Business Development Basics Course

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Biotechnology Industry Organization

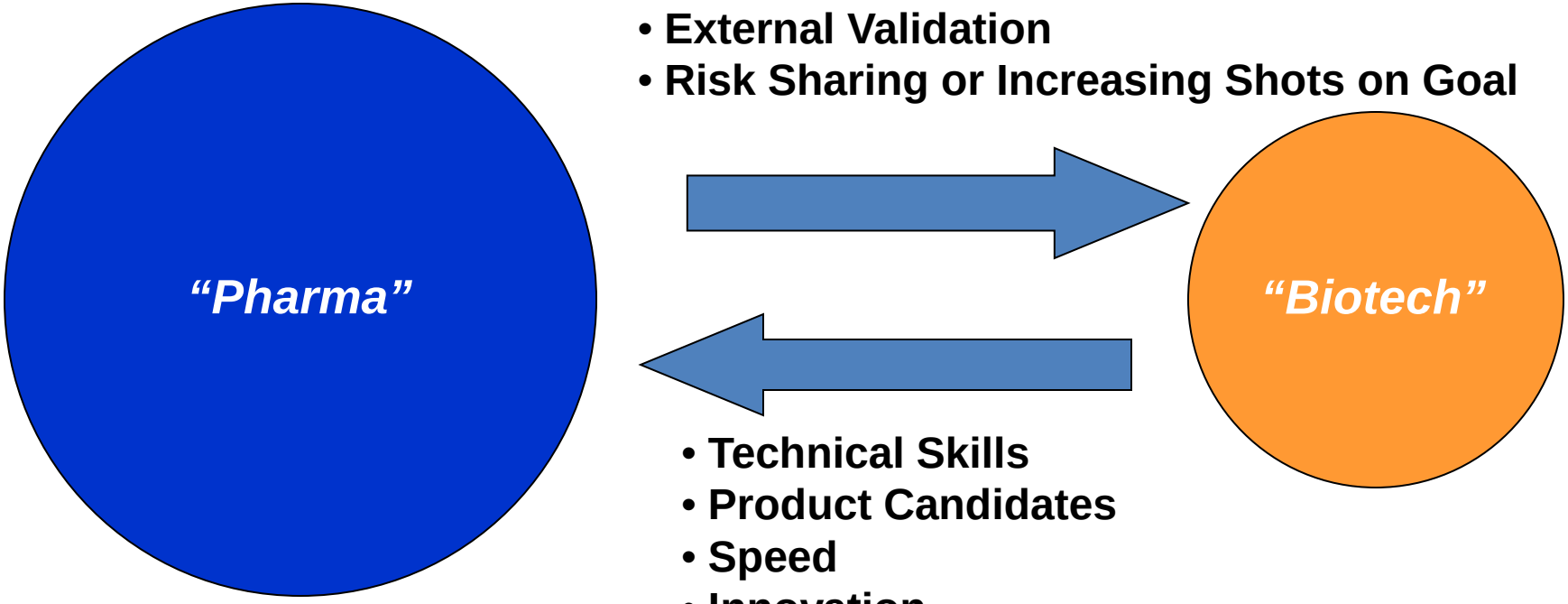
Topics for Today

- Why Partner
- How To Structure a Partnership
- How To Value a Partnership
- The Deal Environment & Current Metrics
- The Deal Process
- Is the Business Model Broken? Considerations for a Business Development Professional
- Recent Examples

Why Partner

Why Partner

- **Cash**
- **Development & Commercial Skills**
- **External Validation**
- **Risk Sharing or Increasing Shots on Goal**

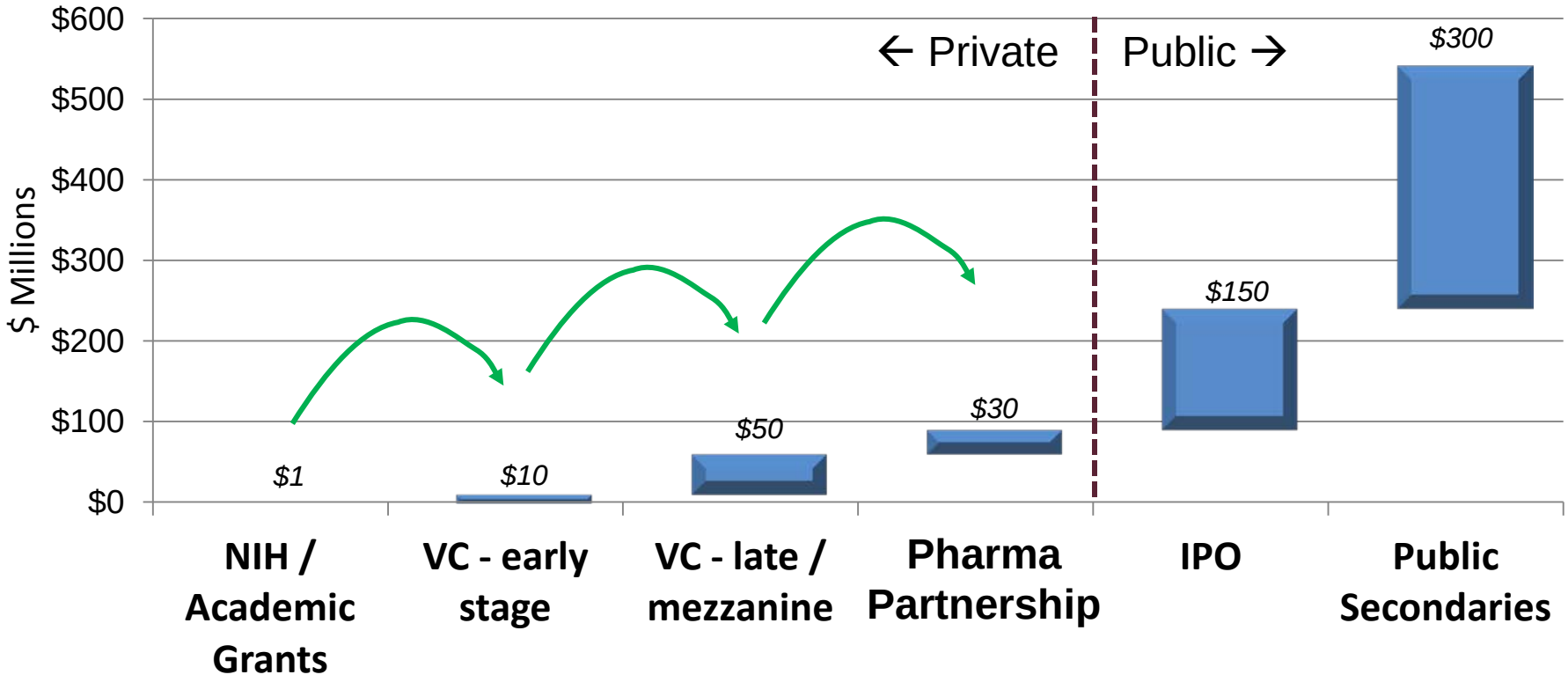


- **Technical Skills**
- **Product Candidates**
- **Speed**
- **Innovation**

But this view ignores some complexities…

"How We Used To Do It"

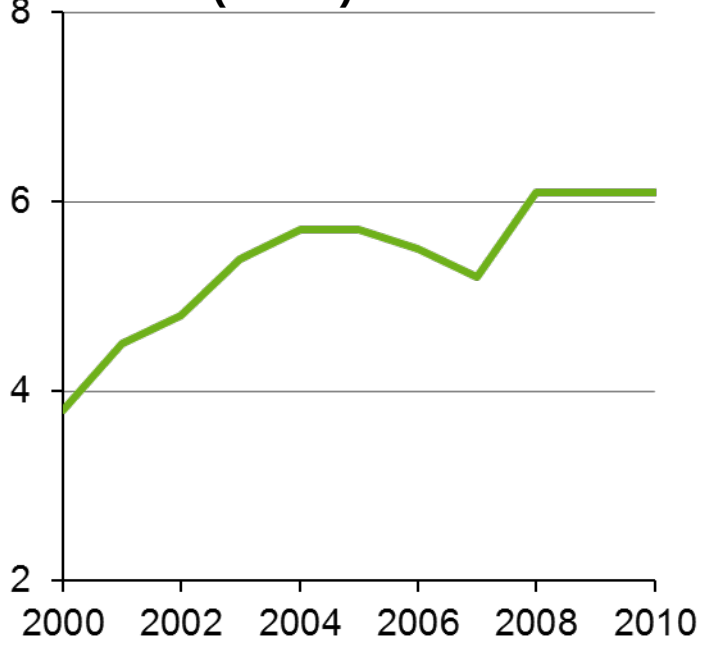
Financing Your Biotech Company - 2001



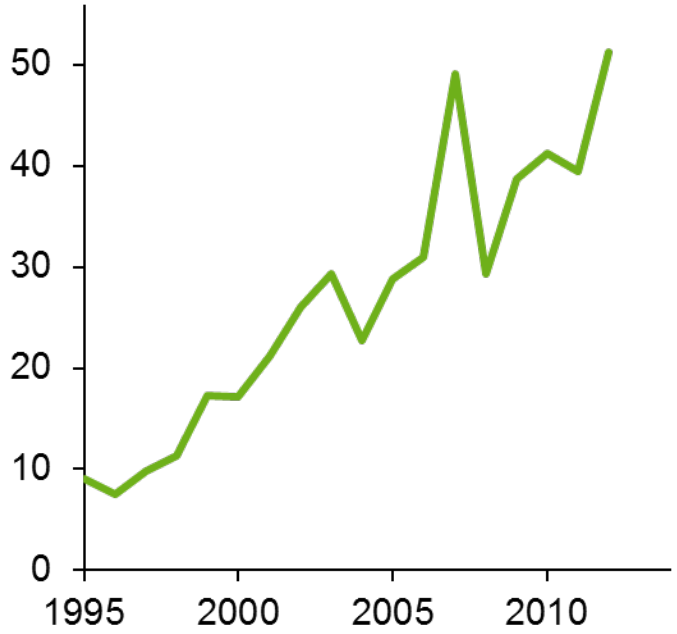
But Things Have Gotten More Complex…

It Is Taking Longer And More Capital For Companies to Exit

Average Time to Exit of US Venture-Backed Life Sciences Companies by Year of Exit (Years)



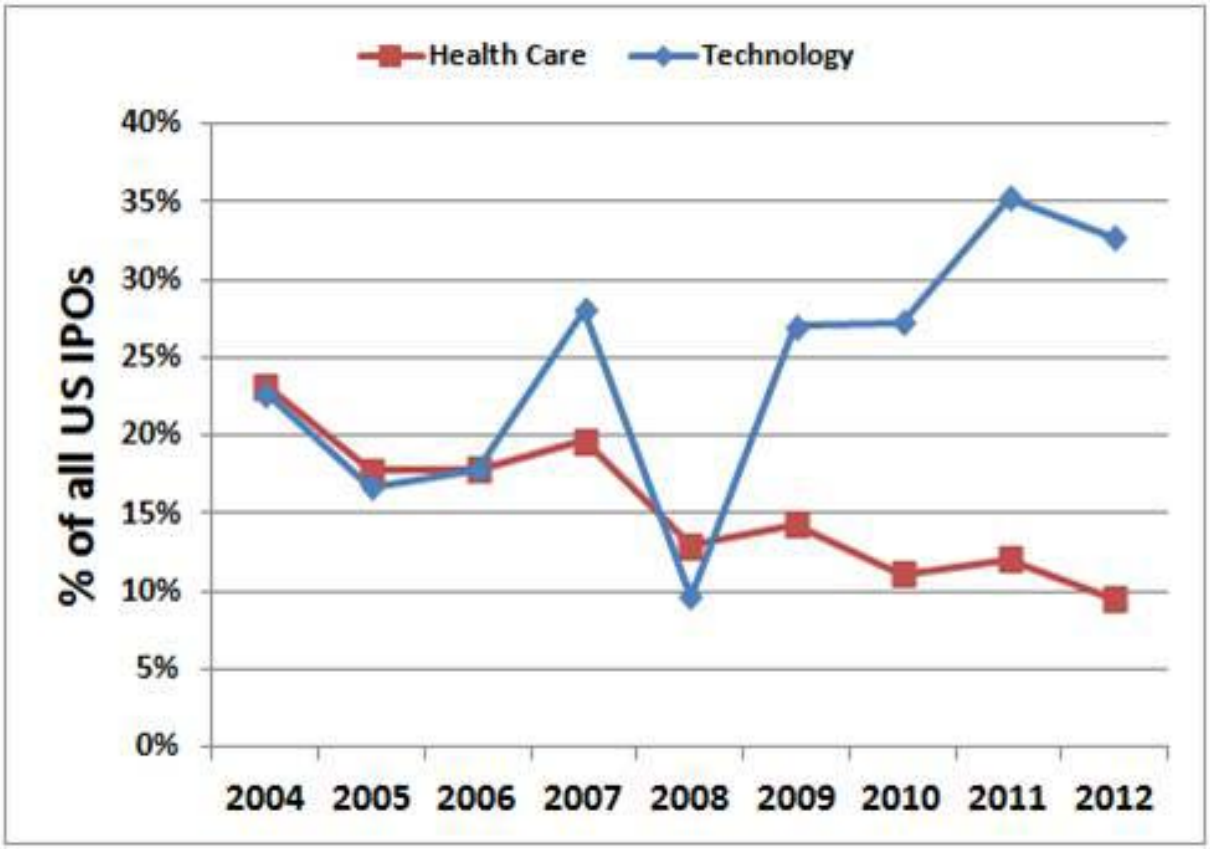
Average Equity Raised by Life Sciences Companies to Acquisition by Year of Exit ($ Millions)



Source: NVCA and Thomson Reuters

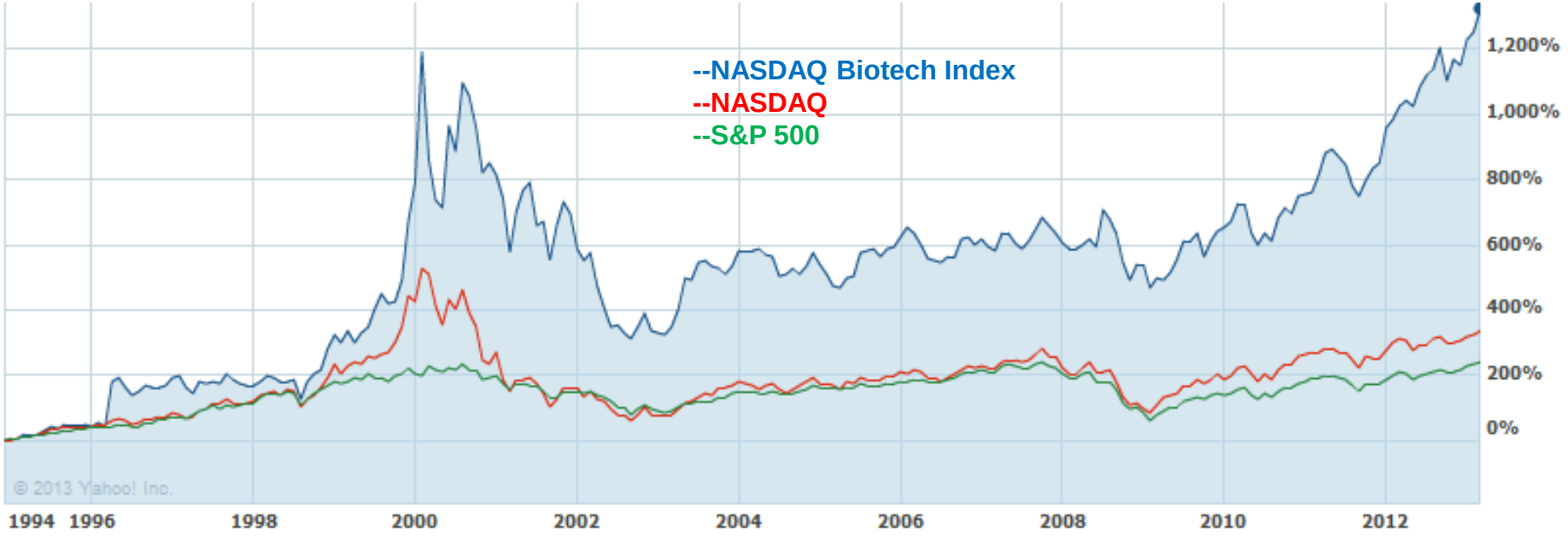
Healthcare IPOs Have Dwindled Over Time

Percentage of Total IPOs per Year, 2004-2012



Source: Renaissance Capital; BIO website

Although Recent Data Suggests Some Reawakening of the Biotech IPO Market…

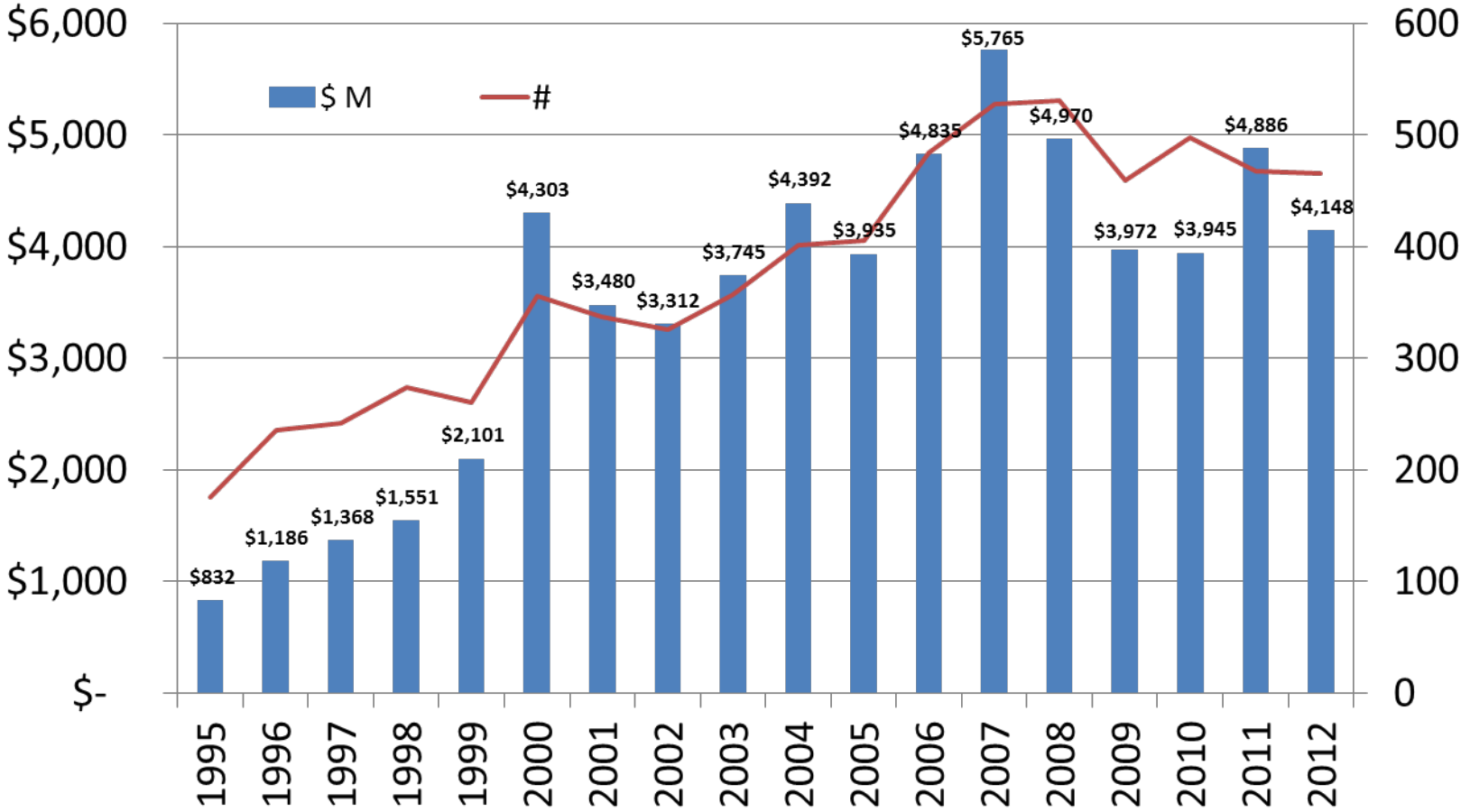


- 2 Preclinical IPOs in 2012: Regulus (RGLS) and Verastem (VSTM)

Source: Yahoo Finance

Biotechnology VC Total Funding and # of Deals
By Year 1995 – 2012

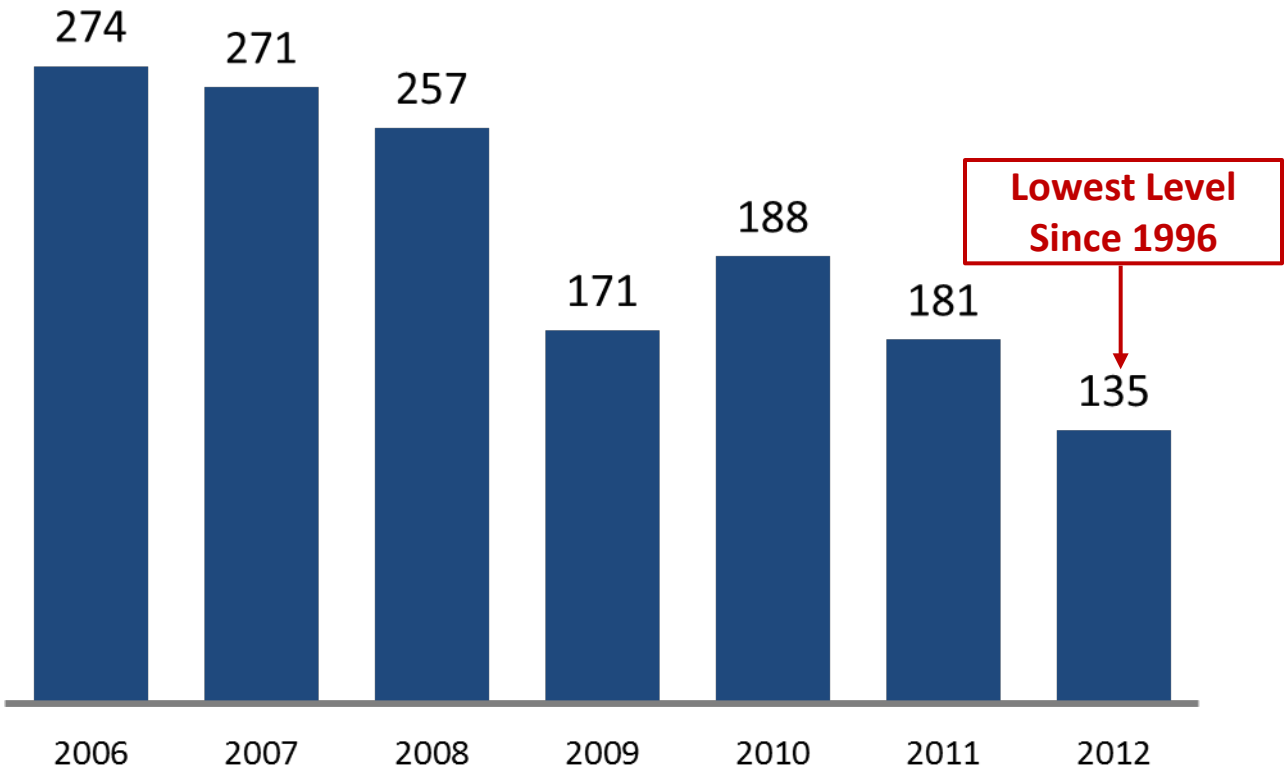
And VC Funding is Down almost 30%



Source: PWC Money Tree

Initial VC Funding Is Harder to Come By

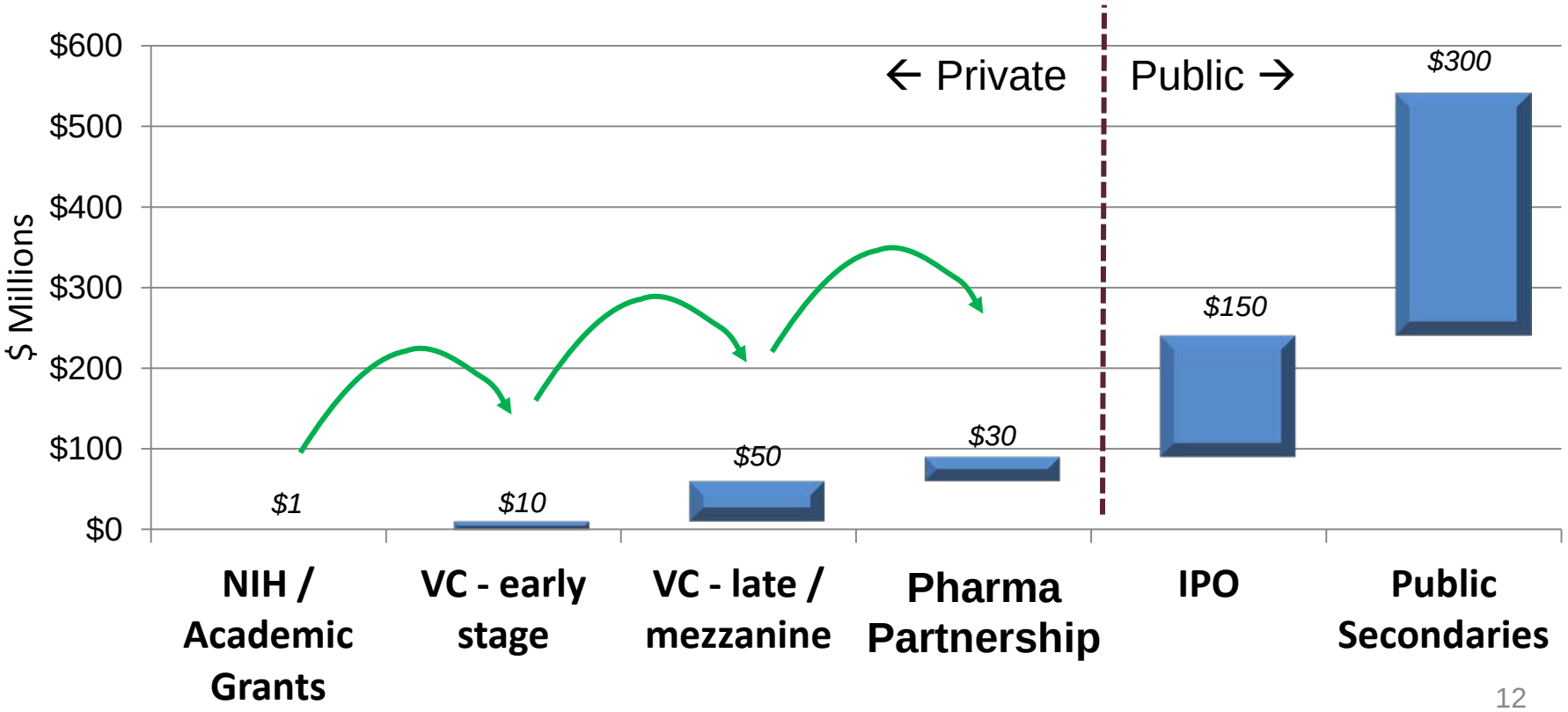
Life Sciences First-Time Fundings



Source: NVCA, PWC Jan 2013 MoneyTree report, Thomson Reuters

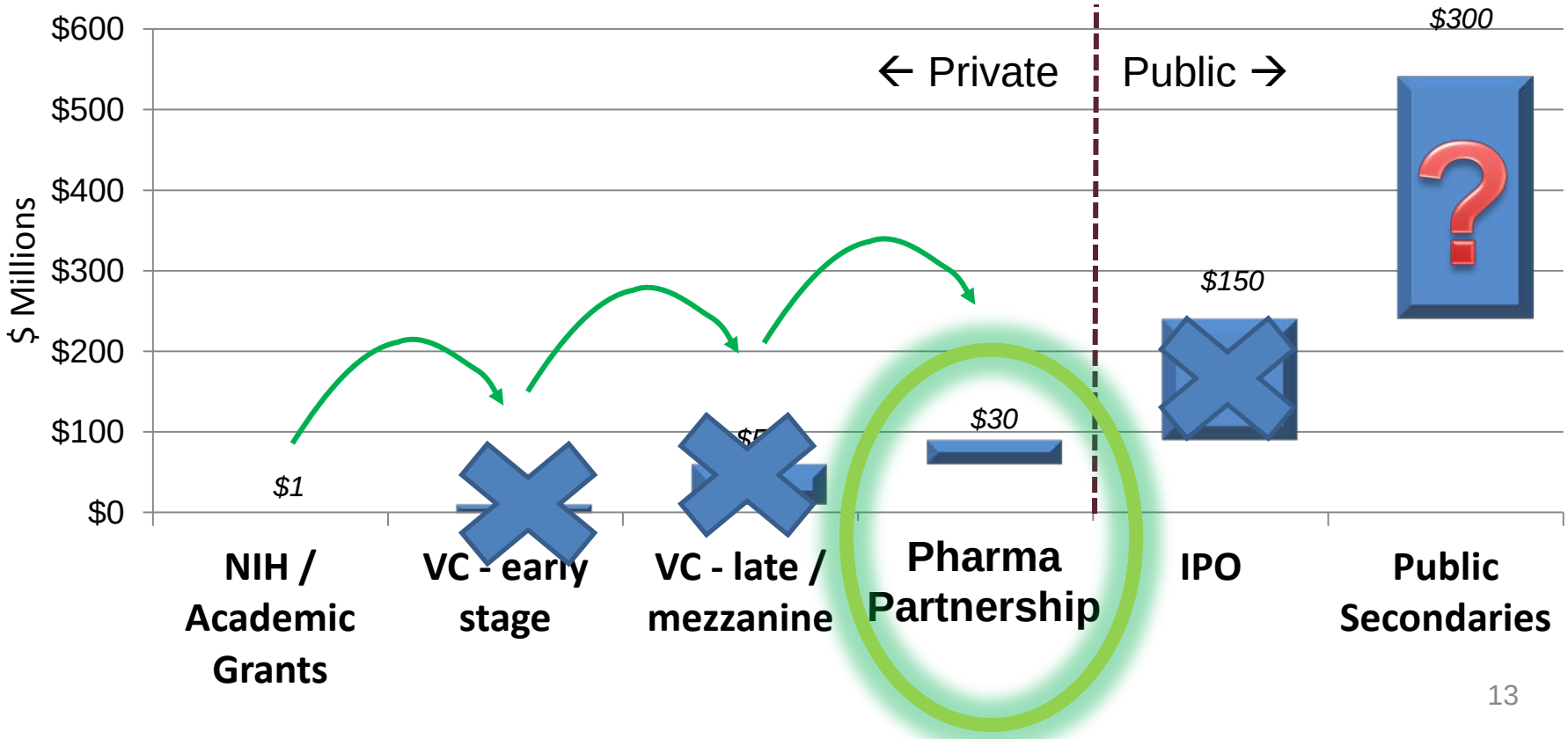
"What Now?"

In 2013 – How's the Model Holding Up?



"What Now?"

Financing Your Biotech Company - 2013



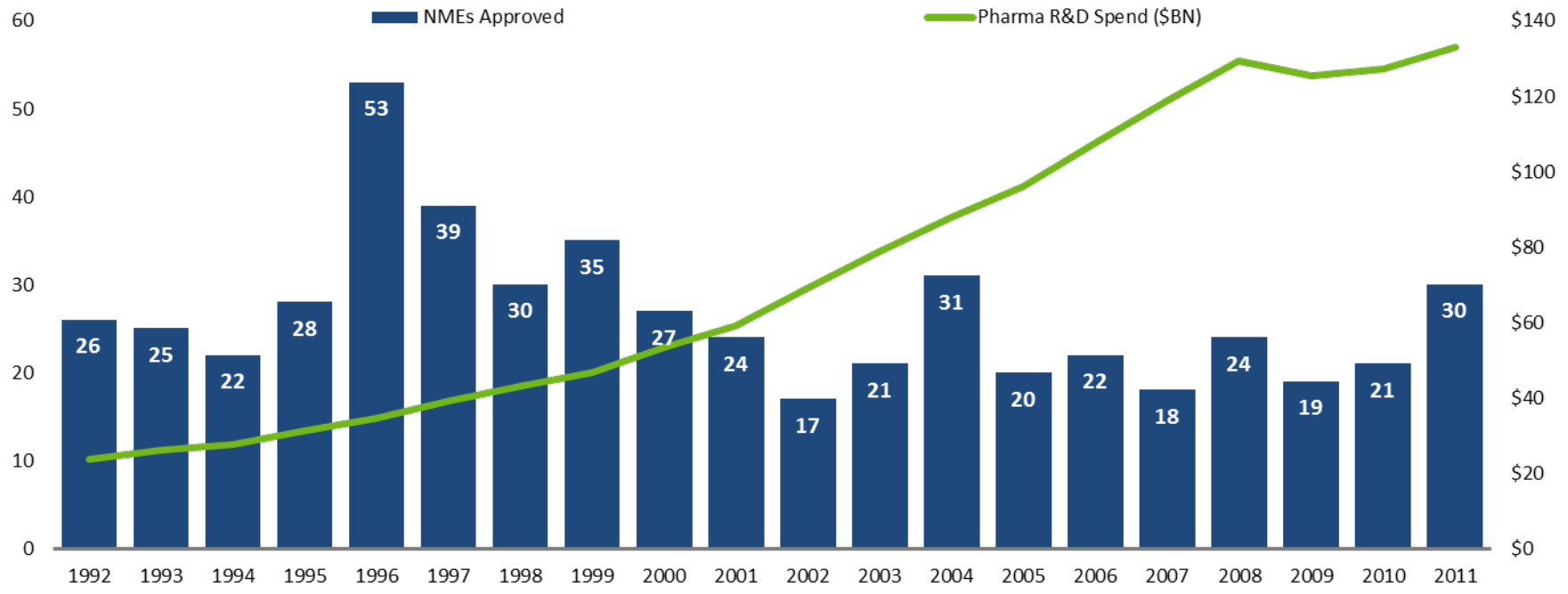
Can we finance this way?

Actually, yes…

Pharma's R&D Productivity Issues

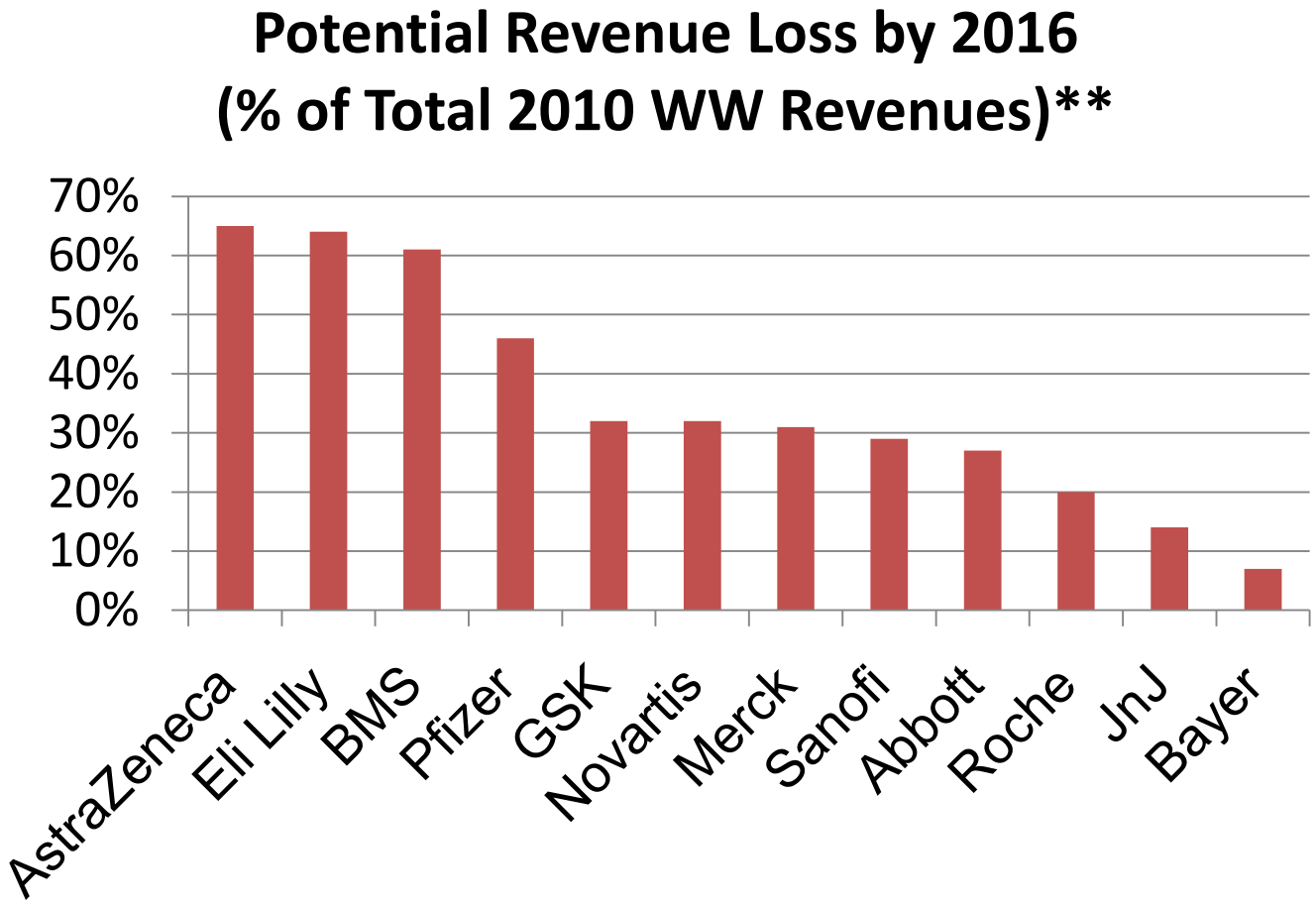
Pharma R&D Spending vs. NMEs Approved

39 NMEs approved in 2012



Source: NVCA, EvaluatePharma and PhRMA

Pharma's Patent Gaps Getting Very Real



Source: Thomson Pharma, SEC 10-Ks

Recent Preclinical Structured Deals

Novel deal structures provide early funding

Quanticel Pharma/ Celgene	• Company launched with VC funding + Celgene funding • Celgene paid $45M upfront; option to acquire at 3.5 years
Warp Drive/ Genentech	•Launched with VC funding + Sanofi funding •Sanofi has option to acquire
Inception 3/ Roche	•Company jointly funded from start by VC funding + Roche •Roche has predefined option to acquire at IND
Resolve Therapeutics/ Takeda	•$8M upfront payment to fund through a Phase 1b lupus study • Predefined option to acquire for up to $247M in upfront+milestones

The public biotech perspective – raising cash while balancing cost and risk

Loan-like vehicle

- Relatively cheap capital
- Minimum dilution
- Potential overhang around time of repayment
- Not available to most biotech companies

Hybrid – Clinical development financing

- Risk sharing - don't have to repay if compounds fail
- Potential overhang around time of repayment
- Not available to most private biotech companies

License compound with Pharma company

- Good way to access additional capabilities and share risk
- Large % dilution in value of specific asset
- Potential loss of control

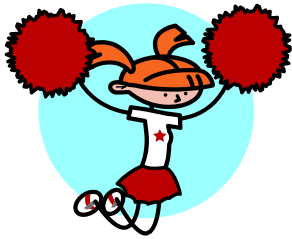
Equity like vehicle

- No payback necessary
- Shareholder dilution - dilution of value of all assets of company, selling small percentage of entire pipeline
- Best risk diversification for investor
- Dependent on equity/venture market

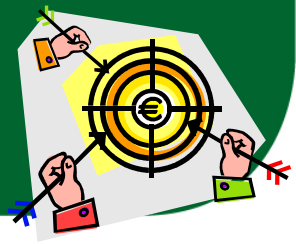
Cost of capital of various fund raising alternatives

Financing Option	Cost of Capital	Comments
Debt/Convertible Debt	10%-20%	• Blend of cost of equity and cost of debt
Clinical Development Financing Vehicle	25%-30%	• Delays and lowers dilution compared to equity now
Partner Compounds	Could be huge depending on value of compound and terms	• No near-term equity dilution • Value dilution in only one asset • Capitalized value of earnings lost
Venture/Private Equity	45%+	• Usually look for cash on cash multiples of 3x-5x
Public Equity	25%-35% (equity cost of capital)	• Higher near-term dilution

If the Objective is Access to Capabilities/Expertise/Validation



- Valuing the partner's contribution/capabilities
  - Increased Probabilities of Technical Success?
  - Shorter time to market?
  - Broader clinical program, larger number of indications?
  - Higher peak sales?
  - Increased valuation of company from "marquee" deal?

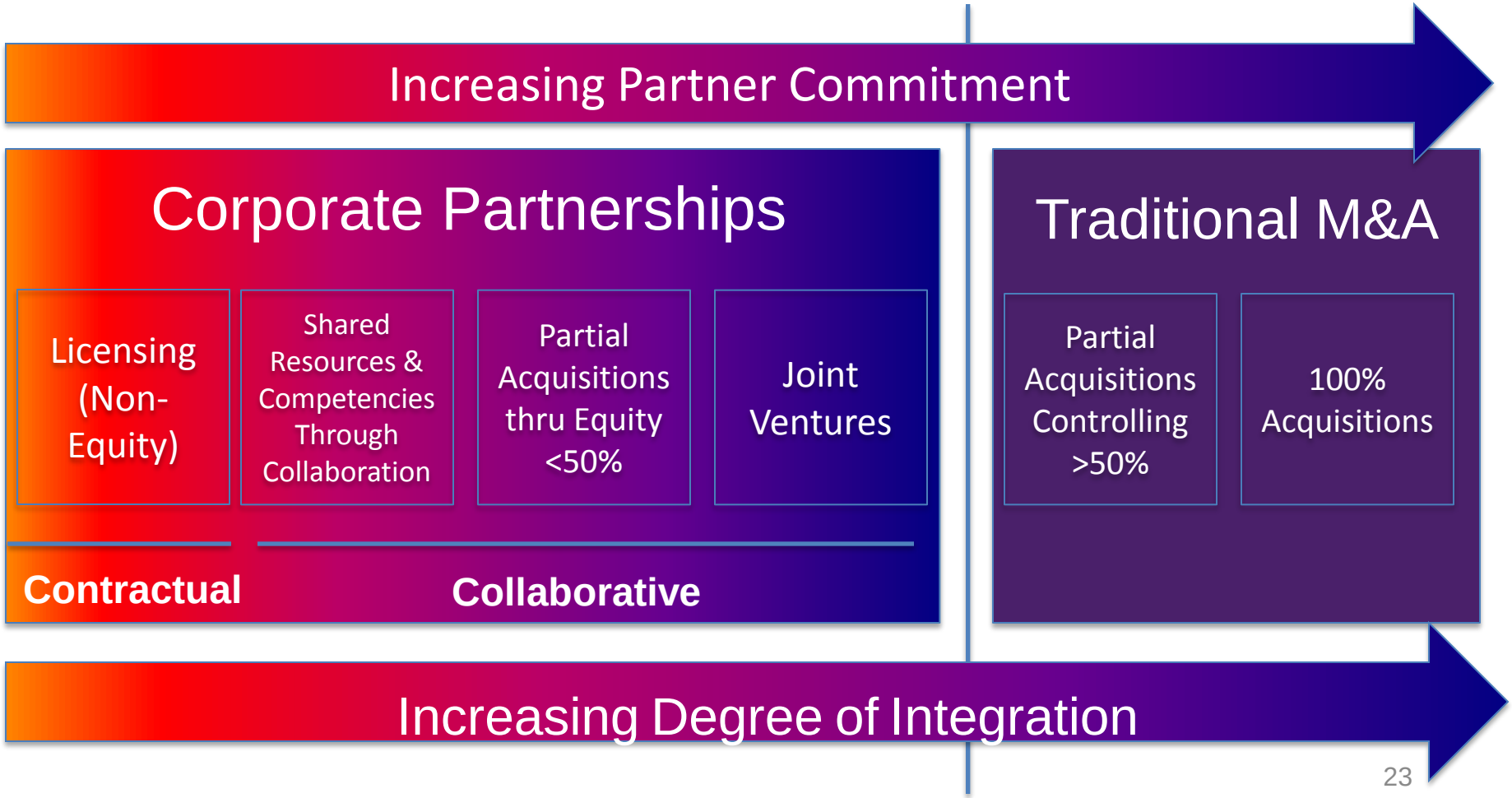


If the Objective is Sharing Risk Or Increasing Shots on Goal

- Consider ways to retain economics, while off-loading some costs
  - Cost and Profit share in compound
  - Retain certain number of compounds/output resulting from collaboration
  - Retain certain geographies
  - Use financing vehicle to fund clinical development
  - Funding mechanisms from pharma partner

How To Structure A Partnership

Partnerships Come in a Variety of Forms
Continuum of Transaction Types



Alliance

vs.

Contractor

vs.

Partner

vs.

Service Provider

vs.

Collaborator

In all transactions…

There is a unique dynamic between the Buyer and the Seller; and

Every deal is different…

Value for the “Buyer”

- New product candidates
- New technologies (innovation)
  - Discovery
  - Development
- IP/Know-how
- Catalyst for change
  - Challenge internal capabilities
  - Speed
  - Decision making

Value for the “Seller”

- Cash
- Ability to advance technology platform
- Ability to develop technology or therapeutic
- Ability to commercialize technology or therapeutic
- Underwrite development of infrastructure
- Market “validation”

What Kind of Transaction?

- Straight license agreement
  - Arm's length
  - No collaboration (not really an alliance)
- Research collaboration
- Development collaboration
- Promotion/Marketing collaboration
- Royalties vs. Profit sharing
- M&A (the ultimate alliance?)

Varying degrees of all three?

What types of payments?

- Upfront payment
  - Proportion of costs to date (all or some fraction?)
  - Recognition of stage of development of IP and Know-how
- R&D Support
  - FTE basis
    - Rate? Tracking? Auditing?
    - Work plan?
- Milestones
  - Research/Technical achievements
  - Clinical achievements
  - Regulatory hurdles (filings vs. approvals? territories?)
- Royalties
  - Percentage of sales? Tiers?
  - Sales milestones?
  - Buy out of future revenue stream?

Forms of Payment?

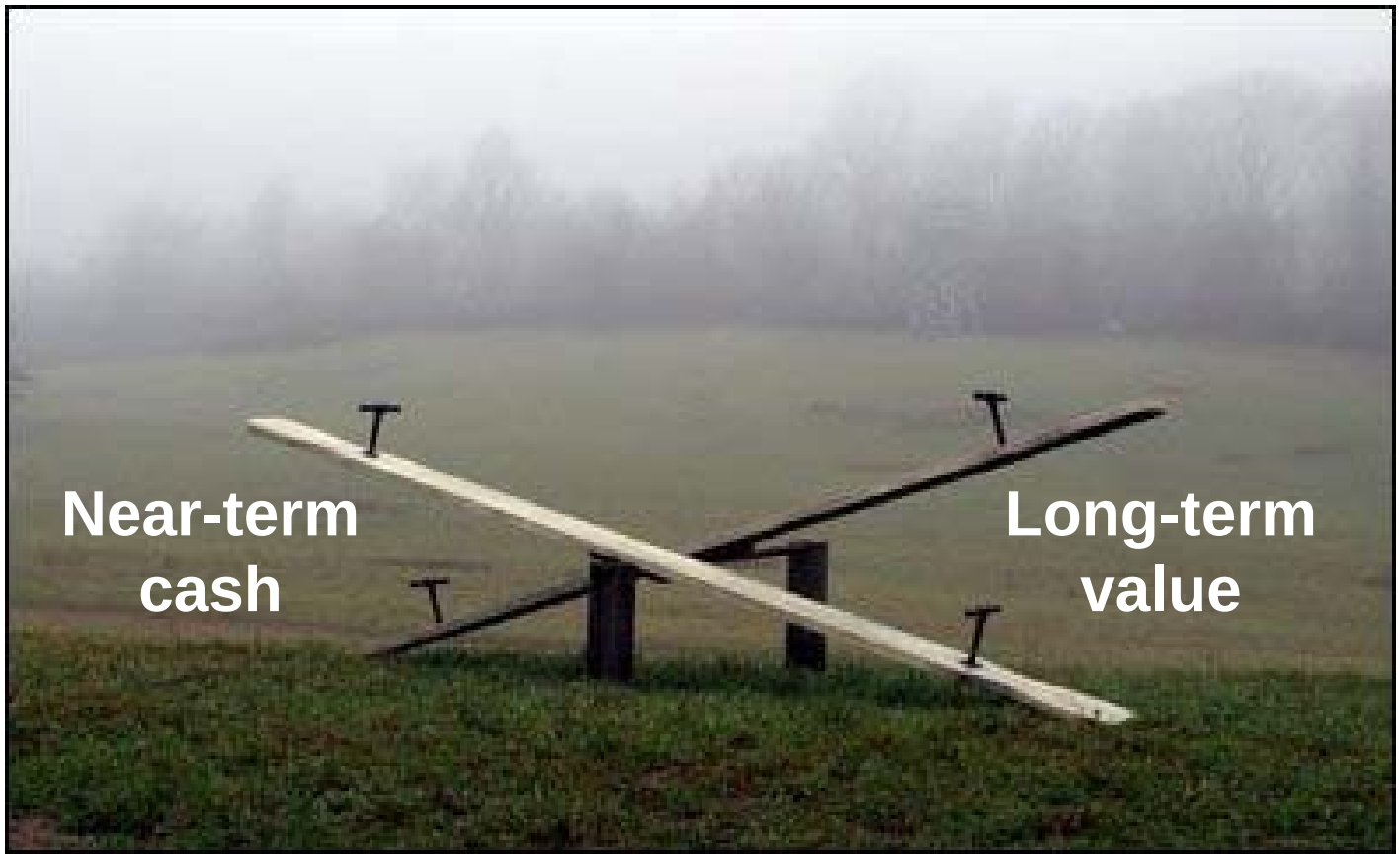
- Cash
  - Non-dilutive for seller
- Equity
  - Spares P&L for buyer
    - Unless written down?
  - Upside potential for buyer?
- Loans
  - Forgivable?
  - Convertible?

Research Support, Milestones

Upfront

More relevant to Development and Commercialization

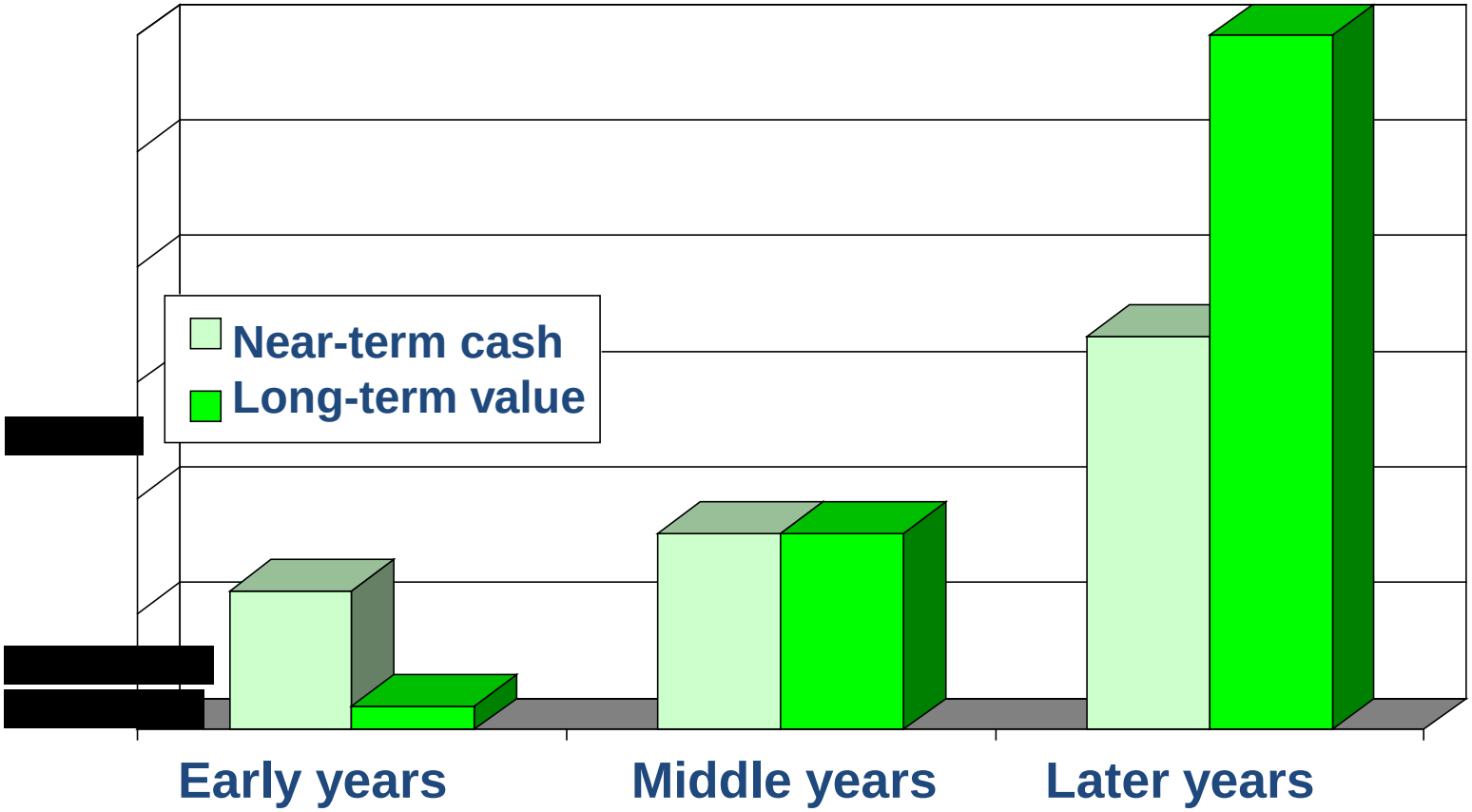
The Challenge



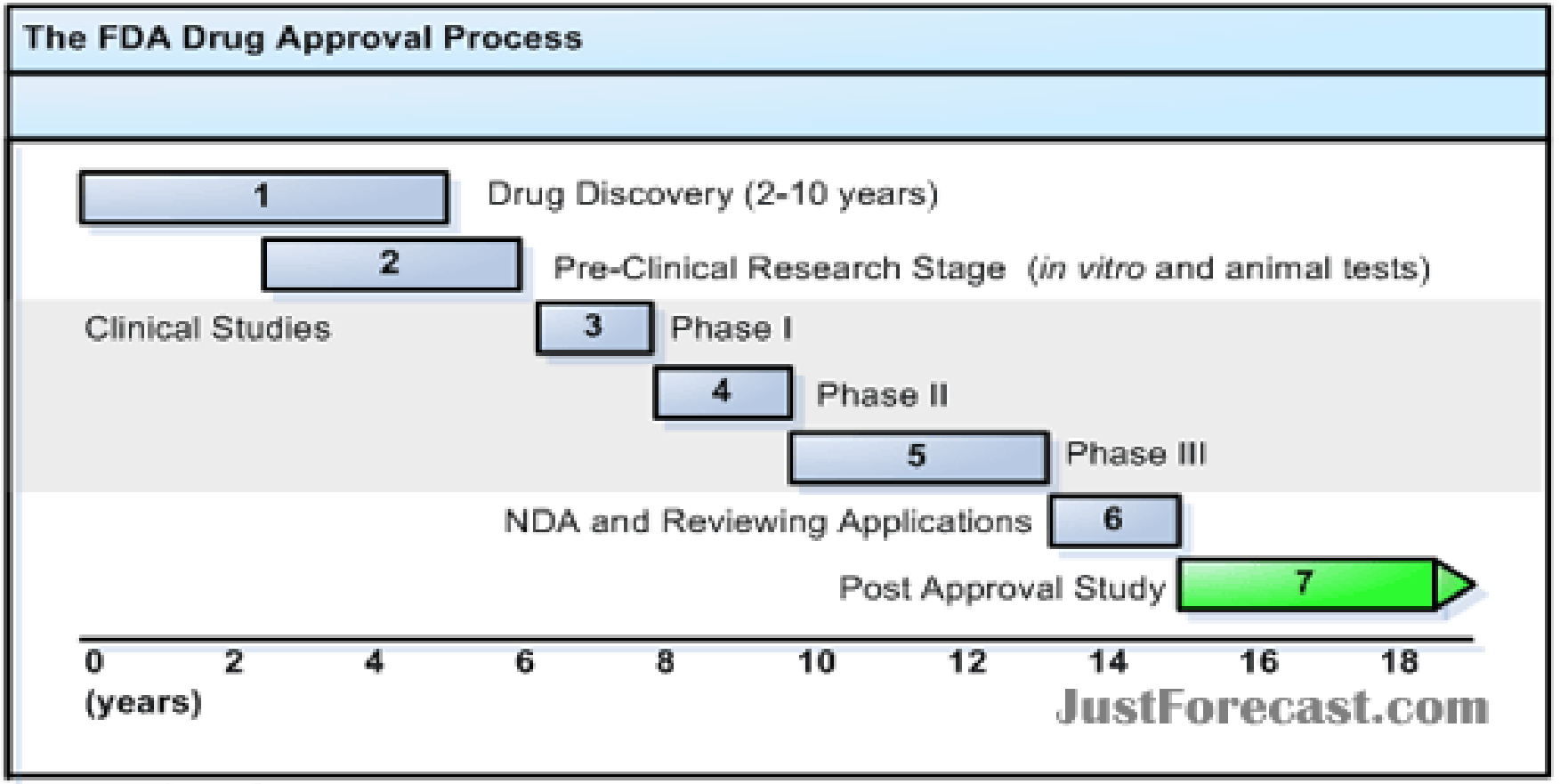
Essential in early years

Essential to attract and keep investors

‘Classical’ Evolution of Deal Structure over Company Lifecycle

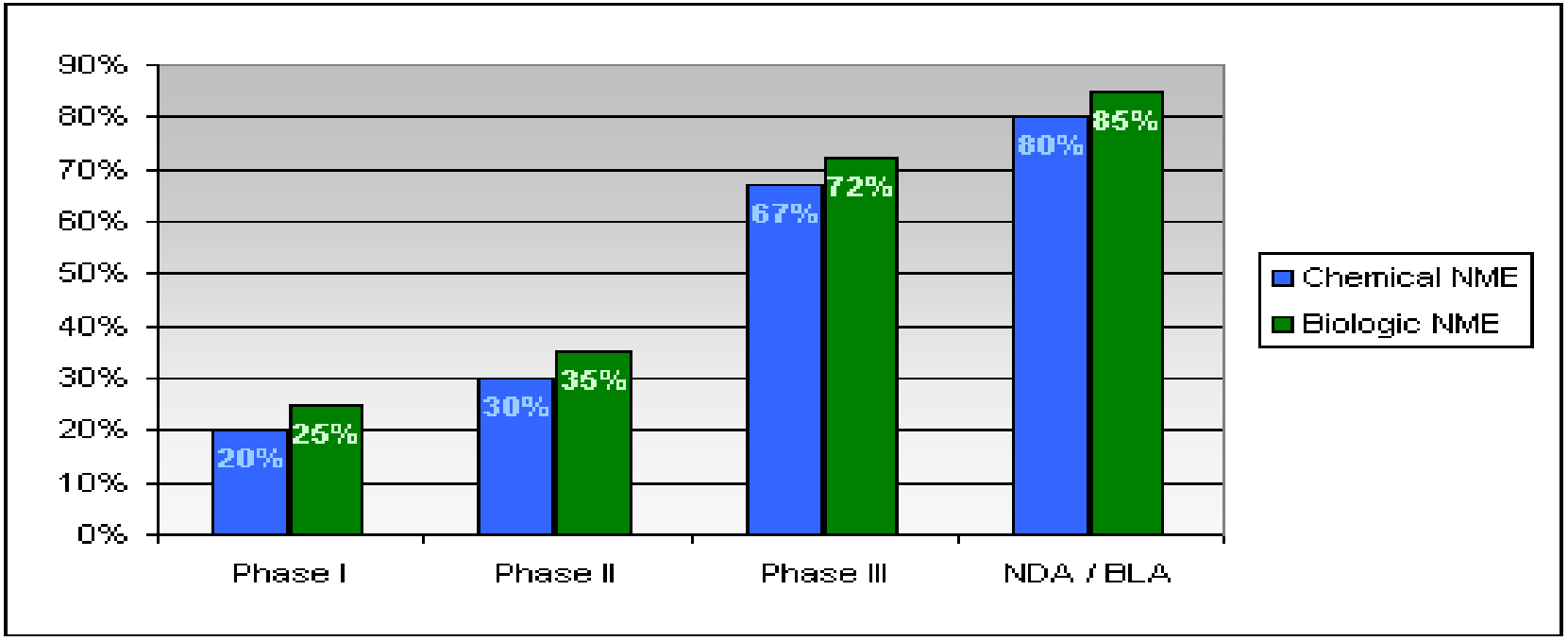


How long does it take?

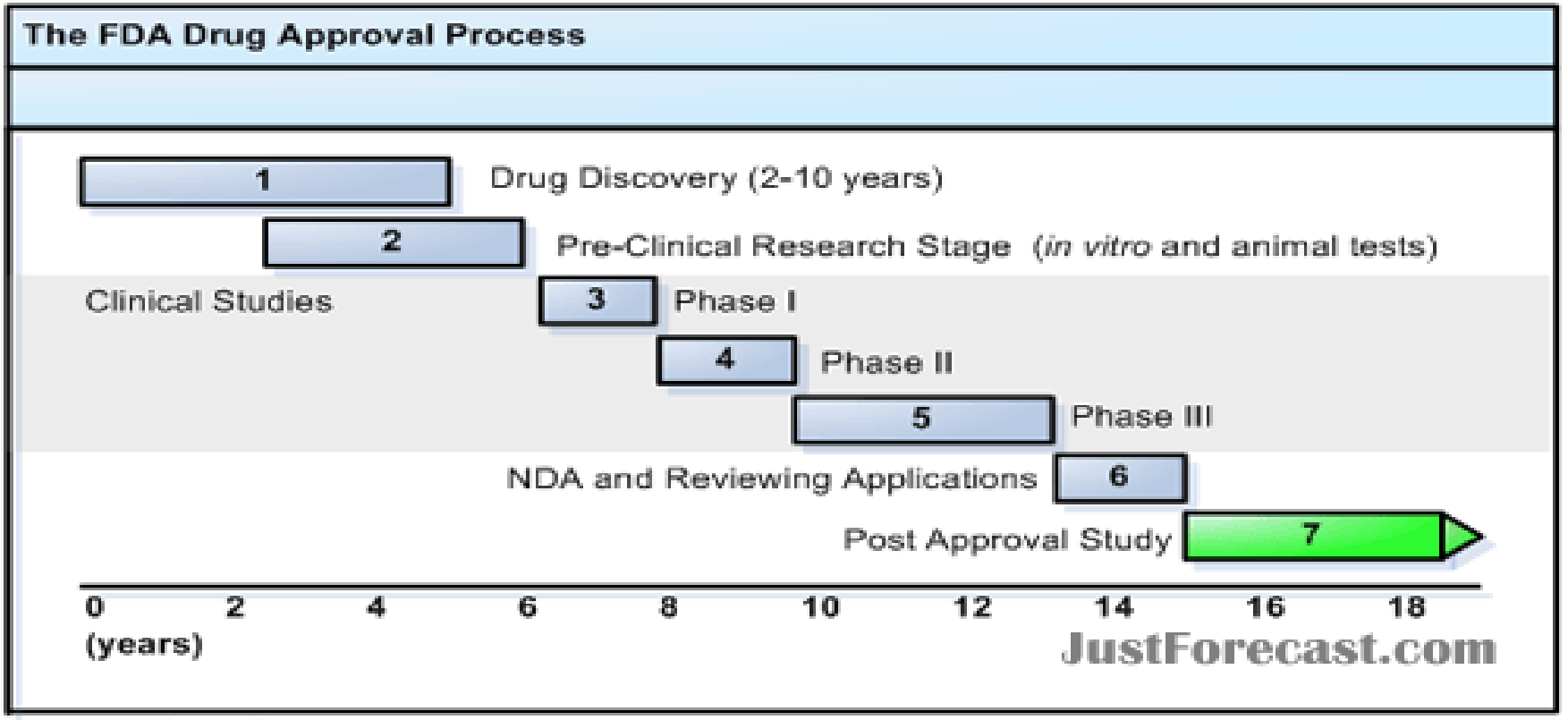


Will your product get approved?

	Chemical NME	Biologic NME
Phase I	20%	25%
Phase II	30%	35%
Phase III	67%	72%
NDA / BLA	80%	85%



How much will it take? BIG $$$$$$

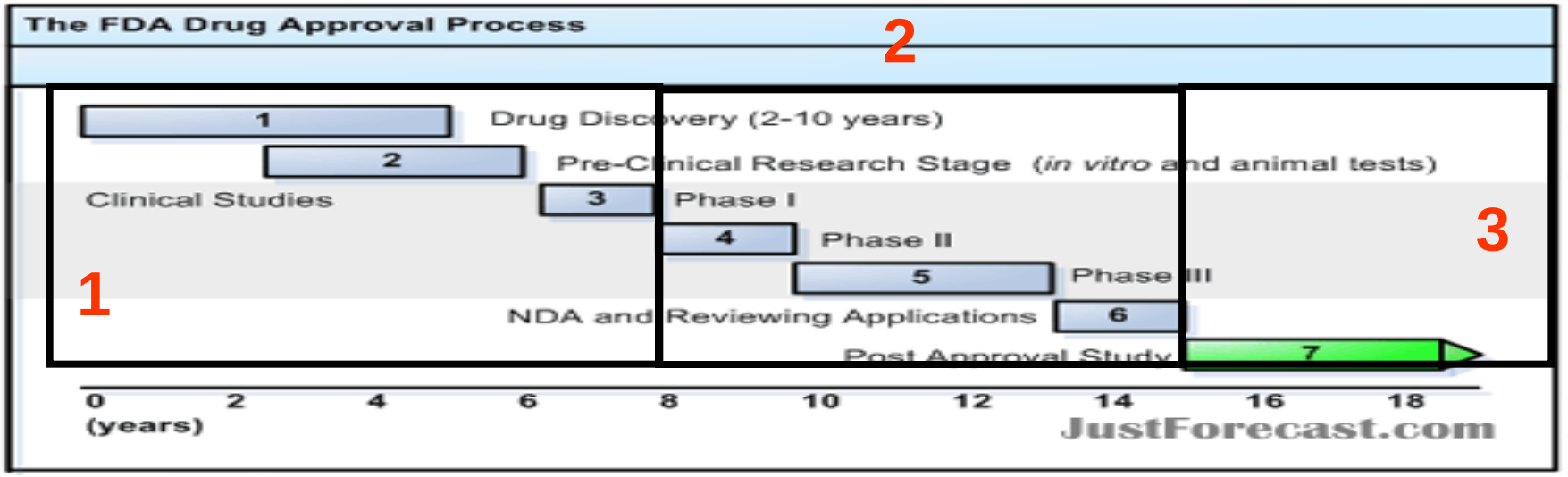


INVENTOR $ > VC $$ > BIOTECH $$$ > PHARMA $$$$

What's the right time to do the deal?

Companies may:

- Be in discovery / doing research
- Have products in development
- At commercial stage



So what structure for a deal?

- Consider "life stage" of each partner
  - Needs of seed and early stage companies cash & survival
  - Needs of companies with promising platforms
    - Cash & proof-of-concept
  - Needs of companies with promising product candidates
    - Cash & growth of infrastructure
  - Needs of the buyer vs. the seller
    - Access to products, product candidates

- Additional considerations:
  - State of the seller's portfolio
  - State of the buyer's portfolio
  - Determining value of payments
    - Risk and NPV?
    - Comparables?
    - "Loading": front end vs. back end

Deal Components - Research

- Research issues include
  - Research term, options to extend, research plan, sponsored vs. self-funded, where is the hand-off?
  - Roles and responsibilities
  - FTE commitment
  - Resource allocation and cost allocation
  - Governance

Deal Components - Development

- Development issues include
  - Development plan, compound criteria, regulatory affairs, resource commitment, roles and responsibilities, cost sharing or reimbursement procedures
  - Selection of development compounds
  - Buy-in for initial development compound vs. follow-ons

Deal Components - Commercialization

- Commercial issues include
  - Commercialization plan
  - Manufacturing
  - Resources
  - Roles and responsibilities
  - Cost sharing and reimbursement
  - Trade-offs for retained rights
  - Royalty vs. profit sharing

How To Value A Partnership

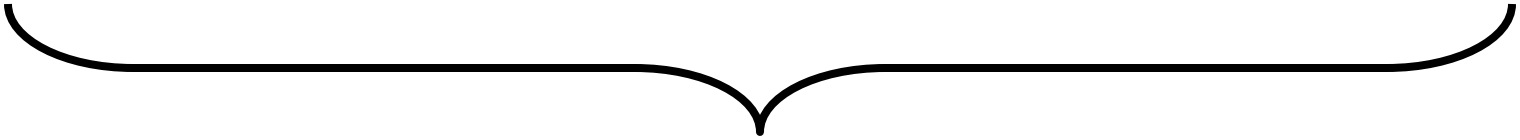
Whatever the Objectives, Need to Analyze the Value

TOO EARLY FOR VISIBILITY INTO CASH FLOWS – Make vs. Buy Approach

- Cost based approach for valuing project

CLOSE TO CASH FLOWS – NPV Analysis or IRR

- Risk adjustment



COMPARABLE TRANSACTIONS ANALYSIS

NPV-Based Approach

- Depends heavily on the following parameters:
  - Timing and amount of revenues
  - Scale and scope of costs
    - Clinical trials
    - Product development costs
    - Sales and marketing costs
  - Risk adjustment for revenues and costs
    - Probabilities of success
    - Precedented vs. novel targets
    - Therapeutic Area
    - Modality
  - Discount Rates/Cost of Capital

Detailed Inputs to Valuation

	Responsible	Deliverable	Methods	Valuation Input
Initial Business Case Objective	Review of opportunity to provide first-pass scale and basis for framing terms/negotiation			
Clinical Dev't Plan and Projected Costs	Clinical Representative	Clinical plan to achieve TPP, including size of trial(s), proposed # of sites, timing for initiation and completion, regulatory filings	• Clinical to partner with PM to incorporate feedback from regulatory, comm'l, dev't, manufacturing • Finance to partner with Clinical & PM to develop cost estimates for development program	• Projected Development Costs and Timing
PTS Assessment	Clinical Representative	Assessment of the Probability of Technical success for the relevant development phases/indications to achieve TPP	• Utilization of Industry benchmarks and internal view of development risk	• PTS % by Phase/Study
PRS Assessment	Clinical Representative working with Regulatory	Assessment of the Probability of Regulatory success for the relevant indications	• Utilization of Industry benchmarks and internal view of regulatory risk	• PRS % by Indication
Revenue Projections	Commercial Representative	Appropriate patient-based forecasting scenarios incorporating market research, etc. that incorporate share uptake, peak share, competition, dosing and other relevant factors	• Commercial to partner w/ outside vendors for mkt rsch, forecasting • Validate w/ stakeholders	• Net Sales in $'s by Indication in Excel linked to commercial assumption inputs • Units Sold if available
Commercial Costs	Commercial Representative	Projected Commercial Infrastructure for Field Force (Details/Reps) and Advertising and Promotional Efforts; Link to potential indications under development	• Commercial to utilize market analogs; Partner with Finance	• Commercial Cost Projections in $'s
Manufacturing Plan / Cost of Goods	Corporate Development (working with Tech Ops, etc.)	Revised manufacturing plan, including assessment of risks to timing, capital expense, evaluation of 3rd party partnerships. Timeline for tech transfer, scale-up, capital expenditure; also COGS estimate(s)	• Corp Dev to coordinate w/ manufacturing lead to link with commercial plan/forecast/pricing	• COGS estimate (unit basis if available – otherwise % estimate informed by Price assumption) • 3rd party Royalty % / tiers • CapEx in $'s
Financial Inputs	Finance Representative	Relevant financial assumptions for Working Capital, Tax Rates and Discount Rate	• Coordinate with relevant finance line functions	• %'s

Illustrative Discounted Cash Flow

	Net Revenue After Rebates and Discounts
-	Cost of Goods / Third Party Royalties
=	Gross Profit
-	Operating Expenses (e.g. Field Force/Marketing/Post Marketing Development)
-	R&D Costs
=	Operating Income / EBT
-	Taxes
=	Net Income After Tax
-	Changes in Working Capital
=	Free Cash Flow
x	Discount Factor (reflects time value of money)
=	Discounted Cash Flow

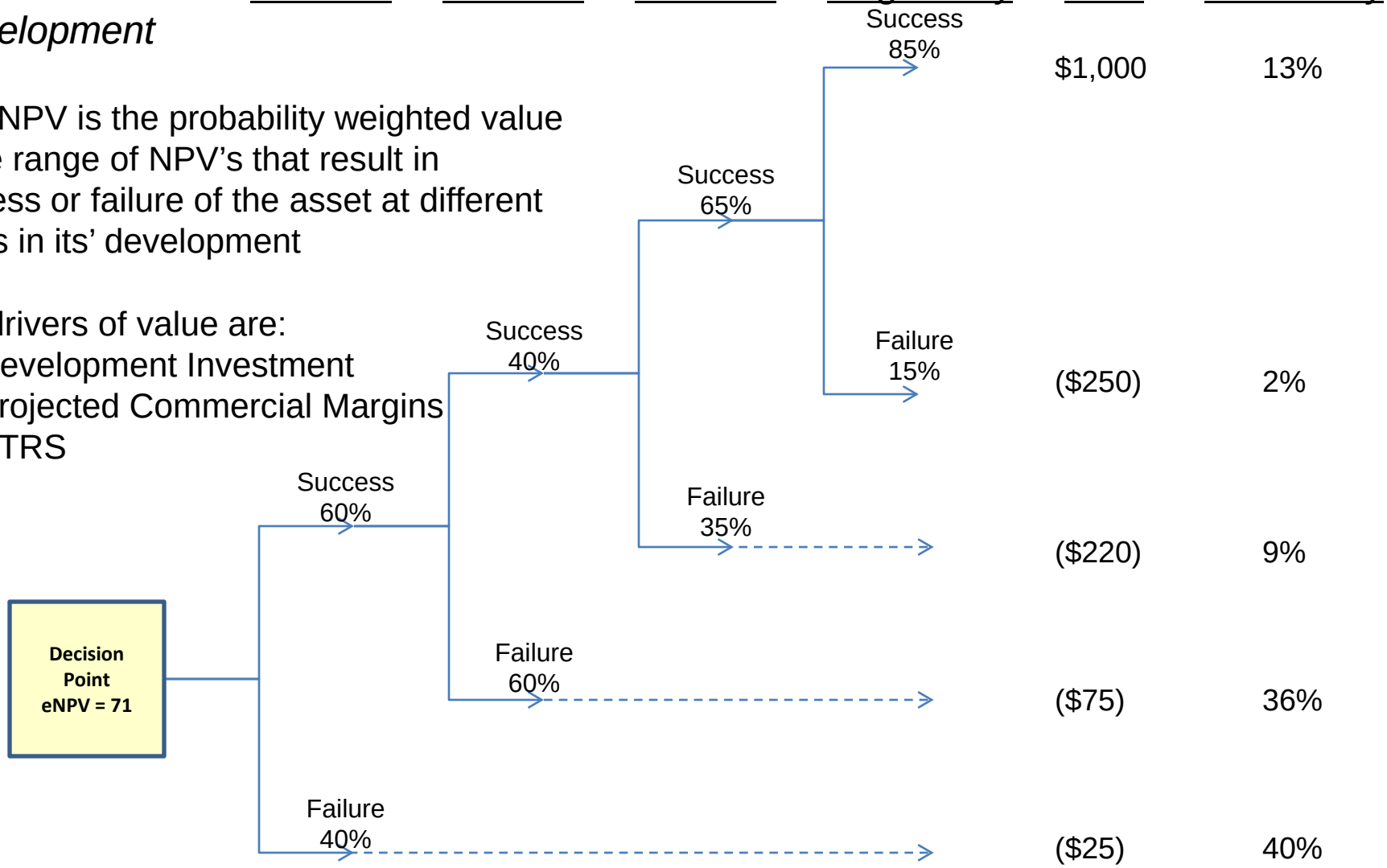
- From Net Revenue, all manufacturing, development and operating expenses are subtracted to arrive at an Operating Income for the project or business
- Taxes are calculated based upon this Pre-Tax Income to arrive at Net Income After Tax (NIAT)
- Changes in working capital reflect a difference between the time the product manufacture is initiated and payment is received for a sale. This is a timing issue rather than value creation or destruction.
- Free Cash Flow represents the actual cash received from the project/business during a specified period.
- In order to reflect the value of a project today, future cash flows are discounted back to today to account for the time value of money using the weighted average cost of capital (WACC). Each dollar in a future year is worth less than a dollar in the previous year.
- The sum of the stream of discounted cash flows reflects the Net Present Value of the opportunity (NPV)

Business Development Basics Course Valuation: Risk Adjusted View

Illustrative

The rNPV is the probability weighted value of the range of NPV's that result in success or failure of the asset at different points in its' development

Key drivers of value are:
1. Development Investment
2. Projected Commercial Margins
3. PTRS



Business Development Basics Course

Proposed deal terms split the total product pie into the respective shares for licensee/acquirer and the potential partner

Total Product Opportunity

Income Statement

Product	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Revenue													
COGS													
Gross Profit													
Operating Expenses													
R&D Expenses													
EBIT													
Taxes													
NIAT													

Cash Flow Statement

Product	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
NIAT													
Change in WC													
Free Cash Flow													

NPV	
IRR	

Deal Terms

Value to Licensee

Income Statement

Onyx	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Revenue													
COGS													
Royalties													
Gross Profit													
Operating Expenses													
R&D Expenses													
Milestone Payments													
Profit Split Payments													
EBIT													
Taxes													
NIAT													

Cash Flow Statement

Onyx	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
NIAT													
Change in WC													
Free Cash Flow													

NPV	
IRR	

Value to Partner

Income Statement

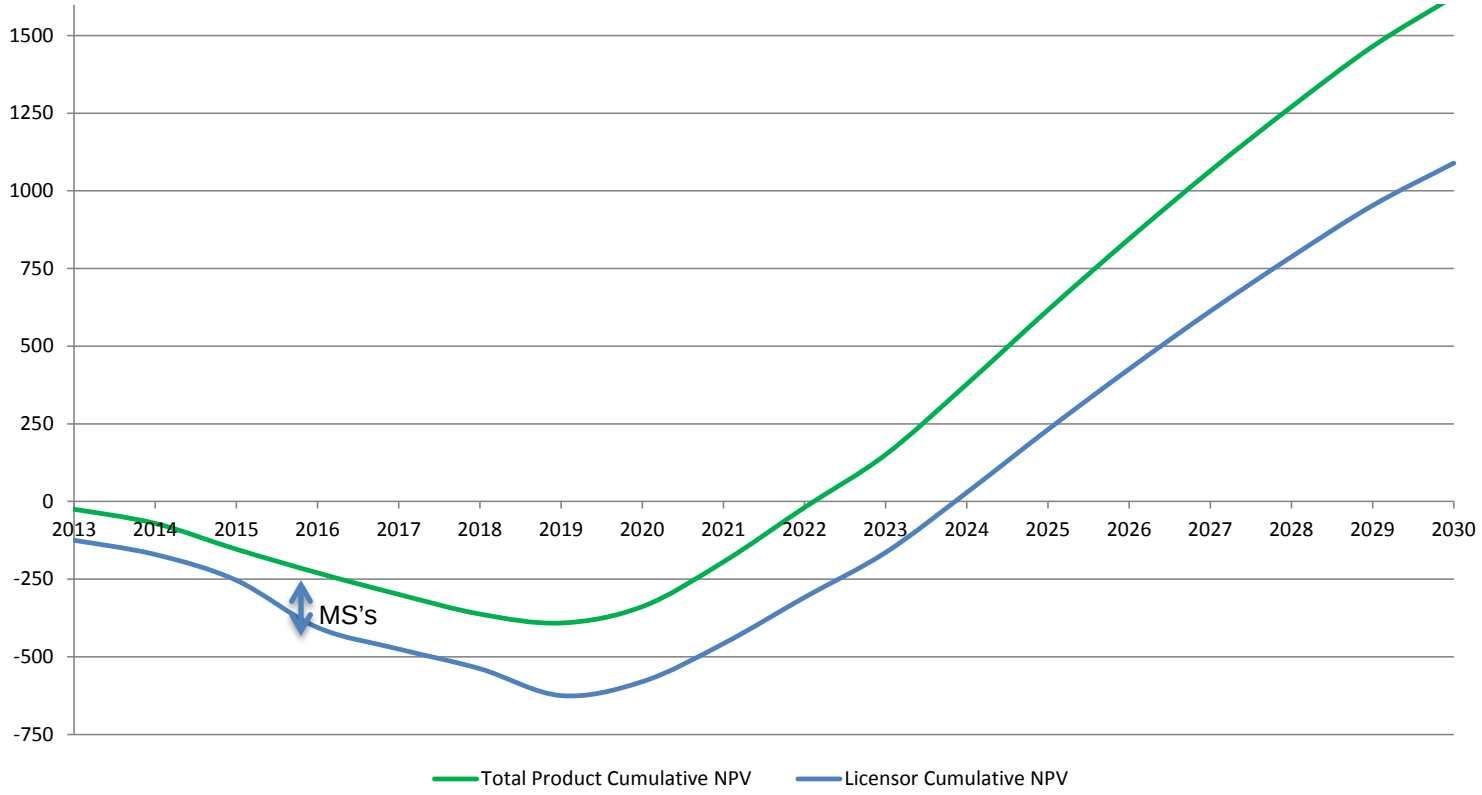
Partner	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
Revenue													
COGS													
Royalties													
Gross Profit													
Operating Expenses													
R&D Expenses													
Milestone Payments													
Profit Split Payments													
EBIT													
Taxes													
NIAT													

Cash Flow Statement

Partner	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025
NIAT													
Change in WC													
Free Cash Flow													

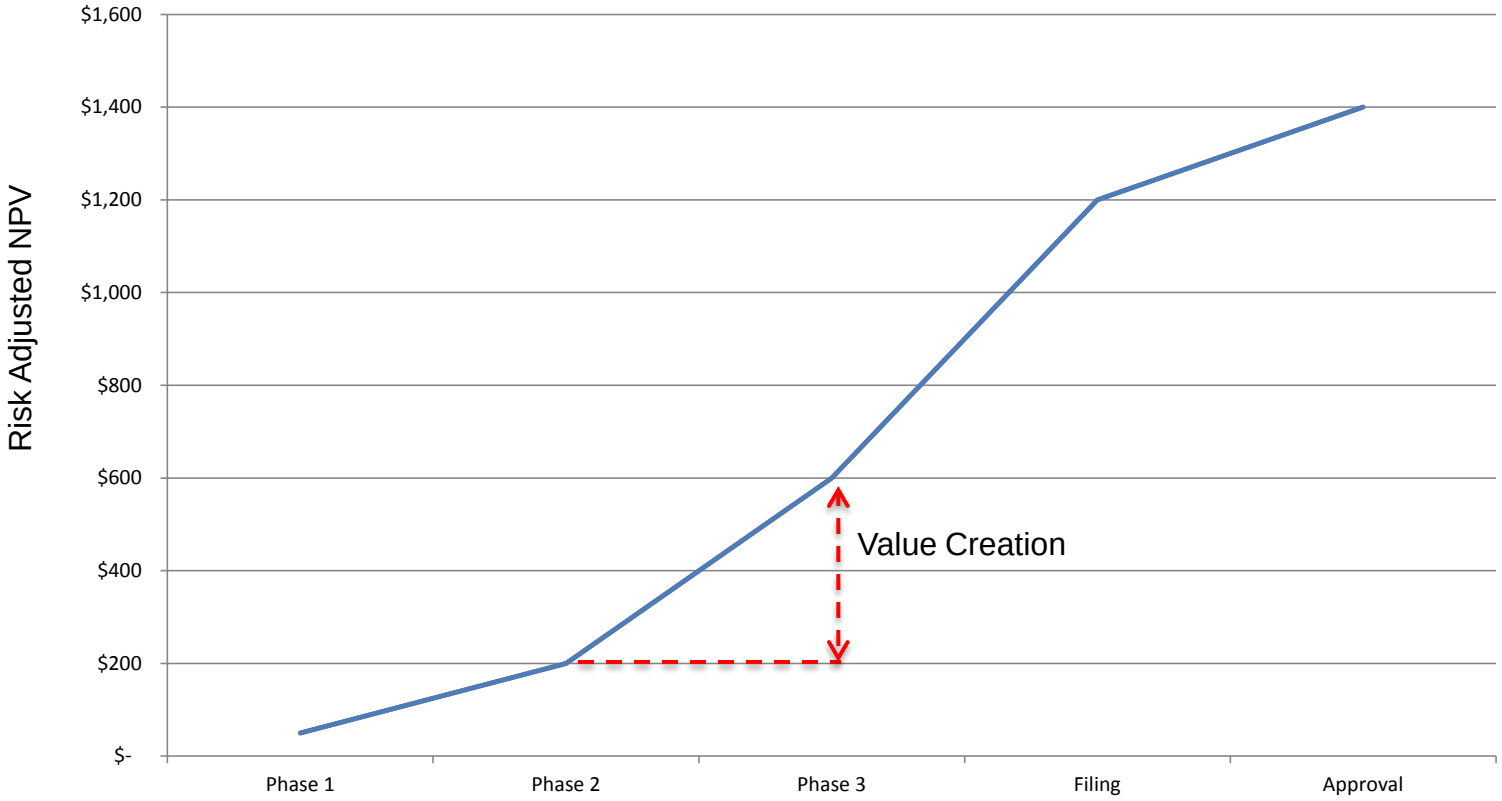
NPV	
IRR	

Cumulative NPV



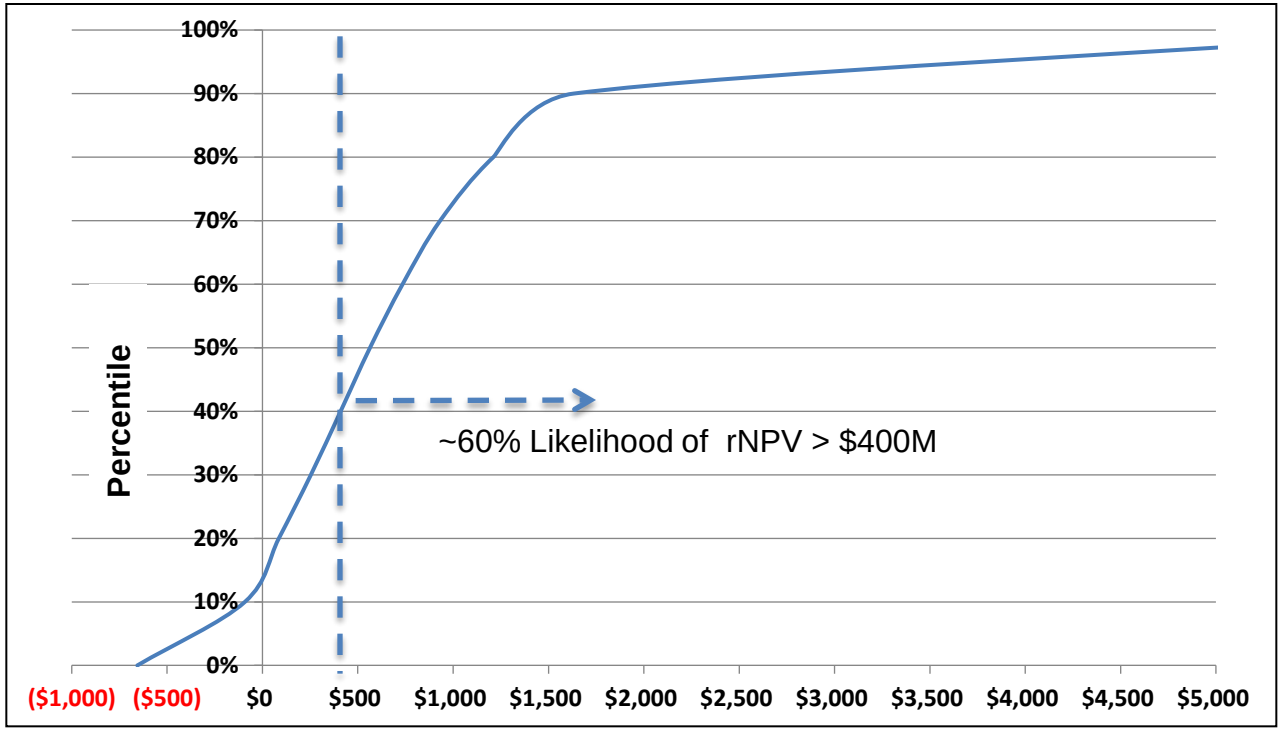
- Cumulative NPV depicts the NPV from today to a forward point in time and is a useful way to show the investment and payback over time of a particular transaction
- As a Licensor, Upfront and Development Milestone Payments increase the total forward investment and delay project profitability on a cumulative NPV basis

Risk Resolution



- As clinical risk is resolved, the value of a development stage asset is increased
- It is useful to understand the inflection points that drive significant changes in value in order to ensure milestone payments are commiserate with value created by de-risking
- The slope of the line above is indicative of greater value inflection between development phases

MONTECARLO SIMULATION IS ANOTHER TOOL TO MODEL UNCERTAINTY



Make vs. Buy Analysis

- Risk Adjusted cost estimation also depends heavily on the following parameters:
  - Probabilities of success
  - Cost of each stage of process
  - Length of time to complete each stage of process
  - Each organization's capabilities and efficiencies are different

How to Split the Pie

- Risk adjusted PV of upfront and downstream payments should compensate licensor for value of program
  - Risk adjusted PV of upfront and future payments in a 50/50 profit sharing partnership should compensate licensor for 50% of risk adjusted NPV of program
- Distribution of value between upfront and downstream payments to reflect remaining risk and upside.
  - Designed for the project to be as self-sustaining as possible

Consider Going Forward With Transaction If

- NPV Analysis
  - Risk-adjusted NPV of Asset (in buyer's hands) is sufficiently > Price of Asset, i.e., Remaining Value of Asset is sufficiently positive
- Make vs. Buy Analysis
- Financial cost of "make" + Opportunity Cost (of time and market value lost) during "make" > Cost of "Buy"

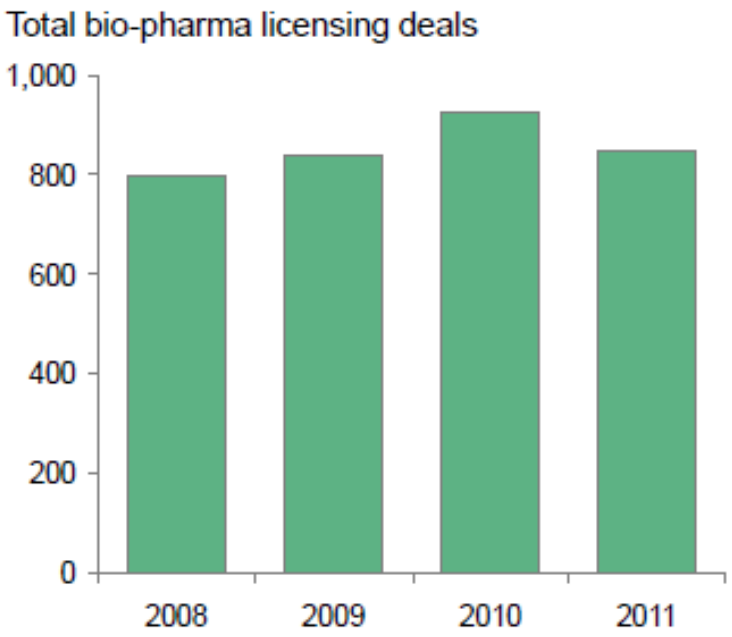
Components of Valuation

- A little analytics
  - NPV
  - Make-vs-buy
  - Comparables Analysis
- A lot of judgment
  - Synergies…is the asset a particularly good portfolio fit for a particular company
  - Does it have strategic importance?
- Painful amount of negotiation
  - Competitive dynamic
  - Structuring for a win-win outcome

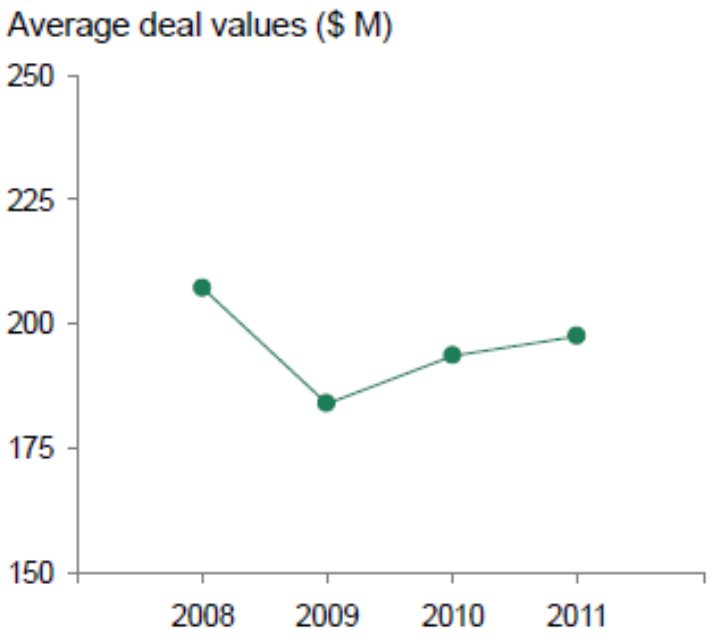
The Deal Environment and Current Metrics

Total Number of Licensing Deals and Values are Holding Steady

Number of total deals[1]

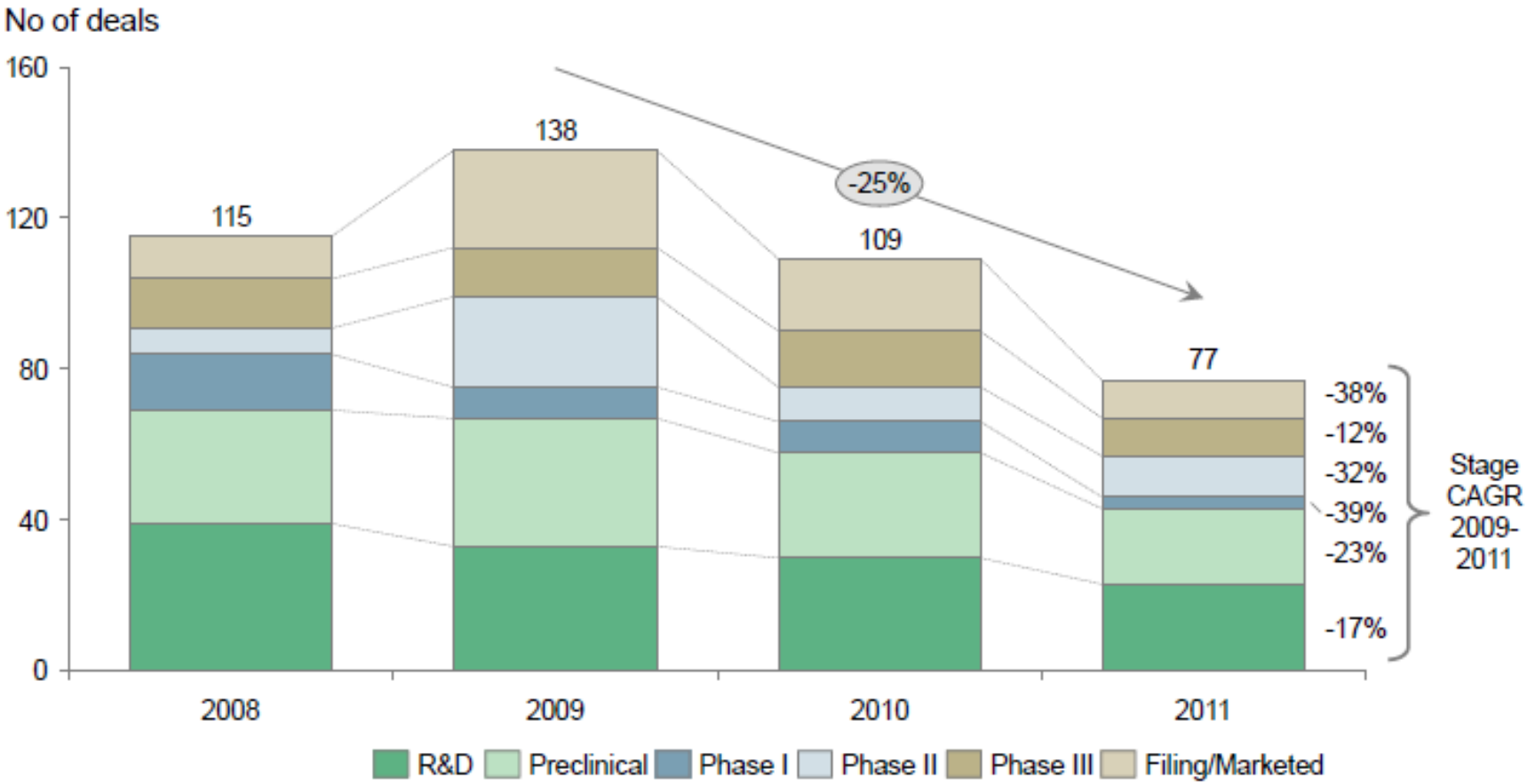


Average deal value[1]



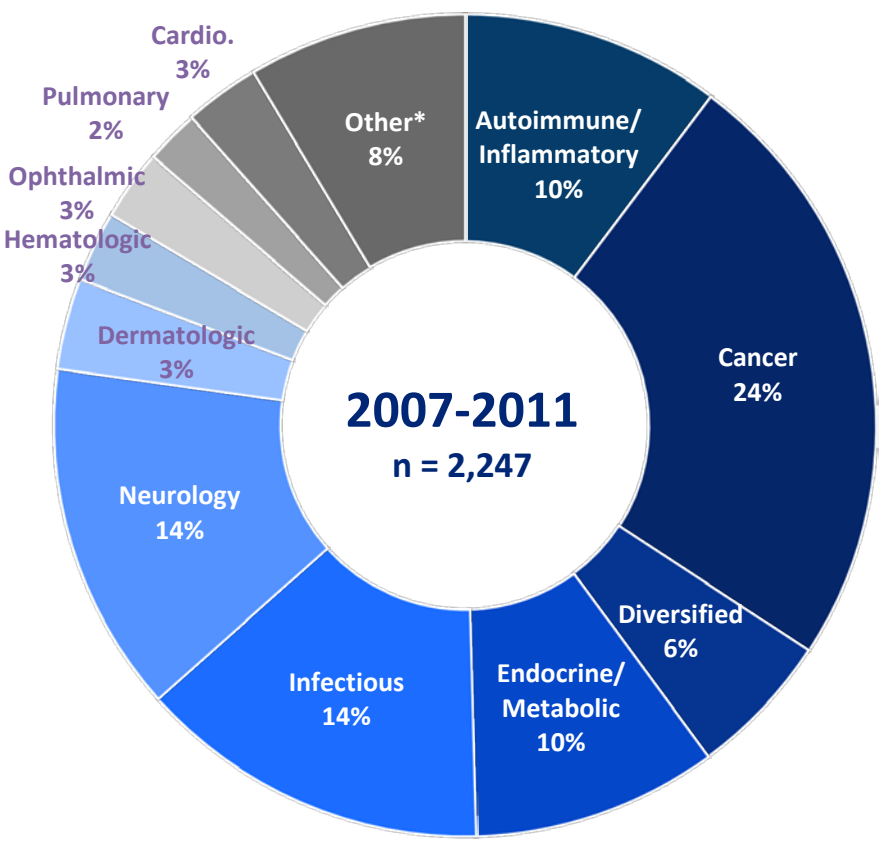
1 Average deal value and total deals taken from EvaluatePharma
Source: BCG, EvaluatePharma Licensing

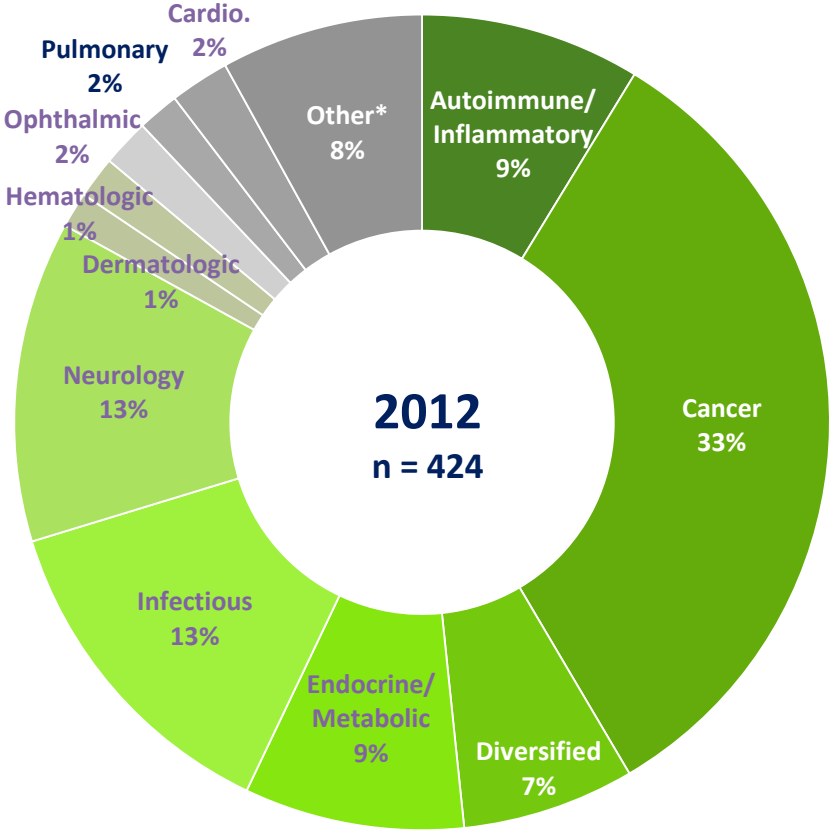
Decline in Number of Licensing Deals by Top 10 Pharma Companies



Top 10 Pharma Companies: defined by highest 2011 sales: Abbott, AZ, Eli Lilly, GSK, J&J, Merck, Novartis, Pfizer, Roche, Sanofi
Source: BCG, EvaluatePharma Licensing

TA Distribution of Licenses Shows Even stronger focus on oncology in 2012

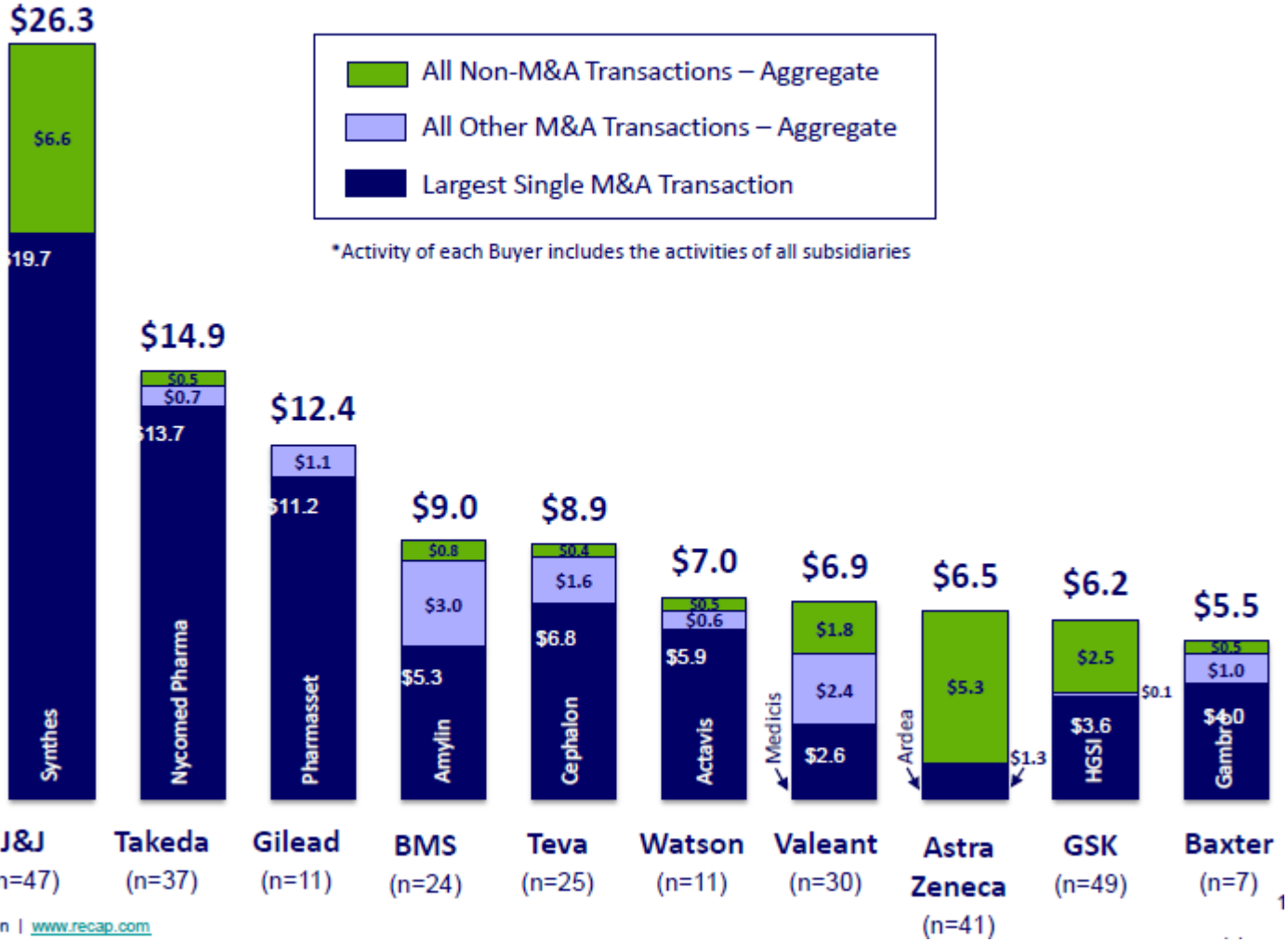




*omits 432 and 104 licensing deals for 2007-2011 and 2012, respectively, for which a therapeutic area was not applicable or not disclosed

Source: The Deloitte Recap of 2012 Deals

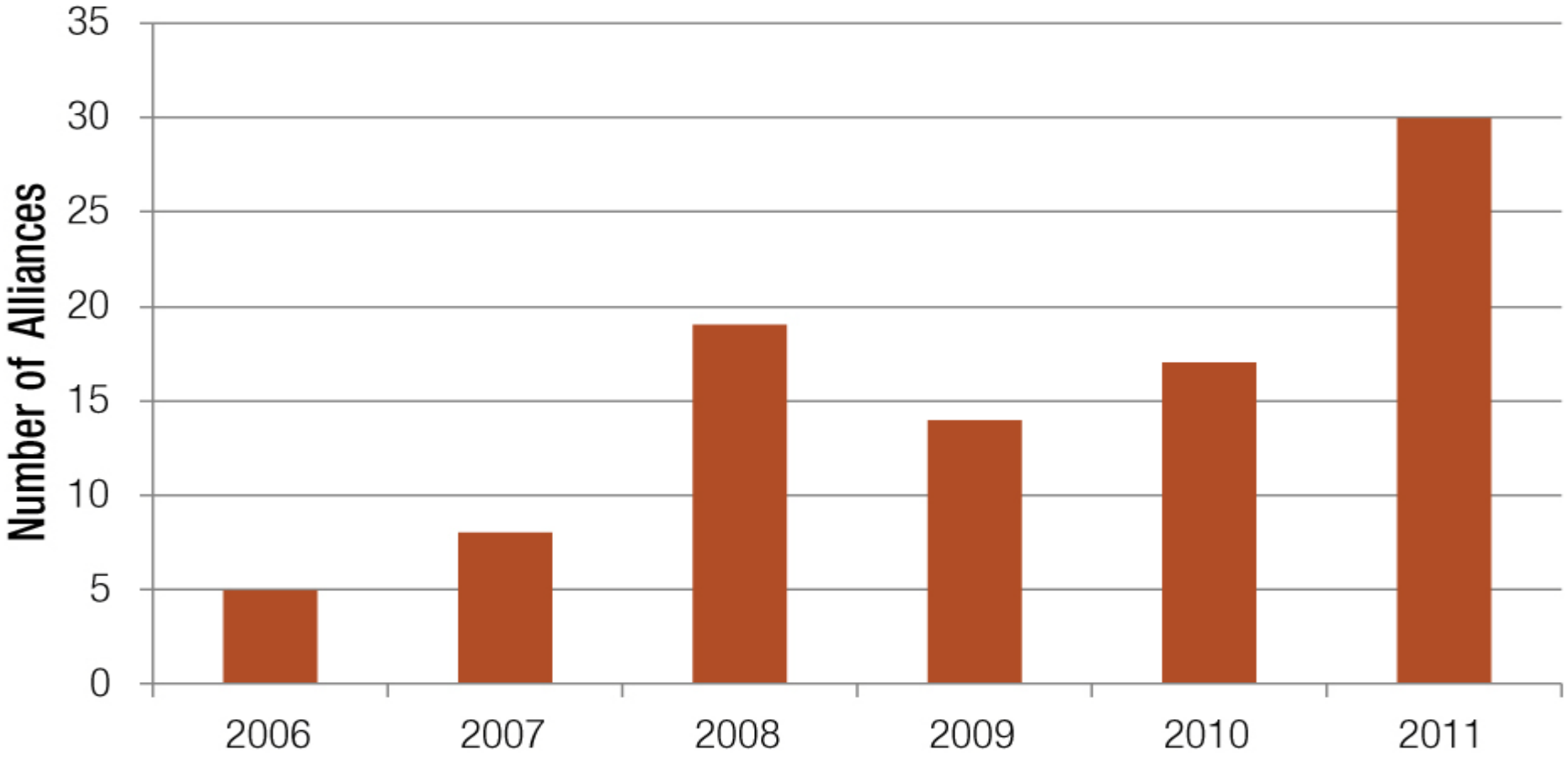
Top Buyers* in 2011 & 2012 by Aggregate Disclosed Deal Size ($B)



ght into Action | www.recap.com

Source: Deloitte Recap

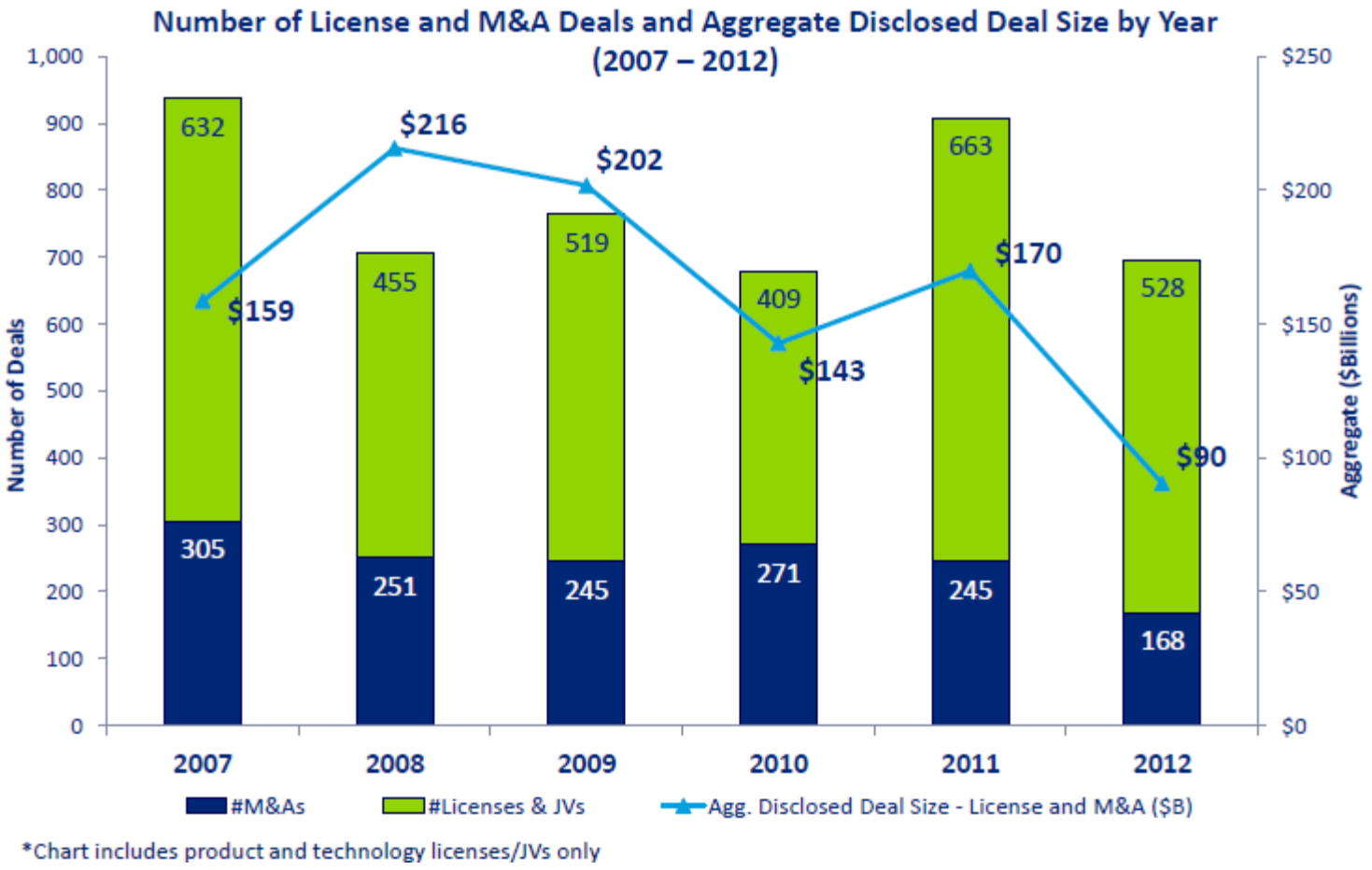
Deals between Big Pharma & Academia are Rising



Source: Elsevier Strategic Transactions

Business Development Basics Course

Life Science Licensing and M&A Trends 2007-2012

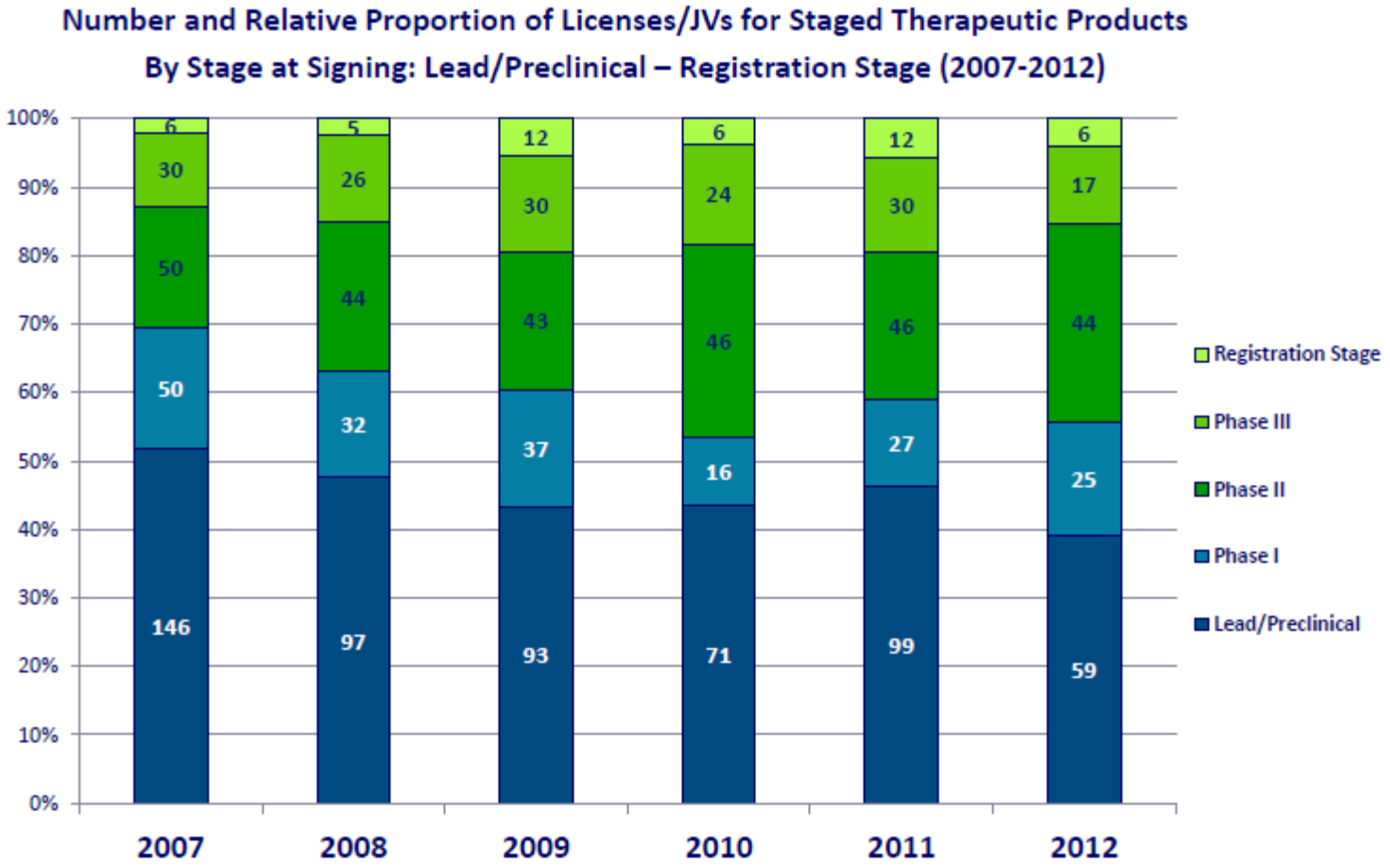


Source: Deloitte Recap

Distribution of Product Deals by Stage 2007-2012

by Deloitte.

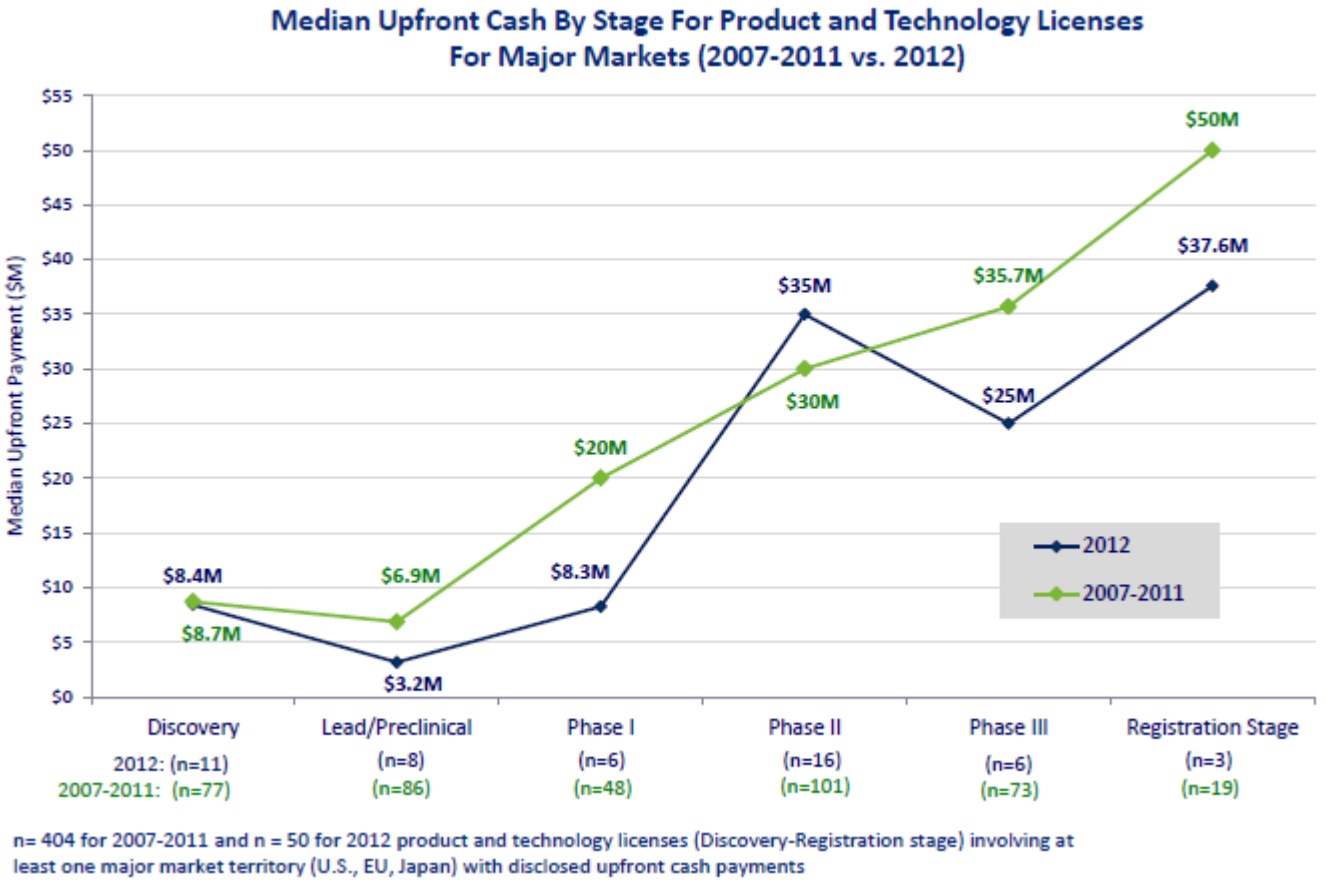
The proportion of late-stage deals has increased since 2007



Source: Deloitte Recap

Deal Upfront Payments

A seller's market for Phase II assets in 2012

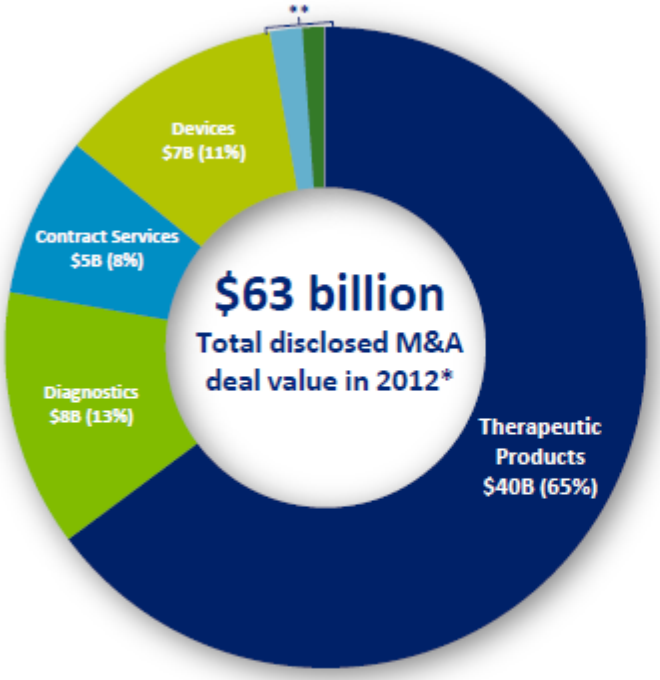


n= 404 for 2007-2011 and n = 50 for 2012 product and technology licenses (Discovery-Registration stage) involving at least one major market territory (U.S., EU, Japan) with disclosed upfront cash payments

Source: Deloitte Recap LLC

2012 M&A Activity

2012 M&A Deals by Market Segment



* 90 of the 168 M&A transactions in 2012 disclosed values – the total disclosed value was $63 billion; Letters of intent and terminated M&A offers excluded

**Technology platform and instrument and software companies

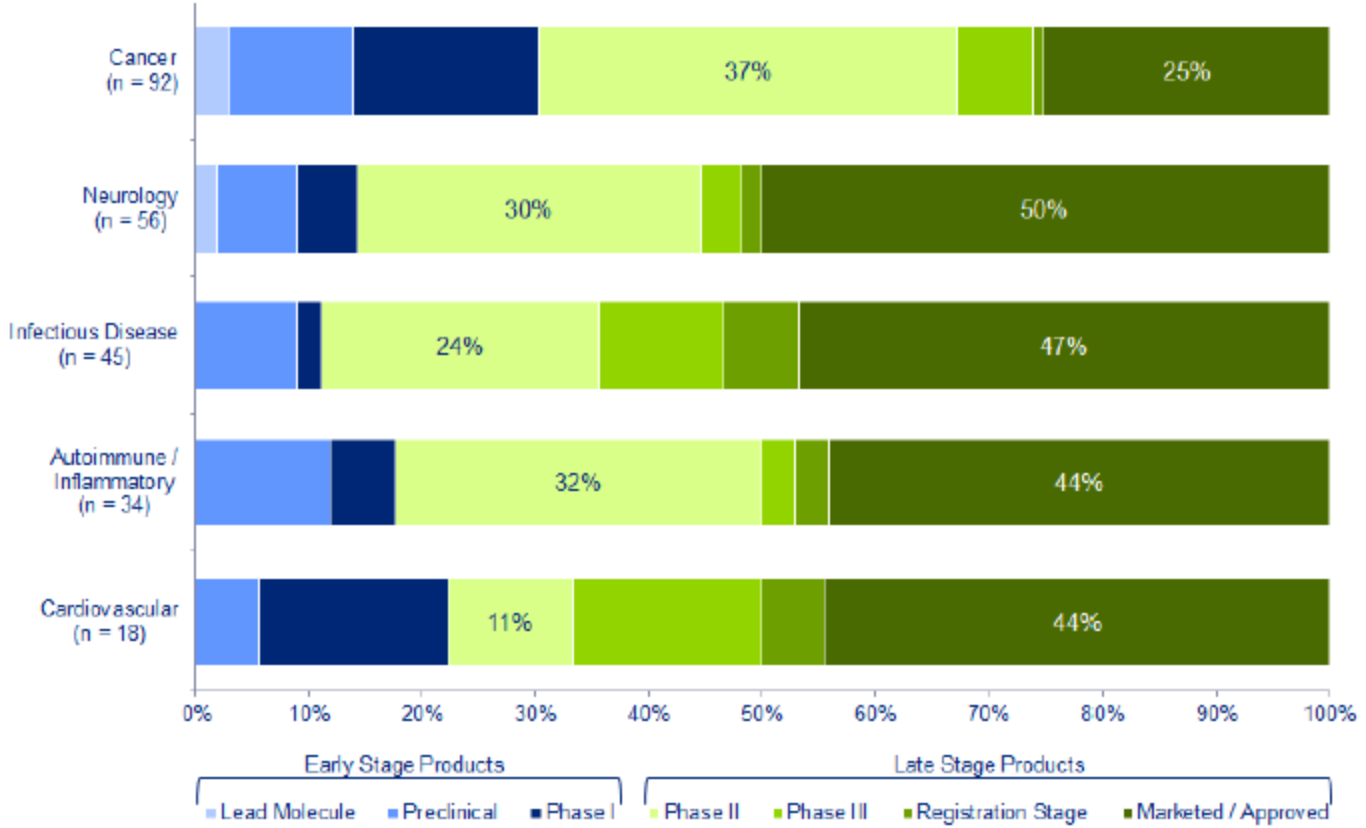
2012 Top Five Therapeutic Areas by Deal Size

Therapeutic Area	Number of Deals	Agg. Total Deal Size	Average Deal Size
Diversified/Broad Focus	10	$9.7B	$1.4B
Endocrine/Metabolic	6	$7.4B	$1.9B
Cancer	10	$5.6B	$807M
Dermatologic	5	$5.5B	$1.1B
Autoimmune/ Inflammatory	3	$3.7B	$1.8B

Source: Deloitte Recap

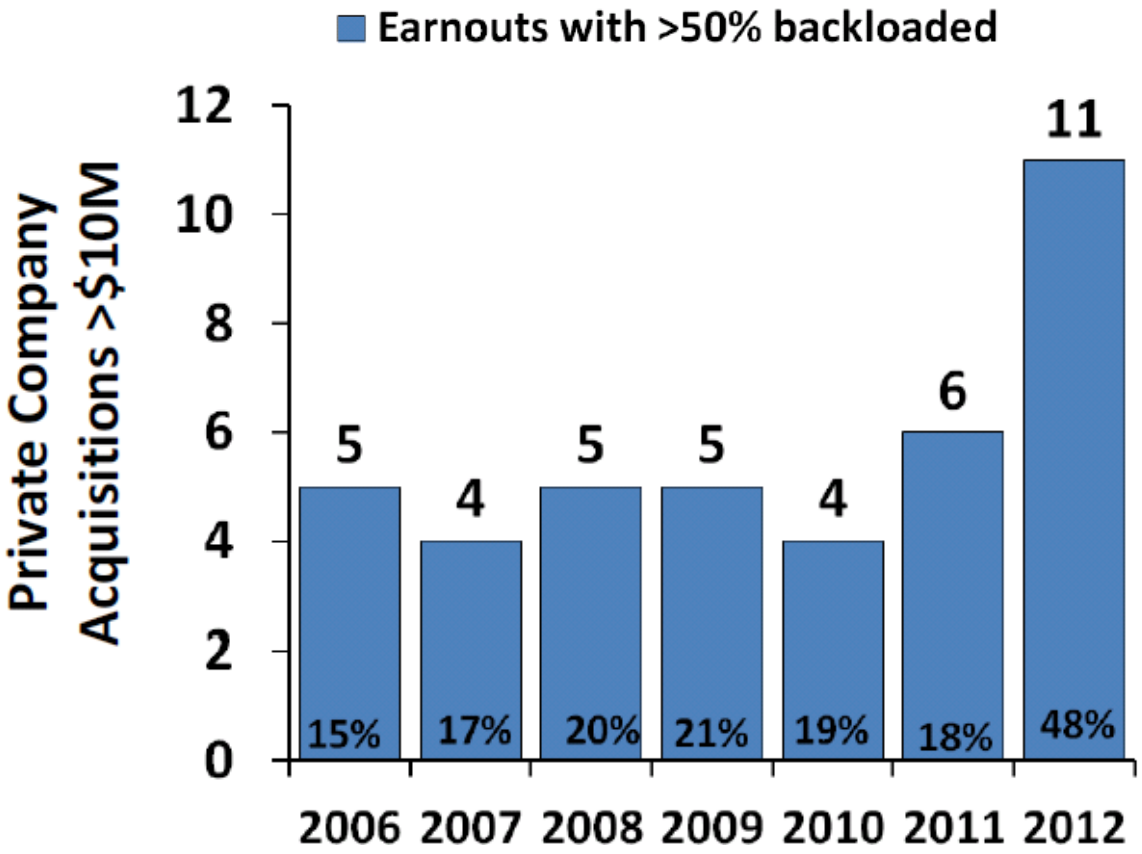
M&A Activity

Top 5 Therapeutic Areas: % Distribution of M&A by Development Stage, 2005-2011



Source: Deloitte Recap

Earnouts from M&A Deals Have Become More Back-ended



Source: BIO Industry Analysis, Elsevier Database

The Deal Process

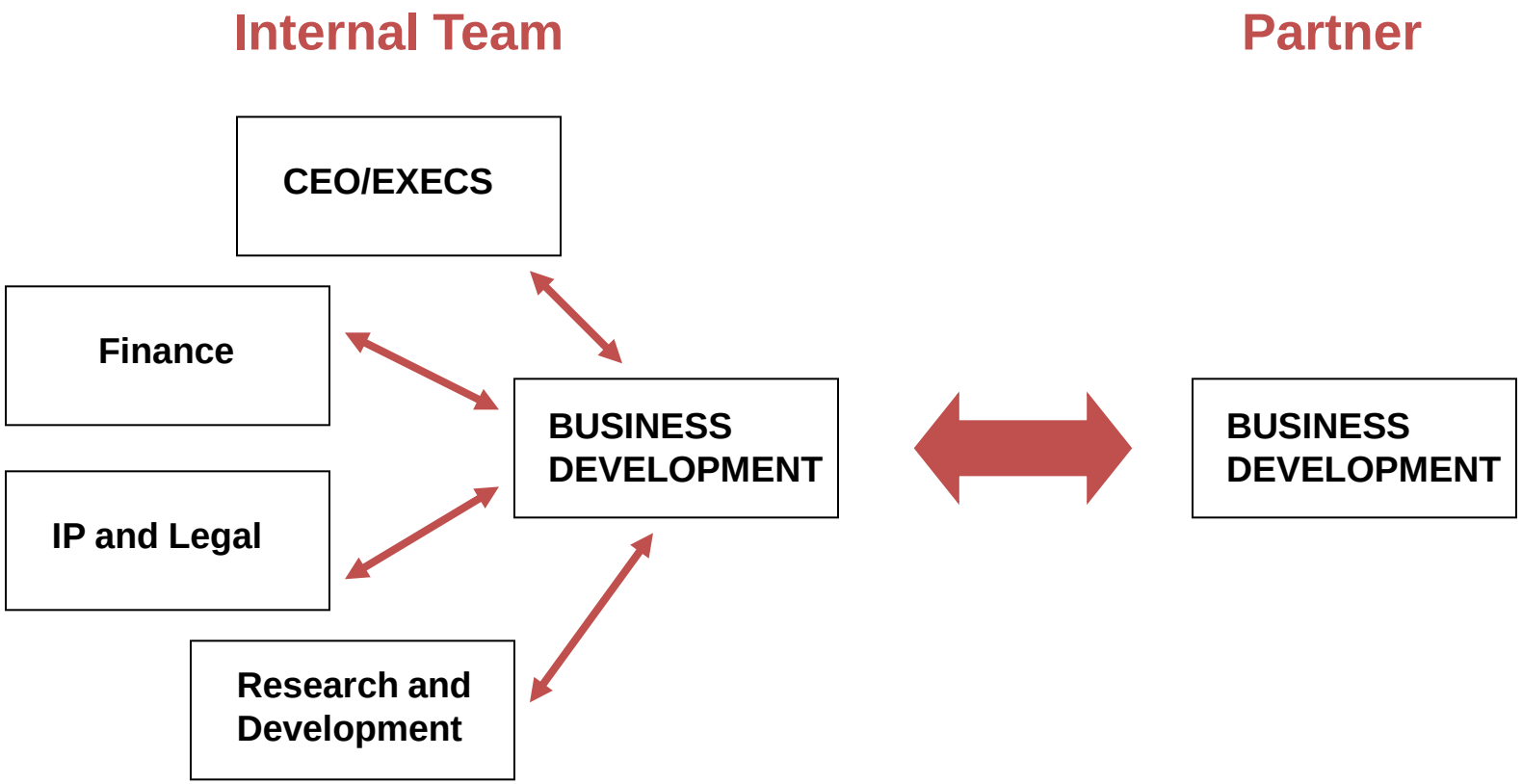
The Business Development Role

- Identify opportunity
- Develop the negotiation strategy
- Manage the negotiation process
- Identify and resolve key issues early, if possible
- Drive process and maintain momentum
- Provide access to high level decisionmakers
- Facilitate meetings
  - Scientific and commercial
  - Due diligence and operational
- Close the deal

Outline

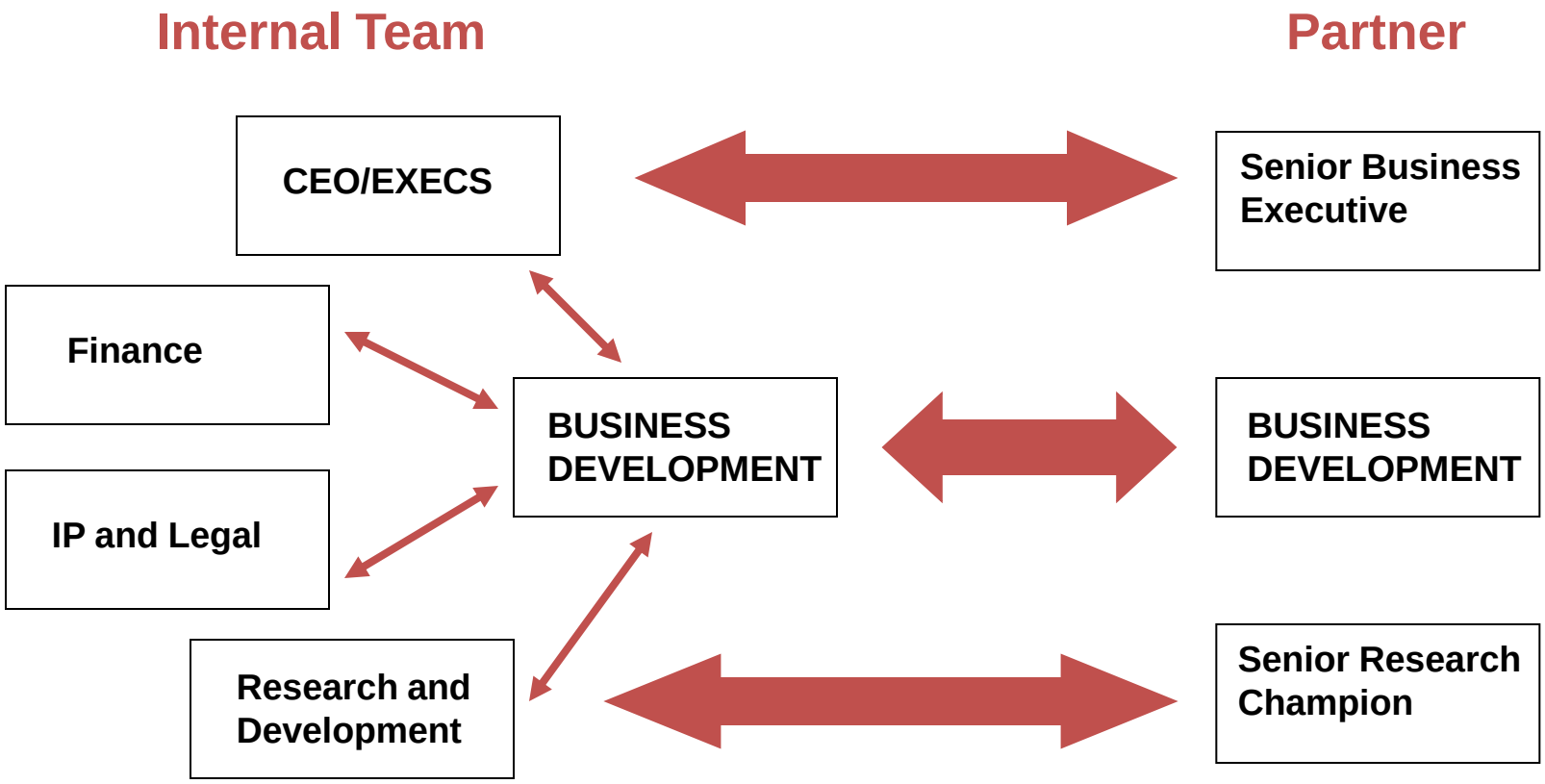
- Preparation and planning
- Components of the process
- Communication is key!

Here's how it's thought of



Here's how it ought to be!

A *coordinated message* backed up by relationship building will help close the deal



Getting Started

- Define the objectives of the deal (corporate strategy)
- Plan for timing – when does it need to be done?
- Have an internal communication plan
- Identify potential partners
- Prepare non-confidential package and confidential packages
- Begin preparing due diligence materials

Internal Corporate Objectives and Planning

- Define the primary purpose for partnering
- Weighting of purposes is important
  - Cash
  - Experience in pre-clinical or clinical development
  - Commercialization
- Define the market opportunity – be realistic, ask experts
  - Elaborate the commercial potential
  - Understand the competition, potential differentiators
  - Develop a financial model and understand how changing the numbers changes the profit sharing between licensor and licensee
- Create a communication plan within the company so the message is always the same
- Identify potential partners
  - Do your homework and prioritize
  - Rolodex and conferences
  - NOT “blast e-mail” solicitations!

Components that are Early in the Deal Process

- Build the relationship
- Utilize your non-confidential package
  - Have all relevant publications, patents, posters, etc. ready in form to send out upon request so your partners don't have to track them down (PDF is best)
- Negotiate a CDA
  - Do this quickly and efficiently (if this is slow, then things are already bad!)
- Have your confidential package ready
  - Any pre-clinical studies in organized form
    - Executive summaries for each section are important
    - Again, PDF is probably best
  - Try to anticipate the questions
- Balancing act between providing enough information to understand the opportunity, while not overwhelming reviewers with too much
- Be careful with really sensitive stuff (e.g. you may not want to disclose compound structures until the deal is actually close to signing!)
- Rough term sheet discussions can occur (very rough)
  - Think in terms of structure, not the numbers (not yet!)

Components that are in the Middle of the Deal Process

- Build the relationship
- MTA (if a “taste spoon” is appropriate)
  - This should be done quickly but carefully if a deal is contingent upon the outcome of experiments
- Detailed due diligence
- Negotiating terms (Field, Territory, Scope, etc.)
- Sell the deal internally
  - Get clarity on deal-stopper issues
  - Inform executive management of progress and identity of partner
- Manage to a short list of issues
  - Ideally the non-binding term sheet is agreed to in full by the end of this process (subject to completion of due diligence and executive management approval)
- Start writing any research, development or commercialization plans that need to accompany the contract

Components that are Late in the Deal Process

- Build the relationship
- Finalize diligence
  - This would include assuring that the patent ownership or registration is correct and valid
  - Providing final scientific updates if the process has taken a long time
- Negotiate the contract (do as much of the drafting yourself whenever possible)
- Refine the research, development or commercialization plans
- Final approvals – know what approvals are necessary and plan for them
- CLOSE the deal!

What is “Due Diligence”?

- Due diligence is the potential partner’s process of “getting under the hood” of your company/program
- Due diligence will be performed on several different fronts
  - Intellectual property
  - Technical (Science, Compound, Facilities)
  - Legal
  - Financial
- Due diligence is perhaps the key to the entire process
  - It shows both your ability to be prepared and professional as well as that of the potential partner
  - Learn from it
  - Do not become defensive
  - Be very responsive

Due Diligence – Intellectual Property

- Intellectual property due diligence
  - Have invention disclosure system ready
  - Have all applications and patents and their status and prosecution history well organized in spread sheets
  - Have a document room ready with all relevant files
  - Exclude any opinions (e.g. FTO)
  - In the best case, have IP counsel “on call” to take questions

Due Diligence – Science and Materials

- Ask the potential partner for a list of questions and documents in order to prepare
- Organize all reports and protocols and have them in the diligence room
- *Convene <u>your</u> team AHEAD of time*
  - Discuss what each person's assignment will be
  - Are there any "off-limit" topics?
  - Answer only the questions asked
  - Encourage them to stick to the facts that they can back-up with evidence
- Tell your team members that it is better to say "I don't know" or to come get you if they don't know whether they should answer

Due Diligence – Hosting Site Visits

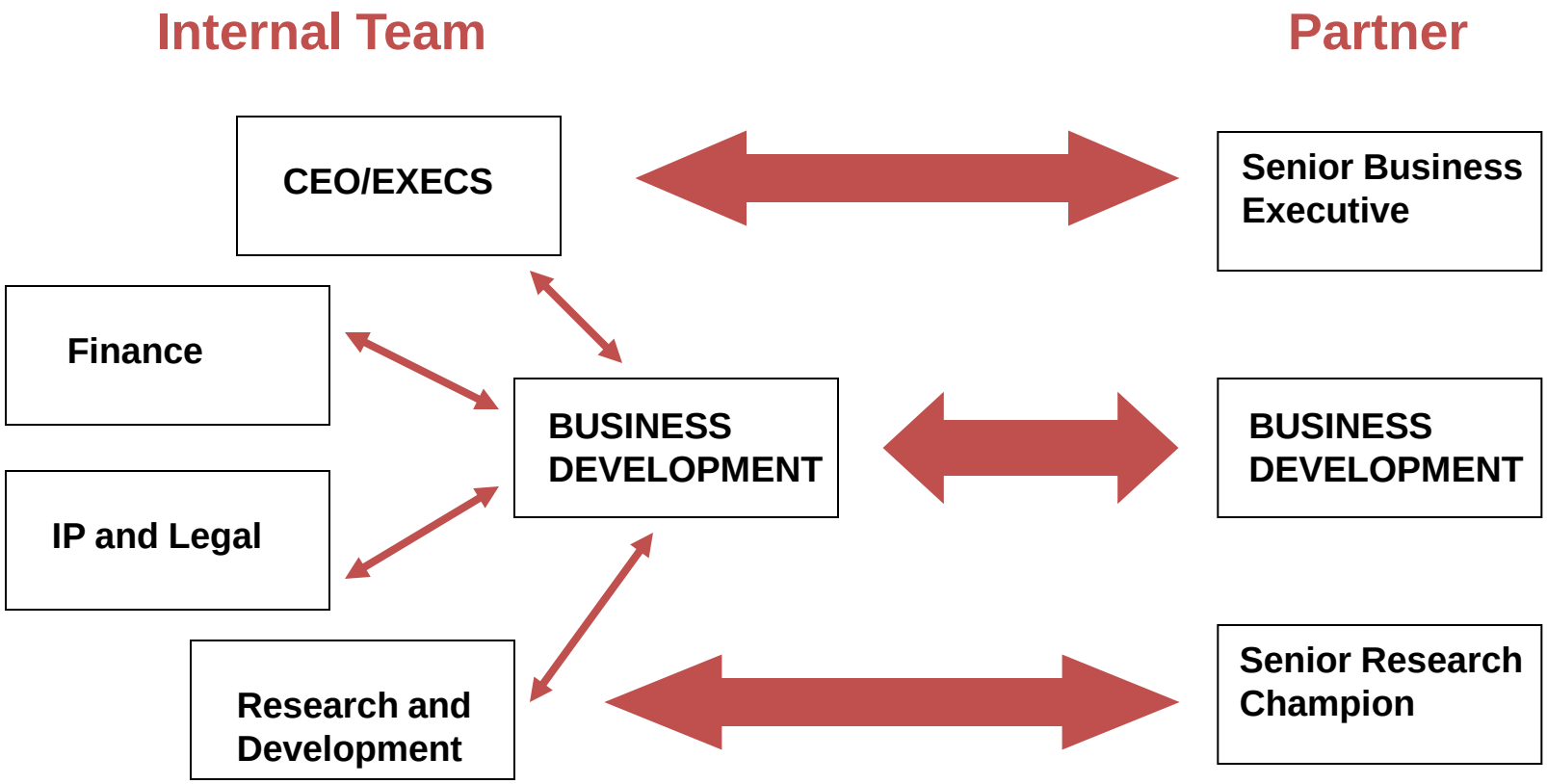
- YOU are in charge
- Offer to arrange their stay and transportation to and from a hotel if needed
- Offer to take them out for dinner with your team (begin to build the longer term relationship)
- Ensure that everyone looks professional for the first day
- Have food and drink ready for your guests
- Give them privacy
- Make sure the labs are cleaned and offices are organized (if their team will be visiting any offices)
- Make sure all white-boards are clean and the meeting room doesn‘t have any left over notes on tables or shelves
- Make sure you and they understand your policy on copies of documents being removed from the building
- Check on progress but don’t hover around your guests

Electronic Data Rooms

- Becoming more and more common
- Advantages:
  - Easy to organize materials and add documents
  - Can track what documents are reviewed and by whom
  - Can have multiple companies reviewing information simultaneously
  - Sometime speeds process
- Disadvantages:
  - Lose some (all?) of the face-to-face interactions
  - Questions don't necessarily get asked as readily – opportunity to correct misunderstandings may be missed
- Be sure to think about how you incorporate an electronic data room in the context of your deal
  - Can make a lot of sense in a competitive deal, one where there is a lot of data, as well as one that strictly licensing
  - Consider still having a face-to-face diligence visit to answer questions and develop relationships

Don't forget!

A *coordinated message* backed up by relationship building will help close the deal



Getting the deal approved

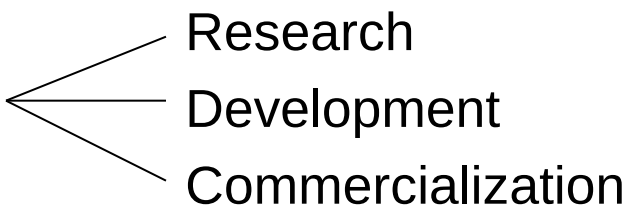
- Internal approval
  - Is everyone on board?
  - Understanding of each person‘s role to make the deal succeed?
- Shareholder approval
  - Board of Directors and shareholder rights (vetos etc)
  - Have you aligned interests of VCs, others and company?
- Wall Street
  - Pre-FDA approval programs are question marks
  - Early stage programs can be viewed as liabilities
- Post-signing
  - Shareholder perspectives might change

Formal Deal Process

- A formal deal process (or auction) with deadlines for key activities, such as term sheets & diligence, can help drive competition that will maximize deal value and speed time to close
- Not all deals are well suited
  - Need true competition for the asset – 4 or more potential partners moving forward with serious discussions
- Do not declare a process prematurely
  - A failed process (no one meeting the deadlines you impose) is much worse than not having one at all
- Make sure to be realistic in timeframes
- Communicate clearly & consistently

Launching the Operating Relationship

- Joint Steering Committees
- Project Teams
- Work plans



Joint Steering Committees

- Oversight for the collaboration
- Typically equal numbers of appropriately senior representatives
  - Most often 3+3
  - “Senior” most often means Directors and VPs
- Responsibilities
  - General oversight
  - Resource allocation decisions/approvals
  - Setting of goals/Determination of success
  - Authorizing 3rd party engagements (e.g. academic labs, CROs, etc.)
  - Resolving disagreements
- Typically meet on a quarterly basis

Dispute Resolution

- The contract will usually say…
  - JSC to resolve disputes
  - Failing that, escalation to senior executives
  - Failing that, typically either of binding arbitration or the more powerful party has final say
- The reality…
  - Should really be handled by the JSC
  - If not, try again… really hard!
  - If still not resolved then… you've probably got a major problem and the contract mechanism may not help
  - That's why relationship-building is so important

Project Teams

- This is the where the real work gets done
- Membership really depends on the stage of the program
- Core members
  - Project leaders (one from each side)
    - Senior Scientist or Clinician
  - Research Scientists/Research Associates
  - DMPK/Toxicology
  - Clinical
  - Regulatory
  - Manufacturing
  - Program manager
- Others?
  - Alliance manager/Business Development (as needed)
  - IP manager/counsel (as needed)
  - Corporate communications (on rare occasion?)

Project Team Activities

- Draft the project work-plan and update as required
  - Align scientific reality with business objectives
  - Make clear assignments of roles and responsibilities
  - Are the resource allocations appropriate?
  - Is the timeframe appropriate?
  - Does plan account for expected timing of milestone events?
  - Have the parties agreed to success criteria so that you'll know when the milestone has been met?
- Meet regularly to review activities/data
  - Weekly or fortnightly are typical
  - Keep minutes/Track action items
- Report to the JSC
  - Informal updates as often as warranted ("managing up")
  - Formal presentations (at the quarterly meeting)

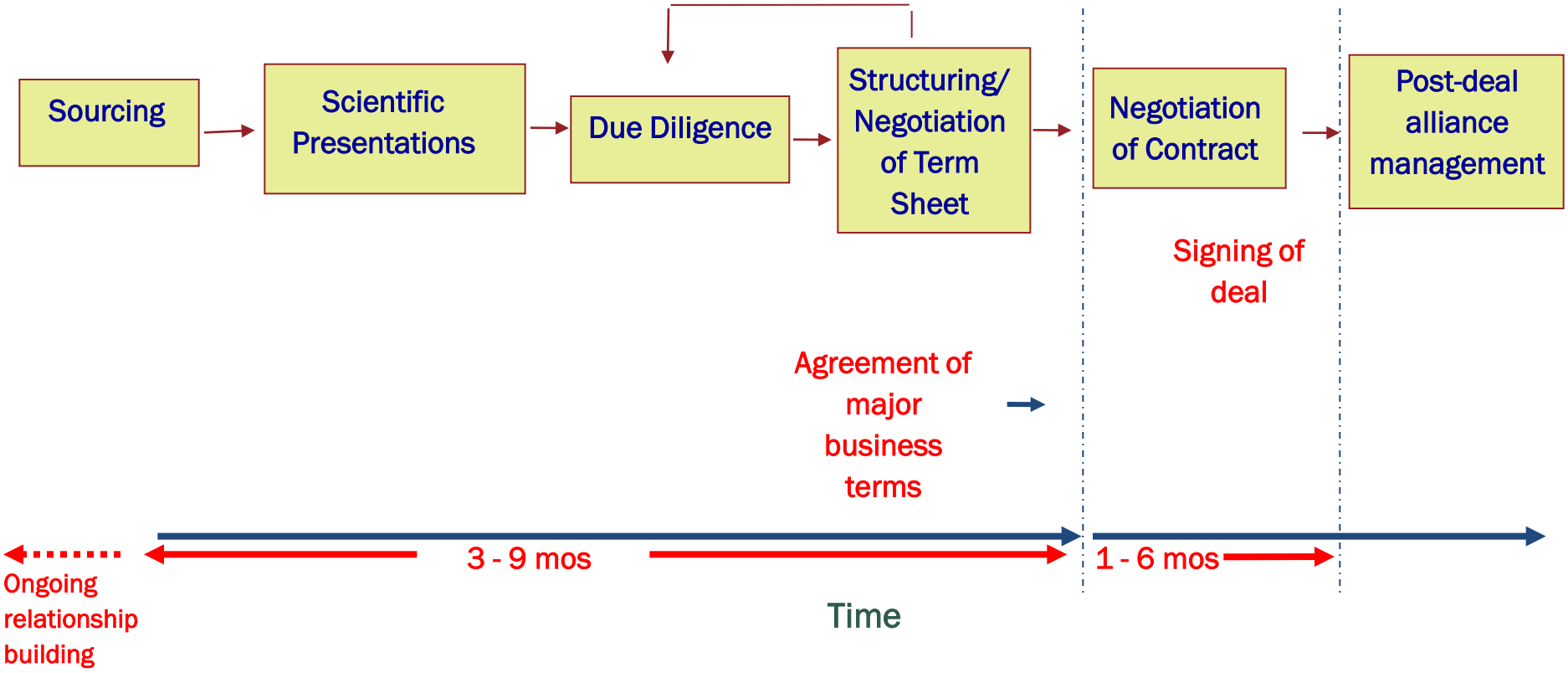
Intellectual Property

- The easy part:
  - What was mine is mine…
  - What was yours is yours…
- What about the new inventions arising under the collaboration
  - Ownership usually follows inventorship
    - Solely-owned vs. jointly-owned
  - How and what to share
    - For the project at hand, a good contract should allow open sharing
    - The tricky part has to do with new IP that a party may want to use *outside* of the partnership
  - How do IP terms affect behavior?

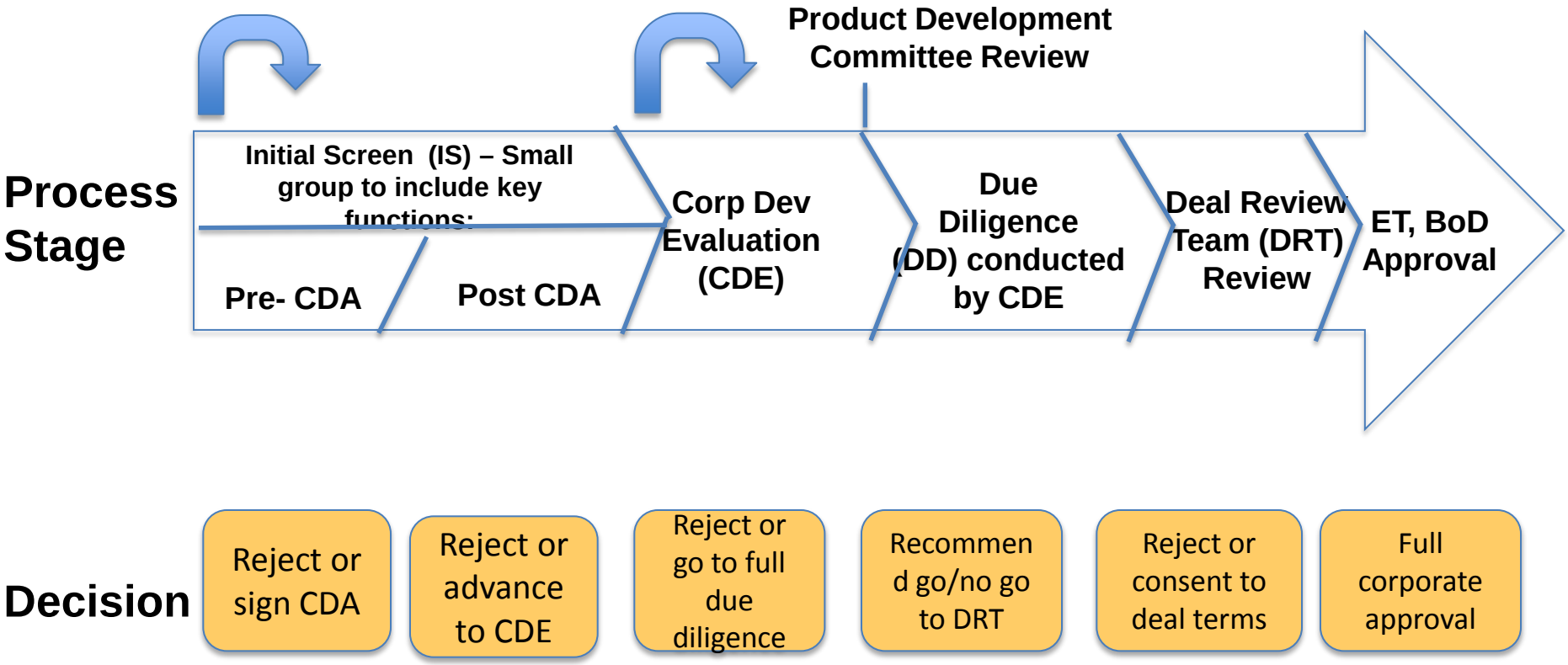
Planning for success

- When to think like a “lawyer”
  - A well-drafted agreement must anticipate worst case scenarios
  - However, a well-drafted agreement should promote positive behavior
- Practical approaches
  - Draft good work plans and communicate the goals upward regularly
  - Meet regularly with your counterparts and build the human side of the relationship
  - Remember that no agreement can anticipate all contingencies… when the terms no longer seem to make sense, it’s time to re-engage the deal folks and examine whether modifications are necessary
    - Draft amendments as soon as possible

Anatomy of a Deal (from the seller's perspective)…



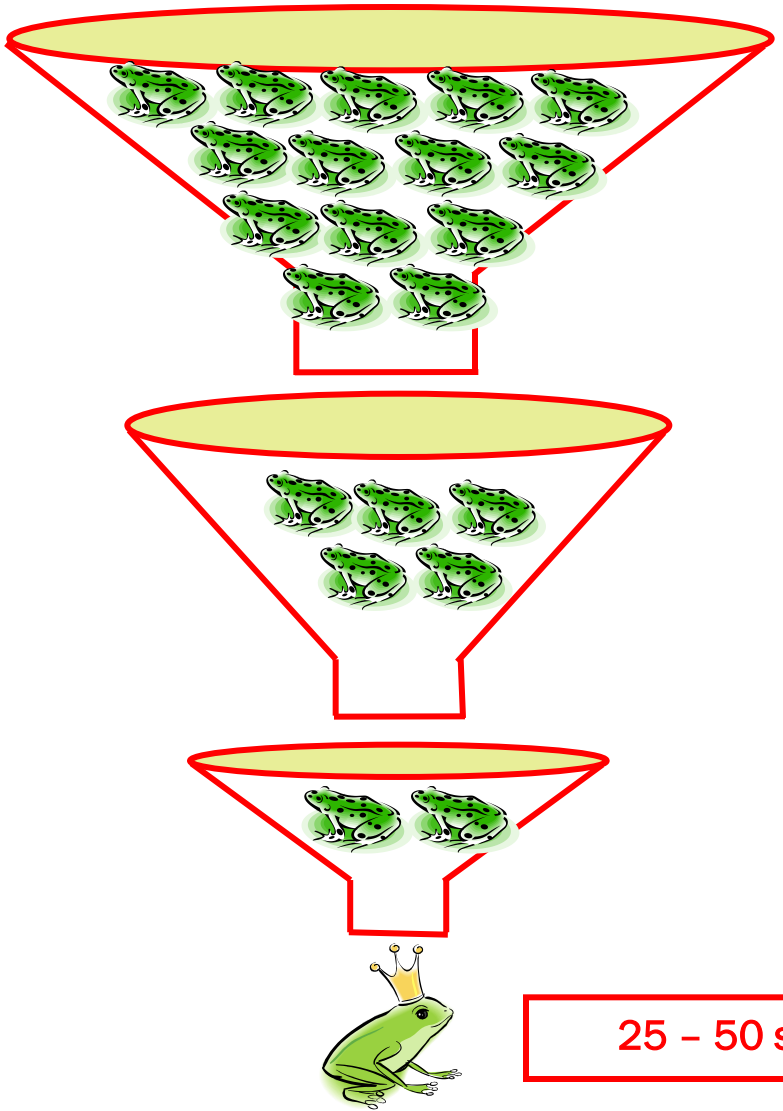
Anatomy of a Deal (from the Buyer's perspective)



*PDC review for resource needs

Example Deal

You have to Kiss a Lot of Frogs before you find the Prince!



- 21 companies contacted for deal
- 2 - 5 initial non-confidential meetings/phone calls per company

- 11 Confidential Disclosure Agreements negotiated and signed
- 4-10 confidential scientific meetings/updates per company
- 6 companies conducted due diligence
- 8-15 due diligence discussions/meetings/ updates per company including IP diligence

- 5 term sheets
- 5-10 negotiation sessions per term sheet
- 10-15 negotiation sessions for contract

25 – 50 substantive interactions per co. before deal was signed!

Business Development is not (usually) a linear process

- Most BD efforts do not end up in a transaction…but you hope you make relationships along the way…
  - Therefore, never burn bridges
- Negotiations are not smooth…often a last minute fly in the ointment…but you hope you learn something from each one (and try to anticipate this in the future)
  - Therefore, there needs to be high level “buy-in” for the deal
- Companies are more inclined to do deals with people they trust…it is all about the people!
  - Biotech’s reputation for strong science and for delivering in past collaborations helps a lot!

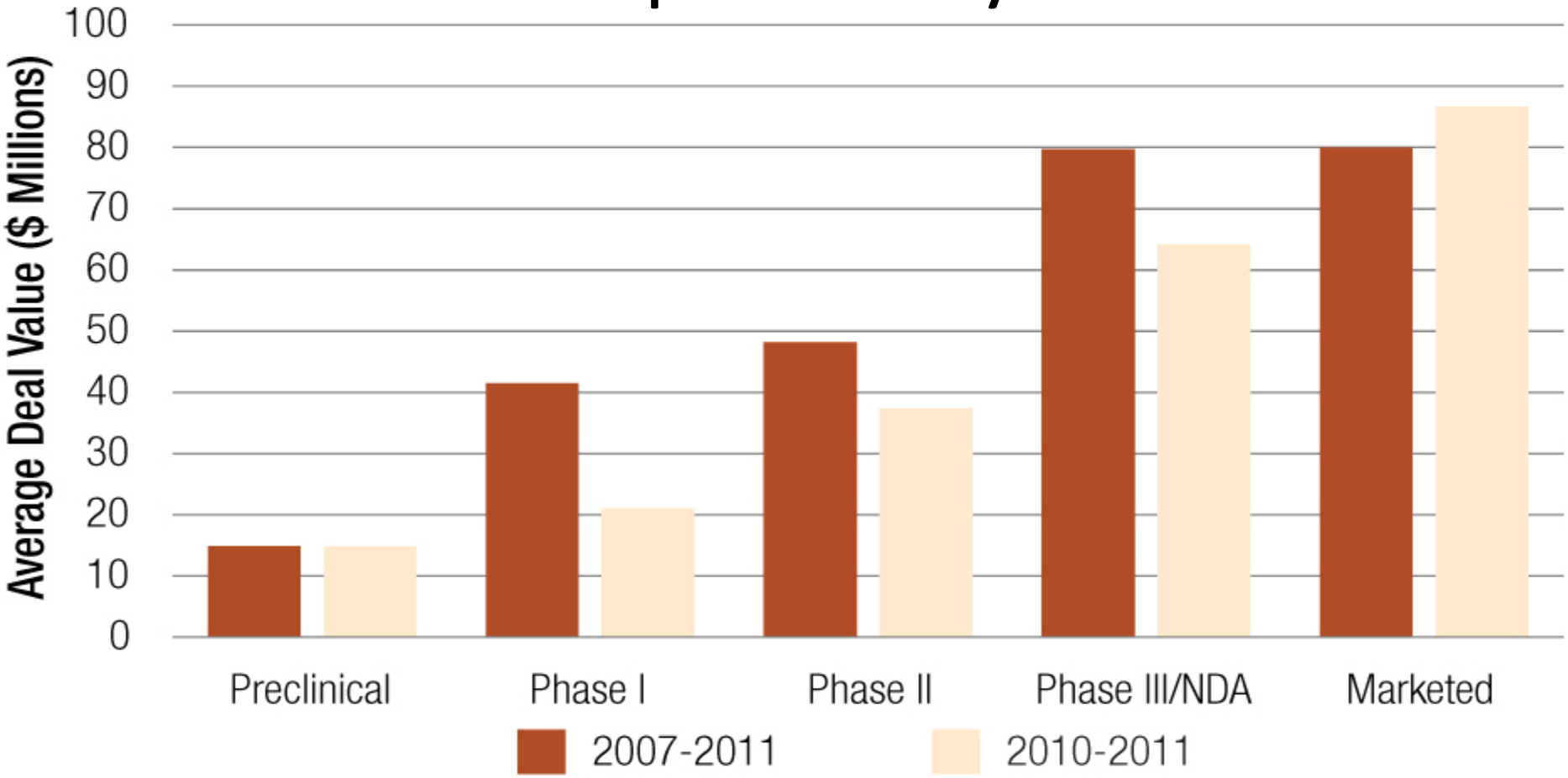
What Makes a Good Bus Dev Professional?

- Selling skills
  - Generating as much interest as possible for the asset you are trying to market
- People skills
  - Managing external discussions/relationships without ever closing the door
  - Internal decision making and consensus building
- Negotiating Skills
  - Every interaction is an opportunity for negotiation
- Analytical skills
  - Making data driven decisions in valuing and structuring a deal
- Project management skills
  - Keeping the process moving smoothly
  - Very important to be responsive and timely to maintain momentum of a deal

Is the Business Model Broken?

Considerations for a Business Development Professional

Deal Upfront Payments



Source: Elsevier Strategic Transactions

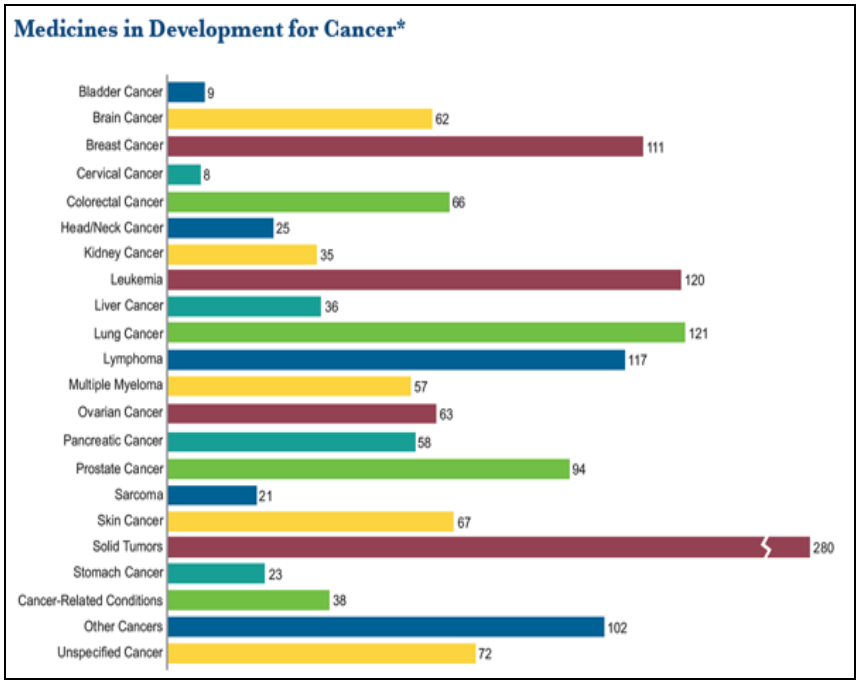
Cost-based approach to valuing an "AVERAGE" compound

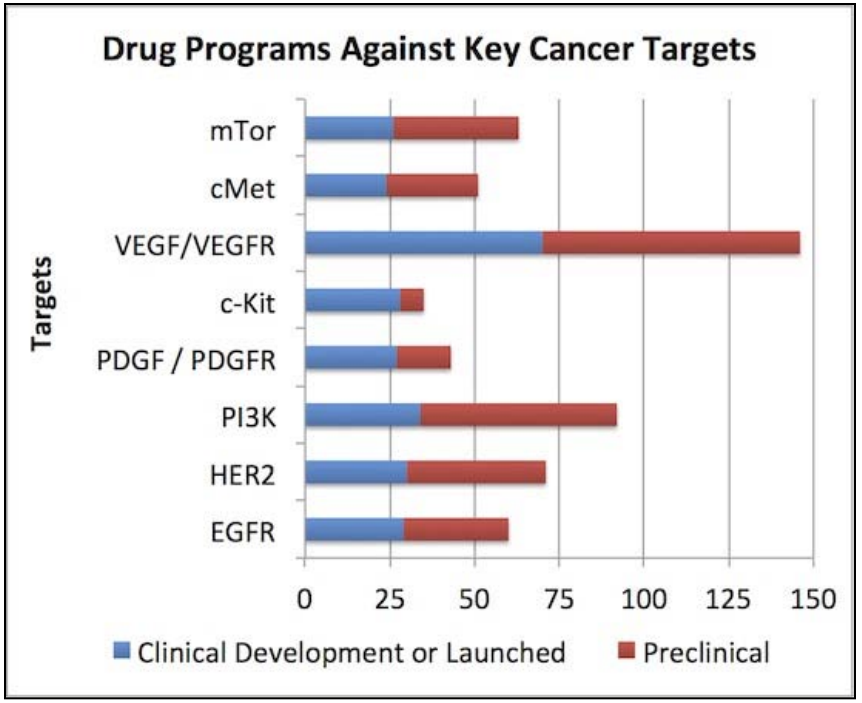
	Screening/ Hit to Lead	Lead Op	Preclinical/ IND		Phase I
Cost per stage($ M)	$1.5	$13.0	$8.2		$10.0
POS per stage	50%	61%	51%		65%
Cumulative POS	50%	30%	15%		10%
# of screening progs for one successful compound			6.5		10.0
Time to IND per stage (yrs)	5.1	3.3	1.4		1
Risk and time-adjusted cost for one successful compound*			$97.0		$184.3

* Cost of capital used 12%

Source: Data through IND from In-Vivo Nov 2006 "The $100 M IND" – based on industry avg. Data for Phase I estimated by Exelixis.

Of the nearly 1000 compounds in development in oncology, >50% address 8 targets





Source: LifeSciVC.com “Cancer Drug Targets: The March of the Lemmings” by Bruce Booth, June 2012

Which Will Contribute To An Already Low Success Rate

- 20% PTRS in mid-stage trials – why do so many fail?
  - 50% for lack of efficacy
  - 20% for safety
  - 30% for "strategic reasons" – most rapidly growing category
- Strategic reasons most commonly due to lack of differentiation from existing drugs against a validated target
  - Neither first-in-class nor best-in-class cannot survive
- What can we do to improve chances of success?
  - Identification of unmet need
  - Novel mechanisms/therapies
  - Patient selection strategies, e.g., biomarkers

Source: Nature Reviews Drug Discovery 10:1 (2011)

Recent Example: Inception Sciences and Roche

In 2005 Versant seeded spin-out of Merck discovery team to form Amira

- Peppi Prasit as Amira CSO
- 3 discovery programs/5 drug candidates completed Phase 1 within 5 years

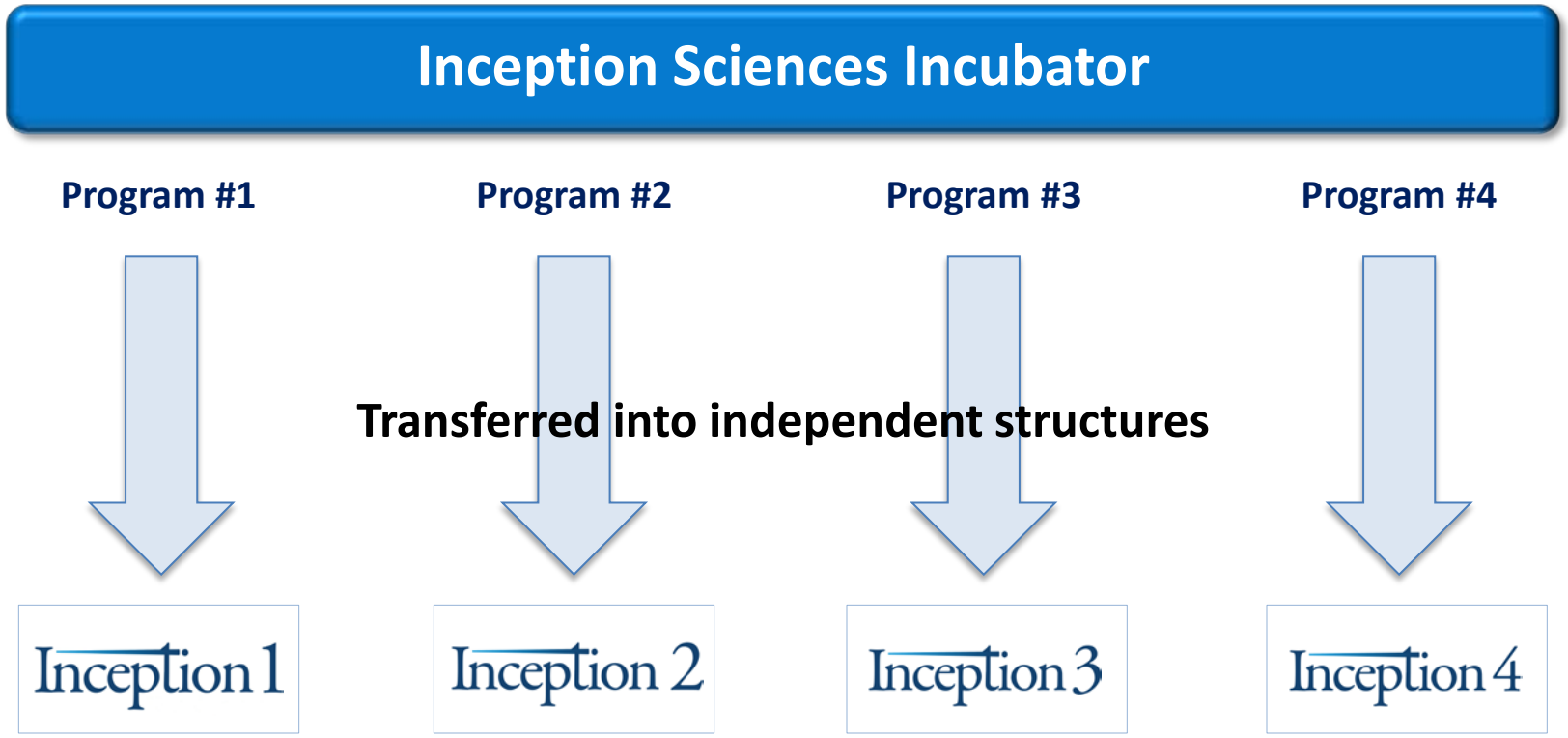
Pharma transactions led to successful Amira exit in 2011

- GSK acquired FLAP asthma program ($425M)
- BMS acquired LPA1 fibrosis program ($475M)

In 2011 Versant backed spin-out of Amira discovery team to form Inception

- Peppi Prasit as Inception CEO, leading ex-Amira drug discovery team
- First “build-to-buy" structured acquisition deal closed within 18 months

Business Development Basics Course



- Independent structure for each program
- Early stage partnerships co-fund to an exit

Business Development Basics Course

Academic program + **Drug discovery incubator** + **Pharma partner**

Inception Sciences

- Academic entrepreneurs provide access to potential new drug targets
- Inception *translates* academic discoveries into drug candidates
- Pharma *develops* drug candidates into commercial products

Business Development Basics Course

Traditional

Launch new company → NewCo project

Develop drugs over multiple years → Venture funded NewCo

Exit path based on Pharma interest → Successful execution → M&A? / IPO?

5-10 years

VERSANT ventures

"Build-to-buy" partnering model

Incubate program with academic leaders based on Pharma interest → NewCo project

Early partnership → Venture & Pharma fund NewCo ← Pharma

Structured exit with partner → Successful execution → M&A

3-5 years

Business Development Basics Course

Advantages for Pharma:

- Early access to breakthrough innovations
- Externalization of R&D cost
- Risk sharing

Advantages for Versant Ventures & Inception:

- Early assurance of Pharma interest and commitment
- Access to Pharma capabilities
- Research funding to supplement venture capital
- Assurance around liquidity timeline

Roche/Inception/Versant Ventures Transaction – Sept 2012

- "Inception 3" co-created for discovery of novel drugs for sensorineural hearing loss
- Inception team conducts drug discovery
- Academic scientists providing rare know-how and unique platform (Stanford)
- Funded by Versant Ventures and Roche research funding
- Roche acquisition at first IND at preset terms

FierceBiotech
THE BIOTECH INDUSTRY'S DAILY MONITOR
Roche, Versant launch new-wave biotech startup
October 10, 2012 | By John Carroll

BioCentury Extra
*Wednesday's Top Story*BioCentury Extra
Roche, Inception launch hearing loss newco

"The Pink Sheet"®
Roche Enters Hearing-Loss Space In Risk-Sharing Venture With Inception, Versant

Recent Example: Onyx and ONO

Carfilzomib: Phase IIb for Multiple Myeloma

Also included Oprozomib (oral compound) in Phase 1

Strong response rate data in 2 large trials

Onyx / Ono Transaction – Sept 2010

Strategic Rationale

- US NDA in 2011
- 2 large Phase 3 studies ongoing
- Onyx: Seeking to focus resources, not likely to build in Japan
- Ono: declining revenues from legacy portfolio
  - Seeking near-term "win"
  - Seeks innovation → reimbursement
  - Safety profile of CFZ is attractive; Japanese treaters are scrupulous about "doing no harm."
- Ono: Seeking to expand in oncology

Deal Structure

- Extremely competitive process
- Japan territory only
- $59M up front
- $339M including milestones
- Significant development funding for global studies
  - Ono bears costs for local studies
- Rights to participate in label expansion (aligning interests)
- Largest economics for Japan rights for P2 molecule

Questions??

Business Development Basics Course

Biotechnology Industry Organization