



Strategic Alliance + M&A in Pharma, Biotech & Academia

Strategic Alliances



- Why Should Pharma, Biotech & Academia develop alliances?
- Strategic Alliances and M&A in 2015
- Different Types of Alliances
- Structuring and Negotiating Alliances
- Alliance Management

Why Should Pharma, Biotech & Academia Form Strategic Alliances?



Why do Academic Institutions, Biotech & Pharma need to form strategic alliances including M&A?

Academic Institutions: Research Translation!

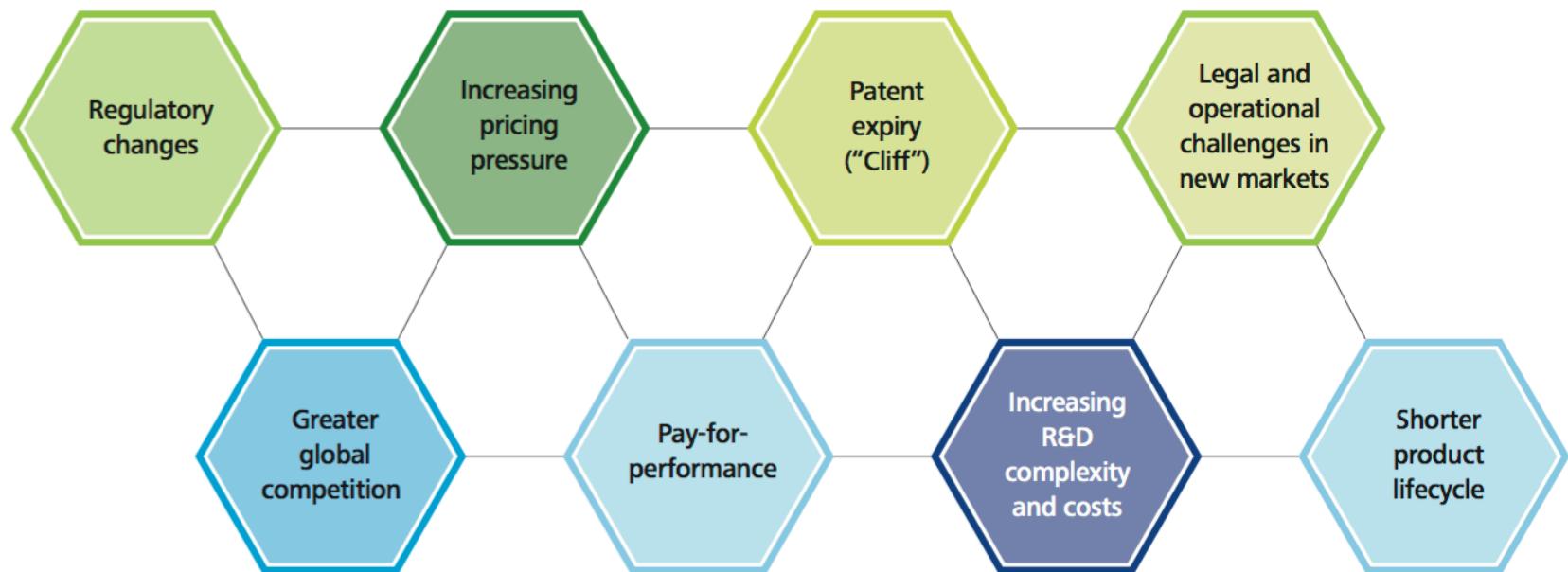
Biotech: Source of Capital!

Pharma: Keep their drug pipelines full!

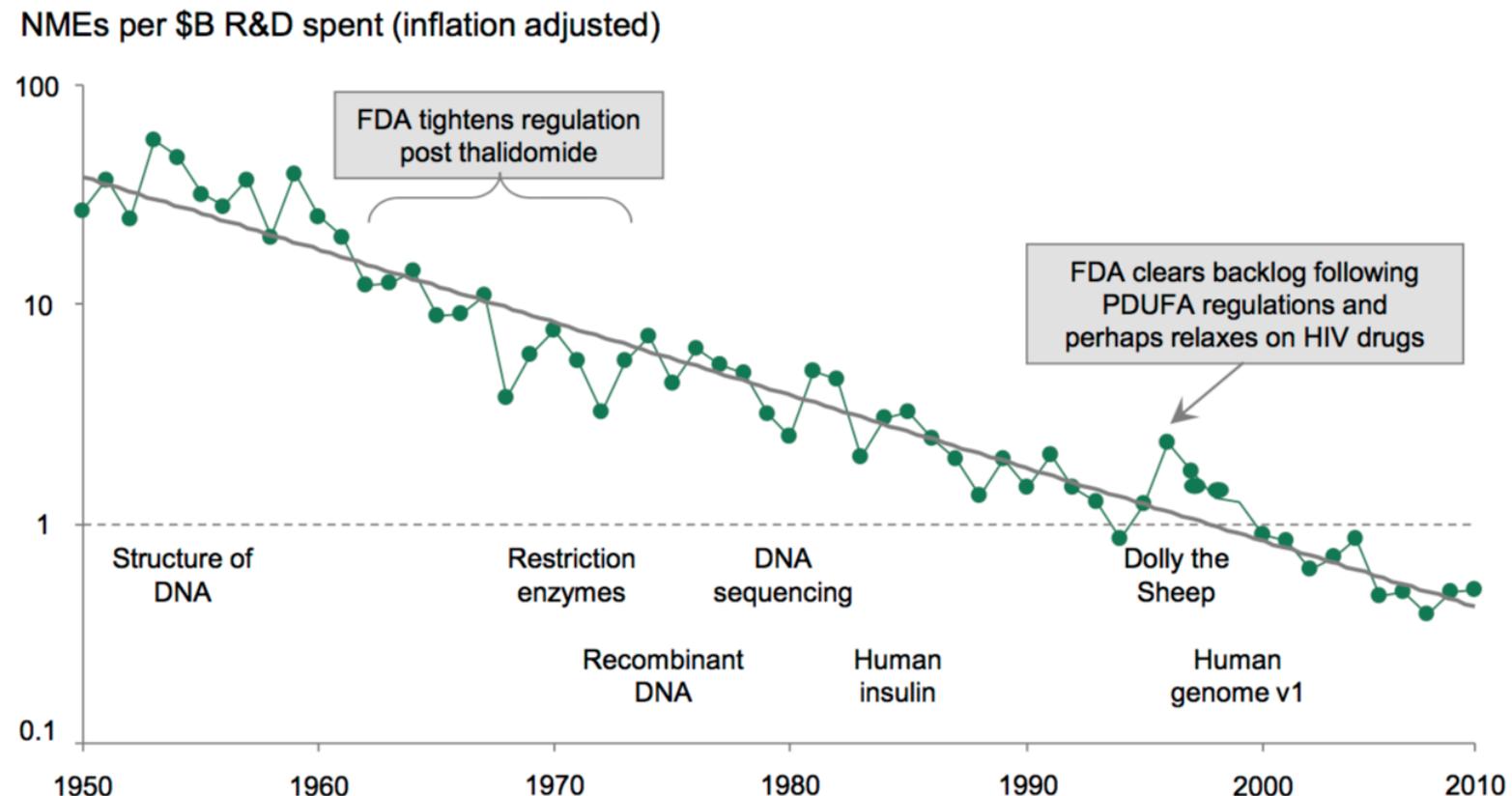
ALLIANCE: A formal agreement between two or more companies to cooperate for specific purposes

Challenges in Life Science Industry

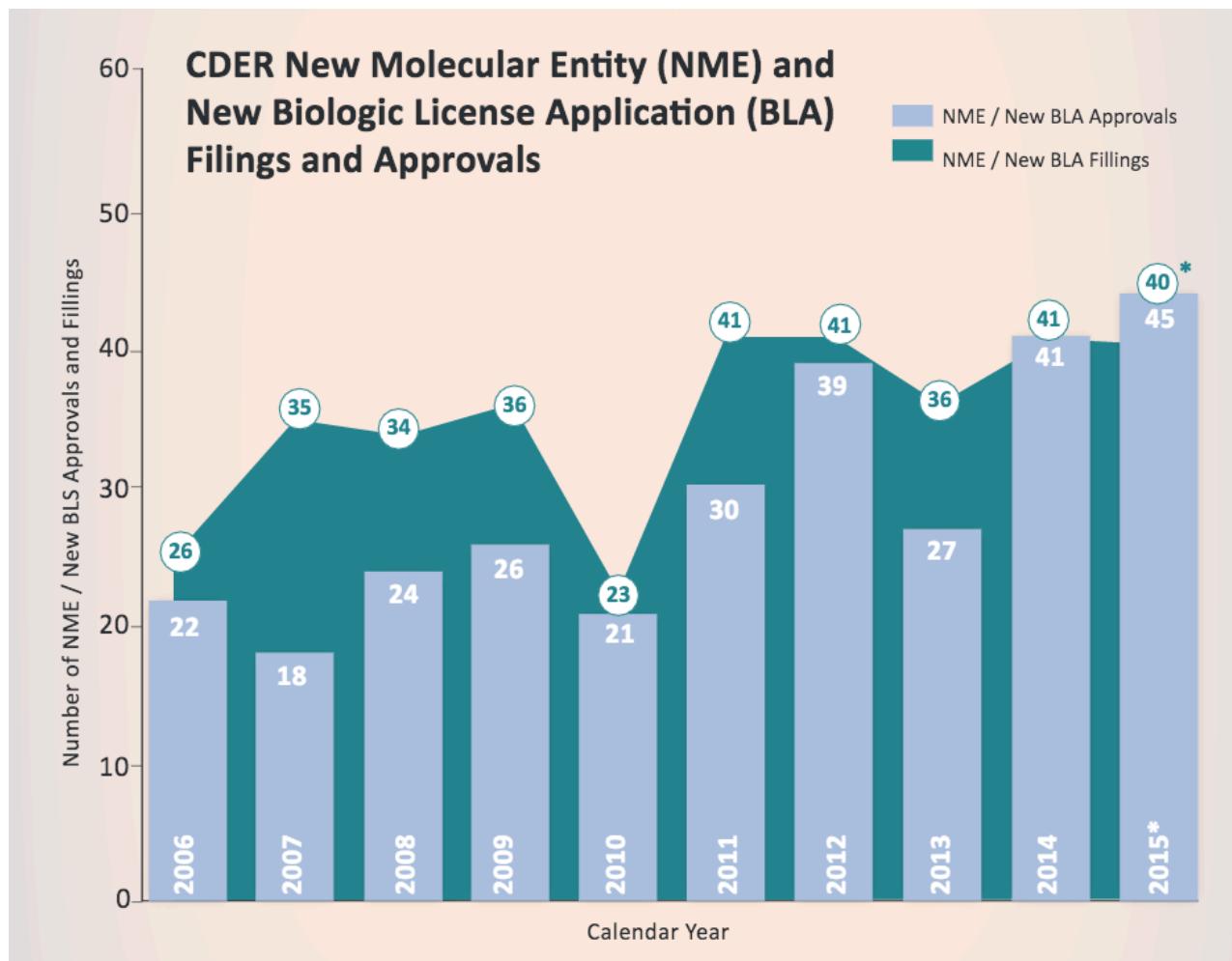
Pharma internal R&D struggling to deliver promising new drug candidates



Is R&D Productivity on the Decline?



FDA TEN-YEAR HISTORIC COMPARISON



From 2006 through 2014 CDER averaged about 28 novel drug approvals per year

In 2015 45 Drugs are approved

- 36% First in class

- 47% Rare or orphan Diseases

Academic Motivations for Alliances with Pharma & Biotech



- Additional funding source, not enough grant money
- Exchange of scientific expertise
- Create collaborative knowledge
- Capitalize on innovation
- Gain access to drug development capabilities
- Translate research to applications
- Address unmet medical needs
- Opportunity to bring new drugs to patients: “Bench to Bed side”
- Cooperative technology development rather than only technology transfer



Pharma & Biotech Motivations for Alliances with Academics



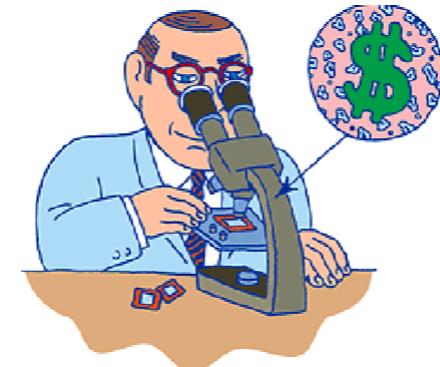
- Gain access to transformative innovation
- Opportunity to diversified drug & technology portfolio
- Access to break through research and disruptive science
- New targets and new pathway expertise
- In vivo disease model expertise
- Access to patient database

During the past 40 years, 153 new FDA-approved drugs, vaccines, or new indications for existing drugs were discovered through research carried out in Public Sector Research Institutions (NEJ 2011)

Biotech Motivations for Alliances with Pharma?



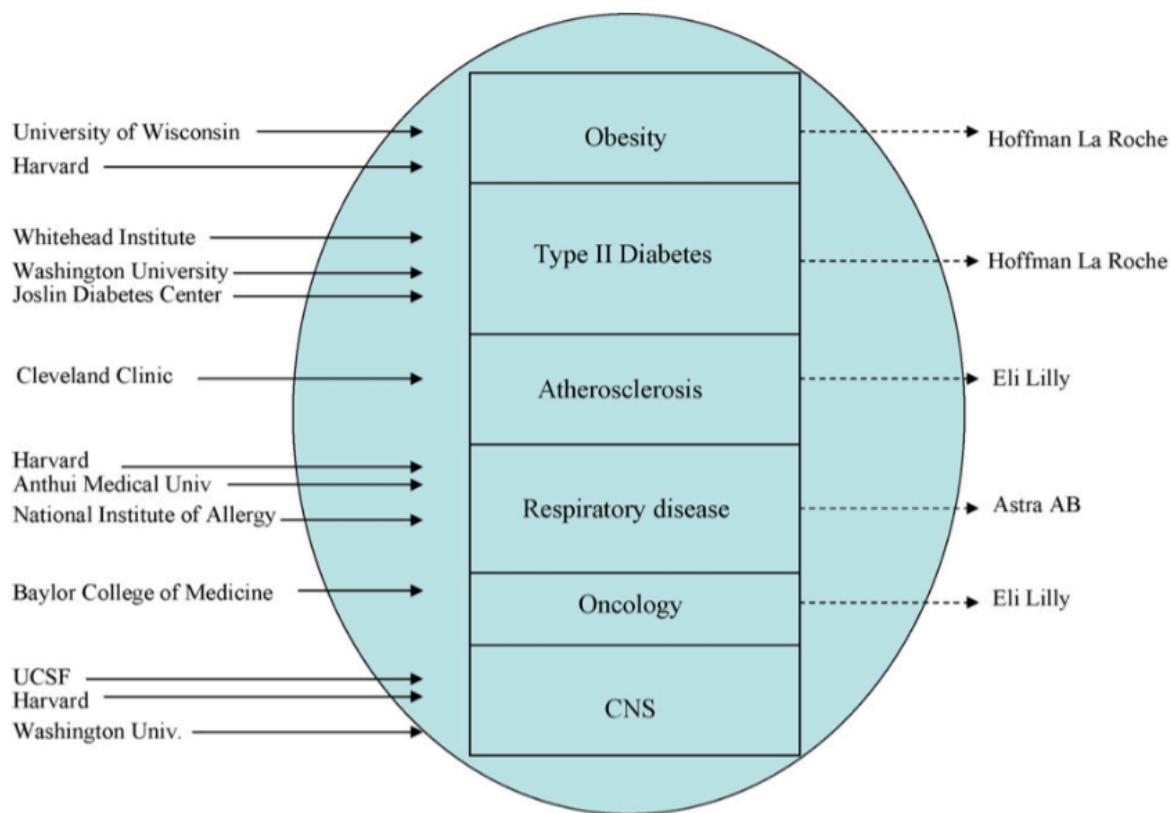
- Get access to non dilutive capital
- Risk sharing
- Accelerating new product development
- Access to clinical development, manufacturing & marketing
- Globalization & gaining access to new markets
- Better acceptability to regulatory agencies
- Enhance visibility & credibility
- Demonstrate high value & help to secure additional financing
- Built in exit strategy acquisition



Millennium Pharmaceuticals



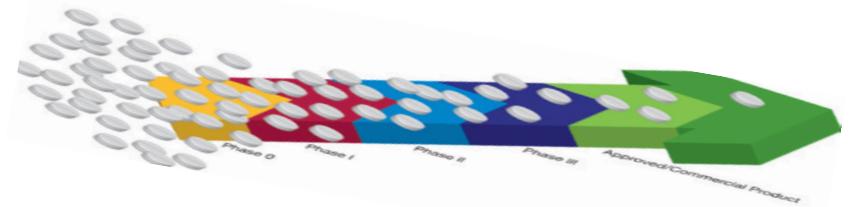
In 1996 all alliances were in place at the time to file for IPO



Pharma Motivations to Develop Alliances Including M&A



- Acquiring new products & technological capabilities
- Replenishing their drug pipelines or Change research priorities
- Increasing innovation
- Be more efficient and reduce costs
- Cheaper & faster to acquire next blockbuster
- Keep revenues growing as fast as investors expect it
- Accelerate translation of innovative discoveries from bench to clinic
- 2015 low interest rates, made capital cheap for many companies
- Tax advantages



Pfizer Replenish it's Pipeline



Through Acquisition

- 2000 Warner-Lambert \$90 billion
- 2003 Pharmacia \$60 billion
- 2009 Wyeth \$68 billion
- 2014 Attempted to buy AstraZeneca
 - For Tax savings reasons
 - Increased offer from \$99b in April to
 - \$106b in early May and to
 - \$119b on May 18 before giving up
- 2015/16 Pfizer Merge with Allergan?

Strategic alliances with Academia; Pfizer Center for Therapeutic Innovations

- 25 Leading academic medical centers
- 70 External academic reviewers
- 8 National Academy of Science Member



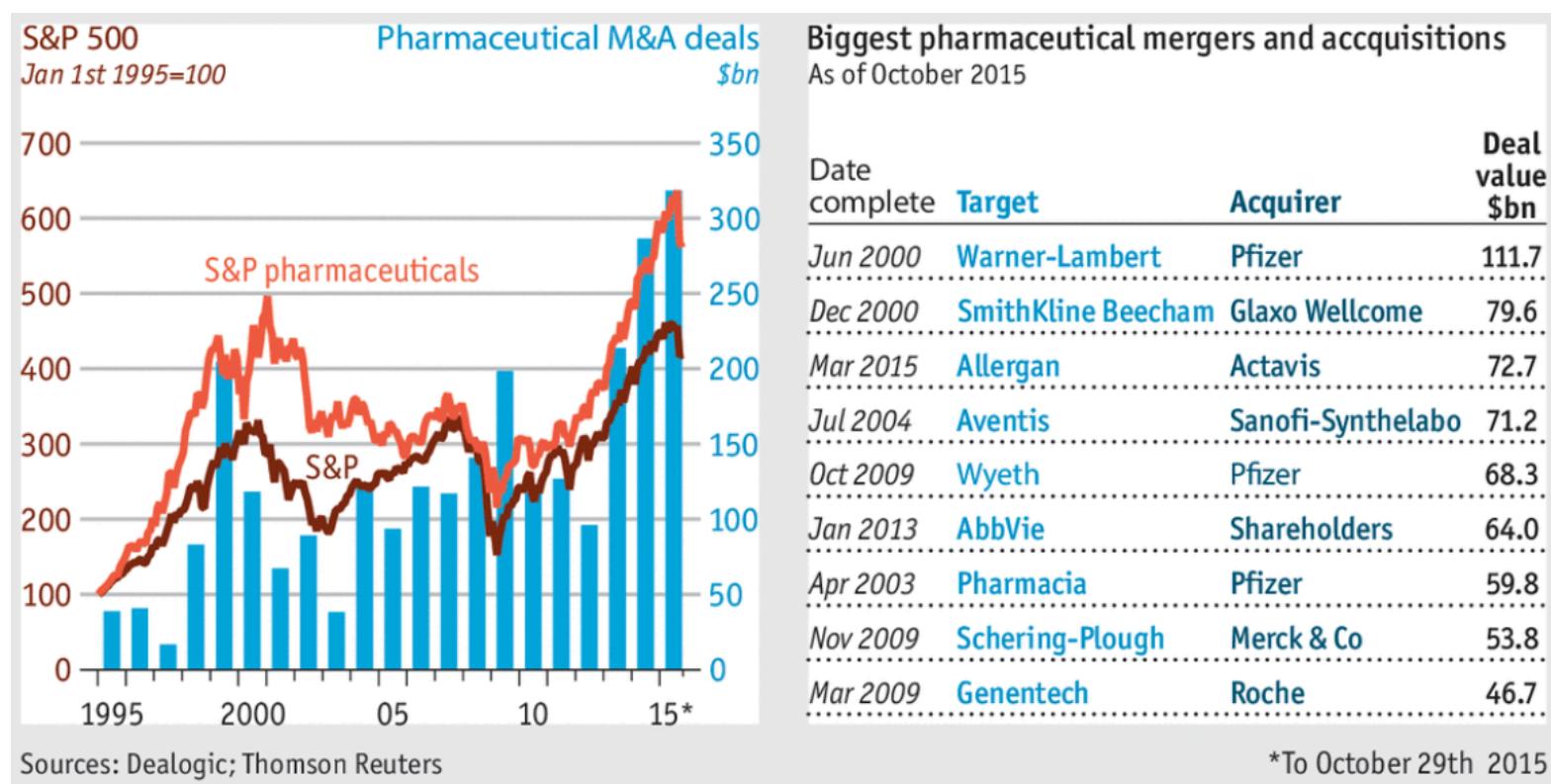
Strategic Alliances & Deals in 2015 in Pharma & Biotech



Pharma M&A

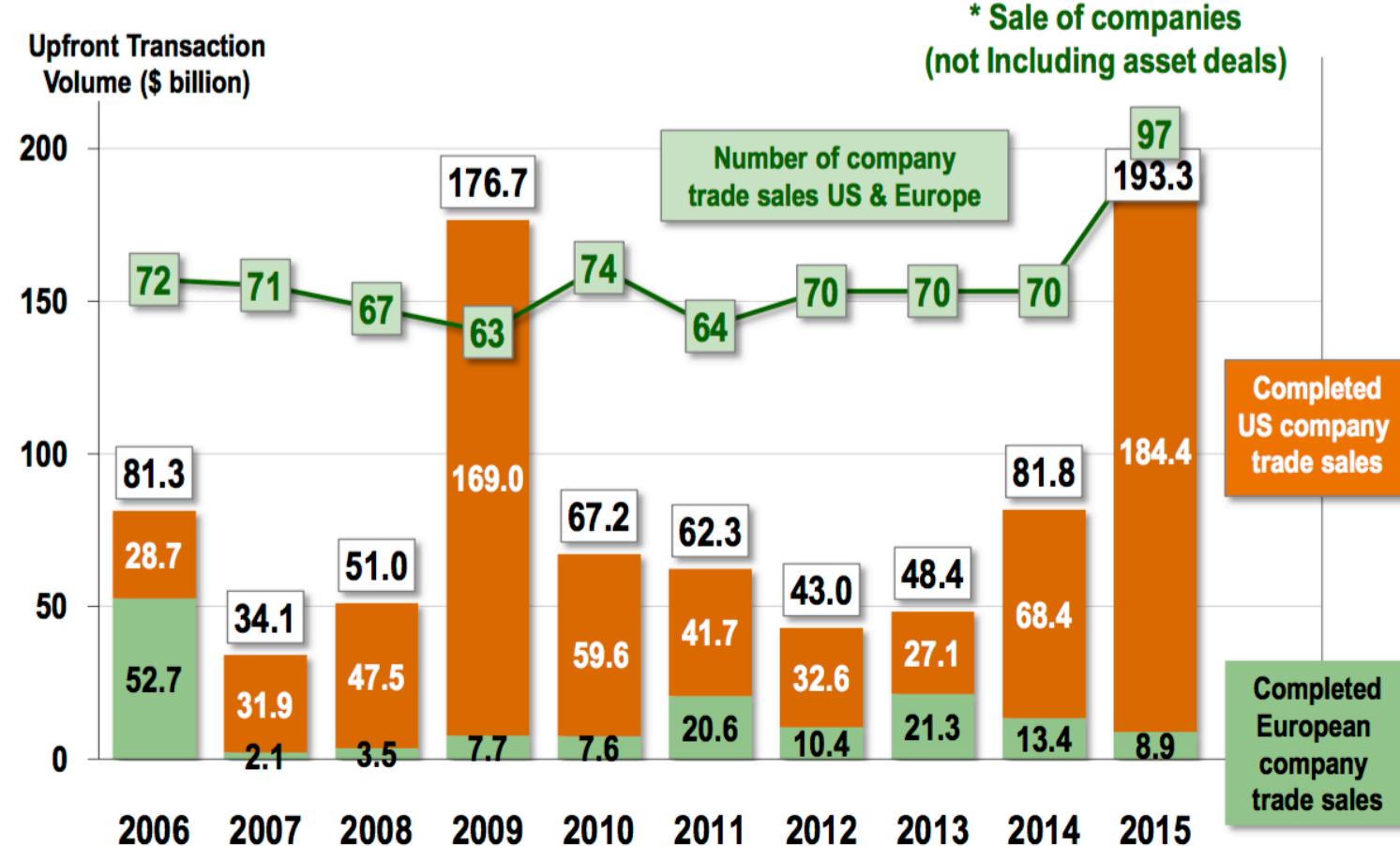


The number of new drugs for every billion dollars of R&D has dropped about 80-fold since 1950 Nature Reviews Drug Discovery



<http://www.economist.com/news/business/21578696-acquisitive-pharmaceutical-company-announces-its-biggest-deal-yet-shop-til-you-drop>

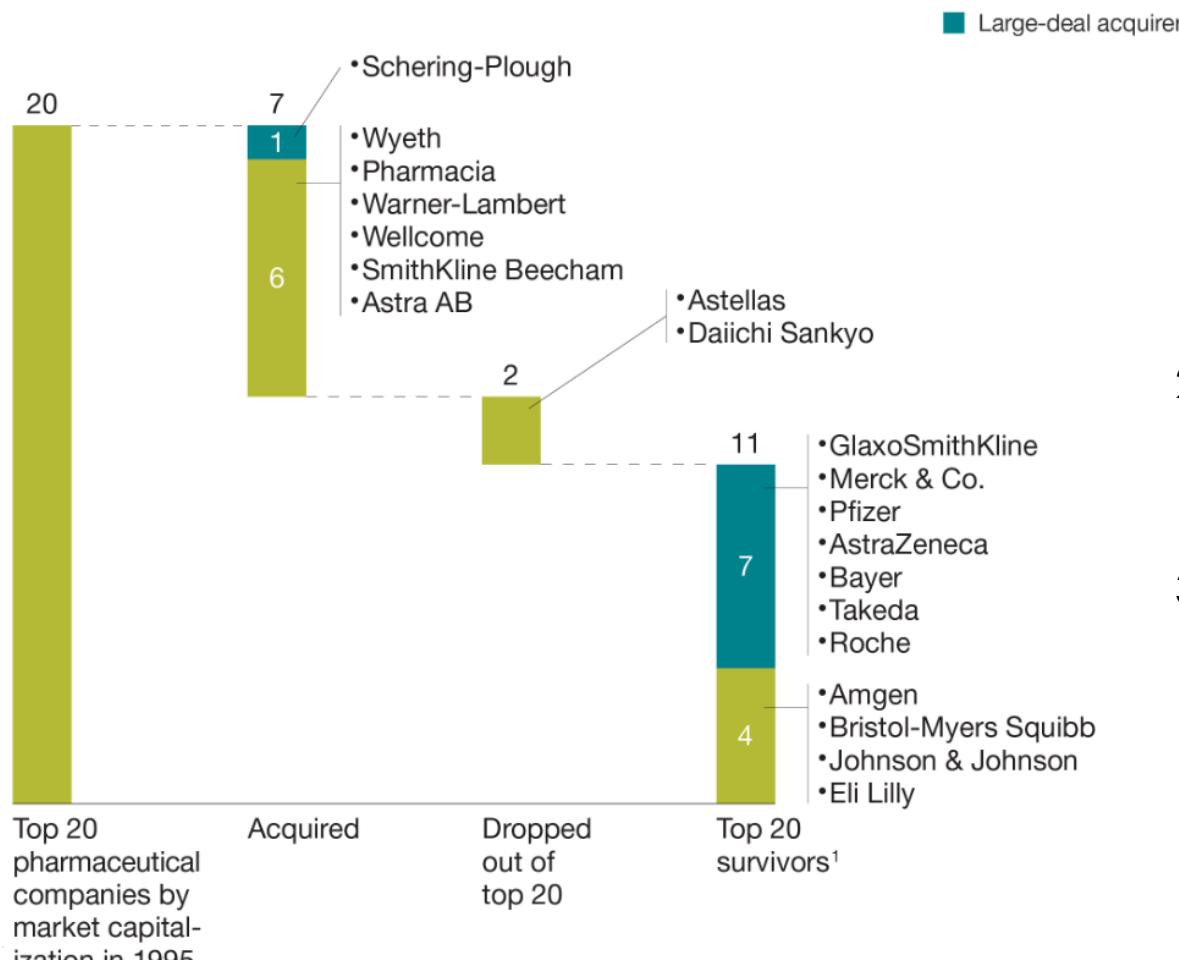
2015 Record Year in M&A US & Europe



In 2015 \$205.8 billion total transaction volume including “biodollars”

Do Pharma Megamergers Work?

Most of pharma that have stayed at the top were large-deal acquirers



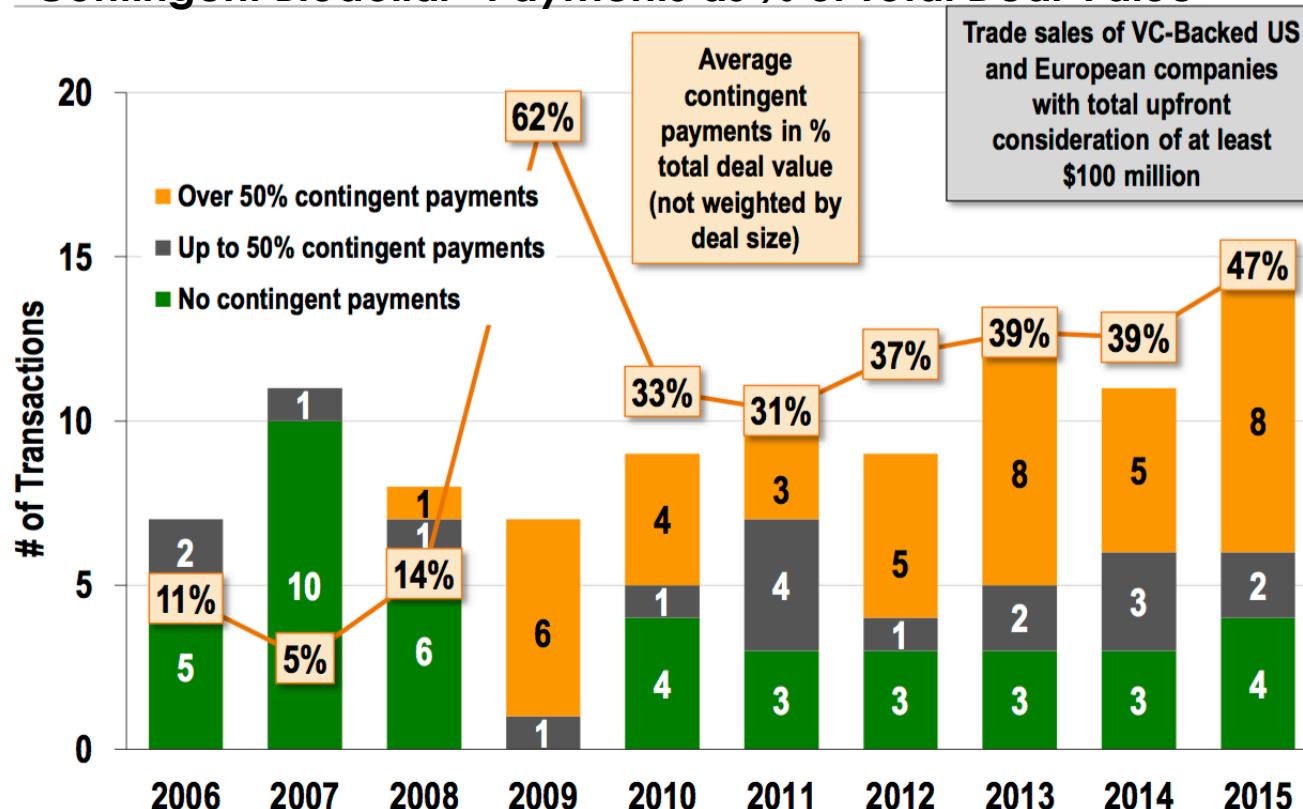
1. Megamergers created shareholder value
2. Consolidation deals generated greater economic profit
3. Growth-oriented deals changed longer-term expectations

VC Backed Companies: Bio \$\$\$



In 2015 more than half of trade sales **contingent payments** were higher than the upfront payments for VC backed companies

Contingent Biodollar™ Payments as % of Total Deal Value



VC-backed private US & European bio with > \$100 million upfront deal value



UC San Diego
SKAGGS SCHOOL OF PHARMACY
AND PHARMACEUTICAL SCIENCES



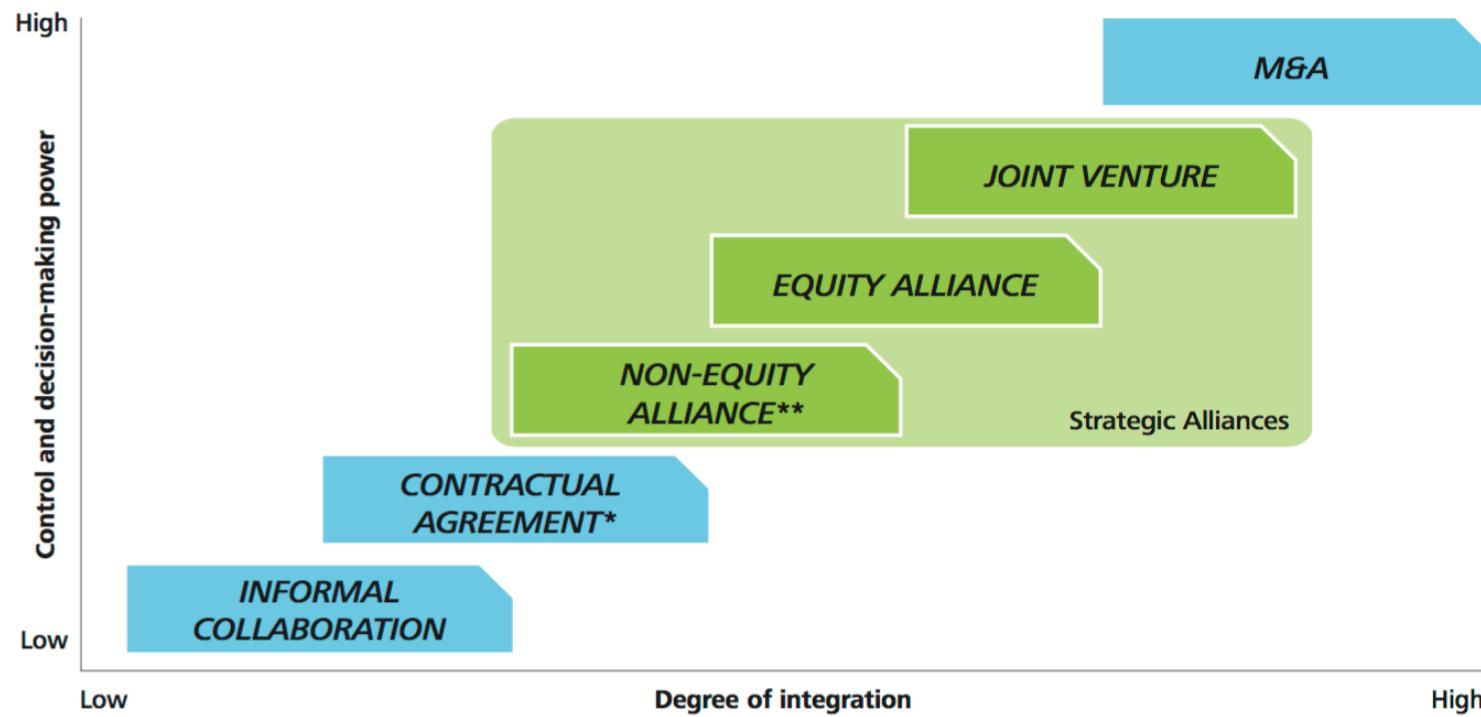
The Different Types of Alliances



Strategic Alliances + M&A



** Joint R&D, joint product development/
manufacturing/marketing, long-term sourcing
agreements



Invent it, Swap it or Buy it



- Research collaborations
- Drug development alliances
- Joint ventures
- Asset swaps
- Equity partnerships
- In-Licensing
- Marketing co-promotions
- Network alliances



R&D Alliances



Sharing risks & rewards through enhanced collaboration

- **Objectives:**

- Risk diversification
- New product development
- Shorten product development lifecycle
- Cost reduction
- Enhance breadth and depth of available knowledge

- **Alliance Focus:** IP, innovation, technology platforms

- **Best practices**

- Clearly defining the scope of the alliance
- Strong governance
- Common process
- Open knowledge exchange
- Legal protection of intellectual property

Models: Academic Industry Collaboration



- **Research relationship with single investigator**
- **Fee-for-service agreement**
- **Unrestricted research support & Master Agreement**
 - Sanofi & UCSF alliance:
 - Share expertise in diabetes research & identify new drug targets
 - \$3.1 m bring scientists in three UCSF labs & Sanofi researchers to translate academic science into drug discovery
- **Minilabs bio cluster: Create center of collaboration**
 - AstraZeneca & University of Pennsylvania
 - Generate new Alzheimer's disease drug candidates for AZ's clinical development pipeline
 - Pfizer Centers for Therapeutic Innovation (CTI), Nov 2010
 - Leverage academic expertise to lower R&D costs and improve productivity; UCSF UCSD and 8 Boston and NY institutions

Pharma & Academia Alliances

- **Gilead Sciences - Yale School of Medicine**
 - Cancer research deal \$100 million over 10 years
- **Sanofi-Aventis**
 - Columbia University, diabetes
 - Harvard, Translational research agreement
- **GlaxoSmithKline**
 - Harvard's Stem Cell Institute 5 year, \$25 million
 - Plan to sign up 10 academic "superstars" for long-term partnerships to develop new medicines
- **Bayer Grant4 Target**
 - <https://www.grants4targets.com/scripts/pages/en/index.php>
- **UCSF**
 - Sanofi Master agreement
 - Pfizer up to \$85 million over five years
 - Bayer Healthcare



Financial Terms: Academic Alliances



Evaluation of about 2000 deals between 2007 – 2015

- **Upfront Cash:** \$80K – \$1.1m *
 - License fee, retrospective patent cost reimbursement
 - Up to 5 years of license maintenance payments
 - Up-Front Equity
- **Deal Size:** \$800K > \$10m
 - All upfront, milestone and sponsored research payments
- **Development, Regulatory & Sales Milestones:** median \$1.1m
 - Patent issuance, IND filing, Phase II, Phase III, NDA filing & first approval
 - Development of second indications \$950K
 - 15% (8 of 52) of licenses Sales Milestones (\$50M-\$1B annual sales) Median \$3.5M
- **Maximum Royalty Rate: Median 3.5%**
 - Only 3% (2 of 59) of licenses have a Maximum Royalty Rate of 10%
 - Tiered Royalty rates to assumed annual sales \$200M, \$500M, or \$1Billion per year
- **Share of Sublicense Revenues: 10 – 45%**
 - Range of sharing of payments received by biopharma from sublicensee(s)

* Source: <http://www.bioscibd.com/university-licenses>

Marketing Alliance

Between Pharma & Biotech or Pharma & Pharma

- **Objectives:**

- Market access
- Increase market share
- Joint commercialization
- Access to assets

- **Alliance Focus:** Salesforce, distribution, expansion

- **Best Practices:**

- Customer segmentation
- Focus on how to measure success, market share and competitiveness
- How to share revenues

- **Example: 2009 Joint Venture: Pfizer & GSK**

- Field of human immuno-deficiency virus, HIV
- Combining research, development and marketing made the business became more economically viable

AstraZeneca Builds Biologic Pipeline

1999 AZ founded by an M&A! Today 1/2 of its pipeline being biologic based

How did it get there? One M&A at a time!

- 2005 KuDOS Pharmaceuticals \$210 million
- 2006 to 2007
 - Arrow Therapeutics \$150 million
 - Cambridge Antibody Technology \$1.07 billion
 - MedImmune \$15.2 billion.
- 2010 – 2011: Novexel and Guangdong BeiKang Pharmaceuticals
- 2012 Joint acquisition with BMS acquire Amylin Pharmaceuticals
 - AZ's share of Amylin deal \$3.4 b; 2013 bought out BMS' share for \$4.3 billion
- 2013
 - Amplimmune \$500 million
 - Omthera Pharmaceuticals \$443 million
 - Pearl Therapeutics \$1.15 billion
 - Spirogen \$440 million

Portola Pharmaceuticals: \$120m Deal



- 2013 Non-exclusive clinical collaboration agreements with Bayer & Janssen
 - Support phase 2 & 3 studies of andexanet alfa & rivaroxaban in US & Europe
- Feb 17 2016, licensed for Japan to BMS & Pfizer andexanet alfa, an antidote for apixaban and other Factor Xa inhibitors
 - BMS & Pfizer responsible for all development, regulatory activities & commercializing
 - Portola will receive from Pfizer & BMS
 - \$15 million up-front payment
 - \$90 million potential regulatory and sales-based milestone in Japan
 - Double-digit royalties based on aa net sales in the territory
- For Bayer to include rivaroxaban in this clinical development program
 - Bayer will provide technical support & fund clinical studies of aa with rivaroxaban
 - Portola will receive
 - \$5 million upfront payment
 - Milestone on approval from Japanese Ministry of Health Labor & Welfare

7 Pharma Join C-Path in Parkinson's Consortium



- Feb 23 2016 Astra Zeneca, Pfizer, Eli Lilly join AbbVie, Biogen, Merck, UCB & Project founders Critical Path Institute (C-Path) to
 - Streamline & accelerate the development of new therapies for Parkinson's disease
 - Share data, expertise and resources
- Parkinson's UK committed over £1 million to C-Path
- “*There is a strong realization from the industry that collaboration among industry, academia, and worldwide regulatory agencies, along with the sharing of data, has the potential to create a more efficient development process.*” Diane Stephenson, Executive Director, CPP
- “*C-Path has created neutral ground that allows FDA scientists to work collaboratively with industry and academic partners on improving the process.*” Janet Woodcock, MD, FDA





Structuring & Negotiating Alliances



Structuring Alliance Key Considerations



- **Defining scope of collaborations:** Clearly define the vision
- **Determining control and management**
 - How are decisions made?
 - Steering or joint management committee
 - Select strong leaders to sponsor and manage the program
 - Size of membership committee, frequency of meetings
 - Authority to make decision
 - Equal division of power, or majority rules framework
 - Tie breaker if deadlock, CEO or Head of R&D negotiate?
- **How are resources to be contributed in kind & dollars**
- **Ownership of Intellectual Property determined?**
 - Joint IP, Sole ownership?
 - Establish the patent strategy
 - Responsibility for filing, prosecuting, maintaining & protecting
 - Who is financially responsible

Structuring Alliance Key Considerations

■ R&D Responsibilities

- Team
- Detailed research plan with Gant chart and Go/No go decisions
- Include number of FTEs for each partner...

■ Regulatory Matters

- Which partner is responsible for regulatory filings?
- Who owns them, pay for them..

■ Clinical Development

- Who has primary responsibility, oversight?
- Define precisely the clinical plan, budget, liability
- Address impact of delays from regulatory..

■ Manufacturing & Supply

- Who is developing the formulation and manufacturing finished product
- Inventory forecasting, pricing cost of goods...

Structuring Alliance Key Considerations

■ Marketing, Promotion & Distribution

- Which partner has responsibility
- Budget, co-promotion

■ Valuation & Financing terms

■ Representations & Warranties

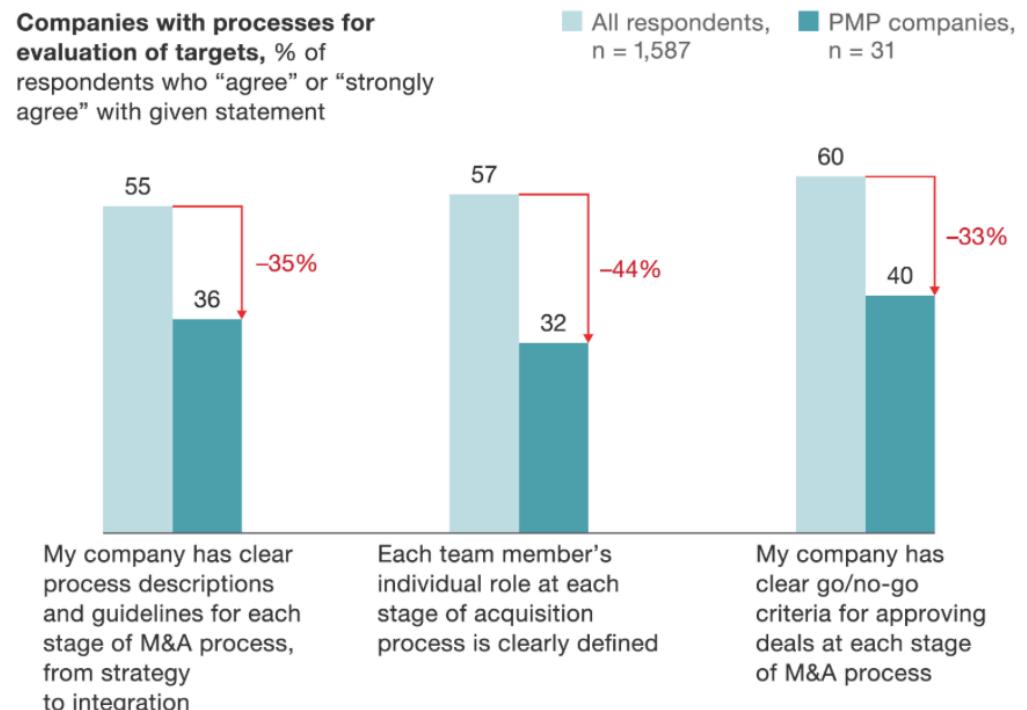
■ Adverse event reporting

■ Recall Indemnifications

■ Performance criteria

- Time line Gant chart
- How is performance to plan measured and monitored?

Pharma firms relies less on standardized processes and guidelines



McKinsey&Company | Source: McKinsey survey on global M&A capabilities, May 2015

<http://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/pharma-m-and-a-agile-shouldnt-mean-ad-hoc>

Structuring Alliance Key Considerations

- **Merger & Acquisition related Issues**
 - Assignment of IP, product
- **Termination**
 - Expected length of collaboration
 - Exit strategy established from day one
 - Protect loss of confidential information
 - Clauses of terminations..
- **Dispute resolution**
 - Who owns assets following dissolution?
- **Guarantee and Financing**
 - What happens if additional capital is needed?
 - Can the alliance borrow? Target debt/equity ratio?
 - Governing Law.....
- **Profit/loss and tax**
 - Benefits allocation and dividend determination

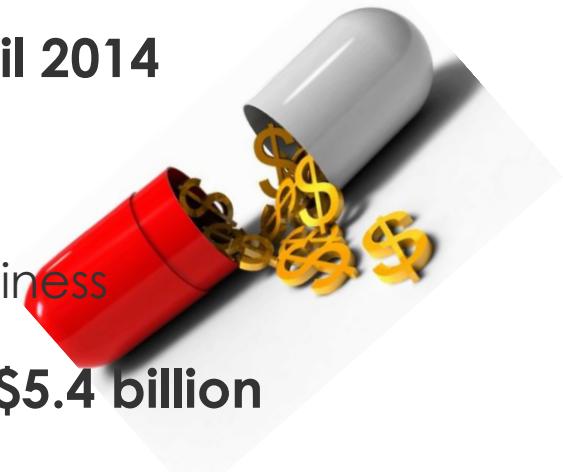


Strategic Deal: Swapping Assets



■ GlaxoSmithKline & Novartis \$19 billion swap, April 2014

- Novartis provided GSK with a vaccine unit
- GSK handed off its cancer treatment business
- Created a JV to develop consumer healthcare business



■ Novartis sell its animal health business to Eli Lilly \$5.4 billion

■ Sanofi & Boehringer Ingelheim in exclusive negotiations

- Sanofi to exchange their animal health business Merial worth €11.4bn
- Boehringer to give consumer healthcare business, worth €6.7bn
- To make up difference in value, Boehringer will pay Sanofi €4.7bn
- Asset swap anticipated to be business EPS neutral for 2017

Transforming the Pipeline



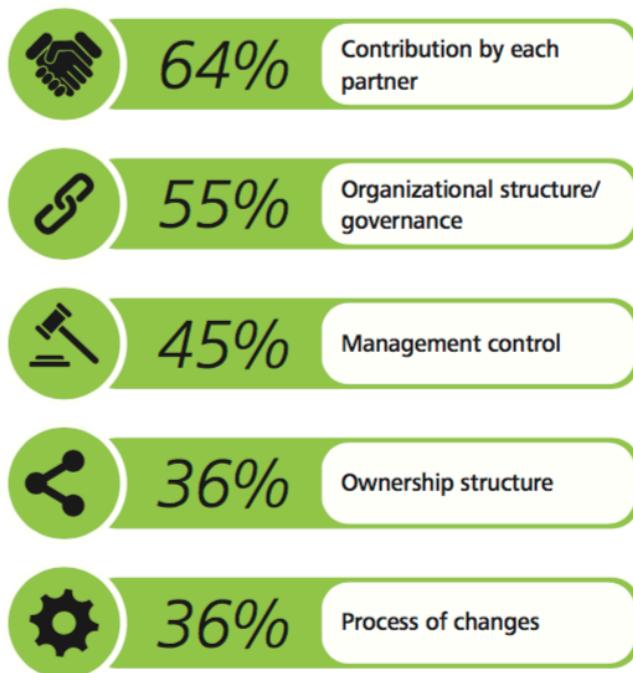
- Sanofi wants a “Transformative” pipeline of immuno-oncology products!”
 - Alliance with Regeneron to gain acces to a PD-1 which is in Phase I
 - Collaboration with BioNTech to discover & develop up to five cancer immunotherapies utilizing mRNA technology
 - Objective to have a "very balanced pipeline between internal and external innovation"
 - 2/3 Early stage projects internally generated, 1/3 external
 - 1/3 Late stage pipeline internal & 2/3 external
- A study by Bain, a consulting firm, found that in the past 20 years those drug companies that consistently did well in various therapeutic areas were earning more than 70% of their sales from products developed elsewhere

Strategic Alliances: Challenges & Success Factors

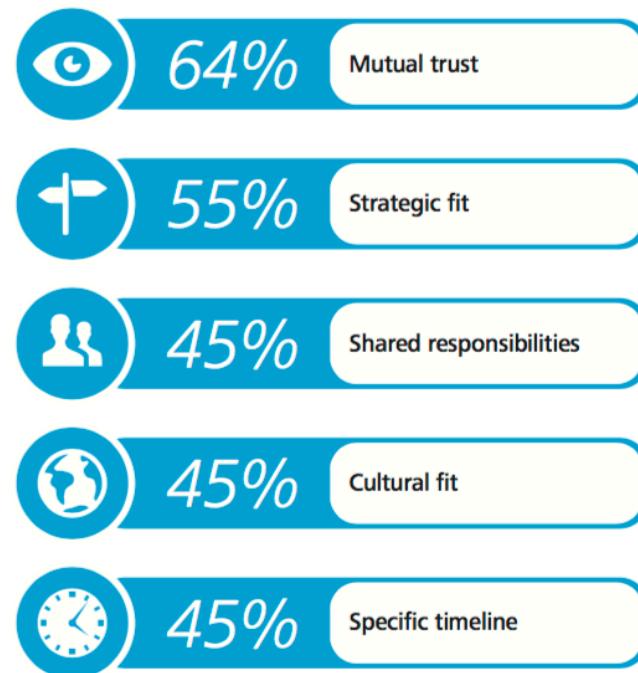


- Survey conducted with leaders actively engaged in alliance functions
 - From Head of Corporate Strategy to Head of Alliance Management
 - Based in Western Europe, pharmaceuticals, biotechnology, or medical devices

Top five Challenges



Top five Success Factors



Alliance Management



The deal is signed; Now the true alliance begin!

- Create Alliance management function
- Clearly define performance measures aligned to the objectives
- Collaborate and be 100% transparent
- Integrate alliance into company's processes
- Keep relationship with partner in good condition
- Always keep the objectives for the strategic alliance in mind

End of Day: To Achieve Successful Strategic Alliances



It's the chemistry between people that
create and sustain successful alliance





Thank You



The Birth of Science

Links



- <http://www.springer.com/us/book/9781461478003>
- [Strategic alliances in Life Sciences, Deloitte](#)
- http://www.stratec-con.net/assets/gottinger_obusinessi.pdf
- <http://www.scheller.gatech.edu/directory/faculty/rothaermel/pubs/06JBV.pdf>
- <http://www.palgrave-journals.com/jcb/journal/v13/n4/full/3050053a.html#fig1>
- http://haas.berkeley.edu/faculty/papers/ding8_vertical%20alliance.pdf
- http://csdd.tufts.edu/files/uploads/tuftscsdd_academic-industry.pdf
- [Mergers and Innovation in Big Pharma, Carmine Ornaghi, University of Southampton, UK International Journal of Industrial Organization](#)
- <http://www.bcq.com/documents/file80247.pdf>
- <http://woic.corporateinnovation.berkeley.edu/wp-content/uploads/2015/12/D.-Tamoschus-Winning-Best-Student-Paper.pdf>
- http://worldstemcellsummit.com/files/2009_report/4-2_2009.pdf
- <http://clearpharma.com/wp-content/uploads/2015/05/15T-00502-2-WhitePaper-NoSpreads.pdf>
- <http://www.kellogg.northwestern.edu/biotech/faculty/articles/newrdmodel.pdf>
- [Where will new drugs come from? Editorial, The Lancet 377\(9,760\): p97, January 2011](#)
- <http://web.iese.edu/mba/health/Master/Reports/Boitech%20Pharma%20Allen%20Jabado.pdf>
- <http://static1.squarespace.com/static/54c910c5e4b0b8e198af4798/t/56097f7ce4b0bd772d29fa29/1443463036693/Pharma-Academia+Collaboration+Directory+-+Pharmagellan+-+version+1.1.pdf>
- <http://www.nejm.org/doi/full/10.1056/NEJMsa1008268#t=articleTop>
- <http://stm.sciencemag.org/content/2/30/30cm16.full>
- <http://www.lupusresearch.org/lupus-research/documents/cti-for-partners-december-2014.pdf>
- <http://www.nap.edu/read/18722/chapter/4#32>
- <http://www.mckinsey.com/business-functions/strategy-and-corporate-finance/our-insights/pharma-m-and-a-agile-shouldnt-mean-ad-hoc>
- http://www.biocibd.com/uploads/pres/NBT_Ivorytower_2006.pdf