

Strategic elements of out-licensing and partnering

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Aqua Partners LLC

BioEntrepreneurship Boot Camp

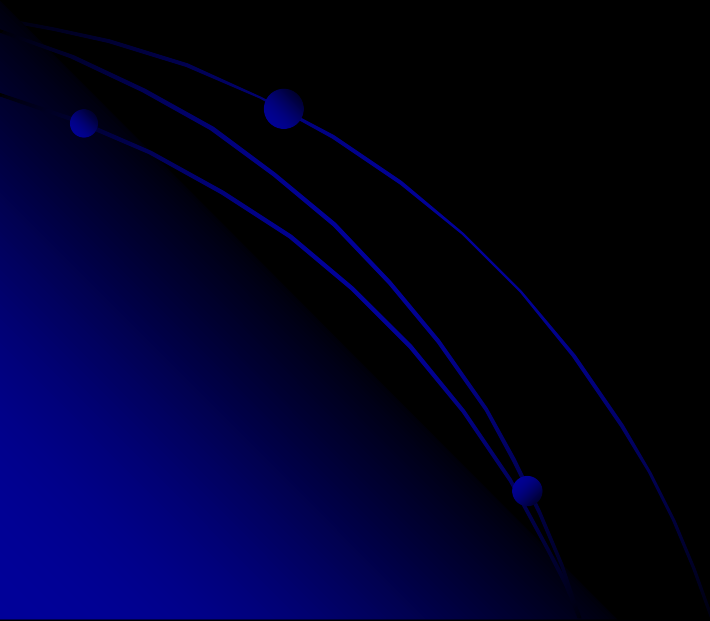
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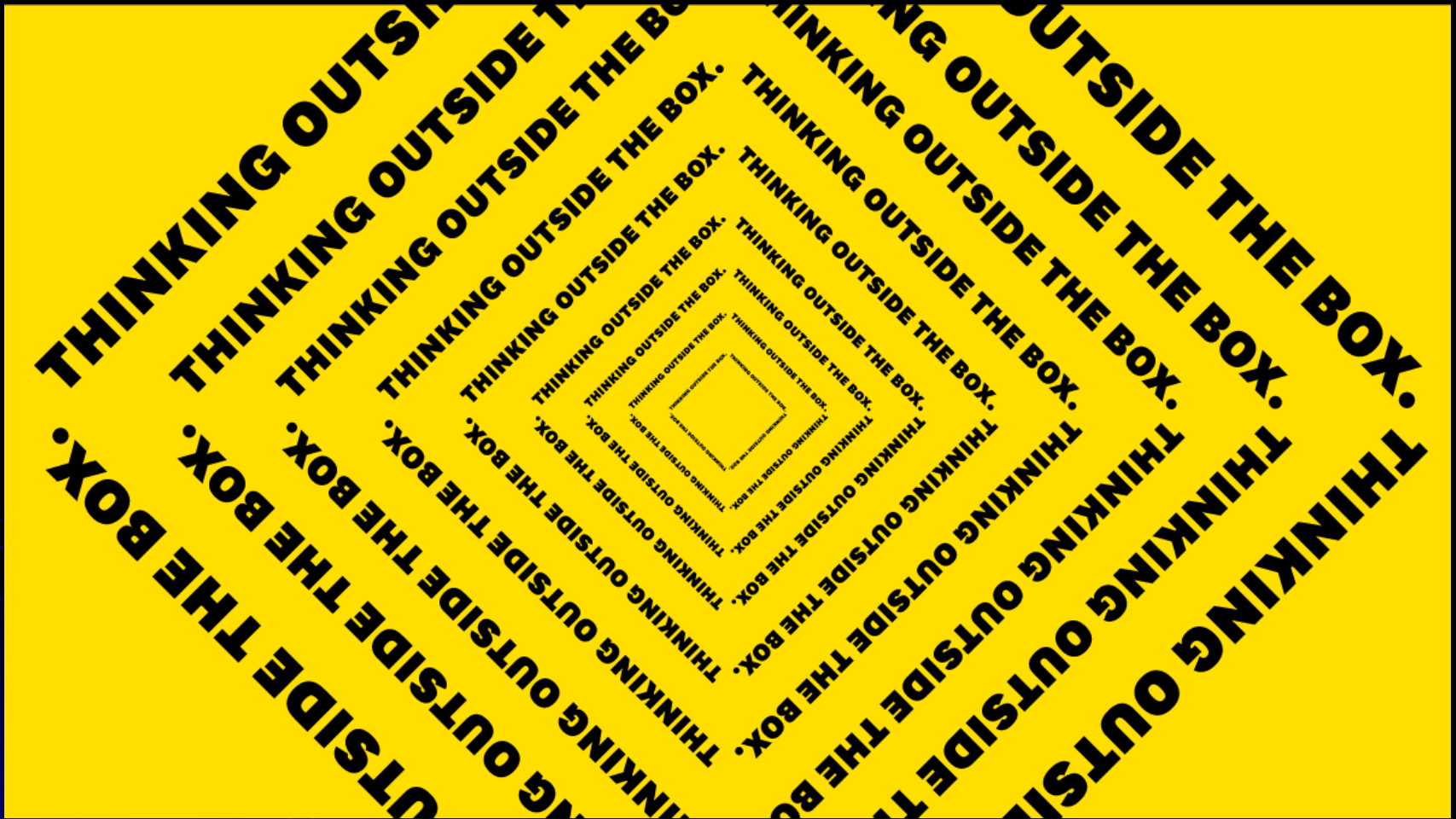
Hurdles on the way to success



Think globally right from the beginning



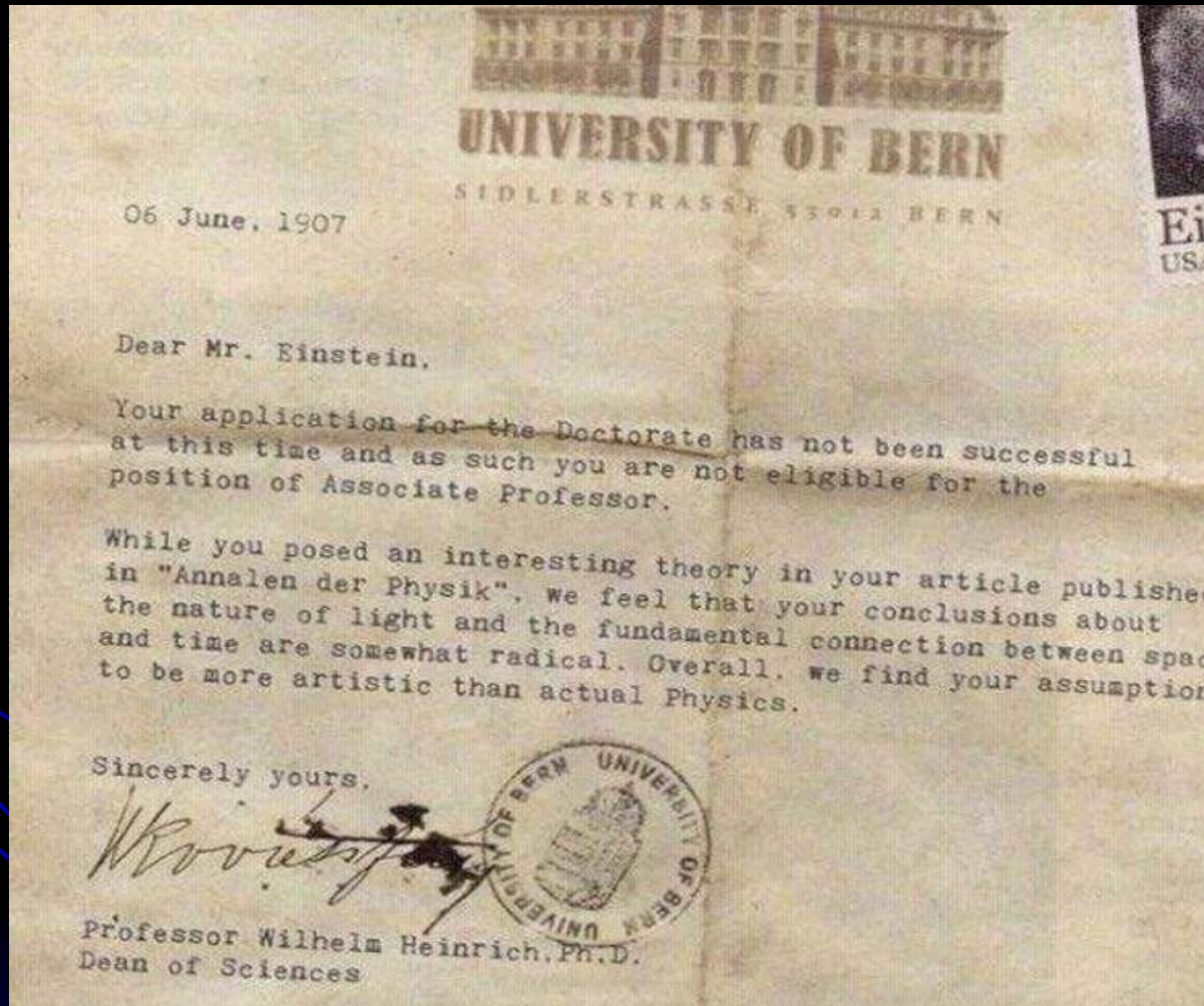
Innovation is ...



... that takes a lot of money...

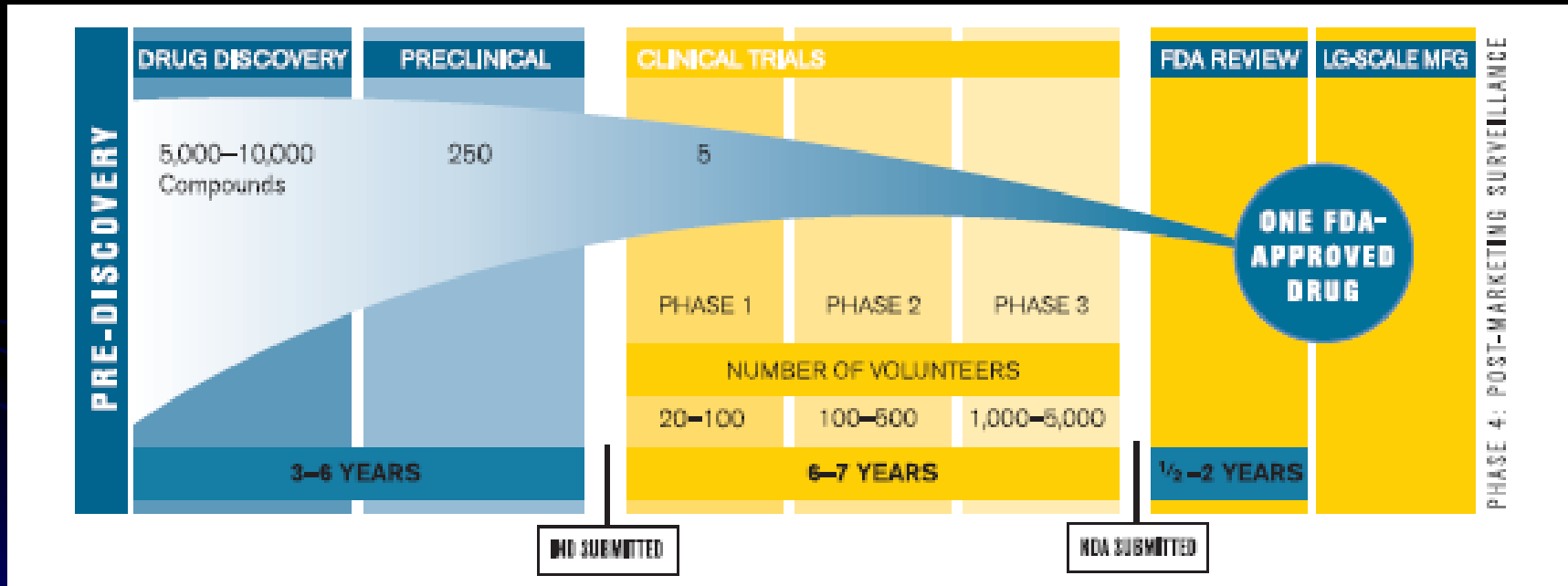


... and an experienced management team : “I will never fund a first-time CEO”



The solution- really know what you don't know

The R&D process is long, complex and costly



Reference: Pharmaceutical Industry Profile 2009, PhRMA (<http://www.phrma.org/files/attachments/PhRMA%202009%20Profile%20FINAL.pdf>)

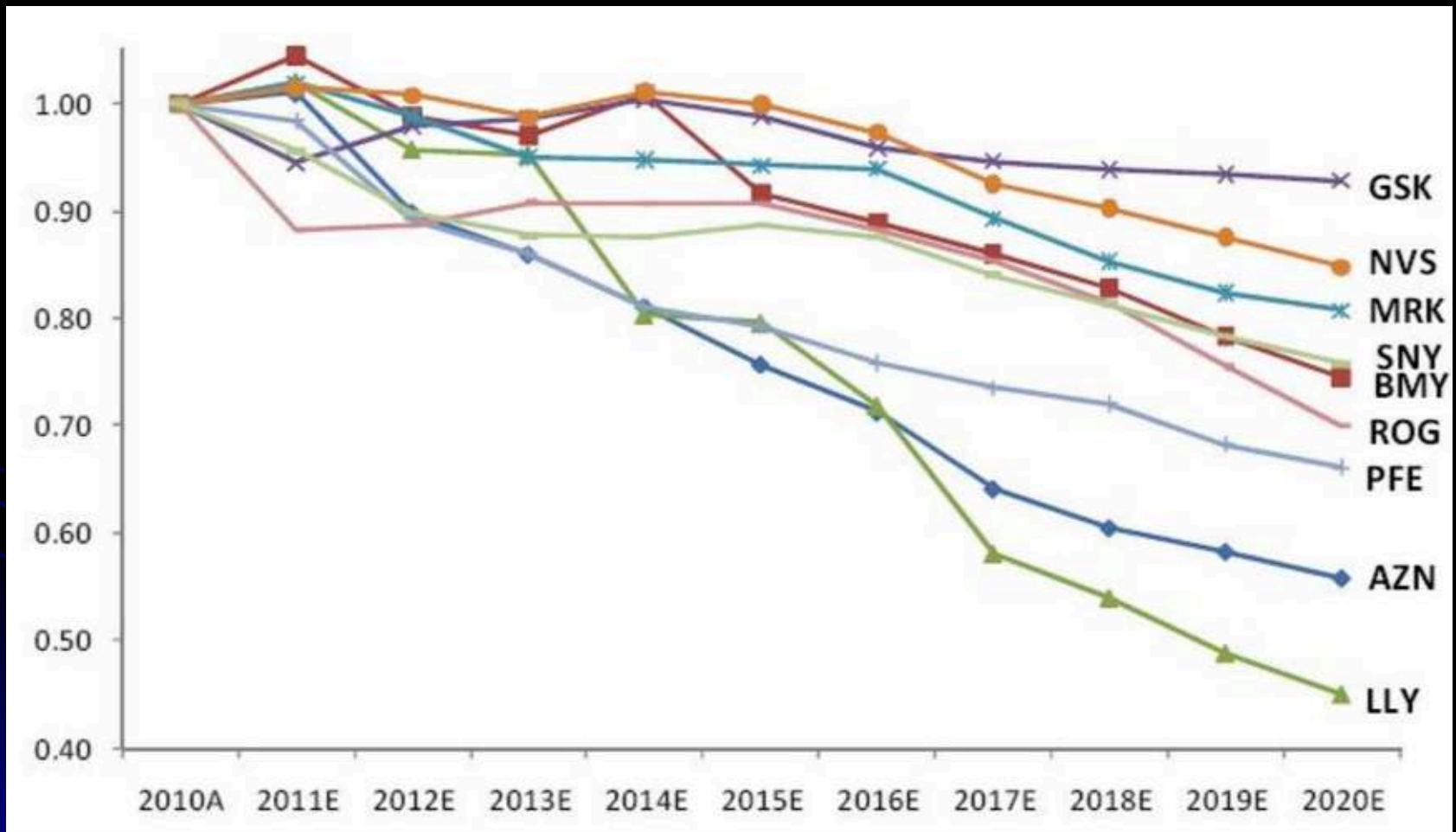


Global Market Spending and Growth 2007–2021

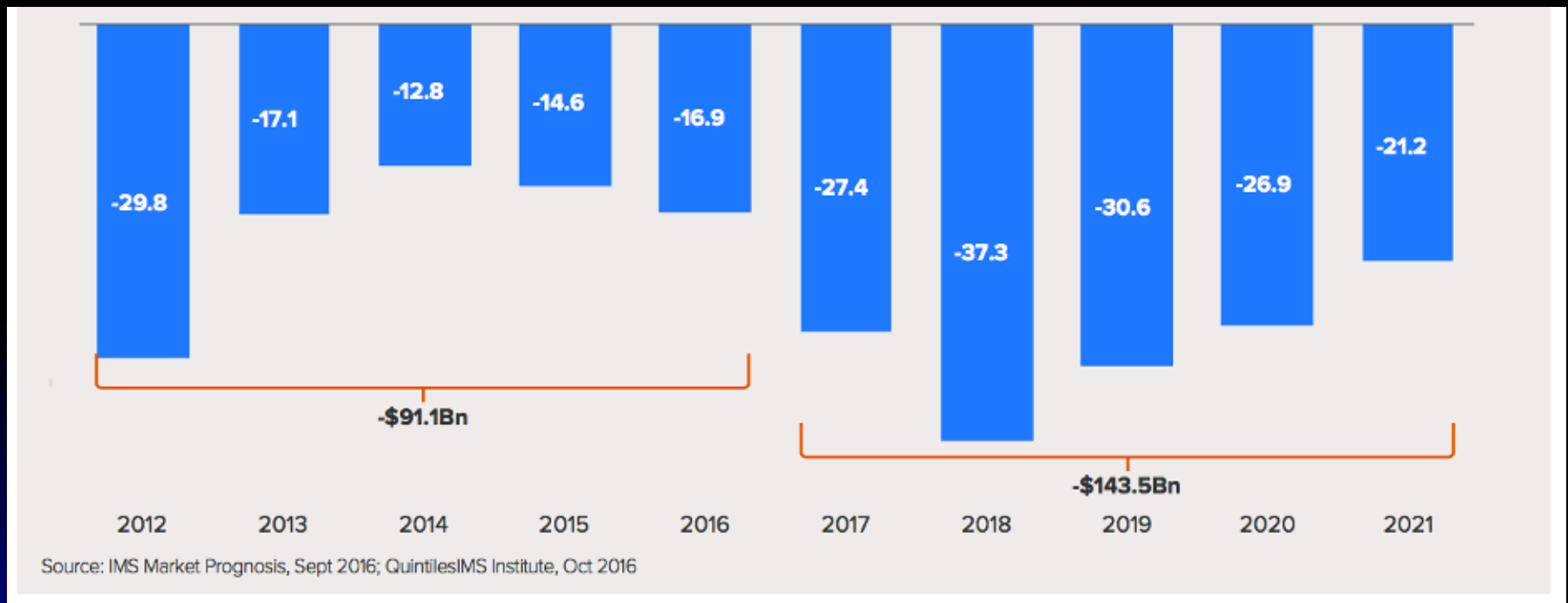


Source: IMS Market Prognosis, Sept 2016; QuintilesIMS Institute, Oct 2016

Big pharma still faces some big patent losses



Impact of US exclusivity losses on brand spending (US\$ billion)



The strategic importance of forming alliances in this industry:

- Money
- Development expertise
 - ✦ Pre clinical
 - ✦ Clinical
 - ✦ CMC
 - ✦ Regulatory
- Commercial capacity and capabilities

Bottom line: You will never cross the finish line without a development partner



Robert Neubecker

<http://www.theispot.com/search/index.cfm?Content=Bio&fuseaction=Stockpreview&StartRow=1&BarCodeNumber=1170S1026&Collection=Stock>

“The greatest change in corporate culture - and the way business is being conducted - may be the accelerated growth of relationships based... on partnership.”
Peter F. Drucker

A few basic principles...

- ❑ Ask “why not?”, even if there is a cast-in-stone corporate strategy.
- ❑ Behind every licensing or collaboration deal, there is one fairly obsessed individual, aka champion .
- ❑ Simplicity- the rationale/ value proposition must be clear.
- ❑ It’ s important to be first- “Second place is first-place loser” (J. Leshley). It provides a vital head start and can make a huge difference by allowing you to set the terms.
- ❑ Try, try again- make persistence a competitive advantage
- ❑ Appreciate that it’ s risky business- Creating something new takes risk to a new level. Babe Ruth held the home run record for over 50 years.... he also held the record for the most strike outs.
- ❑ Synergy is necessary in a partnership. A great team is greater than the sum of its parts.

Build
Buy
or
Outsource



What big pharma CEOs think when it comes to ensuring innovation and rebuilding pipelines

Prefer outsourcing innovation (buying individual licenses or entering into partnerships)	41%
Buying whole companies is the best approach, especially in the biotech area	39%
In-house R&D is the most efficient source of future innovations	20%

What Pharma companies want to see ...

- Technology that provides added value:
 - Novel validated targets.
 - Enabling faster discovery.
 - Predictive of efficacy and safety in man.
 - Reduce failure rates.
 - **MOST IMPORTANT**- IP, IP, and IP with clear freedom to operate
- Drug delivery (life cycle management).



... with companies that have...

- Experienced management.
- Sustainable business plan.
- Realistic views.



Although technology is important, there's a clear preference for product deals

- Products with novel mechanisms and indicated for diseases with significant unmet needs. Hypertension is out, oncology is in.
- Strategic pipeline fit.
- Products with Phase II proof of concept.
- Healthy patent life.
- Worldwide rights including Japan.

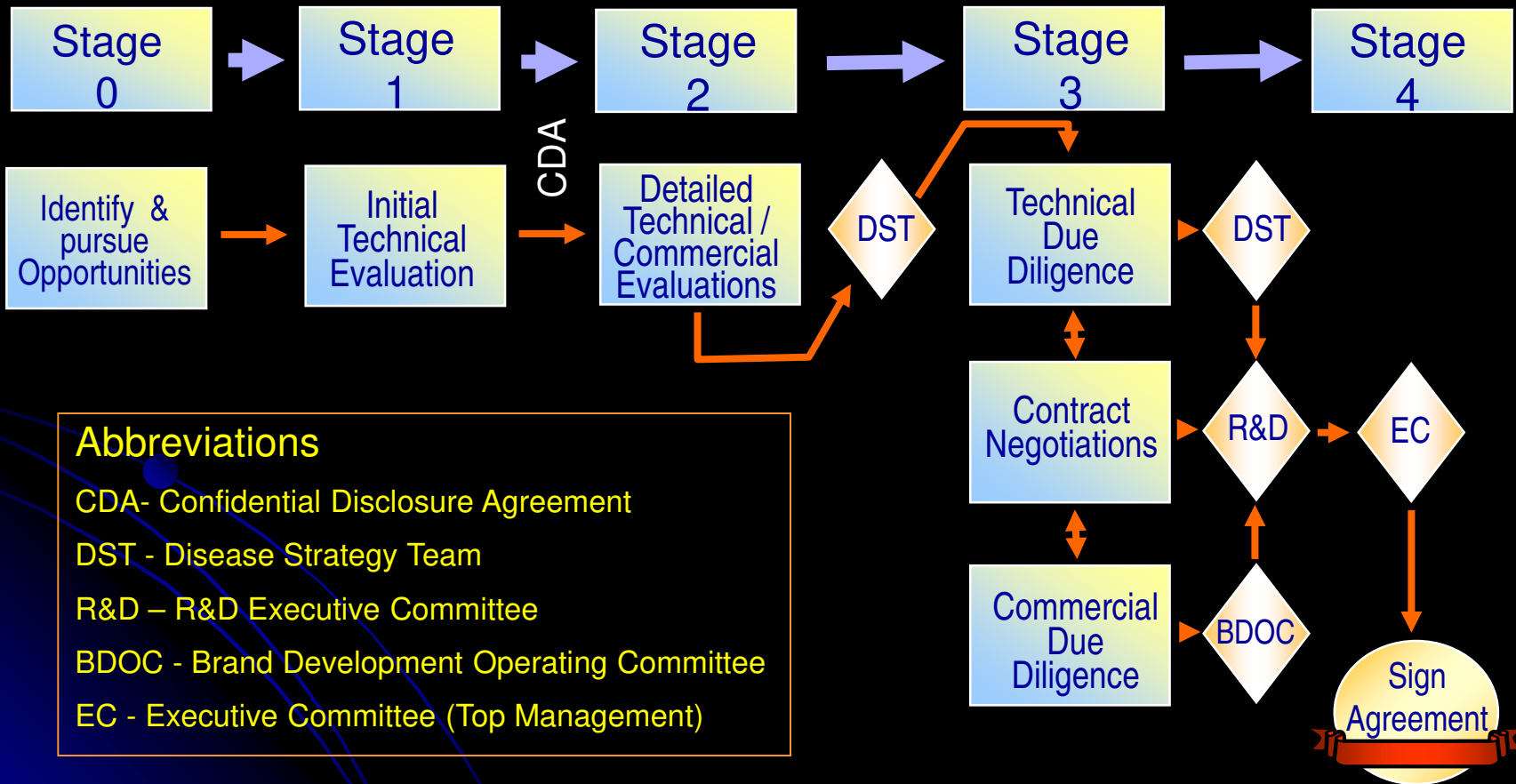


The gate keepers in big pharma: The scientific/commercial jury

- Sr. VP, Regulatory
- Sr. VP, Preclinical research
- Sr. VP, Clinical Research
- Sr. VP, Development
- Chief Marketing Officer
- Sr. VP, Project Management
- Sr. VP, Global Pharmaceuticals
- Sr. VP, Business Development
- President, US Pharmaceuticals
- President, Manufacturing
- President, Pharmaceuticals (ex-US)
- Corporate Controller



In-licensing process



Partnering realities you have to understand

- It's not enough to be innovative, a new drug also has to be cost-effective
- It's not enough to get FDA approval- you also have to make sure that payers will reimburse it
- The FDA is asking for superiority to standard of care (comparative efficacy)
- Life is really expensive and bang for the buck is important
- Companies most likely to get funded today are those that embrace an early partnering strategy from the outset.



What biotech companies should look for in a partner

- Relationship with open two-way communication
- Stable management
- Team play
- Balanced win-win deal
- Strategic, scientific and pipeline fit
- Therapeutic area expertise
- Financial commitment to full development
- Regulatory success
- Developed sales force
- Commercial success
- Strong life-cycle management teams



What management needs to know

- **Strategic fit** with the company's plan
- **Intellectual property** assurances
 - Clear freedom to operate
 - Reasonable commercial exclusivity
- Detailed **scientific assessment/DD/ approval time line**
- **Deal structure** and impact (financial commitments)
- Adequate **staffing** for the deal
- Solid **R&D prioritization** or commercial bang /R&D dollar spent
 - Fully loaded P&L adjusted for the probabilities of technical and regulatory success
- Risk-adjusted **NPV/ROI**



Bow ties get attention... and a lot of respect



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