



## Summary of PIPMG Conference

**“Licensing: a better way forward? “  
The Challenges for Project Managers in Pharmaceutical and Biotech industries.  
November 2005**

The theme of the conference was licensing.

Speakers and delegates at the conference were from primarily Project and Portfolio Management backgrounds from a range of companies: virtuals, biotech’s, CROs, small and large Pharmaceuticals; Roche, Novartis, Pfizer, GSK, AstraZeneca, Stiefel, Solvay, Fulcrum, Covance, Oxagen, CAT Bioaccelerate, Neurotargets, IP21PO, Centre of Excellence Life Science, Panmure Gordon.

Licensing has emerged as a key value driver and now plays an increasing role in the business model of both pharmaceutical and biotechnology companies. In 2004, over a quarter of the sales of the top 15 pharmaceutical companies were derived from in-licensed drugs. While in-licensing mostly remains a luxury of big Pharma, many start-ups have a business strategy that is dependent, at least initially, on out-licensing or partnering their first few drug candidates. In addition, biotech companies seeking clinical stage products to secure funding have bucked the trend recently, and big Pharma have received this as a potential way to focus on their core activities, and/or utilise biotech’s streamlined development approach.

**Presentations were given on:**

### **The City, The Biotech And You**

*Jonathan Kwok, Head of Life Sciences, Pannure Gordon, London UK*

*Please see separate slide set*

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### **Building A Beautiful Biotech**

*David Kennard, CEO of Neurotargets, London, UK*

*Pease see separate slide set*

Biotech development is inherently risky and it is increasingly difficult for small biotech companies to evolve into self-sustaining mature biotech. This talk described how to survive the valley of death, using an extensive collaborative approach to shorten the rather protracted start-up phase, permitting survival on limited expenditure and enabling a fledgling biotech to exhibit the streamlined, low spend profile that is currently so desired.

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### **Table Workshop 1 - “What are the critical factors for in-licensing an early development candidate?”**

Delegates worked in table groups and identified the three top critical factors for in-licensing an early development candidate within six areas of the development process:

Drug Development Area Addressed	Top Critical Factors To Consider
1- Pharmacology	<ul style="list-style-type: none"> <li>• Efficacy in validated model, inc. PK/PD vs. Gold Standard; understanding M of A</li> <li>• Early ADME- e.g. QTC; screening, early toxicology, exploratory</li> <li>• Target specificity On/Off receptor               <ul style="list-style-type: none"> <li>○ Issue of difficulty for biologics</li> <li>○ Estimation of clinical dose</li> </ul> </li> </ul>
2- CMC	<ul style="list-style-type: none"> <li>• Drugability</li> <li>• Phase of Development - scale of requirement of material</li> <li>• Expertise of assessment team</li> </ul>
3- ADME/ DMPK Toxicology	<ul style="list-style-type: none"> <li>• Correct for route, correct tox species</li> <li>• QTc prolong, metabolites, PK/PD -adequate safety margin</li> <li>• Biologics vs. small molecules</li> </ul>
4- Clinical	<ul style="list-style-type: none"> <li>• Due Diligence - Support for development in target population, quality markers of clinical efficacy and opinion leader support</li> <li>• <b>Strategic Fit</b> - Unmet need, partner fit, technical fit/ risk, validated indication, risk vs. interval risk portfolio</li> <li>• <b>Impacts outside clinical</b> - Business impact on clinical portfolio, regulatory understanding of IND, manufacturing and pre-clinical support for clin dev program, profile of unmet need and PR.</li> </ul>
5- Regulatory	<ul style="list-style-type: none"> <li>• <b>Environment</b> - Class effects/ new area, competitor exp. of regs and unmet need</li> <li>• <b>Plan</b> - Probability of regulatory success, cost vs. benefit, Content- depth/ feasibility, consulting- who &amp; when and gap analysis</li> <li>• <b>Experience</b>- In house, existing relationships and strategic fit</li> </ul>
6- Marketing/ IP	<ul style="list-style-type: none"> <li>• <b>IP</b> - Extent of patents and 3<sup>rd</sup> party involvement</li> <li>• <b>Marketing</b> - No part of official drug development, Valuation of deal, Assumptions- are they valid?, pricing in different territories</li> </ul>

*Further details of the table discussions are captured in the document Workshop 1*

Followed by Presentations given on:

**Project Management In Due Diligence And Integration**

Martine Mazzetti, Project Manager and PL Liaison for Roche Pharmaceutical, Basel, Switzerland

*Please see separate slide set*

A reflection based on the ROCHE experience, this presentation provided theory and practical examples on how to address key questions during Due Diligence. For example, ‘Strategic fit’ - does the opportunity conflict with, or complement, an existing portfolio? ‘Scientific merit’ - is there belief in the target or mechanism? ‘Value’ - will there be value generated for both companies? ‘Integration’ - how can companies ensure that the partnership runs smoothly, and what are the challenges of transforming key partnerships into strategic alliances?

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**Rationale For Strategic Collaborations: Early Stage Licensing And Role Of Project Management**

Ravi Sodha, Global Business Development & Licensing Head, Novartis Pharma AG, Basel, Switzerland

*Please see separate slide set*

The presentation described the role of licensing in the pharmaceutical industry. It suggested rationale for early-stage versus late-stage licensing and discussed the difficulties of valuing early-stage deals, both for licensor and licensee. The presentation discussed several key factors necessary for a successful licensing deal. It also proposed what potential licensor and licensee should look out for when dealing with partners and a role for project managers during the in-licensing process, especially in Big Pharma.

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**Table Workshop 2 - Due Diligence Considerations For An Optimal Approach**

Delegates worked in table groups and identified the optimal approach to due diligence considering three different scenarios: Re-profiling, Biologics vs NCE’s and Strategy Planning

Due Diligence Scenario	Considerations for Optimal Approach
Re-profiling	<ul style="list-style-type: none"><li>• Clarify IP position</li><li>• Safety data, pre-clinical and Clinical</li><li>• Deal Structure</li><li>• Business case, impact on both parties</li><li>• Division of labour</li><li>• Safety management</li><li>• Communication &amp; PR, internal &amp; ext</li></ul>
Biologics vs NCE’s	<ul style="list-style-type: none"><li>• Targeted biologics- is there a marker?</li><li>• Stability - master cell reproductivity</li> <li>• Validation of model, transition into man and Toxicology elements</li><li>• Minimal pre-clinical</li><li>• Specialist manufacturing, yields and facility, consider quantities early</li><li>• Storage and shipping</li><li>• Assays</li><li>• Regulatory, Clinical &amp; Marketing</li></ul>

<b>Strategy Planning</b>	<ul style="list-style-type: none"> <li>• Summary of assumptions</li> <li>• Know inter-relationships</li> <li>• Strategic fit &amp; organisation objectives</li> <li>• Commercial benefit vs. Risk</li> <li>• Development milestones, gap analysis &amp; risk assessment - share risk</li> <li>• Governance structure &amp; decision making</li> <li>• Scientific merit</li> <li>• Politics</li> </ul>
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*Further details of the table discussions are captured in the document Workshop 2*

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The Meeting closed with a final presentation on:

**The Licensing Process: How Business Development And Project Management Should Work Together**

Andrew Mackie, IP21PO

*Please see separate Slide Set*

Licensing from the biotech perspective: what are the motives for licensing? An overview of the licensing process was presented, including techniques for making approaches. Also, how project management and business development can work together, revealing deal types and structures, and successes and failures along the way.