

# Strategic elements of out-licensing and partnering

J. E. Foley, Ph.D.

Aqua Partners LLC

BioEntrepreneurship Boot Camp

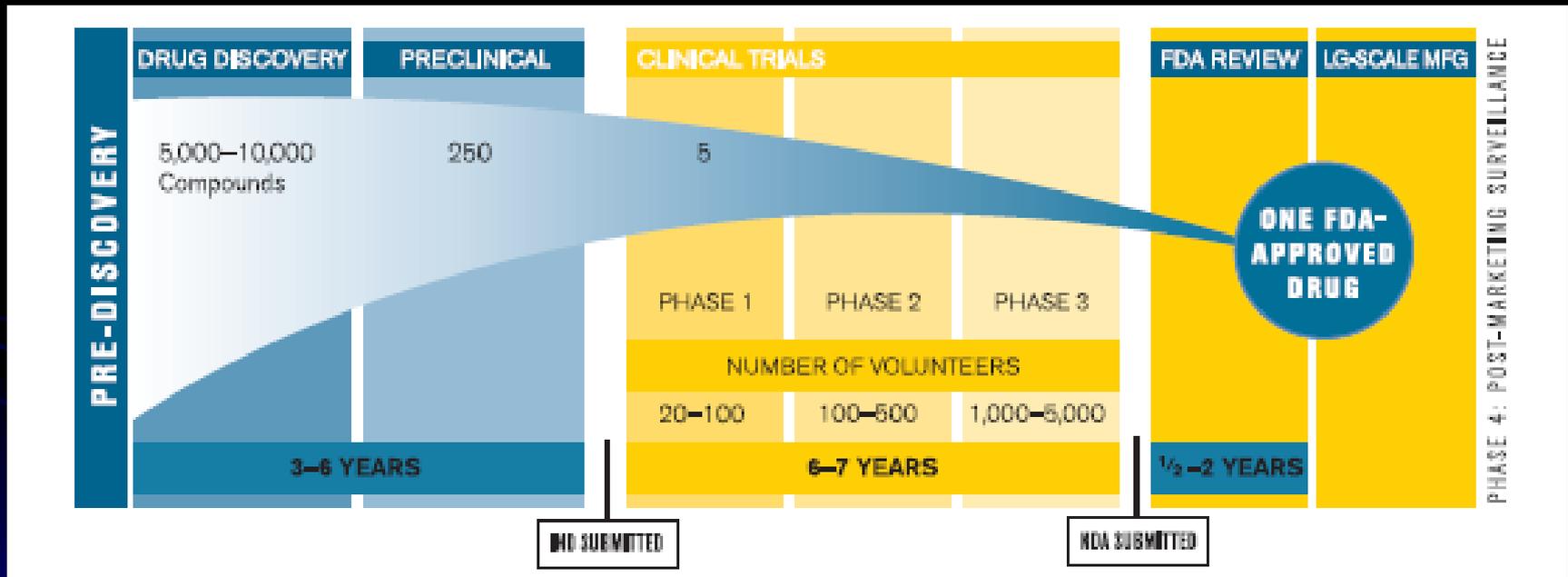
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# The R&D process is long, complex and costly



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

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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...

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- ❑ 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:

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- ❑ 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.

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Reference:

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

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

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- 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>

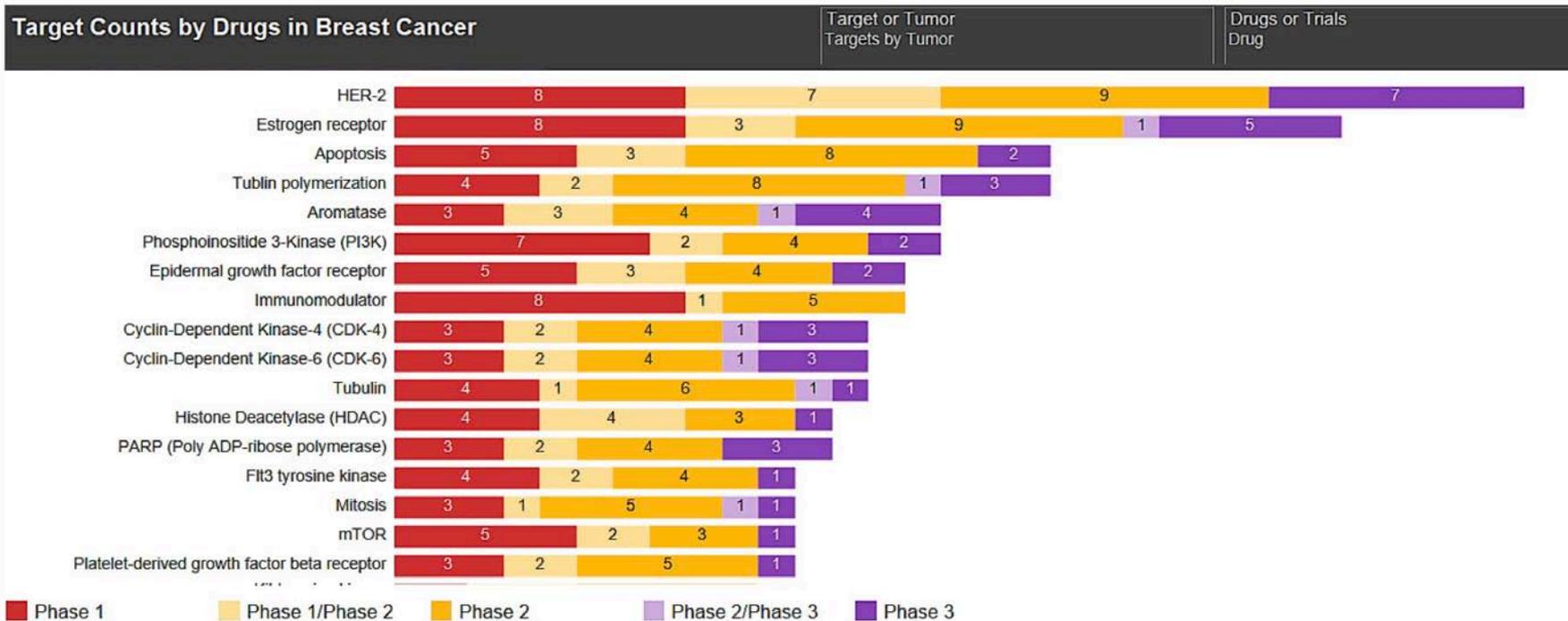
# Partnering realities you have to understand

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- 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...

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- 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...**

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



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

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- 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

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- **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**



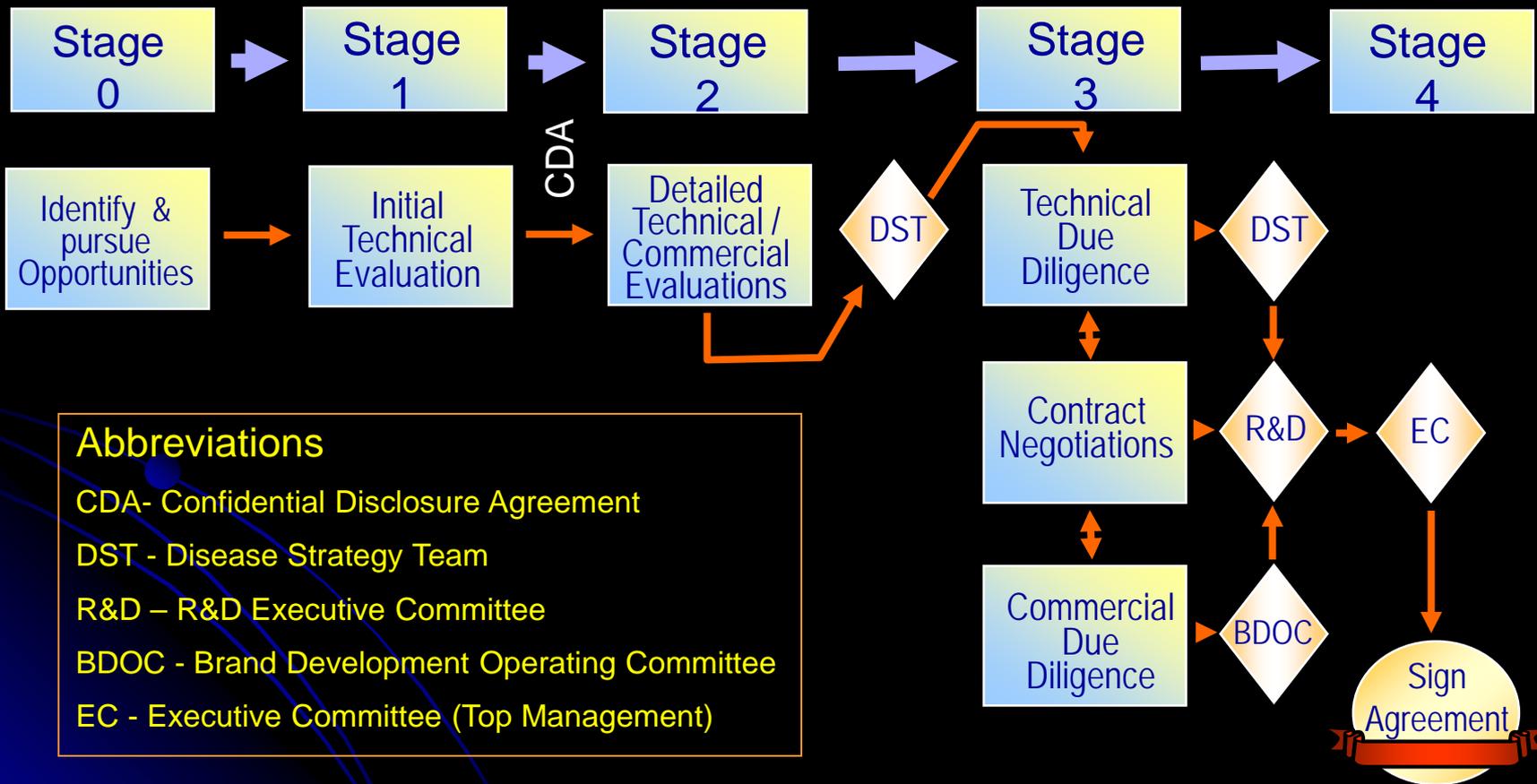
# What biotech companies should look for in a partner

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- 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

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- 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.**

**James E. Foley, Ph.D.**  
**Aqua Partners LLC**

**E-mail:**

**[jfoley@aquapartners.net](mailto:jfoley@aquapartners.net)**

**t**

**Tel: 610-624-3797**

