

Harnessing Open Innovation

to Tackle the Dearth of Novel Antibiotics



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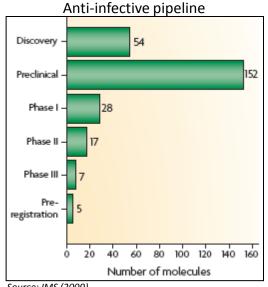
Brussels

May 23, 2011

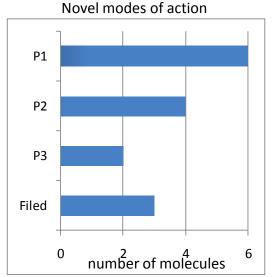
Outline

- A bleak outlook
- A broken R&D model
- Alternative models

A depleted pipeline



Source: IMS (2009)



- Most big pharmas have deprioritized anti-infective research
- Much of their remaining involvement focuses on HIV and hepatitis
- Big pharmas only fund one-third of anti-infective trials
- Most of the research focuses on known targets; only 15 novel modes of action (out of 209 molecules in development)

"We need new and better drugs- and we need them now. Yet the R&D pipeline is distressingly low"

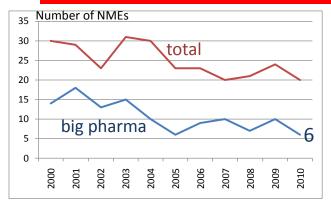
Margaret Hamburg, FDA Commissioner

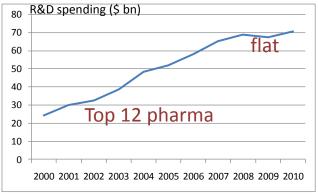


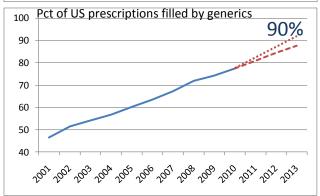
Source: EMA (Sept 2010)

A broken R&D model









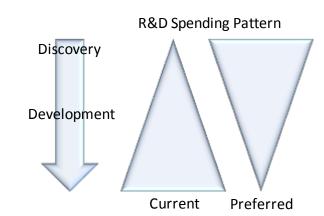
- \$125 bn annual industry R&D spending yields ~20-25 NMEs
- R&D spending/NME at big pharmas is ~\$5-10+ bn range
- Big pharma's retrenchment from anti-infective R&D was likely the first signal that the R&D model was failing
- It has failed again in neuroscience and cardiovascular research, causing further retrenchment from these areas
- Much of the problem seems to be with:
 - A narrow approach to translational research that shuns new innovation pathways (e.g., nanotech, synthetic bio)
 - A poor understanding of the pathogens' biology
 - The model's inability to produce affordable innovation
- Under pressure, most big pharmas have become cautious, seeking the safety of proven targets and drug classes, which lowers the likelihood of achieving breakthroughs, and heightens the risk of failure



How to get out of this?



- Nearly all the major biomedical breakthroughs (~300 in the 20th century) have been the results of high-risk, unconventional research
- Risk-aversion, caused by increasing pressure, has redirected R&D spending toward fewer costly "safe" late clinical projects
- Resulting greater risk-exposure portends disaster
- The focus on blockbuster has distracted from the quest for breakthroughs



- Alternative R&D models, especially collaborative research, show large costsavings opportunities
- We need to redirect R&D spending towards discovery, re-engage in high-risk translational research by assembling large portfolios of potential breakthroughs and pay for it by embracing open innovation, restricting clinical research to genuine breakthroughs, and defunding other projects



Examples: Breaking the Rules with

Open Innovation

"There are rules that chemists follow when looking for new drugs.

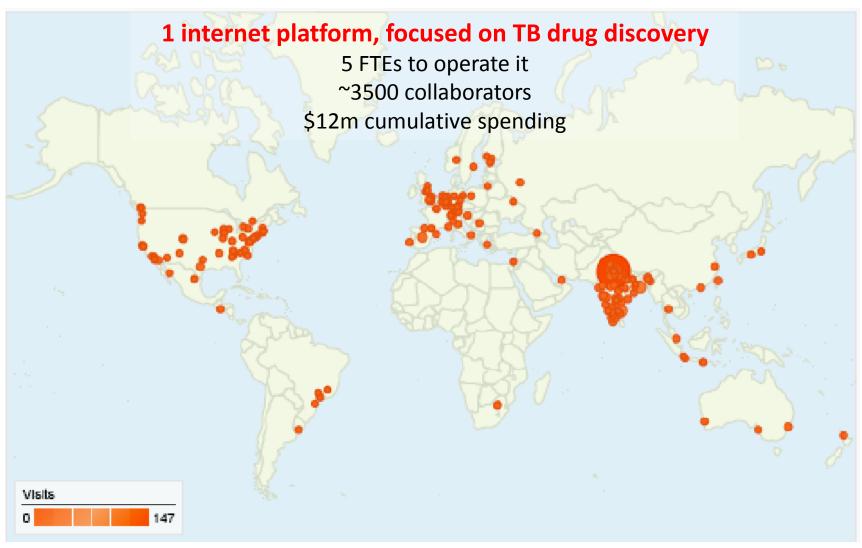
To make an antibiotic, you have to break those rules.

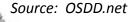
They are different from anything else we make because they are designed to kill a living organism inside another living organism"

John Rex, AstraZeneca

Open Innovation in Action









OSDD projects



Drug Target Identification

Virtual Screening

Chemical
Synthesis/
library

Screening/ Hit identification

Hit to Lead

18

19



Other projects aim to develop tools, databases and repositories for the OSDD community

9

6

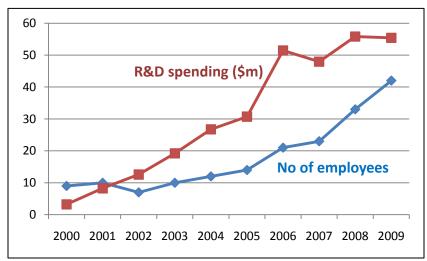
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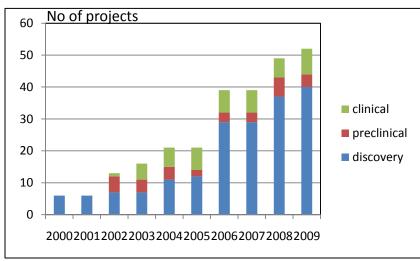
Open Innovation in Action: Public-Private Partnerships



- 42 employees
- 130 partners (pharma and biotech) in 43 countries
- 55 clinical trial sites in 24 countries
- 38 on-going clinical trials
- 19 new classes of drugs under investigation
- \$55 million in total annual spending (87% toward research)
- \$311 million cumulative spending over the last 10 years
- 712 project ideas received from the worldwide scientific community (47 investigated)
- 1 drug approved, 2 under regulatory review



Source: MMV annual reports

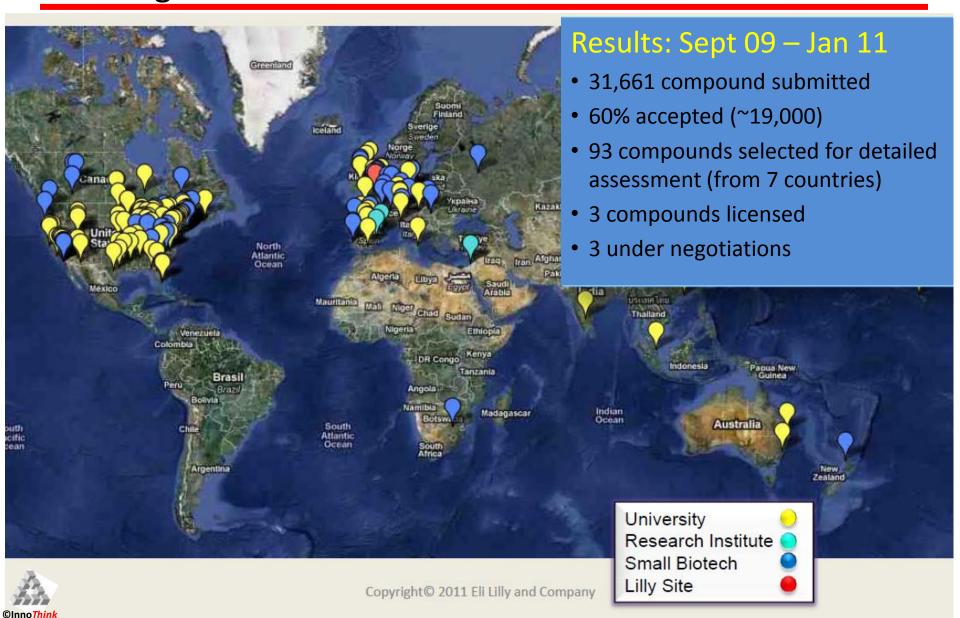


Source: MMV annual reports



Open Innovation in Action: Courting the chemists of the world

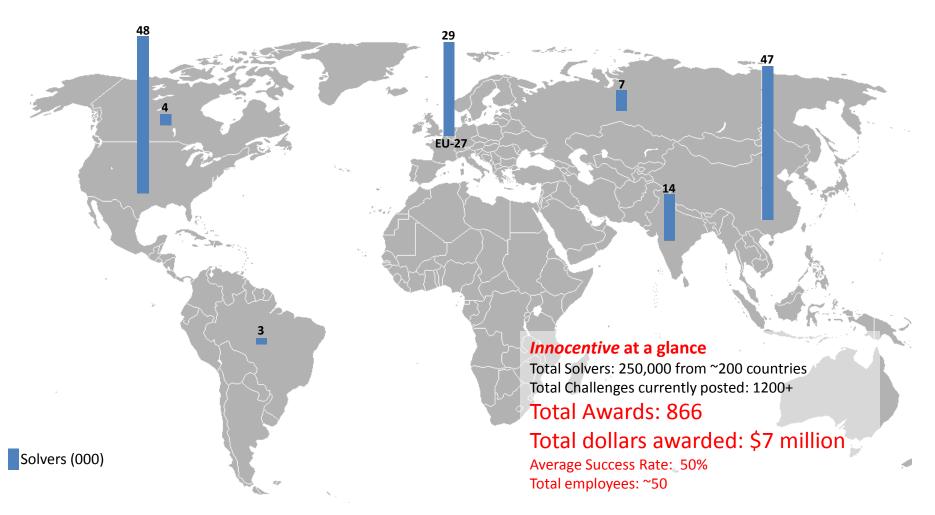




Open Innovation in Action











Open Innovation in Action



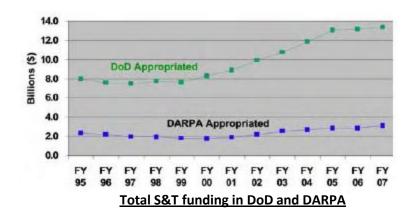
- The discovery engine of the U.S. military
- Created 52 years ago
- Changed the world with a steady flow of repeated breakthroughs:
 - The internet
 - The GPS
 - Night vision
 - Supercomputing
 - Satellite imaging

- -- Biosensors
- -- Laser guidance
- -- unmanned vehicles
- -- Grid computing
- -- VLSI circuits

- -- Stealth fighters
- -- Cruise missiles
- -- Composite materials
- -- Remote-controlled warfare
- -- Mini and micro robots

- Did it on a shoestring
 - Only 240 employees (including 140 professionals)
 - No labs, no facilities (beside a single office building)
 - R&D budget smaller than Lilly's







Thank you!

Questions?

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