

Making a great deal: ingredients for success

BioPartnering North America,
Vancouver, February 4, 2008

James Hatton

FARRIS

Farris, Vaughan, Wills & Murphy LLP:

Experienced advisors on collaborations:



Development and License Agreement



Development Agreement



Collaboration and License Agreement



Development and License Agreement



License Agreement



Collaboration and License Agreement



Strategic Alliance and Exclusive Master Agreement



Joint Development Agreement

Ingredients for success in life sciences licensing: overview

- idiosyncratic look (from the biotech perspective)
- focus on recent important and innovative collaborations
- some deal points, trends and implications for structuring life sciences alliances

Definitive list of alliances of 2007:

- 35 agreements - full text
- text of all agreements linked at <http://del.icio.us/JamesHatton/BPN2008>

The screenshot shows a web browser window with the address bar containing the URL <http://del.icio.us/JamesHatton/bpn2008?settagview=cloud>. The browser's search engine is set to Google. The page content includes the Del.icio.us logo, the user name 'JamesHatton', and the tag 'bpn2008'. Navigation links for 'popular' and 'recent' views are present, along with 'login', 'register', and 'help' options. A search bar is located at the top right. Below the search bar, the page indicates 'JamesHatton's items tagged bpn2008' and provides a view selector for 'all' and 'popular'. The main content area displays three items, each with a title, a 'save this' link, and a date: 'XenoPort GSK Development and Commercialization Agreement of February 7, 2007', 'Targacept GSK Product Development and Commercialization Agreement of July 27, 2007', and 'pSivida Pfizer Collaborative Research and License Agreement of April 3, 2007'. A 'related tags' sidebar on the right lists various tags such as 'Agreement', 'Astrazeneca', 'Bayer', 'BioCryst', 'BMS', 'BreakthroughAlliance2007', 'CellTherapeutics', 'Co-Development&Option', 'Collaboration', 'Distribution', 'Durect', 'Dynavax', 'Epix', 'Exclusive', 'GlaxoSmithKline', 'GSK', 'GTx', 'Halozyme', 'Icagen', 'Idera', 'Interesting', 'INTERMUNE', 'IpSen', and 'Isis'. At the bottom right, there is a green button with the text 'FARRIS'.

del.icio.us / JamesHatton / bpn2008

popular | recent
login | register | help

JamesHatton's items tagged **bpn2008** → view **all**, popular

del.icio.us search

« earlier | later » page 1 of 4

XenoPort GSK Development and Commercialization Agreement of February 7, 2007 [save this](#)
to XenoPort GSK Collaboration Agreement bpn2008 ... on jan 03

Targacept GSK Product Development and Commercialization Agreement of July 27, 2007 [save this](#)
to Targacept GSK Collaboration Agreement bpn2008 ... on jan 03

pSivida Pfizer Collaborative Research and License Agreement of April 3, 2007 [save this](#)
to pSivida Pfizer Collaboration Agreement bpn2008 ... on jan 03

▼ **related tags** + Agreement + Altana
+ Anacor + and + Archemix + ARIAD
+ AstraZeneca + Avalon + Bayer + BioCryst
+ BMS + BreakthroughAlliance2007
+ CellTherapeutics + Co-Development&Option
+ Collaboration + Distribution + Durect
+ Dynavax + Epix + Exclusive + GlaxoSmithKline
+ GSK + GTx + Halozyme + Icagen + Idera
+ interesting + INTERMUNE + IpSen + Isis

FARRIS

Environment & ingredients:

- environment for pharma and biotechs
- expectations regarding ingredients
- ingredients: the reality

Environment: pharma

- 'empty pipeline' - drugs coming off patent faster than new drugs coming on to market
- rising development costs
- research productivity down; declining number of NDAs
- increasing uncertainty regarding regulatory treatment

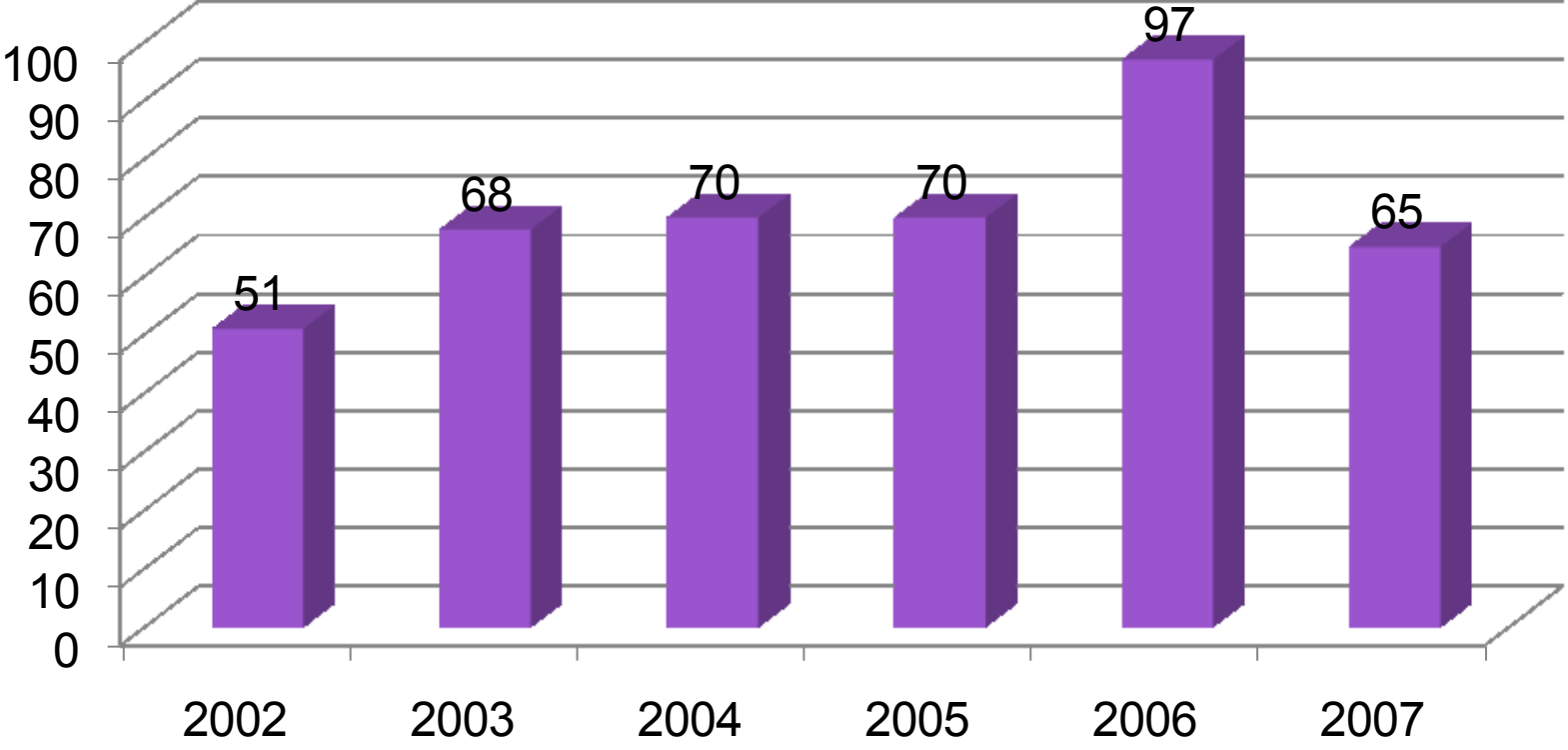
Environment: biotech

- competition for programs
- tighter money
- biotechs want to build the company through vertical growth
- biotechs seek higher returns by bearing more of the risk

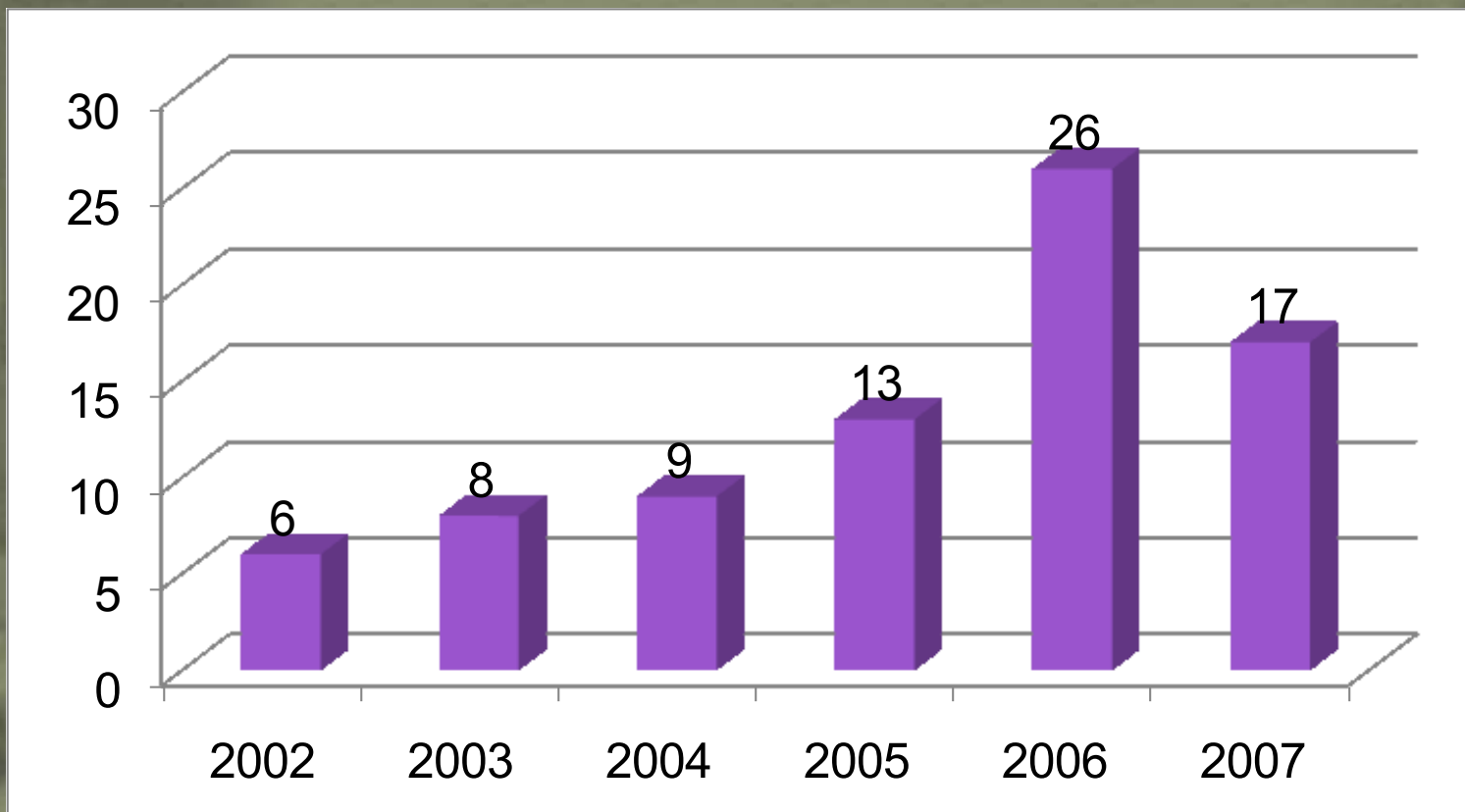
Expected ingredients:

- more biotech involvement in development and commercialisation
 - sole conduct of development to an endpoint; co-development; retention of some commercialisation rights; product supply by biotech
- biotech may have options on funding or conduct of development
- increased biotech input into alliance decision-making during development
- more profit sharing deals

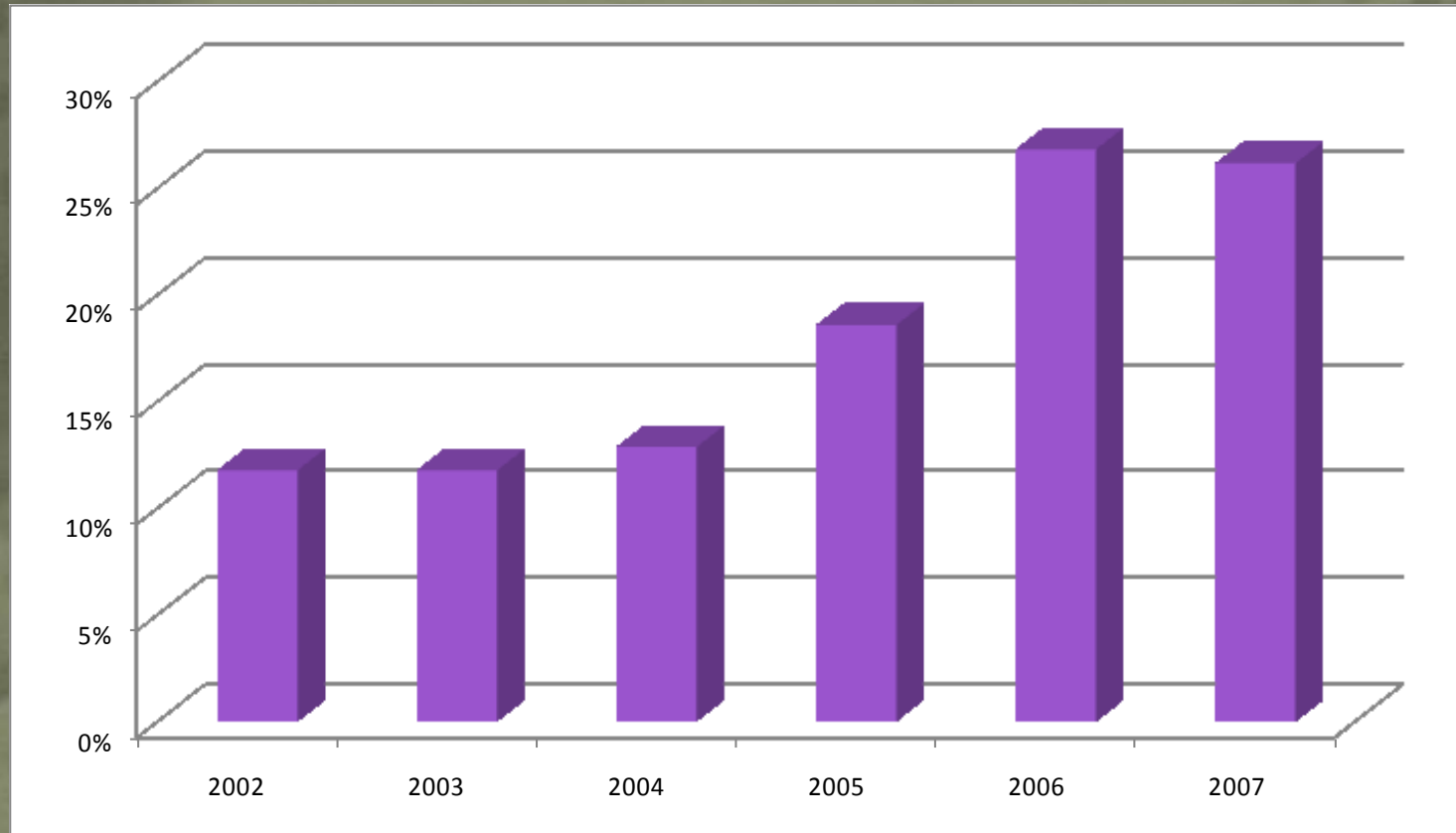
Co-development agreements:



Co-development agreements with options:



Percentage of co-development agreements with options:



Publicly disclosed co-development agreements with options:

- Archemix Merck of 06/07
- ARYx P&G of 06/06
- Cell Therapeutics Novartis of 09/06
- Cytokinetics Amgen of 12/06
- Exelixis Genentech of 12/06
- InterMune Roche of 09/06
- MedImmune Infinity of 08/06
- Nycomed NPS of 09/07
- Pharmacopeia Organon of 02/07
- Seattle Genetics Agensys of 01/07
- Targacept GSK of 07/07

Biotech may have conduct of development to an endpoint:

- lead selection (Pharmacoepia Organon)
- proof of concept (MedImmune Infinity; Targacept GSK)
- phase I (Exelixis Genentech; InterMune Roche)
- phase II (CytoKinetics Amgen)

Biotech input into alliance decision-making during development:

- typically, in the end, the licensee decides
- exclusions from JSC process:
 - conduct of development to endpoint
 - increases in effort above specified level; replacement targets; achievement of milestones (Archemix Merck)
 - changes to key parameters of development plan (NPS Nycomed)
 - breaches, achievement of milestones, diligence or money disputes (ARYx P&G)

Rise of the option in co-development: opting in to fund development

- Archemix Merck; ARYx P&G; Cytokinetics Amgen
- SGI Agensys (for second collaboration product)
- NPS Nycomed (for additional indications)

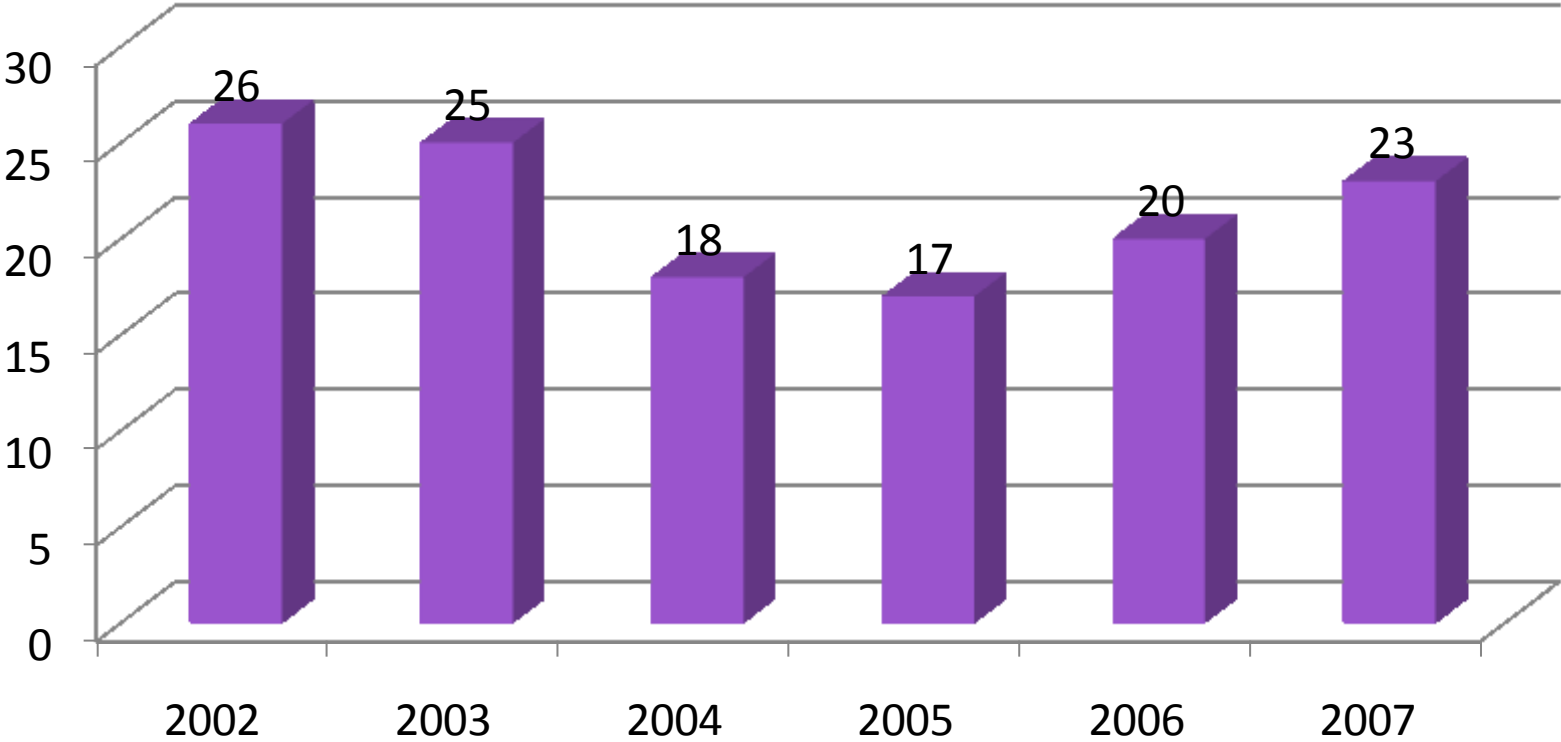
Rise of the option in co-development: opting out

- ability to opt out
 - Archemix Merck; Exelixis Genentech; InterMune Roche; MedImmune Infinity; Pharmacopeia Organon; see also Altus Genentech
- consequences
 - conversion from profit sharing to royalties
 - milestones may not apply (Archemix Merck)
 - royalty rates vary based on timing of the opt-out (MedImmune Infinity)

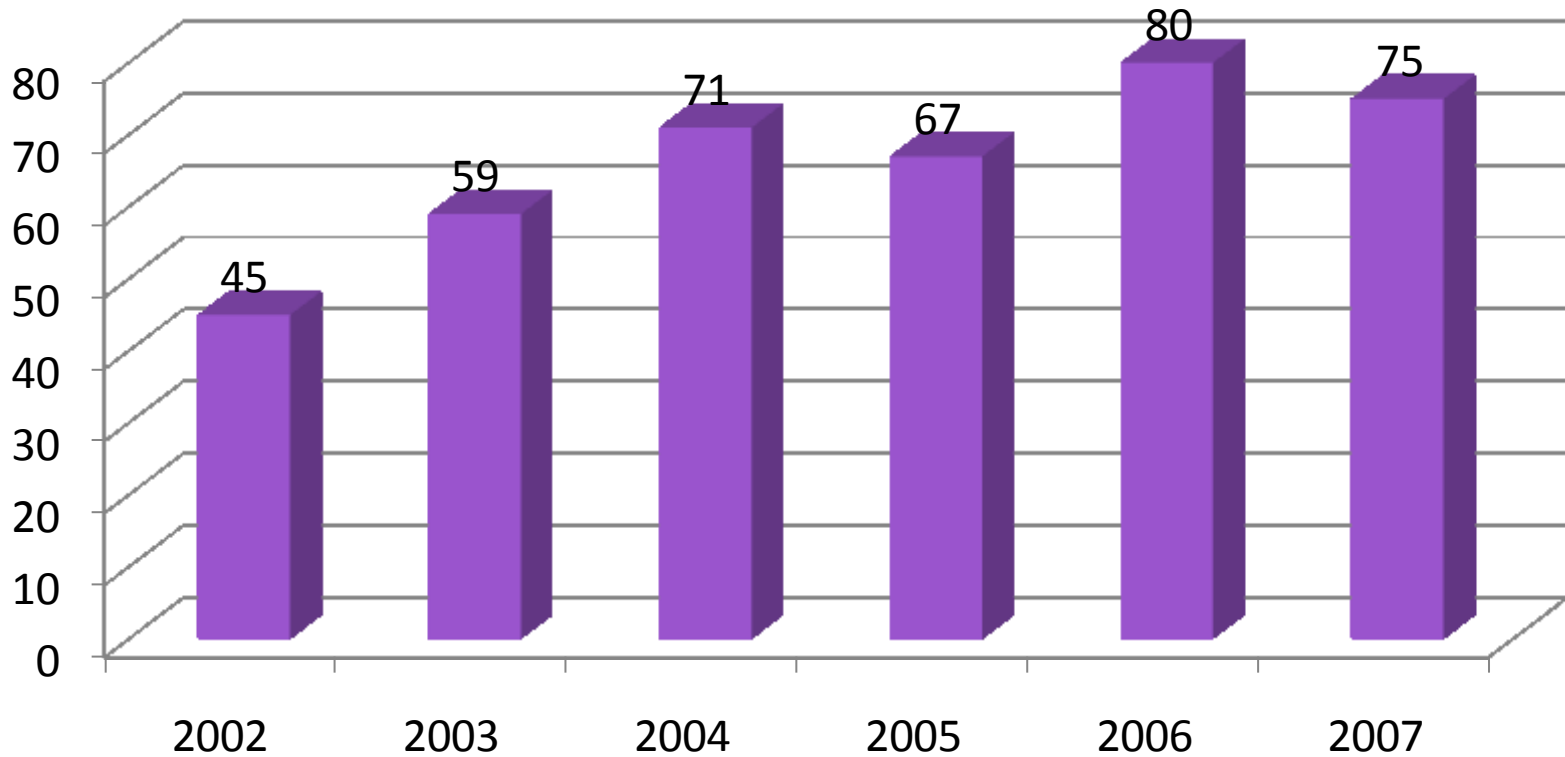
More biotech involvement in commercialisation:

- co-marketing
- co-promotion
- input into alliance decision-making during marketing
- more profit sharing deals
- biotechs building supply capability

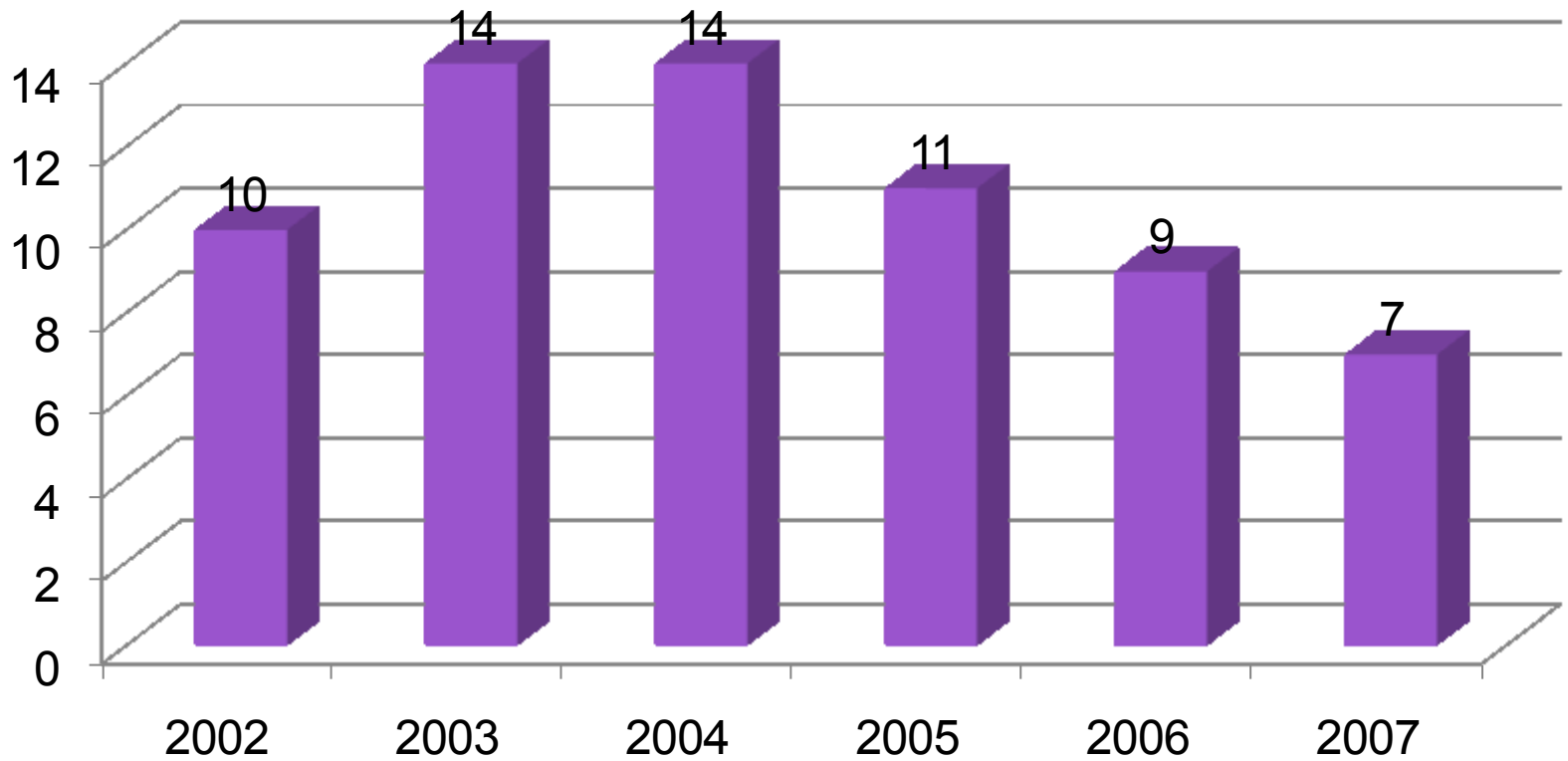
Co-marketing agreements:



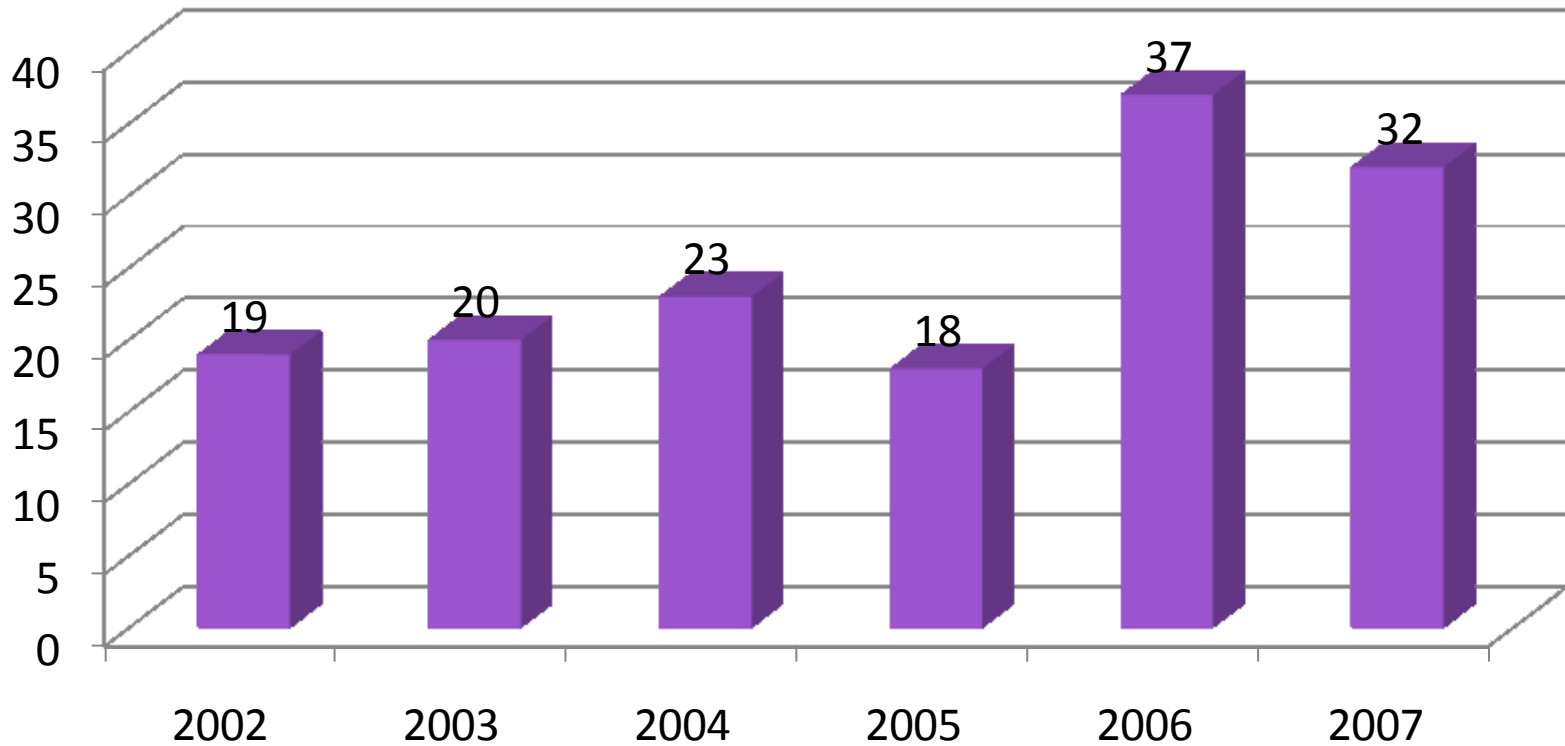
Co-promotion agreements:



Profit sharing 50/50 deals:



License agreements with supply terms:



How biotechs opt in to co-promotion agreements:

- new agreement based on material terms as listed (Archemix Merck; ARYx P&G; Cell Therapeutics Novartis; Exelixis Genentech; InterMune Roche; Targacept GSK)
- if the parties cannot agree:
 - arbitrate (ARYx P&G)
 - option expires (Archemix Merck)

Biotech input into alliance decision-making during commercialisation:

- typically, limited information rights and perhaps consultation rights
- consultation on everything but price (Cell Therapeutics Novartis)
- if joint commercialisation team cannot agree, go to CEOs and then arbitrate (MedImmune Infinity)

Summary

- co-development deals and options on the rise
- biotechs retaining more marketing rights, but little decision-making authority
- profit sharing development deals are giving way to development deals exploiting options

For an electronic copy of today's presentation and the full text of all background licenses, please contact:

James Hatton
Farris, Vaughan, Wills & Murphy LLP
jhatton@farris.com

or visit:

<http://del.icio.us/JamesHatton>; or
www.jameshatton.com/public

FARRIS