

Strategic elements of out-licensing and partnering

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BioEntrepreneurship Boot Camp

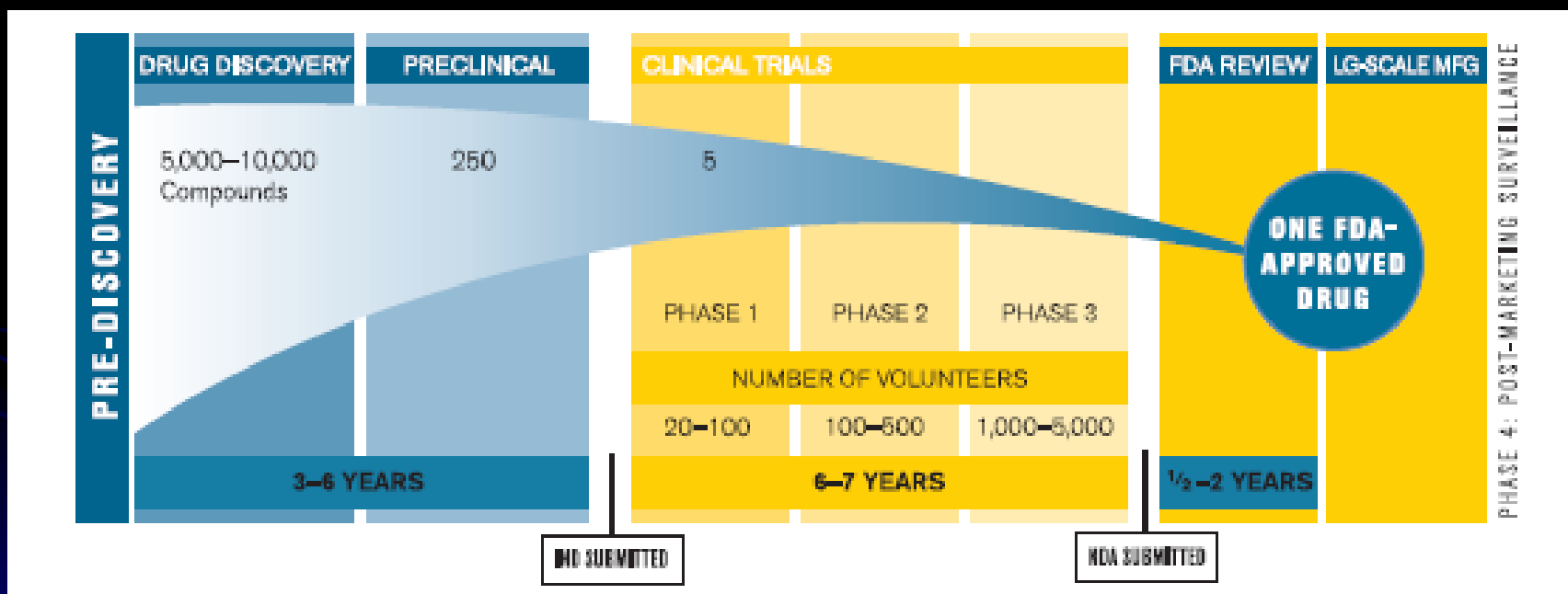
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The R&D process is long, complex and costly



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



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

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%

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.

Long-term considerations to appreciate for business-development strategies:

- ❑ Big pharma and investors see a lot of deals and can only do a few. Understand their therapeutic and discovery strategies and pick a short-list on which to concentrate from the beginning.
- ❑ Later-stage (Phase - ready and beyond) assets make the most sense and are the easiest to get done.
- ❑ Early-stage assets have significantly more PTR risk and require \$\$\$\$\$\$\$ in capital. These are the purview of venture capitalists.
- ❑ The good news- Biotech discovery is important for the future of Big Pharma pipelines- 70% of novel NME FDA approvals are for partnered assets. This will not change.

Reference:

<http://www.thedeal.com/pdf/Healthcare%20Dealmaking%20Round%20Table%20Report.pdf>

Long-term considerations to appreciate for business-development strategies (continued):

- Focus on biologics is gaining share on small molecules- the gap is narrowing..
 - 40% of marketed pharma products are large molecules or specialty in nature,
 - Biologics account for 60%-70% of the current clinical development pipeline .
 - Understand that Pharma company discovery competes with in-licensing (with in the same or different TA)
 - Long-term, the industry is moving from a volume-based to a value-based model of healthcare. Business development is clearly taking notice.
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<http://www.thedeal.com/pdf/Healthcare%20Dealmaking%20Round%20Table%20Report.pdf>

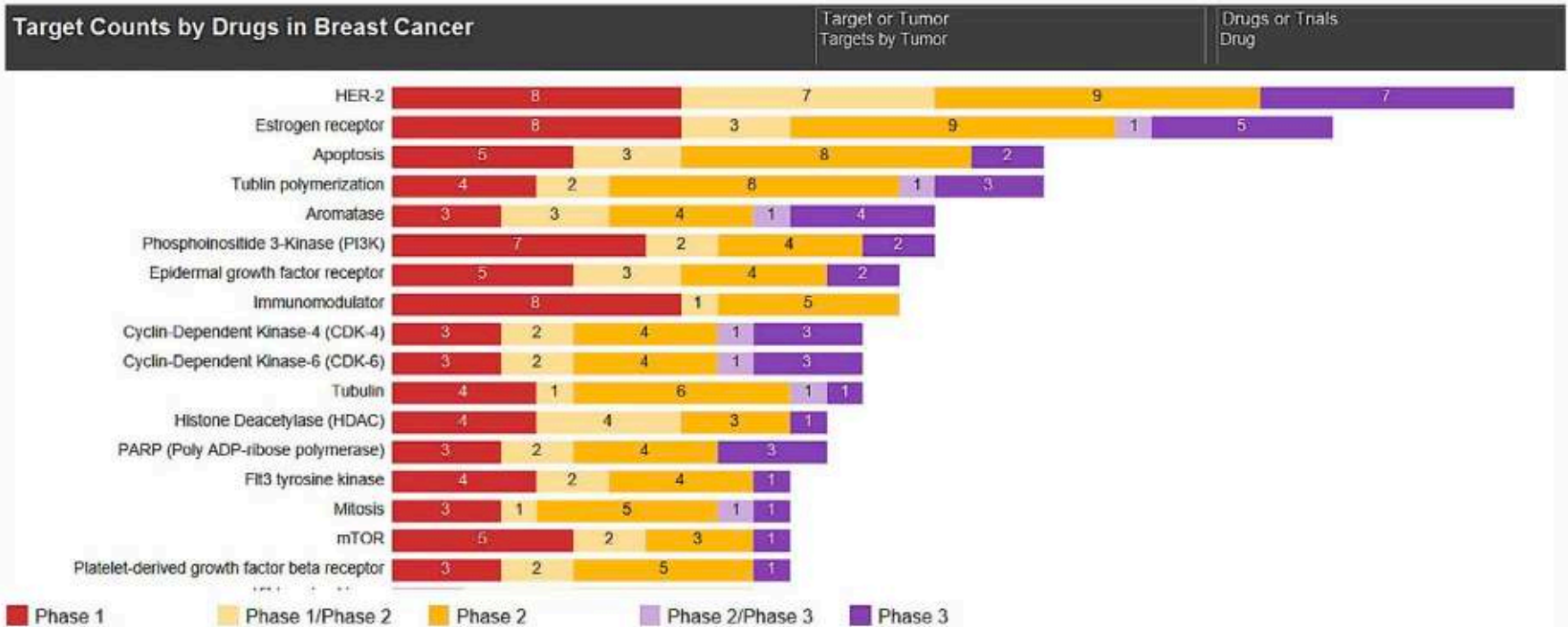
Partnering realities you have to understand

- 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.



Compound development can be a crowded place

Target Counts by Drugs in Breast Cancer



Reference: Kantar Health, December 15, 2017

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.



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**

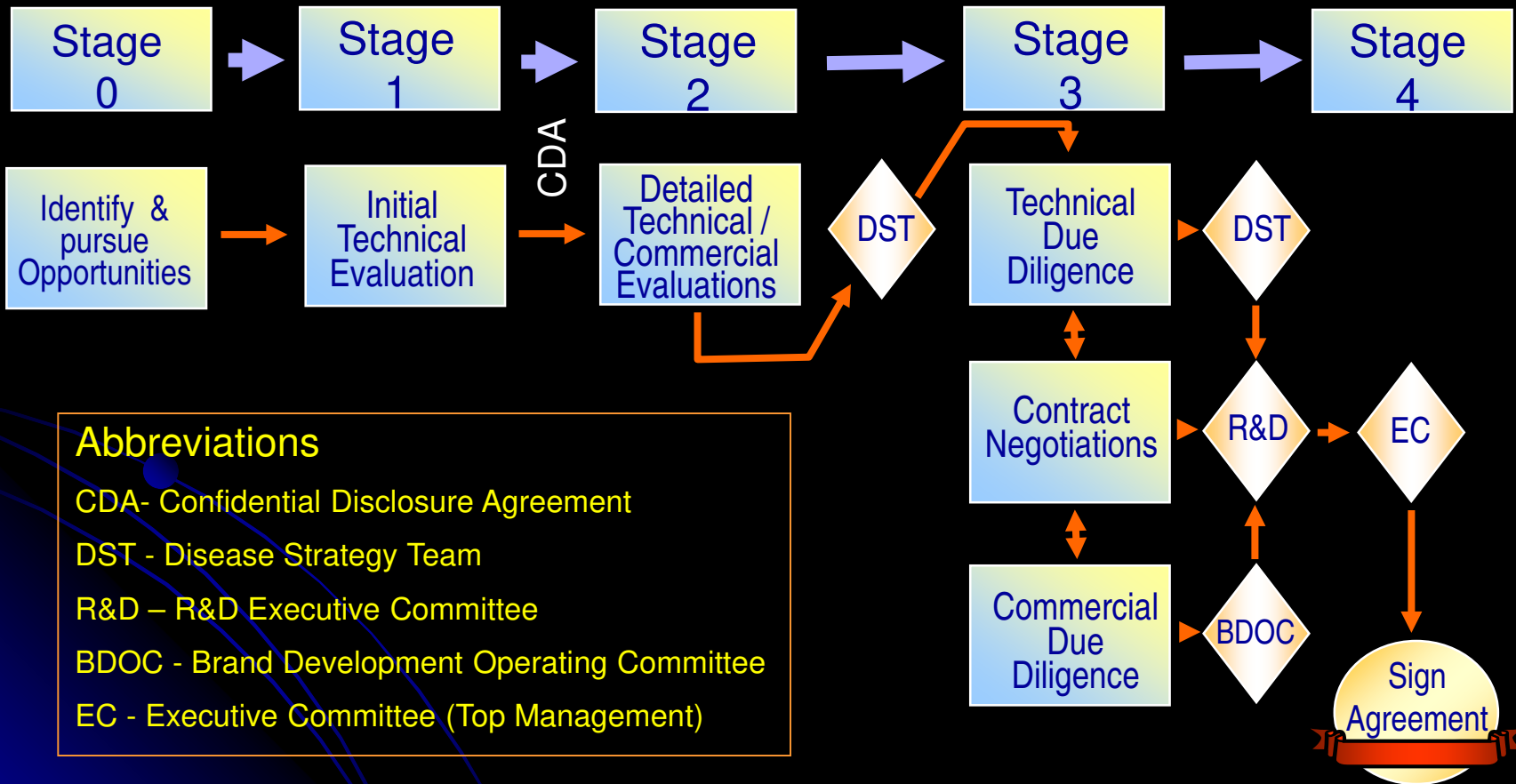


What biotech companies should look for in a partner

- 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



In-licensing process



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



Understand there are a lot of hurdles on the way to success.

Know what you don't know.

Understand the difference between a “science project” and a “company”.

Surround yourself with those who do.

Scientist founders should not be CEOs.

Develop a connected and involved BOD/SAB.

Plan for the future- think ahead in everything.

Try not to take stupid shortcuts- science rules.

Focus.

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