

Evolving Deal Terms: Recent Trends & How Far You Can Go

**LES Vancouver Chapter Luncheon
June 2018**

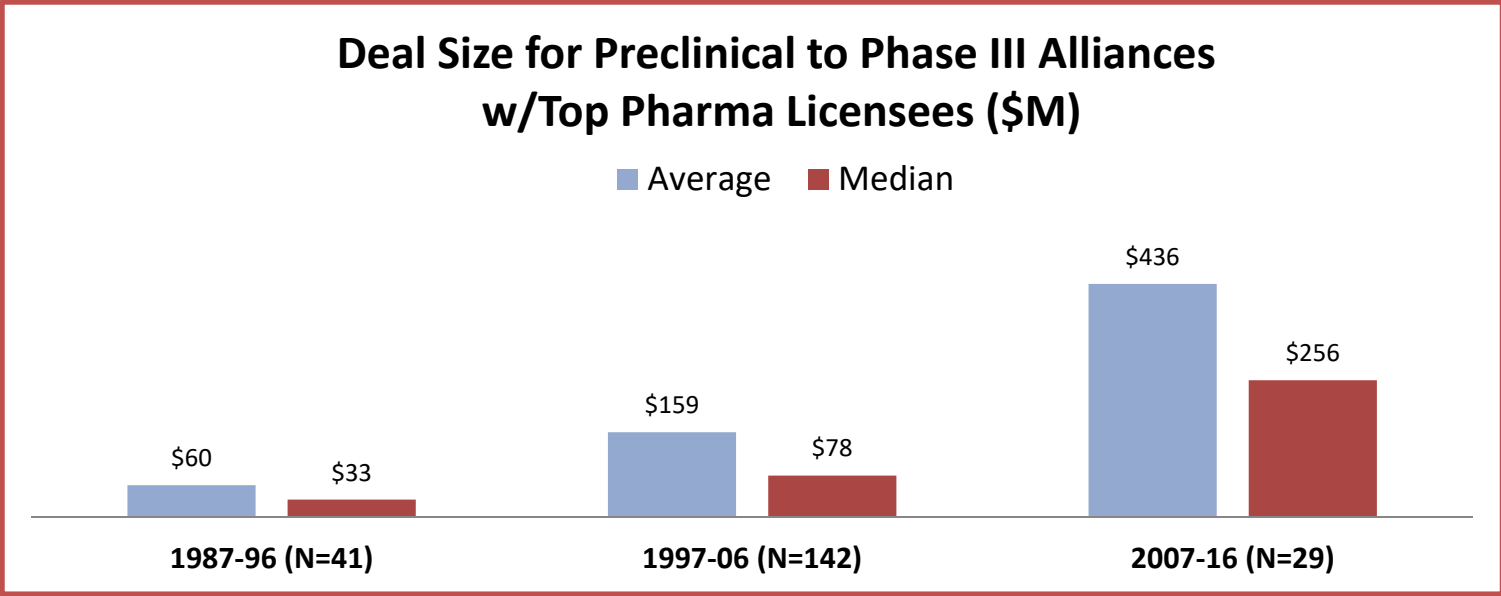
Mark G. Edwards
Managing Director



Evolving Deal Terms: Recent Trends & How Far You Can Go

- A Quick “Recap” of Biopharma’s Alliance Landscape
- Effective Royalty Rates – The Going Rate for Success
- Sharing the Wealth – Getting Beyond Sublicense Revenue
- Changing the Deal – How Far and How Often

Biopharma Alliance Payments Were MUCH Lower In the Early Days of Pharmaceutical Licenses



Compound Originator Obtains Optimal Terms for a Blockbuster Phase III Compound

Lipitor for NA, Europe & China (6/96)

Parke-Davis

- \$25M as upfront payment
- \$180M in milestones (\$20M US filing, \$105M US & \$55M ex-US approvals)
- 50/50 cost sharing Yrs 1-7, then 35%
- 1M details between parties per year
- 28% transfer price in Licensed Territory (Brazil, Chile, China, Denmark, Iceland, Italy, Korea, Norway, Russia, Spain & Turkey)

Pfizer

P-D has Baseline sales growing from \$263M in Yr1, to \$588M in Yr5, to \$753M in Yr10

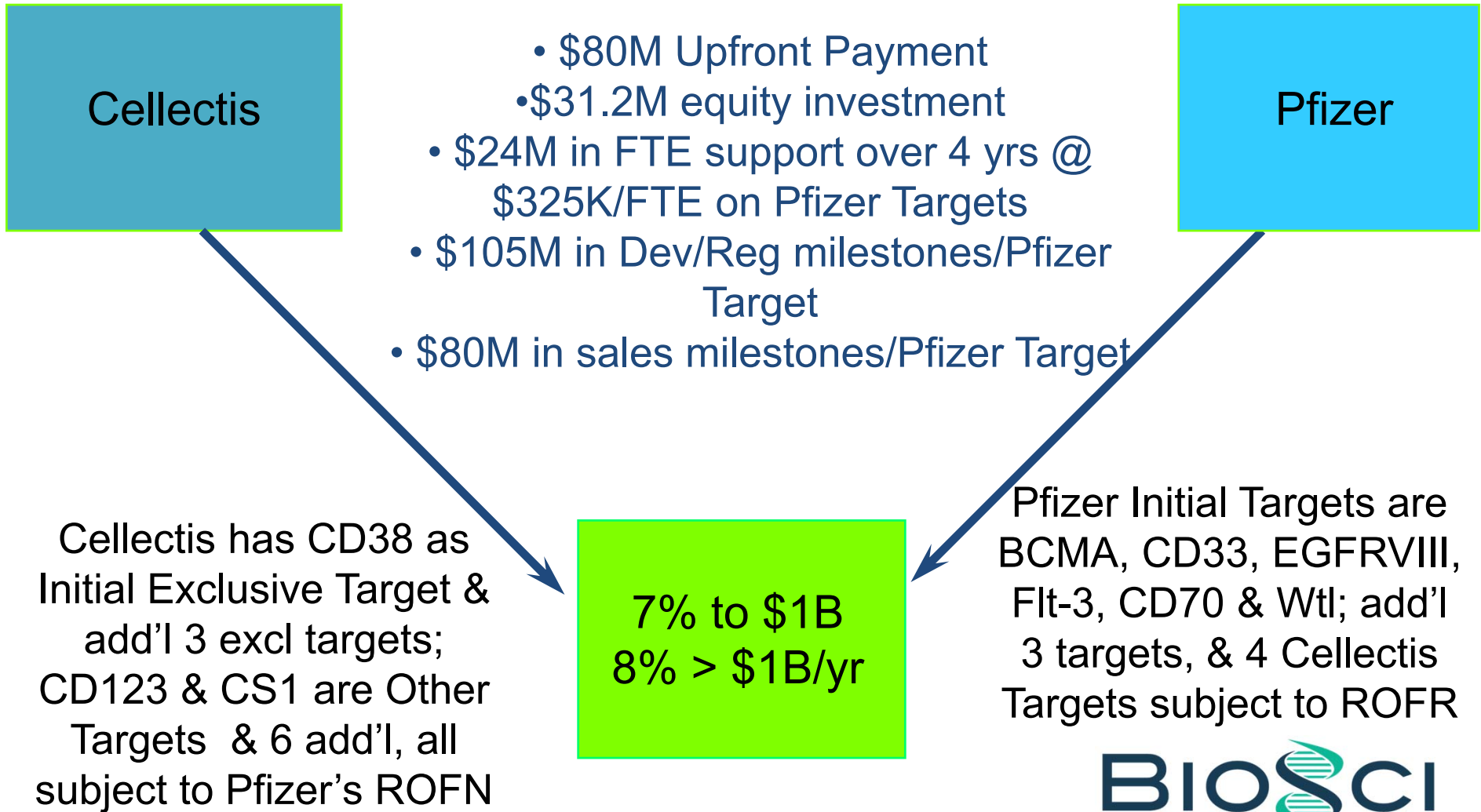
13.5-44.5% US Promotion Fee To Pfizer (revised to 48%)

Pfizer grants option to co-promote a Pfizer product on NDA filing, subject to 120 day negotiation and \$30M payment if not selected within 5 yrs

P-D may terminate after 5 yrs (of 10), subject to 10% royalty on average net sales (2 prior yrs) for 3 yrs post-termination

Worldwide Discovery Collaboration for CAR-T Approaches to Six Selected Oncology Targets

CAR-T Immunotherapies for Oncology (6/14)



Worldwide Phase II Co-Co Alliance for Immuno-Oncology Compound to Join Combination Therapies

NKTR-214 CD-122 Biased IL-2 Agonist w/Opdivo & Yervoy for Treatment of Cancer (2/18)

Nektar

BMS

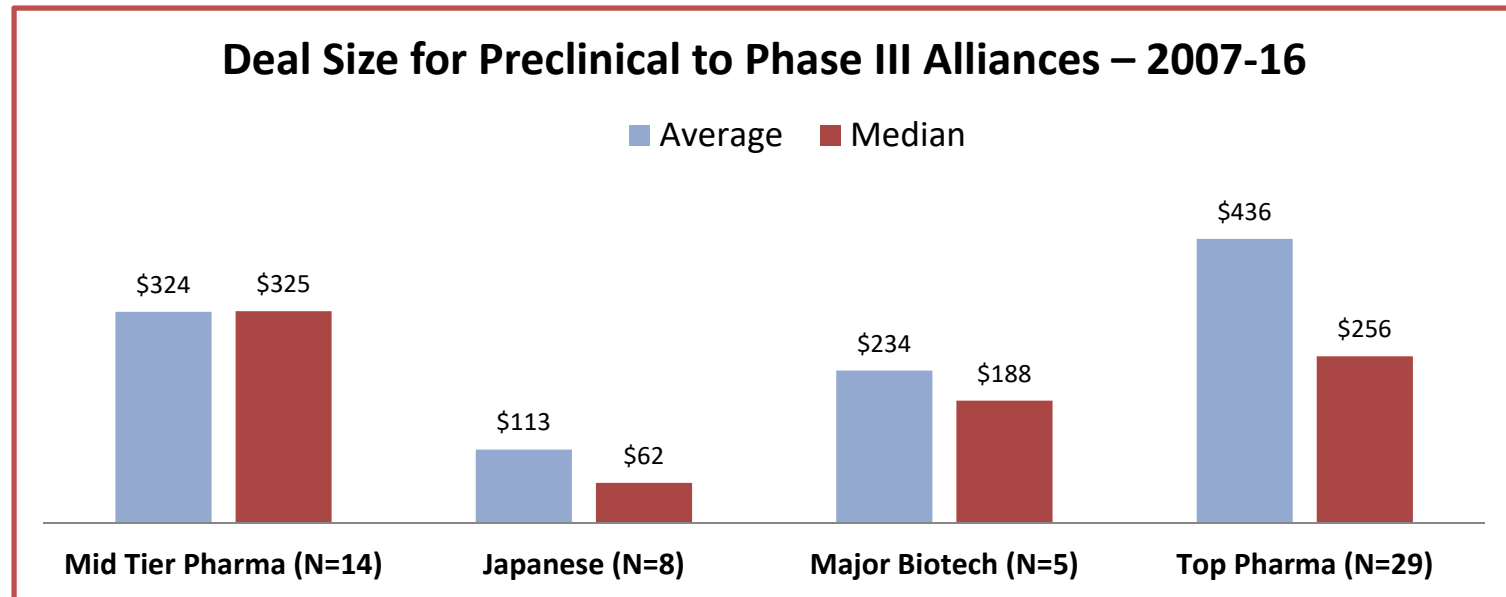
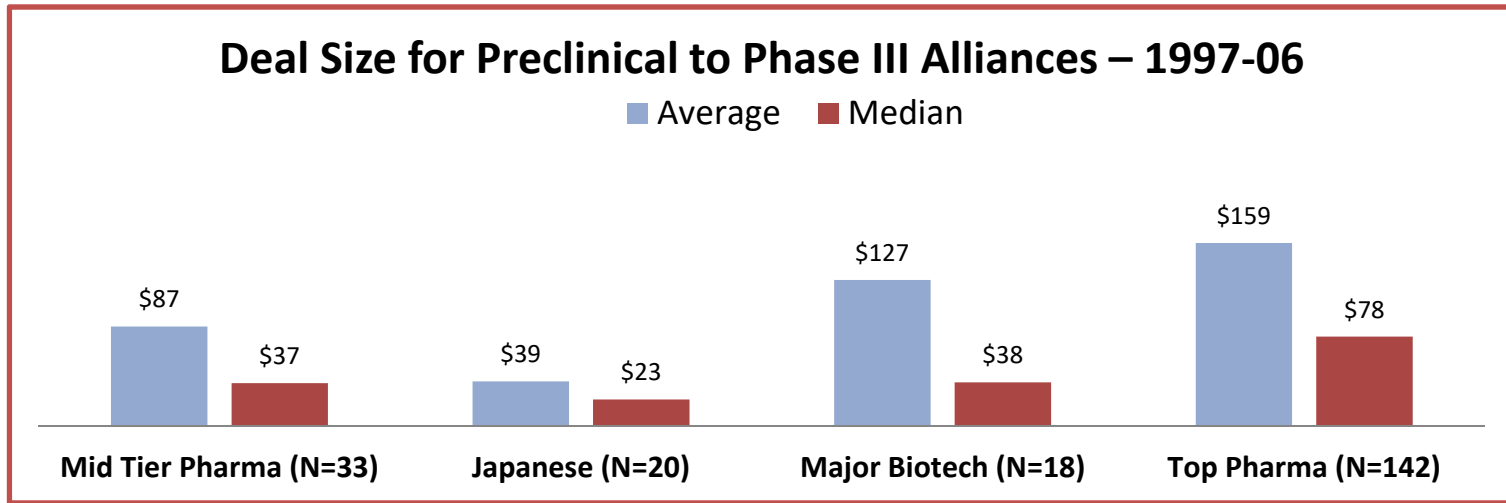
- \$1.0B Upfront Payment
- \$850M equity purchase
- Nektar pays 32.5% of dev costs w/Opdivo & 22% of dev costs w/Opdivo+Yervoy, all subject to a \$125M/year dev cost cap
 - \$650M in Dev/Reg milestones 1st
 - \$260M Dev/Reg milestones each of 2nd to 4th indications
 - \$350M in sales milestones

Nektar prices & books all sales of NKTR-214; also leads all but BMS-combo commercialization efforts

65% of Worldwide Profits (15% of losses w/Carryforward)

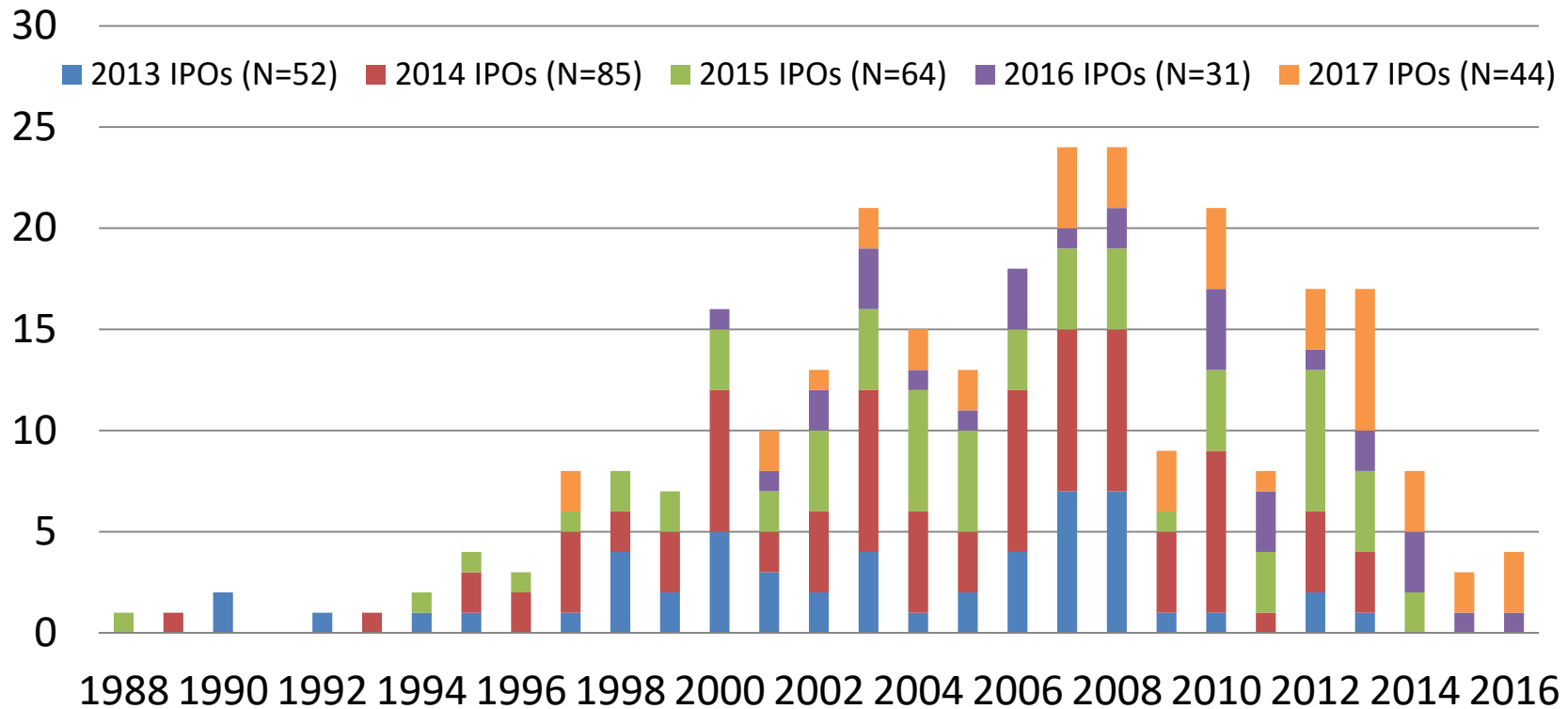
BMS leads commercialization with BMS-proprietary combos

Top Pharma Spent 3x More Cash for Compound Alliances in the Past Decade ... But Other Licensees Stepped Up As Well



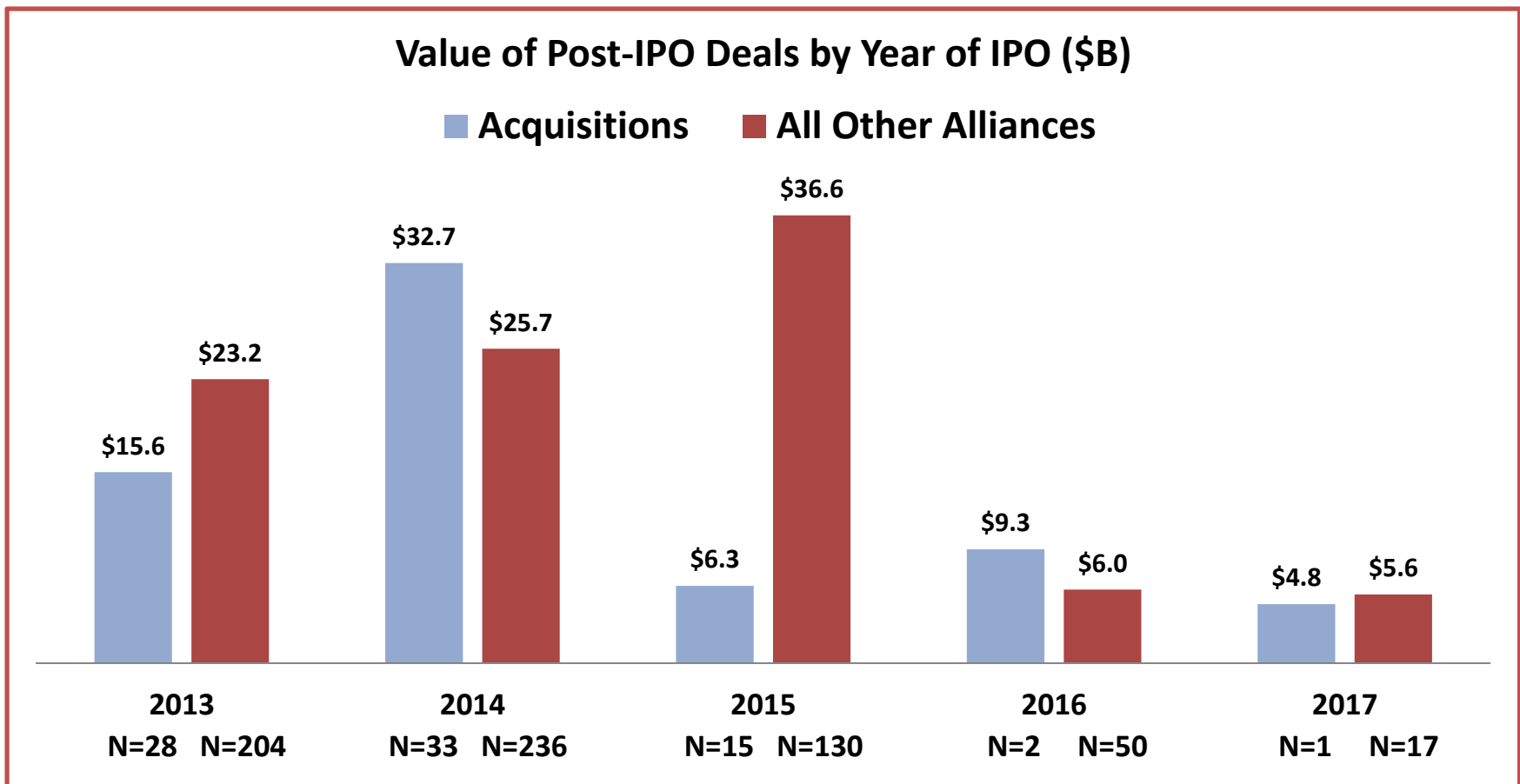
Over 300 Biotechs Have Gone Public Over the Extended 2013-18 Biotech IPO Window*

Number of IPO Companies by Founding Year



* 19 Additional Biotech IPOs from Jan-May 2018

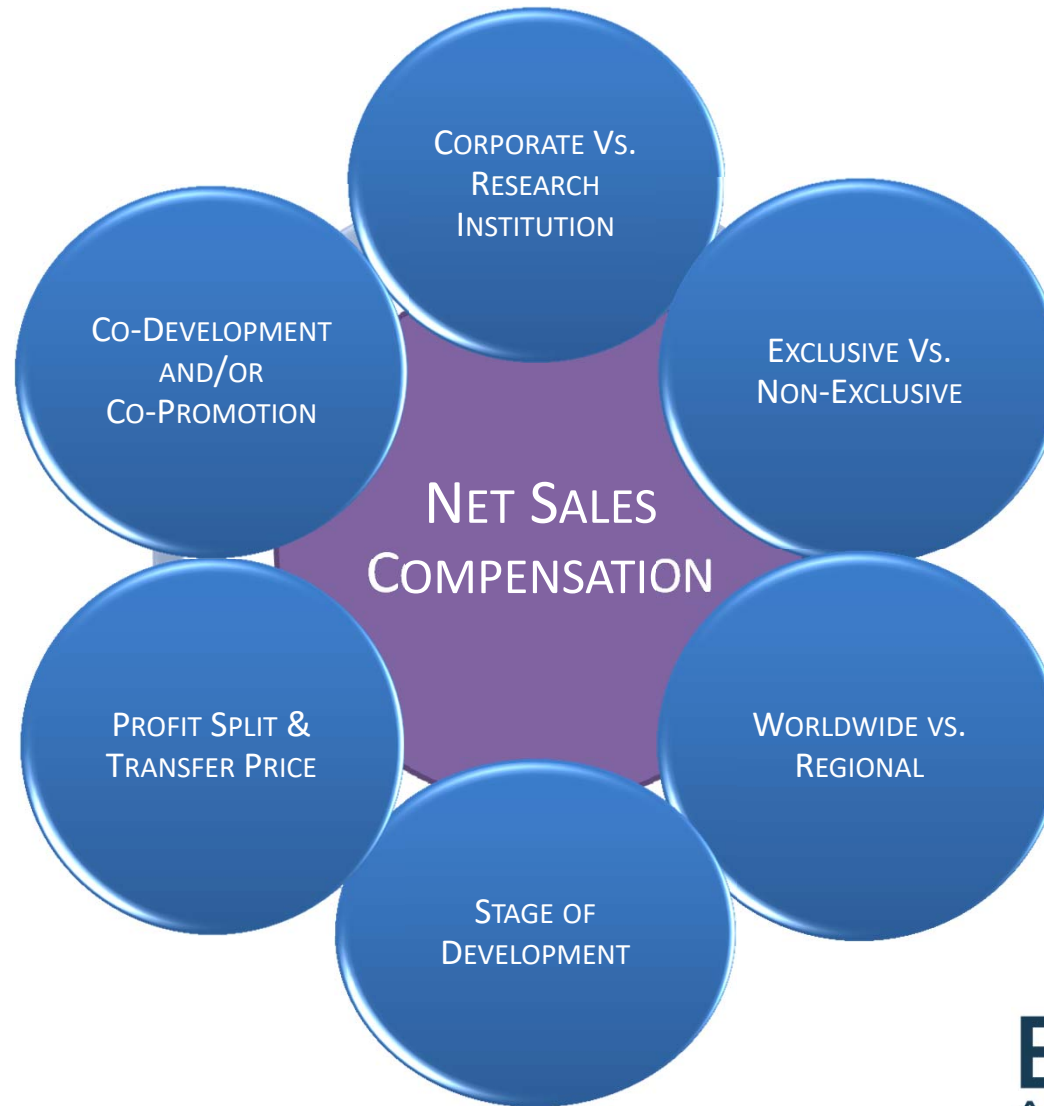
Biotech IPO Class of 2013-18 Have Done 700+ Deals Since Going Public -- \$69B in Acquisitions & \$97B in Alliances



Evolving Deal Terms: Recent Trends & How Far You Can Go

- A Quick “Recap” of Biopharma’s Alliance Landscape
- Effective Royalty Rates – The Going Rate for Success
- Sharing the Wealth – Getting Beyond Sublicense Revenue
- Changing the Deal – How Far and How Often

What are the Key Elements in Evaluating Net Sales Compensation in Biopharma Alliances?



Effective Royalty Rates are a Better Measure of Net Sales Compensation than the Use of a Maximum Royalty

- When Evaluating Comparable Transactions, Use Effective Royalty Rate (“EFR”) As the Basis of Comparison, Rather than the Maximum Royalty Payable to the Licensor
- For example, if a license calls for 8% royalty on the first \$100M in annual sales, then 10% to \$500M, 15% on sales from \$500M to \$1 Billion per year, and 20% on sales greater than \$1B/yr, the EFRs would be as follows:

If \$200M in Sales:

\$ 8M on \$100M

\$10M on \$100M

\$18M = 9.0% EFR

If \$500M in Sales:

\$ 8M on \$100M

\$40M on \$400M

\$48M = 9.6% EFR

If \$1B in Sales:

\$ 8M on \$100M


\$40M on \$400M

\$75M on \$500M

\$123M = 12.3% EFR

Average EFRs Increase For Later Stage & Exclusive Licenses, But Vary Substantially by Corporate Vs. University Licensor

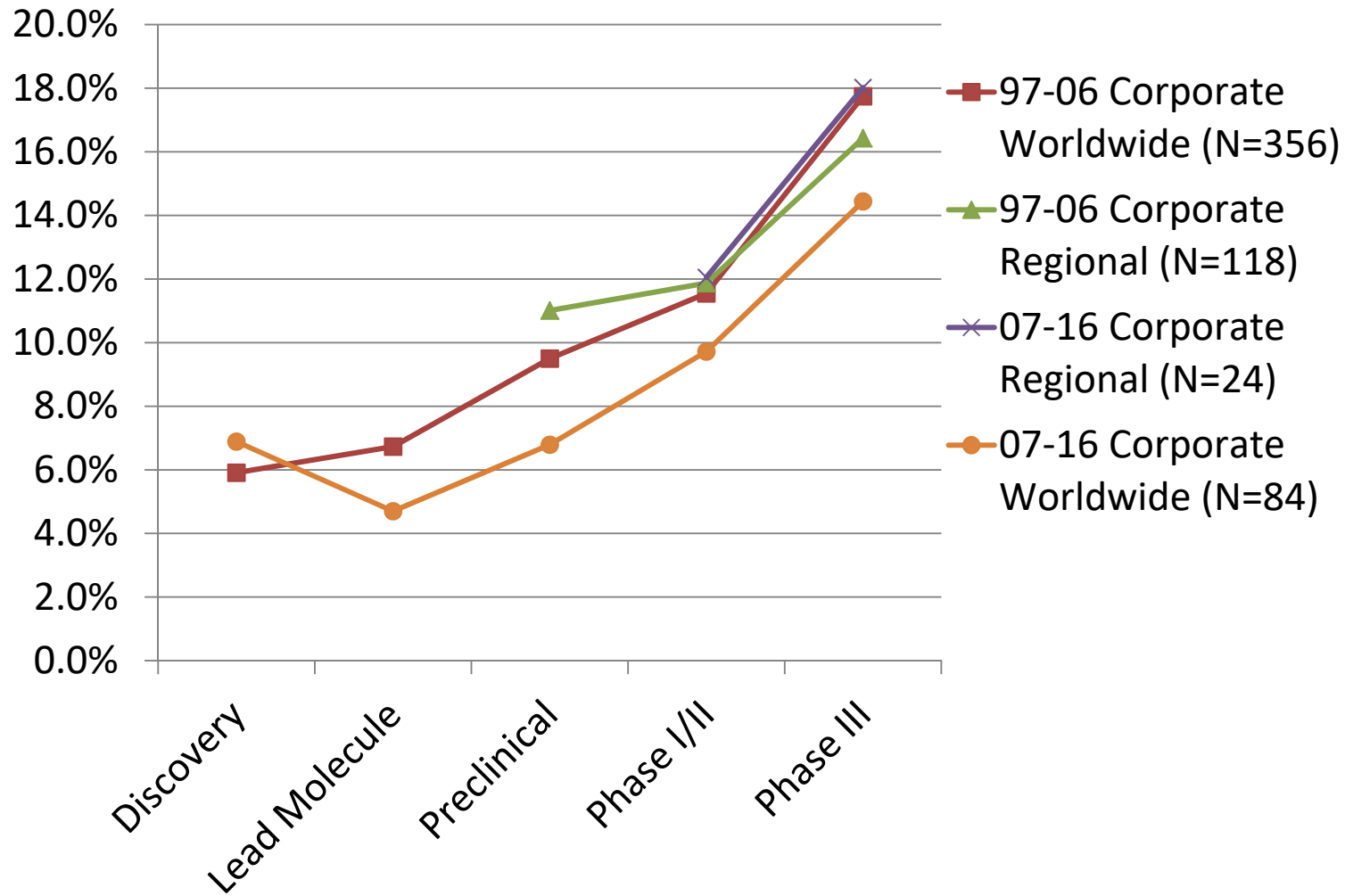
For 276 Biopharma Alliances signed between 2007 and 2016, EFRs Increased on the basis of (i) Clinical stage at signing, (ii) Exclusive vs. Nonexclusive license & (iii) Corporate vs. University licensor,



		EFR \$200M	EFR \$500M	EFR \$1B	Max Share
By Stage (Corp & Excl)	• Phase III (N=18)	15.29	16.54	17.57	22.06
	• Phase I/II (N=44)	9.73	10.36	11.23	14.49
	• Preclinical (N=28)	6.54	7.14	7.75	11.87
Corporate	• All (N=182)	9.39	9.93	10.50	13.58
	• Exclusive* (N=165)	9.93	10.52	11.15	14.48
	• Nonexclusive (N=17)	4.19	4.22	4.24	4.44
University	• All (N=94)	3.40	3.41	3.45	3.64
	• Exclusive (N=82)	3.47	3.48	3.52	3.75
	• Nonexclusive (N=10)	3.10	3.10	3.10	3.10

* Corporate exclusive licenses include 3 semi-exclusive deals for data aggregation purposes

As Compared to A Decade Earlier, Average Corporate Deal EFRs Declined 2-3% for All but Discovery & Regional Deals*



* Average Effective Royalty Rate (EFR) calculated for assumed annual sales of \$500M/yr

Worldwide Deals Have Higher Deal Cash But Lower EFRs Than Regional Deals for Clinical Stage Compounds

	EFR \$200M	EFR \$500M	EFR \$1B	Max Share	Deal Size \$M
Discovery					
Worldwide	6.61 Av 07-16	6.89 Av 07-16	7.44 Av 07-16	9.22 Av 07-16	\$154.4M Av 07-16
Lead Stage					
Worldwide	4.61 Av 07-16	4.70 Av 07-16	5.00 Av 07-16	9.94 Av 07-16	\$177.0M Av 07-16
Preclinical					
Worldwide	6.21 Av 07-16	6.79 Av 07-16	7.41 Av 07-16	11.82 Av 07-16	\$202.0M Av 07-16
Phase I/II					
Worldwide	9.31 Av 07-16	9.72 Av 07-16	10.50 Av 07-16	13.87 Av 07-16	\$269.1M Av 07-16
Regional	10.83 Av 07-16	12.05 Av 07-16	13.18 Av 07-16	16.08 Av 07-16	\$194.3M Av 07-16
Phase III					
Worldwide	13.45 Av 07-16	14.44 Av 07-16	15.15 Av 07-16	22.00 Av 07-16	\$457.8M Av 07-16
Regional	16.76 Av 07-16	18.02 Av 07-16	19.27 Av 07-16	22.10 Av 07-16	\$195.3M Av 07-16

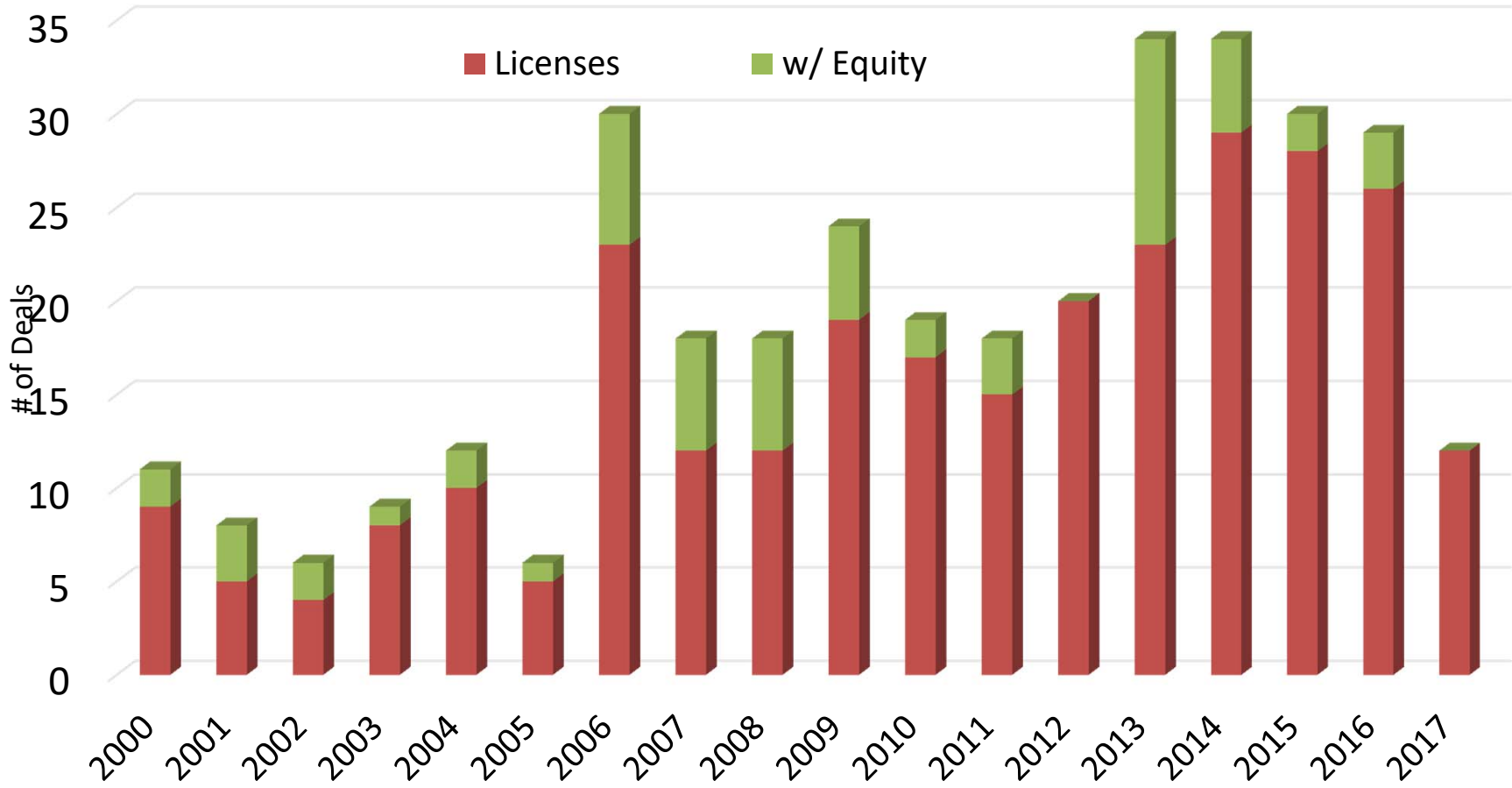
Evolving Deal Terms: Recent Trends & How Far You Can Go

- A Quick “Recap” of Biopharma’s Alliance Landscape
- Effective Royalty Rates – The Going Rate for Success
- **Sharing the Wealth – Getting Beyond Sublicense Revenue**
- Changing the Deal – How Far and How Often

Sharing the Wealth: Getting Beyond Sublicense Revenue

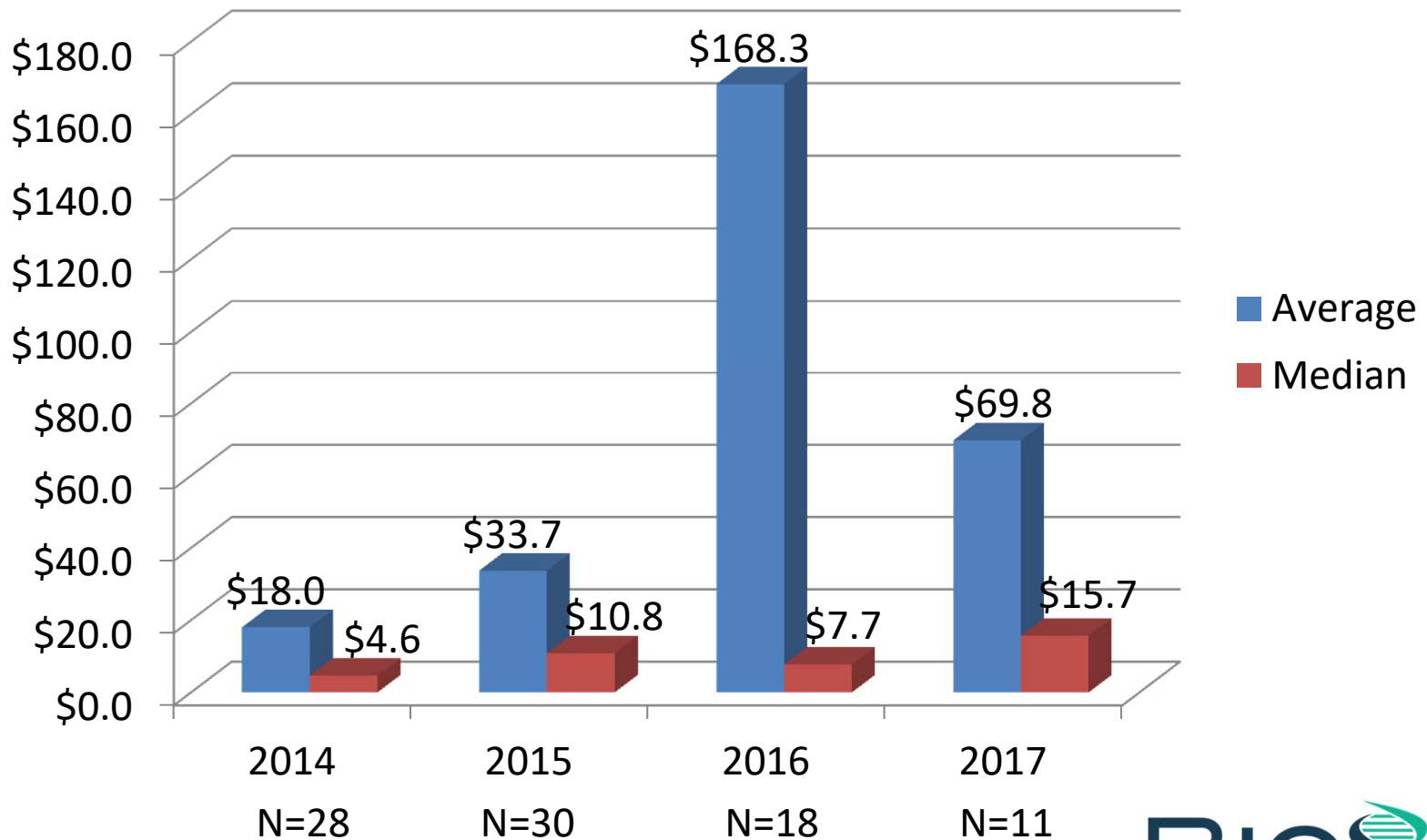
- Over the past three decades, 82% of Biopharma Licenses with Research Institutions have been Early Stage:
 - Discovery (34%)
 - Lead (18%)
 - Early Preclinical (30%)
- Median License Terms were Static for two decades:
 - \$80K Upfront
 - \$720K Milestones
 - 3.5% Royalty
 - 20-25% of Sublicense Revenue
 - 1 in 10 Licenses have an Equity Component

There are 277 University Licenses with Members of the Biotech IPO Class of 2013-18, & 22% have Equity



Research Institutions Have Benefited from Recent Increases in Total Deal Payments

Deal Size of Biopharma Licenses from Research Institutions (\$M)



Worldwide Lead Stage License of Fully Human Antibodies to Novel Immunotherapy Targets

GITR & OX40 Activators & TIM-3 Inhibition MABs for Treatment of Cancer (12/14)

Ludwig Institute
& Sloan
Kettering

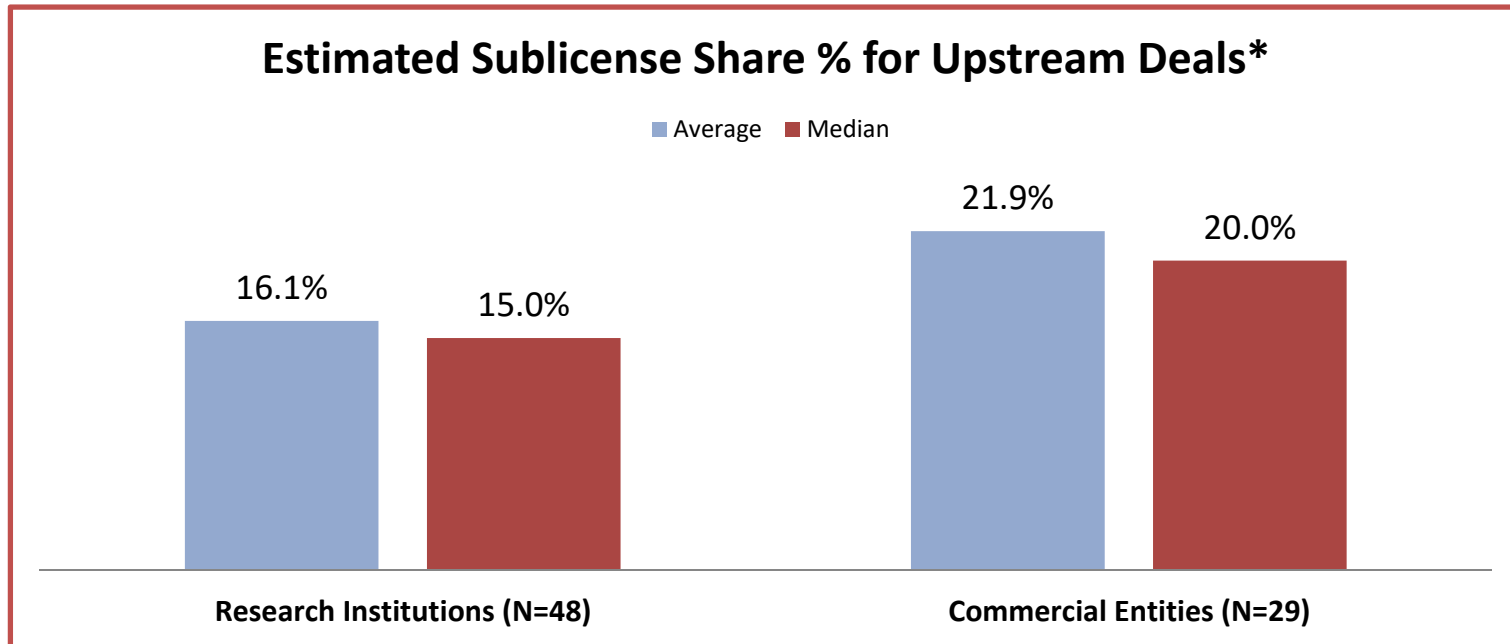
Agenus

- \$1M upfront payment
- Agenus pays all dev costs
- \$52.5M Dev/Reg milestones GITR 1st
- \$14.38M Dev/Reg milestones GITR add'l
- \$4M Dev/Reg milestones OX40 or TIM-3
- \$30M sales milestones for GITR

50-10% Sublicense
Revenue sharing,
depending on stage
of dev & co-funding
by Agenus

GITR Royalty:
5% to \$1B
6% > \$1B/yr;
3% Royalty for
OX40 or TIM-3

Sharing the Wealth: Sublicense Revenue Sharing in Upstream Licenses from Research Institutions Vs. Commercial Entities



* 207 Upstream Deals Associated with 150+ Commercialization Alliances Commenced 2008-2017

Sharing the Wealth: Writing a Sublicense Revenue Definition with Teeth

... Sublicense Revenue consideration extends to and includes consideration paid on the basis of rights (including options and covenants not to sue) under any intellectual property relating to Licensed Products and/or Licensed Technology, even if not owned by Licensor and even if Licensee structures its grant of rights so that the grant of rights under the Licensed Products and/or Licensed Technology formally occurs in a separate written agreement. The Parties have negotiated the percentage(s) for Sublicense Revenue sharing on the basis that all consideration will be included in the calculation. There is no proportional adjustment to Sublicense Revenue for the inclusion in the grant of rights of intellectual property other than Licensed Technology. For the avoidance of doubt, if Licensee receives consideration under an option for a sublicense of Licensed Product and/or Licensed Technology, that consideration shall be included in Sublicense Revenue.

Worldwide Phase I License of Small Molecule Cancer Compound

Tucatinib Oral HER2 Inhibitor for Treatment of Breast Cancer (12/14)

- \$21.2M upfront payment
- Cascadian pays all dev costs except for transition services (@ \$300K/FTE)
- 25-15% sublicense rev share if no Cascadian Change of Control (CoC)
- \$5M signing, \$35M dev/reg and \$240M sales milestones on Cascadian CoC

Array
Biopharma

Cascadian

Agmt replaces 5/13
Co-Co Alliance with
straight license

10% to \$500M
11% to \$1.5B
12% > \$1.5B/yr*

* Array royalty drops
to 7% after
Cascadian CoC

Sharing the Wealth:

Array/Cascadian as a Template for University Tech Transfer

- Scenario 1 (Licensee goes to market directly):
 - 1. Upfront payment -- \$20M (plus clean-up, e.g. patent reimb)
 - 2. Dev/Reg & sales milestones -- None!
 - 3. Royalty -- 10-12%

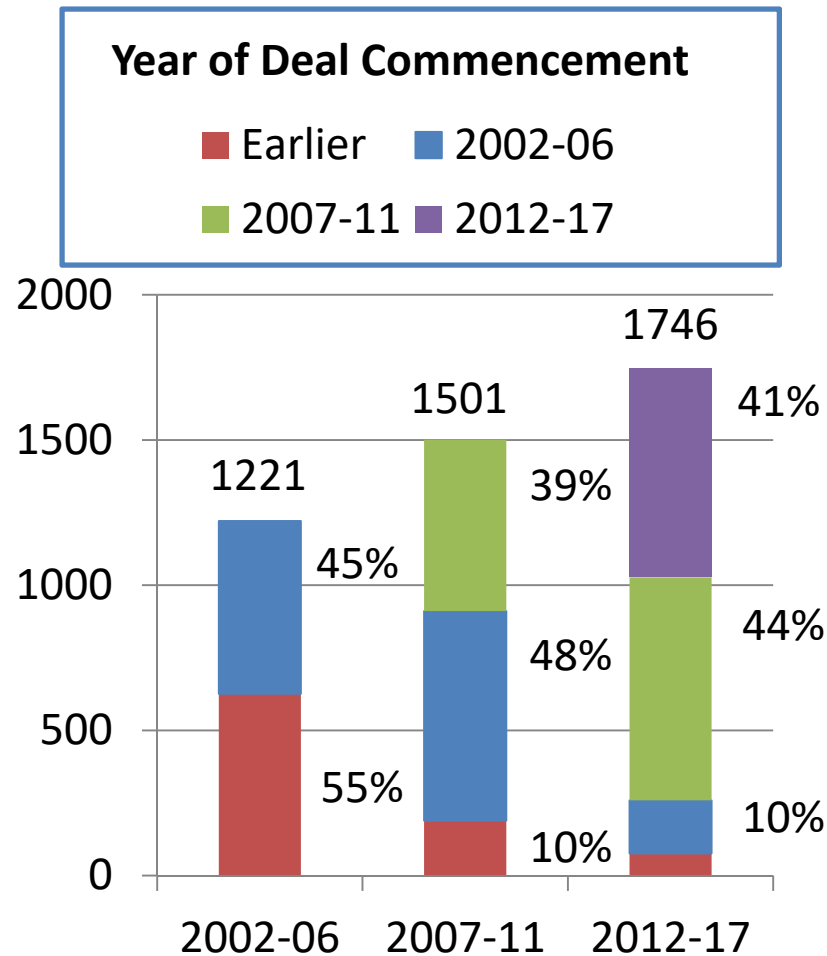
- Scenario 2 (Licensee sublicenses commercialization in one or more territories):
 - 1. All same as Scenario 1, plus
 - 2. Sublicense revenue sharing of 25-15%, falling with dev stage progression

- Scenario 3 (Licensee has a Change of Control event):
 - 1. \$5M on CoC signature
 - 2. \$35M in Dev/Reg milestones
 - 3. \$240M in sales milestones
 - 4. Royalty to Array drops to flat 7%

Evolving Deal Terms: Recent Trends & How Far You Can Go

- A Quick “Recap” of Biopharma’s Alliance Landscape
- Effective Royalty Rates – The Going Rate for Success
- Sharing the Wealth – Getting Beyond Sublicense Revenue
- Changing the Deal – How Far and How Often

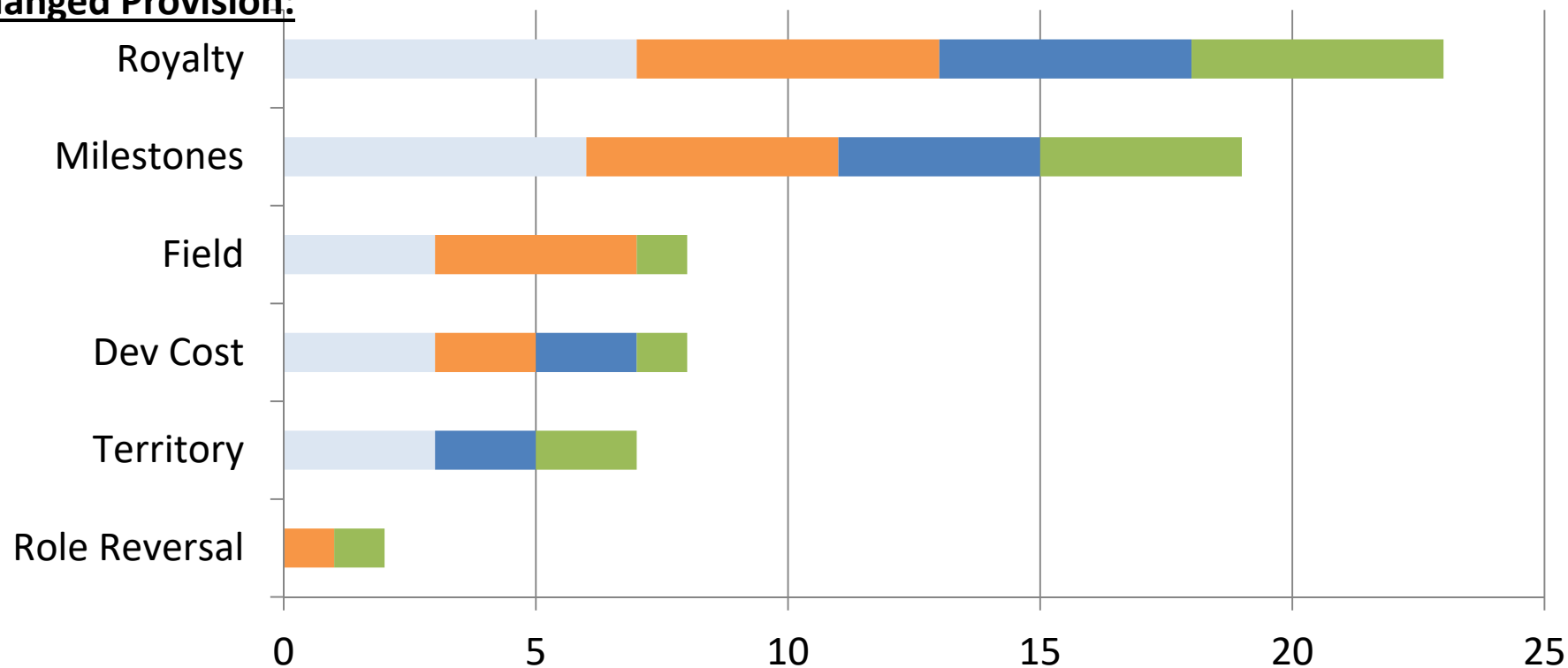
SEC-Filed Amendments to BioPharma Alliances Are Evenly Split Between Recent (0-5 yr) and Older (6-10 yr) Deals



Royalty & Milestones are the Most Frequently Changed Provisions in Restated Biopharma Commercial Alliances*



Changed Provision:



* 32 Commercial Alliances Restated between 2005 and 2012, for which Unredacted (FOIA) contracts were available for both Original & Restated Agreements

Worldwide Phase III License of Psychiatric Compound

Fanapt Iloperidone for Treatment of Schizophrenia
(6/04-12/14)

Novartis

- \$0.5M upfront payment
- Vanda pays all dev costs
- \$17.5M in Dev/Reg milestones
- \$75M in sales milestones

Vanda

ROFN for co-promotion in US

25%
Royalty

Vanda sold NA rights back to Novartis in 10/09

Regional Take-Back License of Approved Psychiatric Compound in North America

Fanapt Iloperidone for Treatment of Schizophrenia
(10/09-12/14)

Vanda

- \$200M upfront payment
- Novartis pays all dev costs in NA for Depot Formulation development
- \$40M in Dev/Reg milestones for Depot Formulation
- \$225M in sales milestones

Novartis

Vanda licensed worldwide rights from Novartis in 6/04

10% to \$250M
12% to \$500M
14% to \$750M
16% > \$750M/yr

ROFN for co-commercialization in ROW

The Use of Conditional Provisions Remains Infrequent in Biopharma Alliances

➤ Right of First Refusal (ROFR):

- Disclosed ROFR in 61 (4%) of 2007-17 License Agmts
- Disclosed ROFR in 98 (5%) of 1997-06 License Agmts

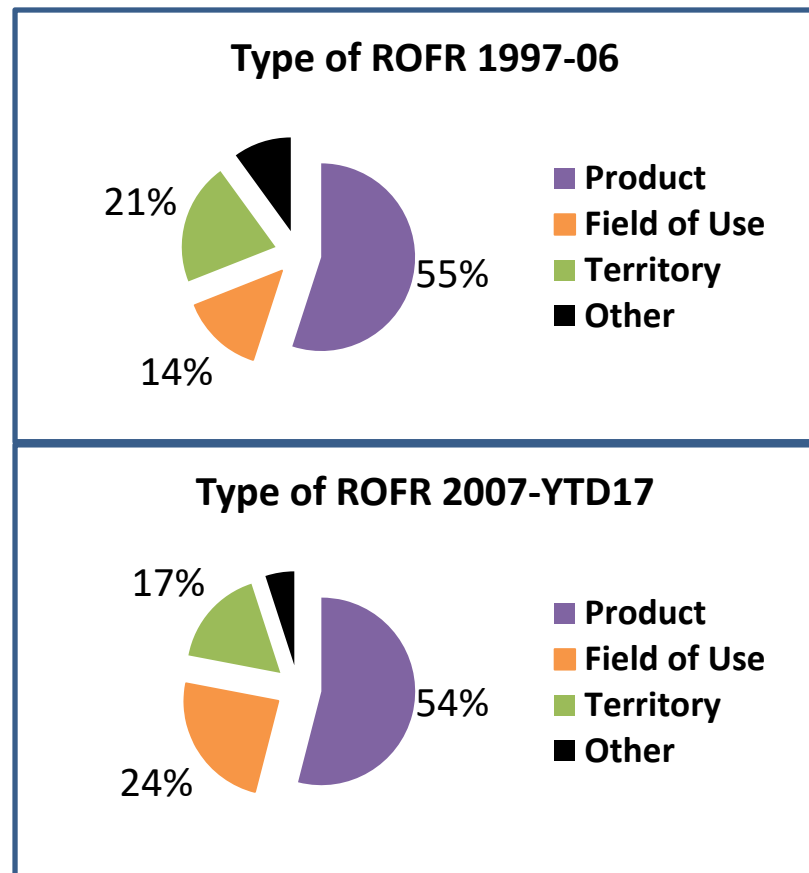
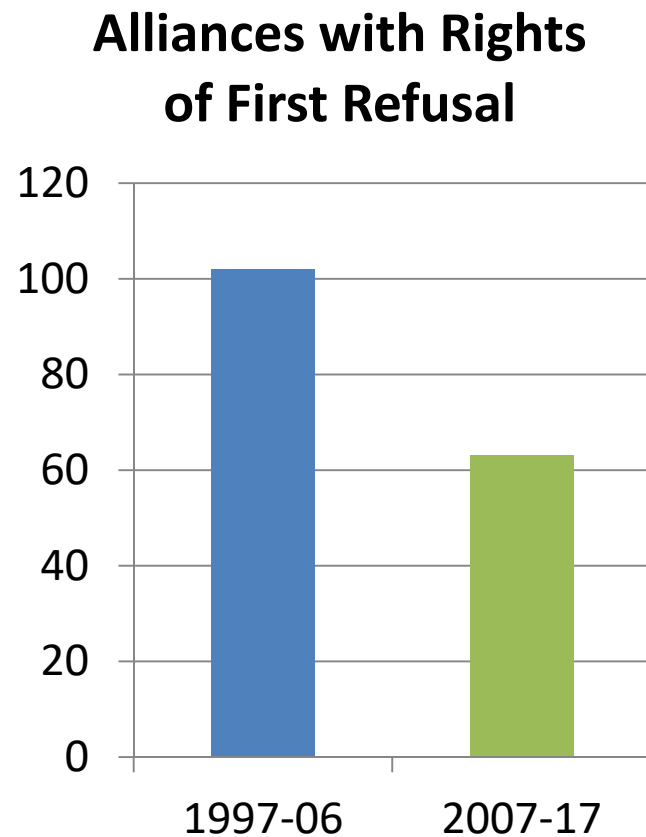
➤ Right of First Negotiation (ROFN):

- Disclosed ROFN in 168 (11%) of 2007-17 License Agmts
- Disclosed ROFN in 221 (11%) of 1997-06 License Agmts

➤ Impact of Change of Control (CoC):

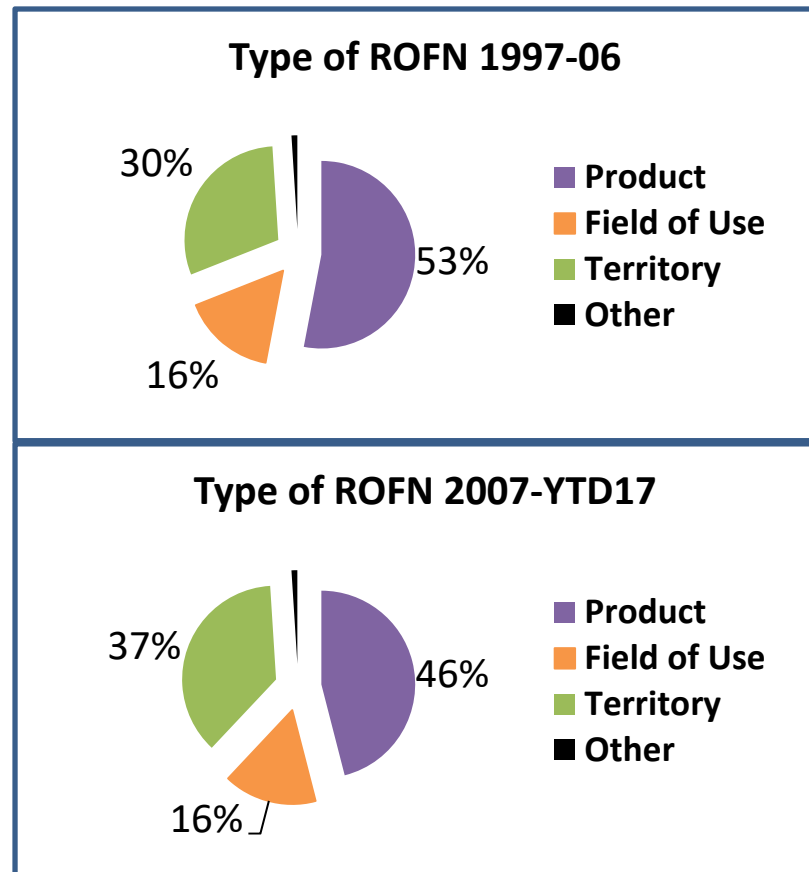
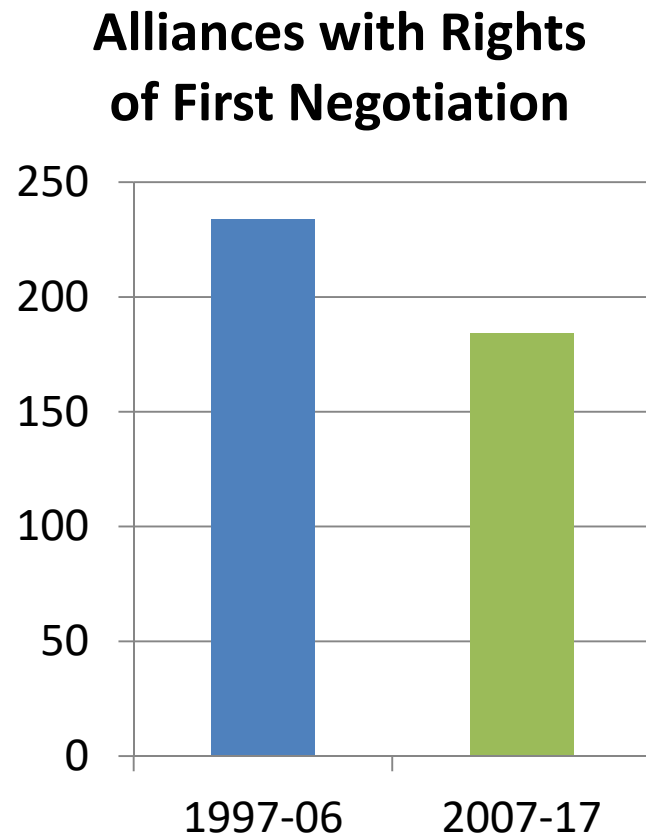
- Disclosed CoC in 224 (14%) of 2007-17 License Agmts
- Disclosed CoC in 252 (12%) of 1997-06 License Agmts

ROFRs: Additional Product Inclusion Dominates ROFRs, but Field Expansion has Overtaken Territory Expansion Recently



ROFR = Typically a right held by licensee, conditional on an action by the originator or third party, wherein the terms of exercise are pre-determined or subject to third party equivalence

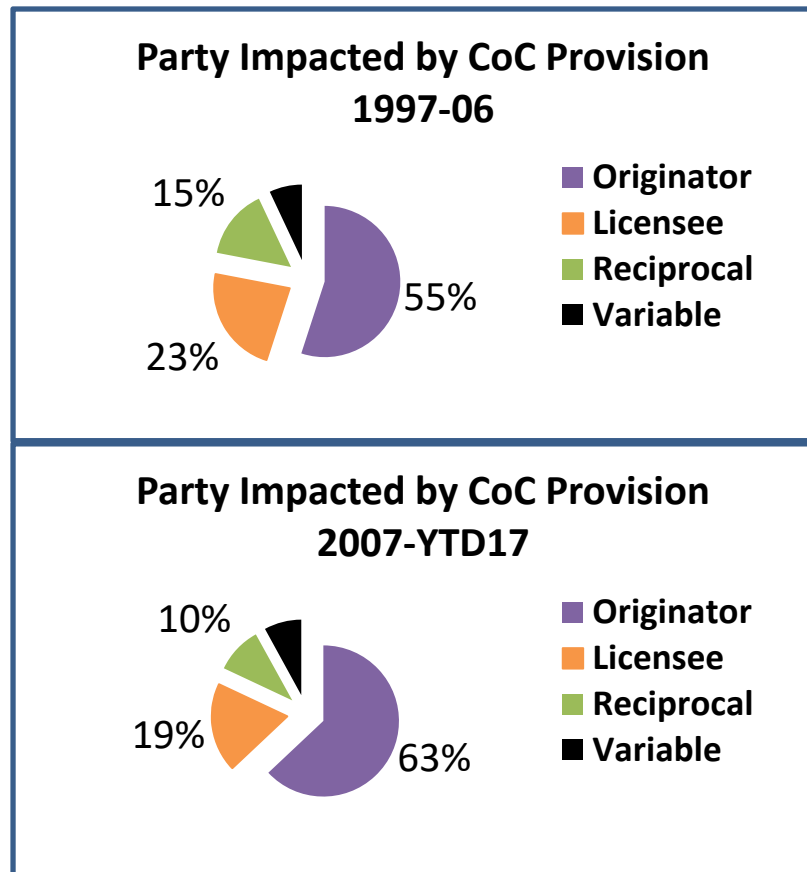
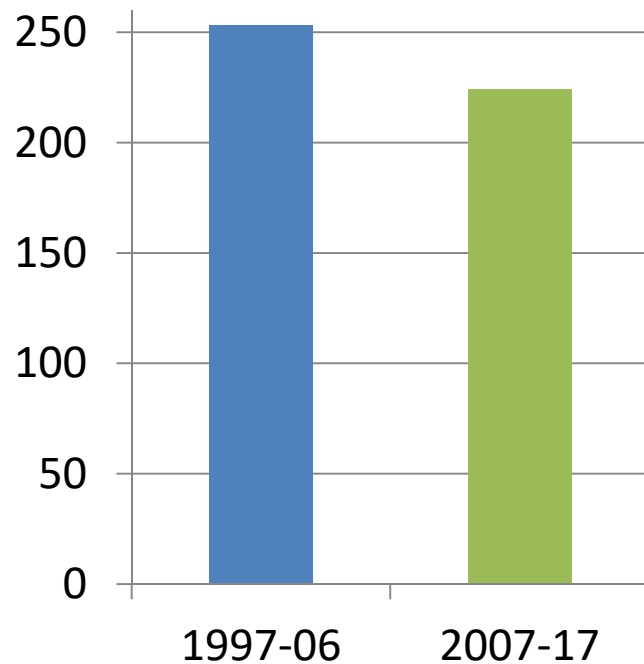
ROFN: Additional Product Inclusion Also Dominates ROFNs, with Territory Expansion Twice as Common as Field Expansion



ROFN = Typically a right held by licensee, conditional on an action by the originator or third party, wherein the terms of exercise are to be negotiated at a future time

CoC: Change of Control Provisions Mostly Impact Deal Originators, with Less Application to Licensees in Recent Years

Alliances with Change of Control Provision



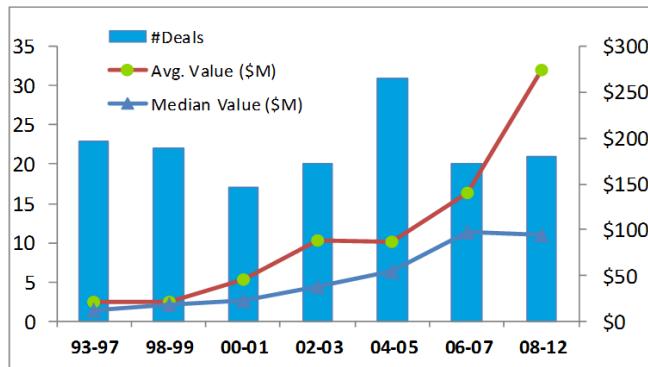
CoC = A right held by a party to modify the alliance terms in pre-determined respects in the event the other party experiences a majority change of ownership

This Presentation will be Available on our Discussion Website,
BioSciBD.com



BioSciBD.com Has BioPharma
Industry Insight & Analysis

Sales Milestone Payments have Grown Substantially ...



BioSciDB.com Shows You
Best Practices, Then & Now

