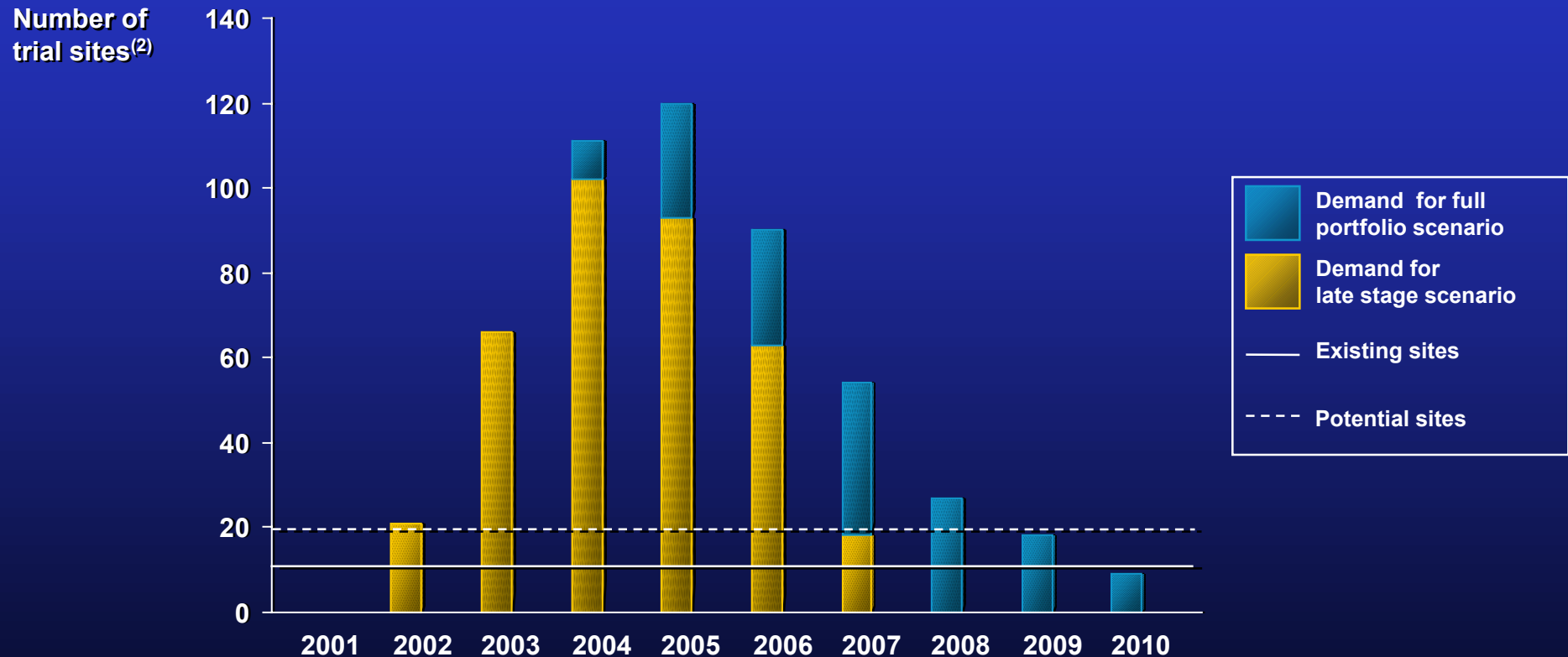


Creates opportunities for increased coordination and consolidation of activities

CLINICAL TRIAL OPTIMIZATION

Projected Demand for Phase III Trial Sites Exceeds Supply

Projected Supply and Demand for Phase III Trial Sites⁽¹⁾



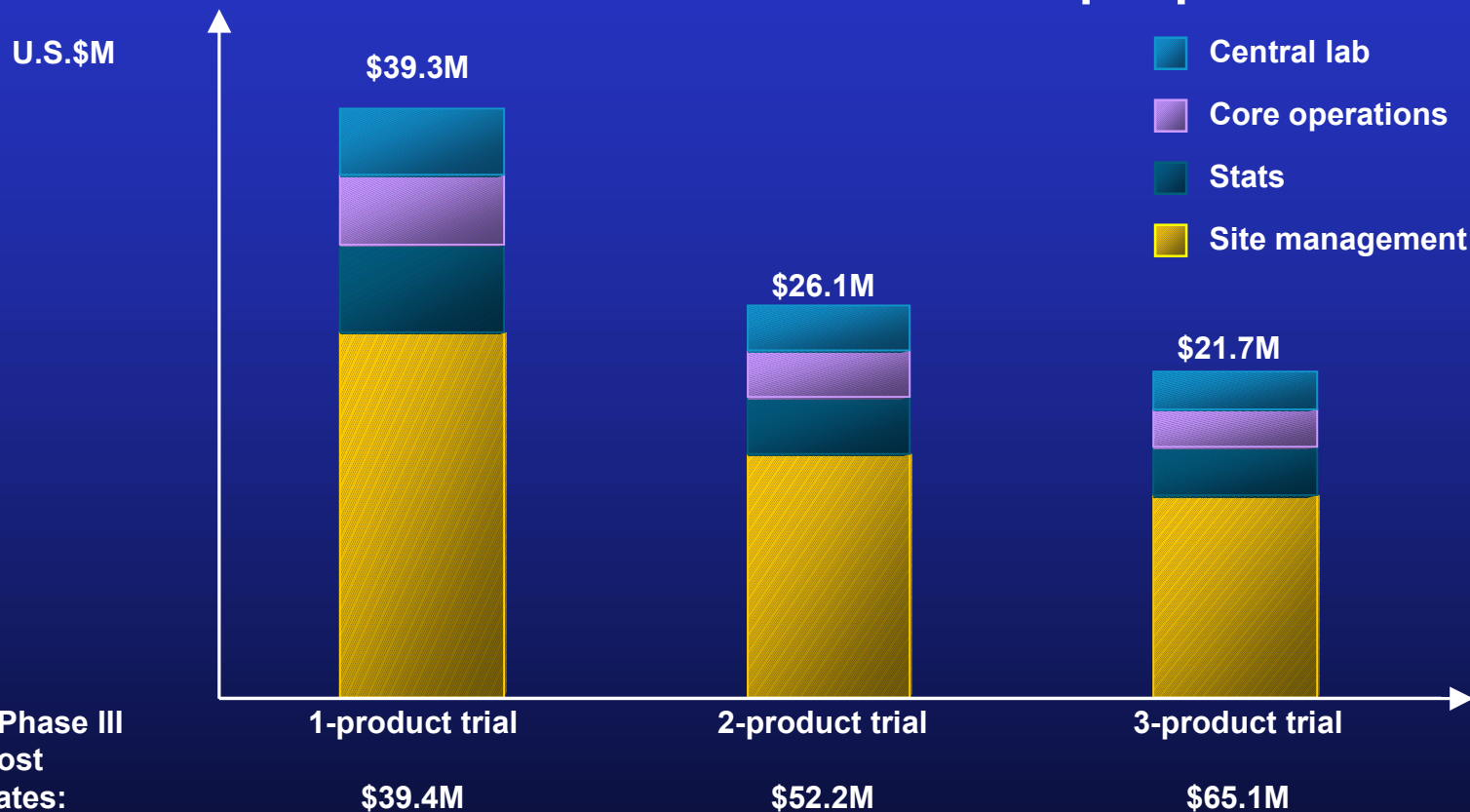
(1) Required sites derived based on current late stage pipeline of Carraguard, Dextrin Sulphate, CSS, PSS, Pro 2000, Buffergel, Acidform, C31G and UC781 requiring 9 sites for a 1 product trial and 12 for a 2 product trial

(2) Assumes each site has 2 clinics enrolling a maximum of 500 patients each

Source: BCG interviews; BCG probabilistic portfolio model

COMBINING PRODUCT TRIALS OFFERS ECONOMIES OF SCOPE

Total Phase III trial cost estimates per product



Combining 4 products in 5 years could save \$53M

Note: Assumes products can be blinded with common placebo; 1 placebo arm and 1 condom-only arm per trial; 3000 women per arm; 3 year trial; costs do not include manufacturing costs

Source: FHI; BCG analysis

THREE AREAS WHERE COMMON CAPABILITIES WOULD HELP ALL DEVELOPERS

Activities

Benefits to field

Regulatory liaison

- Common interface to regulatory agencies
- Common site of knowledge on regulatory requirements and process

- Gets product developers down learning curve
- Helps prevent regulatory confusion and paralysis

Synthesis

- Outsource manufacturing and synthesis to established network of industry contractors
- Manage costs

- Creates greater contracting leverage, longer-term relationships
- Builds resident expertise

Formulation

- Create capability to optimize common formulations across range of active ingredients

- Speed process for new compounds
- Economies of scope and learning benefits

**Largest opportunity from sharing
resources in manufacturing**

POTENTIAL SAVINGS FROM COORDINATION

Coordination of phase III trials offers greatest opportunity to reduce required funding for the field

- **Selective combing of 4 product trials could save up to an additional \$53M**
- **Portfolio management could significantly reduce expected funding requirements in the next 5 years**
 - **estimated late stage funding requirement could be reduced by up to \$184M (\$508M to \$324M)**

Manufacturing coordination offers the opportunity to reduce development costs by \$20M in the next five years

- **Shared resource for manufacturing**
- **Bulk purchase applicators and use of a common design**

Increased coordination creates business value

AGENDA

The cost : complexity of development

The potential : pharmaco-economics results

THE PRIVATE INVESTMENT VIEW

Women need to protect themselves against HIV

- Clear need for microbicides
- If product meets need, market could grow to \$900 million by 2011
 - Double by 2020

Potential for product to exceed forecast by meeting broader needs

- daily hygiene, vaginal health, and general infection protection

Market smaller if it fails to meet women's high standards of acceptability

Pharma and biotechs have not invested in microbicides because likely returns do not cover expenses and cost of capital

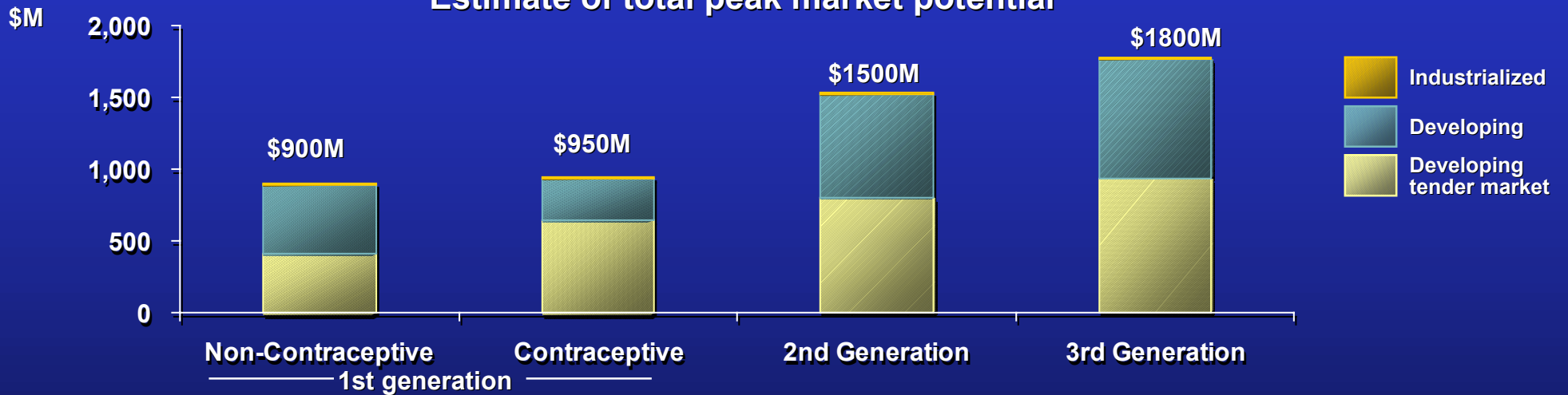
- Donor support critical

Donor support continue to be critical through first generation

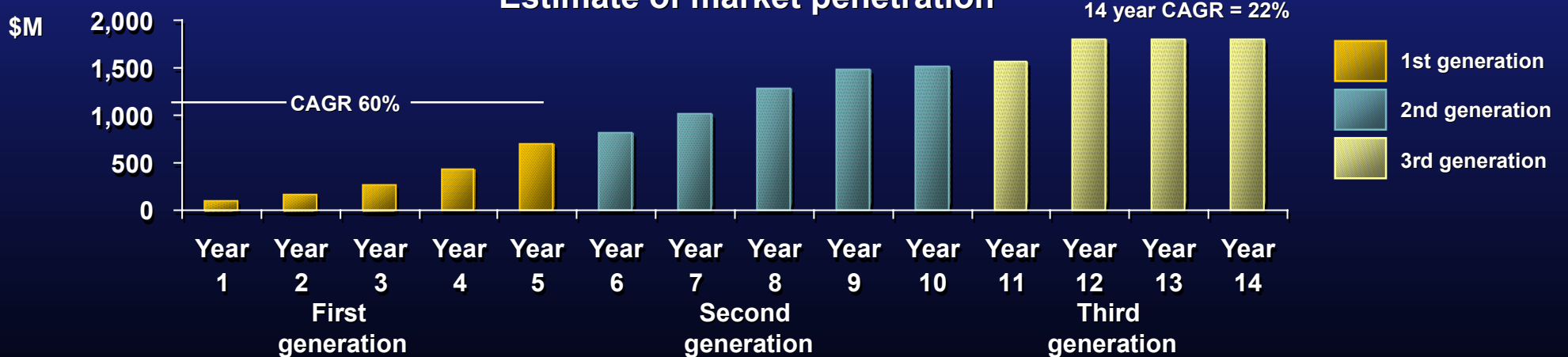
- If first generation successful, second generation may be self-supporting

CONSERVATIVE ASSESSMENT SUGGESTS GLOBAL MARKET COULD BE \$2B

Estimate of total peak market potential



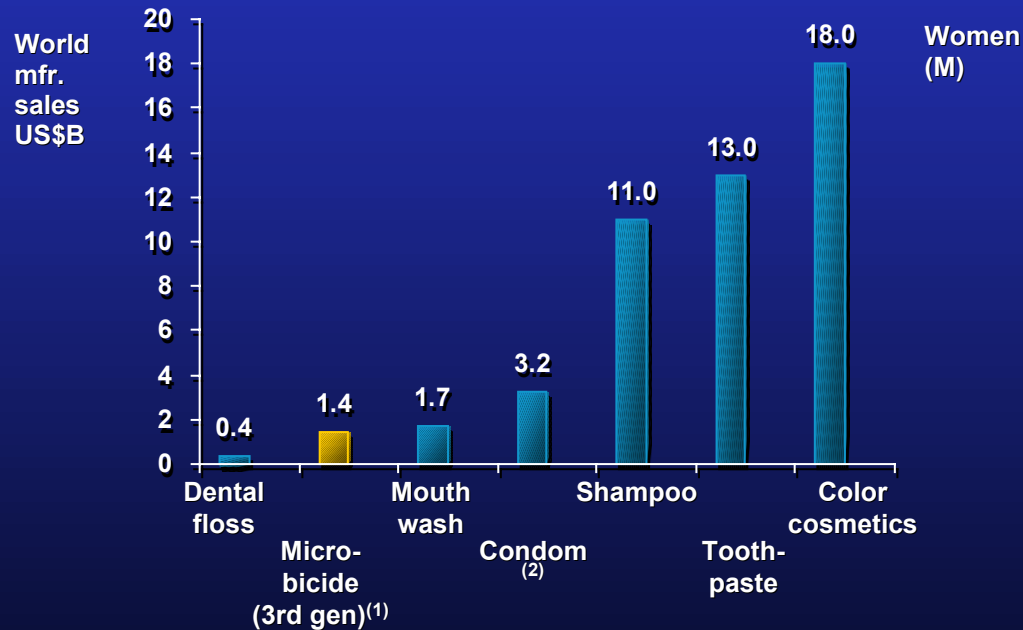
Estimate of market penetration



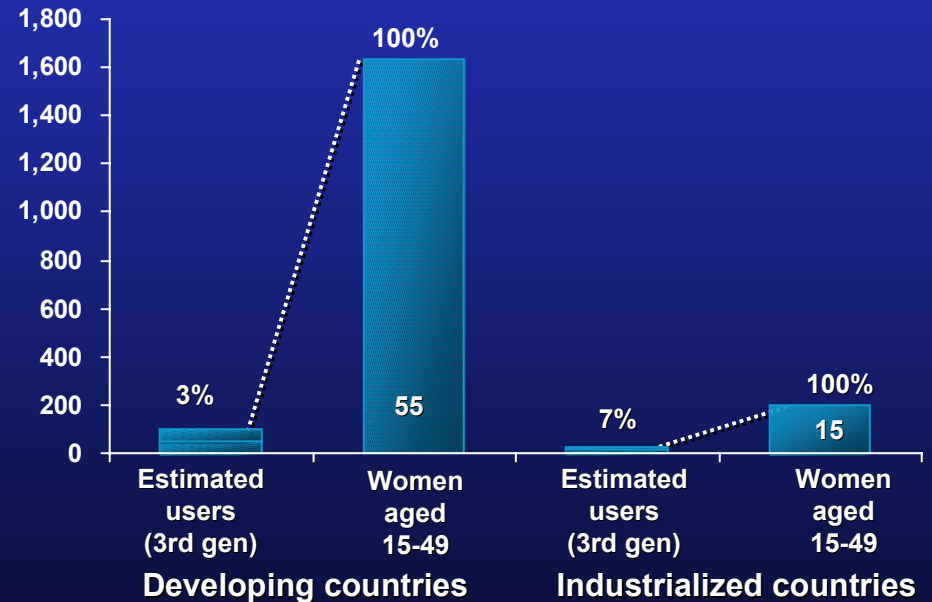
SUBSTANTIAL UPSIDE IF MICROBICIDE BECOMES A CONSUMER PRODUCT

Microbicide market could be much larger...

If women used it more often



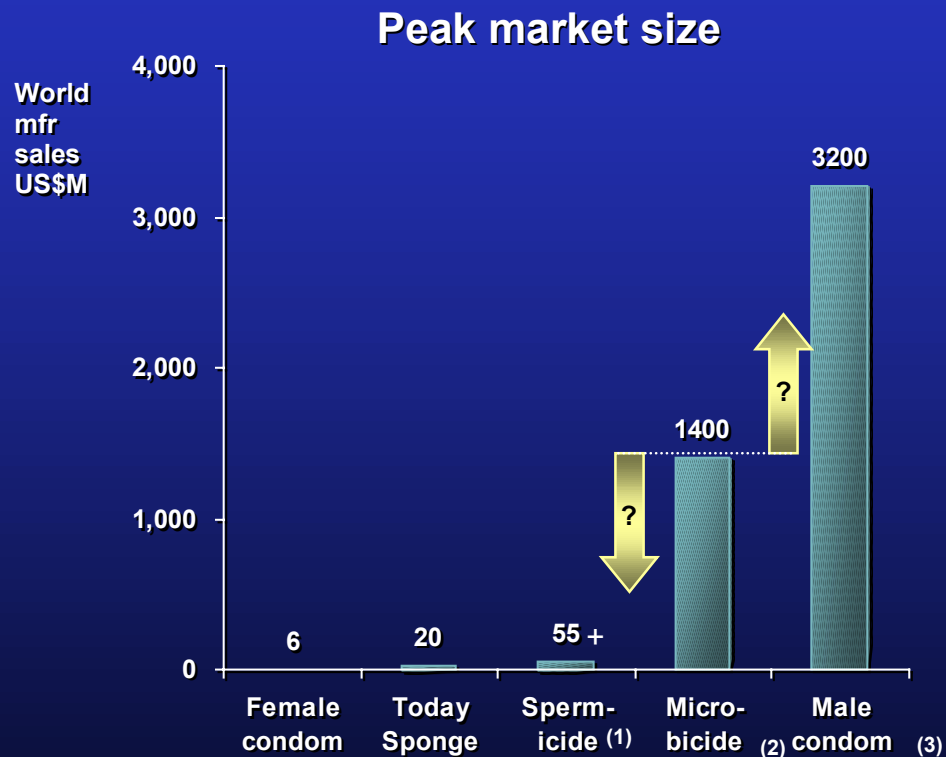
Or if more women used it



- Assumed manufacturer's sales were 80% of forecast retail sales of \$1800M
- Estimate

DOWNSIDE IF MARKET EVOLVES LIKE WOMEN'S OTC CONTRACEPTIVES

Small Markets for Other Topical Women's Products



What happened?

Female condom

- Expensive
- Difficult to use

Today sponge

- Popular among users
- Difficult to learn to use
- Market did not sustain re-investment in plant

Spermicide

- Low effectiveness
- Abrasiveness of nonoxynol-9

The standard for product acceptability is high

- However, AIDS epidemic may speed acceptance

1st GENERATION REQUIRES SUBSIDY Later Generations Can Create Economic Value

Example: For 25% chance of developing a microbicide, at a discount rate of 12.5%

	Pessimistic case "Niche product"	Expected case "Widely acceptable product"	Optimistic case "Regular hygiene product ⁽¹⁾ "
1st generation <ul style="list-style-type: none"> • launch 2007 • 8 yr lifecycle • 100% share 	Market \$20M NPV = (\$65M) IRR = N/A	Market \$900M NPV = (\$27M) IRR = 7%	Unlikely scenario
2nd generation <ul style="list-style-type: none"> • launch 2012 • 15 yr lifecycle • 50% share 	Market \$40M NPV = (\$56M) IRR = N/A	Market \$1500M NPV = \$37M IRR = 18%	Market \$3000M NPV = \$122M IRR = 24%
3rd generation <ul style="list-style-type: none"> • launch 2017 • 33% share • 3% growing perpetuity 	Market \$100M NPV = (\$49M) (of which terminal value=\$6M) IRR = N/A	Market \$1800M NPV = \$117M (of which terminal value=\$112M) IRR = 14%	Market \$5000M NPV = \$428M (of which terminal value=\$307M) IRR = 26%

Negative NPV at 12.5% cost of capital
 Positive NPV at 12.5% cost of capital

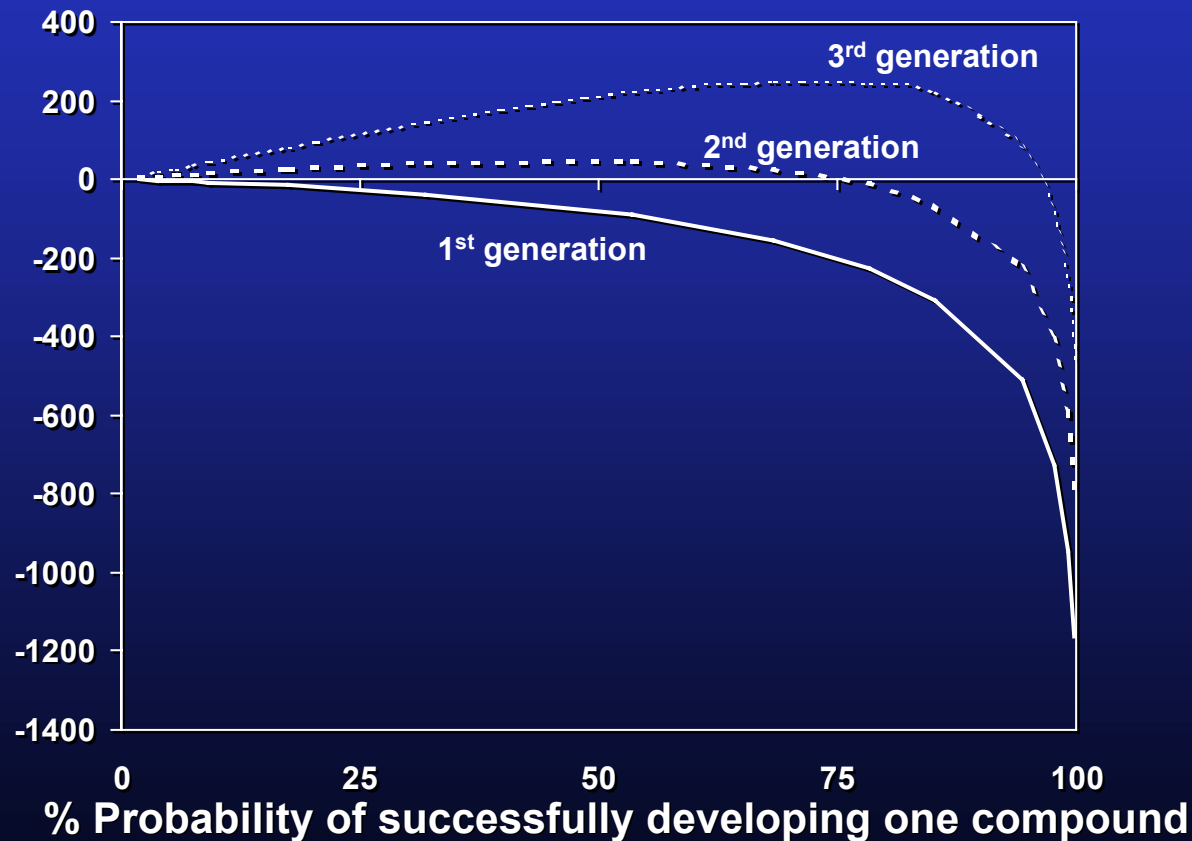
Knowledge and certainty about market will increase with each generation

(1) Unlikely that first generation product would become a daily hygiene product because it will have relatively low effectiveness and limited set of indications.

LARGE INVESTMENT TO INCREASE PROBABILITY OF A MICROBICIDE Costs Are More Certain Than Revenues

Net present value for developing and marketing a microbicide, by probability of development success⁽¹⁾

Net present
value in \$M
(at 12.5% cost
of capital)



(1) Assumes 100% share of \$900M market in 1st generation, 50% share of \$1500M market in 2nd generation, and 33% share of \$1800M in 3rd generation. Return would be lower if market is smaller or share of market is less.