Deal or No Deal?:

Option Based Partnering Deals
& other Risk-Modified Dealmaking Trends

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Risk-Modified DealMaking Trends in 2010
- Agenda

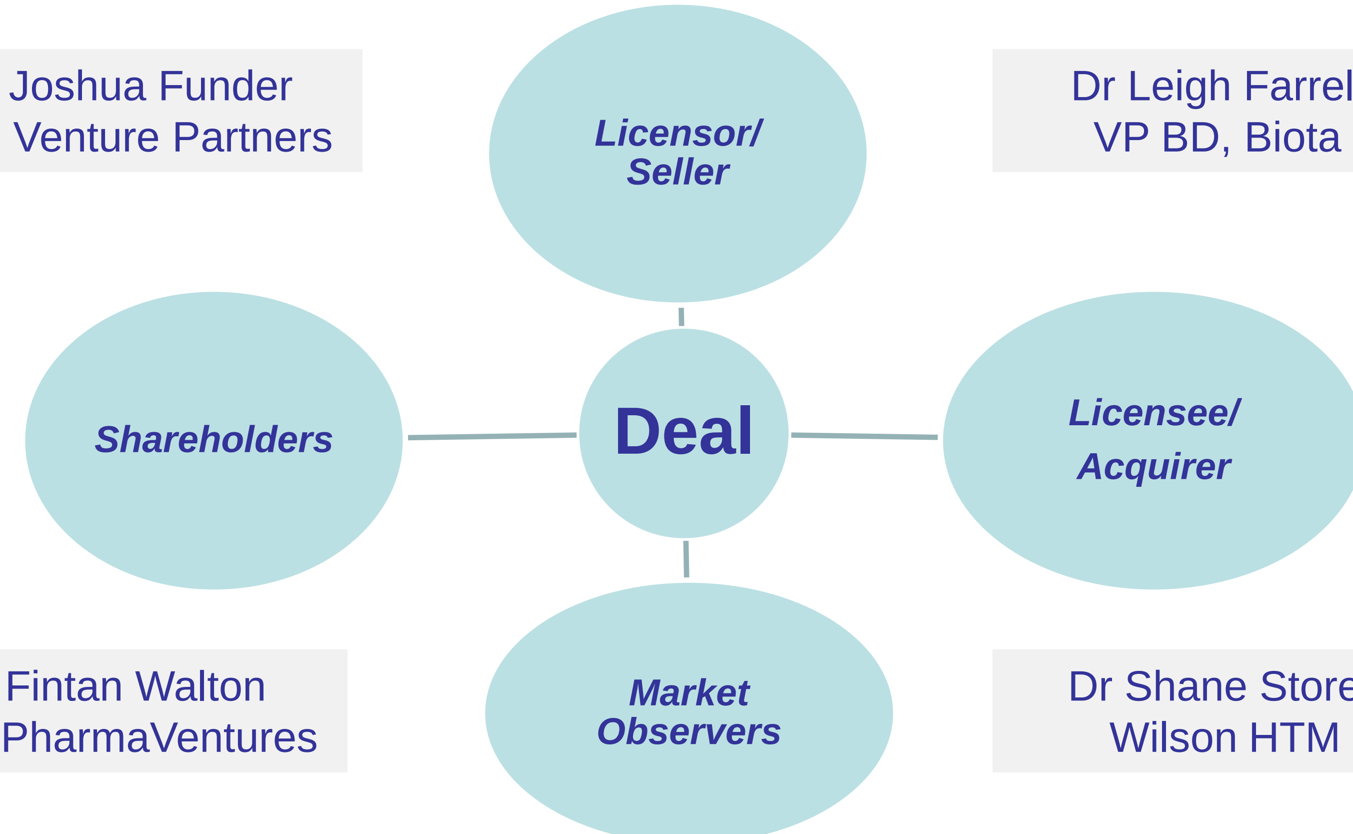
- **Pharma-Biotech dealmaking is still highly active**
- **How the Global Financial Crisis impacted deal structures**
- **Risk/Reward Share: A new era for Deal Structuring**
- **Conclusions**

About The Panel
- 360 View of Deal Structures

Dr Richard Treagus
CEO, Acrux

Dr Joshua Funder
GBS Venture Partners

Dr Leigh Farrell
VP BD, Biota



Dr Fintan Walton
CEO PharmaVentures

Dr Shane Storey
Wilson HTM

About me

- **11 years with GlaxoSmithKline, London**
  - 5 years in Global Finance Roles
  - 6 years to 2006 as Transactions Director, WorldWide Business Development
    - Global licensing deal valuation, structuring, negotiation

- **5 years in Australian pharma-biotech industry**
  - Principal, PharmBio Deals consultancy
  - Business Development Director, Advent Pharmaceuticals

- **Fellow, Institute of Chartered Accountants**

Pharma/Biotech Dealmaking

- 2010 Overview

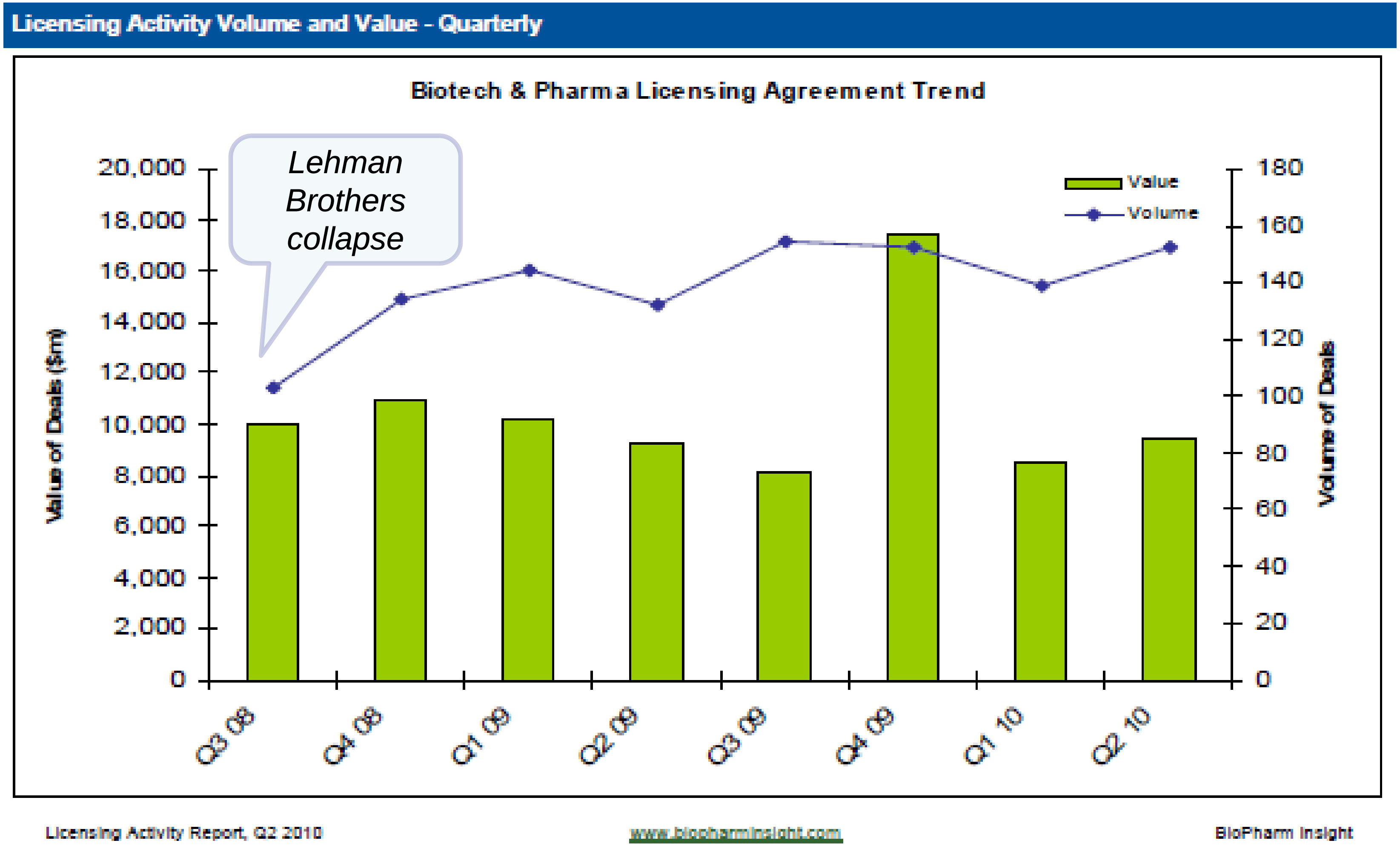
Pharma Industry Key Strategic Issues

- Generic competition (2011/12 patent cliff)
- Increased regulatory hurdles
- Medicine Pricing and Access Issues
- Shift to personalised medicines
- Intense competition on few targets
- Globally dispersed talent pools
- Novel R&D approaches
- Increasingly externalised innovation

Source: Sanofi Aventis Acadamie de Pharmacie Feb10

Rate of R&D Externalisation increases

- Deal Value average declines



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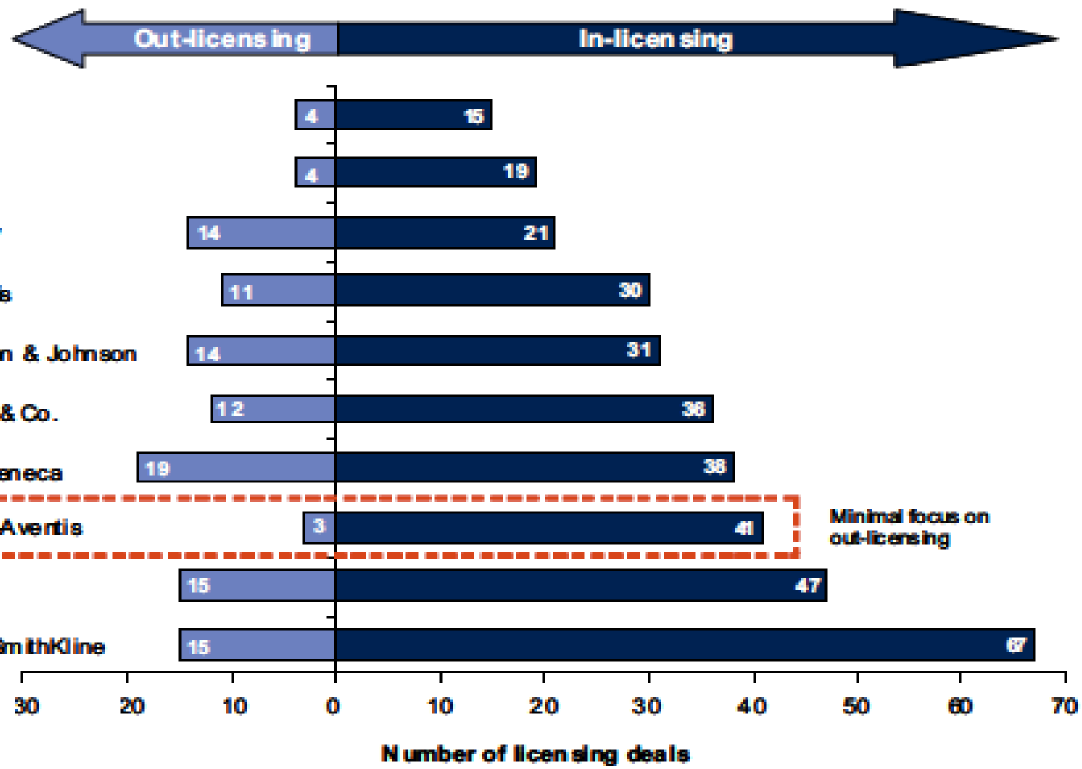
Big Pharma highly active: up to 3 in-licensing deals a month

Figure 10: In-licensing deals performed by the top 10 pharma companies by category, 2008–09



Note: base is 458 as it does not include the 17 manufacturing/supply license agreements signed by the same top 10 pharma companies during 2008–09.

Source: Datamonitor Pharma Licensing Overview report Mar10

Late Stage Deals are still a Sellers' Market

Lilly/Acrux ink $335M deal for Ph3 underarm testosterone therapy 16Mar10

Lilly will licence exclusive worldwide rights to commercialize AXIRON.

Acrux will receive:
- **an upfront payment of $50 million**
- plus $3 million on the transfer of manufacturing assets.
- $87 million upon the issuance of marketing authorization by the FDA
- up to $195 million in potential commercialization milestones , and
- royalty payments on future global sales if AXIRON is successfully commercialized.

_Late Stage Deals

- Risk Reduced, Short Supply & High Demand

(only Late Phase Medicines Can Help Address 2011/12 "Patent Cliff")

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10 years of Pharma-Bio DealMaking

	Good Old Days 2000-2007	Global Fin. Crisis 2008-2009	Brave New World 2010…
Whose Market?	Seller's	Buyer's (except for Ph3 and later medicines)	Buyer's (except for Ph3 and later medicines)
Deal Trends	High rate of deals, especially clinical stage. Licensing dominates. Strong upfronts & near term milestones. Licensee achieves product quid and/or commercialisation participation.	Fewer deals. Hostile, backloaded M&A. Big pharma distracted by consolidation (Roche/Genentech; Pfizer/Wyeth; Merck/ScheringPlough)	Deal rate recovering; trend to preclinical deals. Options & heavily backloaded (if <Ph3) deals.
Risk Capital	Plentiful – VCs strong and IPO frenzy	VCs reserving funds for follow-on investments. Public risk capital in deep-freeze	Public risk capital markets – slow thaw, US-led

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Option-Based Deals

& other Risk-Modified Deal Structures

What is an Option Deal?

- **Buyer/licensee invests in exclusive right, but not obligation, to transact on an underlying asset on (typically) predetermined terms, when certain future conditions are met.**

- **Seller/licensor is obligated to fulfil the transaction, if requested by the buyer.**

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Example:
'Plain Vanilla' Option-to-Licence from Research Collaboration

Lundbeck-Genmab Research Collaboration & Option to Licence 13Oct10

Lundbeck will have access to Genmab's antibody creation and development capabilities, ... Furthermore, **Lundbeck will have an option to take selected antibodies into clinical development at its own cost and subject to the payment of milestones and single digit royalties to Genmab**…**Additionally, Genmab will have a similar option to take selected antibodies into clinical development for certain non-CNS indications at its own cost and subject to the payment of milestones and single digit royalties to Lundbeck.** Under the terms of the agreement, **Genmab will receive an upfront payment of EUR 7.5 million (approximately DKK 56 million). Lundbeck will fully fund the development of the antibodies**. If all milestones in the agreement are achieved, the total value of the agreement to Genmab would be approximately EUR 38 million (approximately DKK 283 million), plus single digit royalties

Source: FierceBiotech

Example: ‘Plain Vanilla’ Option-to-Ph2 Licence

Novartis options Quark program in $680M pact 18Aug10

Underscoring the rich potential of new siRNA therapeutics, Novartis has agreed to pay Quark Pharmaceuticals **up to $680 million** to nail the licensing rights to a new therapy for kidney-related diseases.

Quark will get $10 million upfront for an option on QPI-1002, which is currently in Phase II for kidney-related conditions. If Novartis decides to pull the trigger on the option, it will pay out up to $670 million more in fees and milestones. The drug is being developed for acute kidney disease and delayed graft function in kidney transplantation. The therapy targets the p53 gene, saving cells that could be killed by ischemia and other stress-related conditions.

“BioBucks”
-Upfront is <2% of total (potential) deal value
-(6 weeks later, Quark announced $20m IPO)

Source: FierceBiotech

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Example of Double-Dipping: Option-to-Acquire...Twice!

Incline Therapeutics lands $43M round, option to sell for up to $228M 22Jun10

Incline Therapeutics has landed a $43m Series A to back the development of a pain med delivery system and **landed a $3.5 million upfront for an option to sell the** company to Cadence Pharmaceuticals. Cadence gets the right to buy Incline **for $135 million during the first option period, with the price rising to $228 million in the second option period--plus a $57 million bonus if the FDA approves its pain delivery technology.**

Incline is developing Ionsys, a needle-free delivery device for opioid meds that was originally advanced by Johnson & Johnson. Approved by the FDA four years ago, Ionsys was never marketed and Incline is adding new patient safety features to the technology.

Source: FierceBiotech

Turning the Tables: Licensor Opt-Back-In

Genmab, Seattle Genetics ink cancer research deal 14Sep10

Genmab and Seattle Genetics have signed an antibody-drug conjugate (ADC) research collaboration agreement. Under the agreement, Genmab has rights to utilize Seattle Genetics' ADC technology with its HuMax-TF antibody. …. Genmab is responsible for research, manufacturing, preclinical development and Phase I clinical trials of ADCs. **Seattle Genetics received an undisclosed upfront payment and can opt into an ADC product at the end of Phase I development.**

Source: FierceBiotech

Pros & Cons of an Option Deal
- Buyer's/Licensee's Perspective

Pros

- Minimises investment until a key technical outcome is known. ("Try before you buy").
- Assists "multiple shots on goal" strategy
- Enables buyer to influence option-dependent outcome (eg advises clinical trial design)
- Locks out competitors in option period.
- Deal terms set before option trigger event outcome known (got a bargain?)

Cons

- Weaker offer than an option-free structure; may lose out in negotiations.
- Less immediate influence on program than if seller had direct licence
- Deal terms set before option trigger outcome is known (overpaid?)

Pros & Cons of an Option Deal
- Seller's/Licensor's Perspective

Pros	Cons
• Immediate capital injection - Partner's option fee • Partner's commitment (of sorts) • Partner's resources to help you achieve option condition (possibly) • No long-term commitment (possibly) to partner or program • If research collaboration, and option not exercised on some compounds, may leave some preclinical assets for further internal development/other partnering	• "The deal you took because you couldn't get an option-free deal" – Exclusive tie-in, with (possibly) no commitment long-term future – Losing the Upside – Risk of non/slow program/ company recovery if partner does not exercise option

Case Study:

Peplin Ltd

Dr Joshua Funder

GBS Venture Partners

Peplin History

1998 – Peplin founded by Dr James Aylward

1999 - Restructure prior to ASX listing seed investors in pre-IPO round

2000 - IPO on ASX

2001 - Lead compound identified

2002 - Dermatology applications licensed to Allergan in US

2004 - INDs filed for AK & BCC, Allergan license terminated

2006 - Established US operations

2007 - Redomiciled to US, US IPO prospectus (NASDAQ), US$15m GE loan

2008 - US prospectus pulled, Tom Wiggans CEO, Phase III trial, GBS invests

2009 – Dual M&A / Equity raise process initiated Feb 09,

Merger Agreement signed 2 Sept

Getting Together: $23m Biodollar Deal

- In November 2002, Peplin licensed PEP005 Topical, its proprietary product for the treatment of actinic keratosis (AK) and non-melanoma skin cancer to Allergan, Inc. of Irvine California.

- Peplin kept rights to other indications
  - US$1m upfront
  - US$22m additional in development fees and milestones
    - IND
    - Ph III
    - NDA filing
    - NDA approval
  - Low royalty rate on net sales

Breaking Up: It's About You, Not Me

- IRVINE, Calif. -- Allergan, Inc. (NYSE:AGN) and Peplin Ltd. have agreed to discontinue their collaboration for the development and commercialization of skin cancer products in North and South America based on Peplin's proprietary and novel anti-cancer compound PEP005. **Allergan continues to believe that Peplin's lead investigational product PEP005 Topical has potential** in the large, growing and under-served market for treating non-melanoma skin cancer.

- "Allergan maintains a disciplined portfolio planning process that seeks to ensure a focus on core programs that project the highest return and is concentrating resources on high potential products with approvals expected between now and 2008," explained Dr. Scott Whitcup, Executive Vice President, Research and Development. "PEP005 was one of the technologies which did not make the funding list for 2005. However, the Company remains committed to the skin care business through its strong presence in the dermatology market with BOTOX(R) Cosmetic and the tazarotene franchise."

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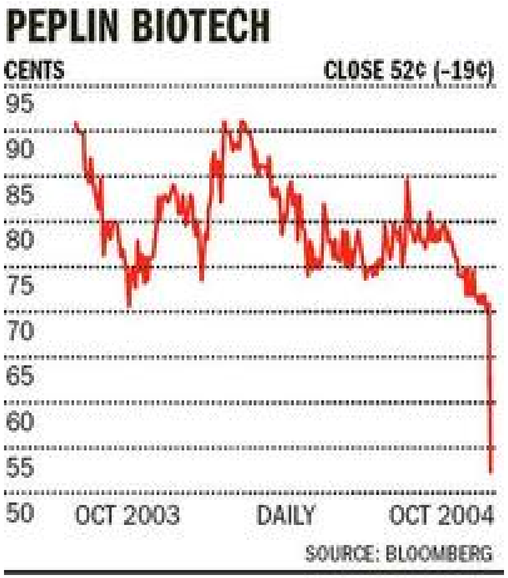
Give Back, Take Back

Peplin Got:
•US$1.3m outstanding obligations paid to Peplin
• US IND for Actinic Keratosis, Basal Cell Carcinoma
• Commitment to complete Ph I study underway
• All IP to proprietary development program
• Scientific data and regulatory filings returned

Allergan Got:
• Option for Allergan to re-license in 2006 (if PEP005 remains unlicensed)
• On relicense Peplin to pay Allergan 25% of pre-commercialization payments up to US$3m
• On relicense 25% of post commercialization royalties and revenue up to a cap of US$4m (inc $3m above)
• If Peplin itself markets PEP005 Topical in the Americas, pay Allergan 10% royalty up to US$4m



Happy Ending

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Peplin shares surge on cancer gel test

By Rebecca Urban
January 11, 2005

Shares in drug developer Peplin surged yesterday after it reported a clinical trial to test the safety of its skin cancer treatment had cleared sun spots in several patients.

While the 16-patient study was supposed to evaluate the safety of a single dose of Peplin's topical gel when applied to actinic keratoses, or sun spots, it also found that 29 per cent of lesions disappeared within three weeks of treatment. A further 11 per cent were almost cleared.

The unexpected news lifted Peplin's share price 40 per cent before it settled 7¢ higher at 49¢.

With the result hailed as vindication of Peplin's decision to assume control of the product after its commercial partner, Allergan, dumped it from its portfolio last year, the Queensland-based company is preparing a broader and longer-term trial to further test the findings.

Peplin: sold for $350 million
Thursday, 3 September 2009
Nick Evans

PEPLIN has become the latest late-stage Australian biotech to be bought out, announcing early this morning it has entered a definitive merger agreement with privately owned Danish pharmaceutical company LEO Pharma.

Marc Sinatra's Bioguide

Monday April 27, 2008

BIG PHARMA GETS IT WRONG - PEPLIN A FIVE-BANGER

Overview: I gave up following Peplin back in 2004, when Allergan handed back PEP005 after licencing the non-melanoma skin cancer drug from them in 2002.

The willingness of investor of note, MPM Capital, to lead a $40 million dollar capital raising for Peplin in 2006 should have been the signal for me to take another look at them, but it wasn't until August last year, when they raised $US24 million in very difficult conditions that they again caught my eye. The positive signal was reinforced by the fact that arguably Australia's leading life science investment firm, GBS Venture Partners, led the raising.

Could big pharma Allergan have got it wrong?

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Options aren't the only Risk-Modified Deal Structures

- **"Structured Acquisition"**
  - Acquisition price satisfied over a series of payments. Final price of acquisition will be determined on whether/when a series of conditions are ultimately met
    - eg technical milestones, measurable commercial success

      20Jul10 (Reuters) – "When Celgene agreed to buy Abraxis for $2.9 billion, it set aside $650 million in "milestone payments" if key drug Abraxane meets certain development goals -- a carrot held out to encourage the success of the merger."

- **Traditional methods of 'downstream economics'**
  - Milestones, backloaded rewards
  - Tiered royalty structures

Conclusions

- Pharma-Biotech Dealmaking remains highly active
- GFC and increased Externalisation of R&D Engine have driven buyers'/licensees' need for more risk-modified deal structures
- Late stage medicines (Ph2b onwards) are still in a sellers' market
- Option-based deals and other modified risk structures will remain as deal structure templates for pre Proof of Concept medicines
- Licensor/Seller should negotiate terms that maximise their interests in all scenarios!

Panel Discussion:

Are Option-Based Deals a “Deal or No Deal”?

About The Panel

- 360 View of Deal Structures

Dr Richard Treagus
CEO, Acrux

Dr Joshua Funder
GBS Venture Partners

Licensor/ Seller

Dr Leigh Farrell
VP BD, Biota

Shareholders

Deal

Licensee/ Acquirer

Dr Fintan Walton
CEO PharmaVentures

Market Observers

Dr Shane Storey
Wilson HTM

Panel Themes

- Are option deals “non-deals” until the option conditions vest?
- Are option deals best avoided by seller/licensor if possible?
- What creates a good option deal for the seller/licensor?
- How do you value the option price?
- How will the market react to and value an option deal?

One that got away..
- Did Buyer try to negotiate Option for this asset?

Durect's pain drug fails to clear key hurdle in PhIIb 17Jun10

7Jun10 -- Hospira and DURECT announced a licensing for DURECT's POSIDUR™ in Phase III clinical trials. .. **Hospira will make an upfront payment of $27.5 million, with the potential for up to an additional $185 million in performance milestone payments** based on the successful development, approval and commercialization of POSIDUR. …..

17Jun10 - 10 days after signing, Durect reports that its pain drug Posidur-..**failed to demonstrate an ability to reduce patients' use of rescue opioids.**

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Source: FierceBiotech

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