

Biotech-Pharma Partnering Forum

Strategic Alliances and Business Development

Medicine in the 21st Century
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Strategic Alliances and Business Development

- “Current Trends and Provisions in Pharma-Biotech Strategic Alliances” -- *Randy Sunberg, Morgan Lewis*
- “Issues of Licensing From/To a Big Pharma” -- *Nicholas Franco, Head of Primary Care Negotiation, Global Business Development & Licensing, Novartis*
- “Strategic vs. Financial Venture Investments -- Legal Perspectives” -- *John Sasaki, Morgan Lewis*
- “Hospital and Bio/Pharma Collaboration on Clinical Trials” -- *Pat Stanfill Edens, Assistant Vice President, Hospital Corporation of America*

Morgan Lewis: *Life Sciences Focus*

- Founded in 1873, today 1,200 lawyers in 18 offices worldwide
- 200 Life Sciences professionals, including 90 with advanced degrees in biochemistry, molecular biology, immunology, virology and plant genetics
- Interdisciplinary coordination of business transactions, IP, litigation, FDA and antitrust expertise to meet our clients' strategic objectives
- Named by many *Fortune* 250 companies as one of their primary law firms
- Recognized by corporate counsel for exceptional client service in a survey of *Fortune* 1000 companies
- Ranked among the leaders for deals valued at \$100 million or more by *Corporate Counsel Alert 2003 Mergers and Acquisitions*

Life Sciences Industry: Current Environment

- **Pharmaceutical industry reliance on “life cycle management” of existing products**
 - Prevalence of “me-too” drugs
 - 2/3 of prescription drugs approved by FDA between 1989 and 2000 were identical to existing drugs or modified versions of them*
- **Big pharma and big biotech looking for late-stage products**
 - Innovation gap
 - Patent expirations
- **R&D payoff slower than expected**
 - FDA appears to be tougher
- **Big pharma and big biotech strive for double-digit growth**
- **Wave of consolidation in industry “raises the bar”**
 - Aventis - Sanofi
 - Pfizer - Esperion

*(May 2002 Survey by National Institute for Health Care Management Foundation)

Current Trends

- **Pharmaceutical and biotech drivers toward partnering**
 - Access to technologies and expertise
- **Interdependent relationship of collaboration partners**
 - “Lead partner” status vs. “niches” of control
- **Maintaining alignment of interests among partners**
 - Non-competes, exclusivity and ex-program activities
- **Special deal factors and terms driven by current environment**
 - Lower valuations, shedding of low-performing assets and aversion to risk
- **Surprises - Good and Bad**
 - There’s no such thing as a “typical” deal

Current Trend: Biotech Shift “Downstream”

- **Move from research focus (platform technology and FTEs) to drug development and commercialization and booking sales**
- **Biotech negotiating leverage over big pharma and big biotech due to need for late-stage products (supply and demand)**
- **Need to demonstrate drug discovery ability and “product promise” to investors**
- **Willingness and ability to do more early clinical development before partnering**
- **Looking to partner for late-stage development risk-sharing, expertise in regulatory and/or manufacturing supply chain and/or marketing, and to maximize opportunity for potential blockbuster**
- **Demonstration of value of contribution translates into profit split (and expense and detail sharing)**

Current Trend: More Demanding Partners

- **Biotech values driven by recent product development disappointments**
 - E.g., FDA advisory panel recommendation against approval of Genta's lead antisense product
 - However, ImClone's Erbitux recently gained FDA approval
- **Increased due diligence**
 - FDA due diligence on filings, correspondence, clinical study protocols, meetings and approval strategy
 - Late-stage partnering drives need for increased due diligence on clinical development, manufacturing supply chain and pricing/reimbursement
 - IP due diligence and equity investment-related due diligence
 - Current economic environment may require "financial ability" due diligence
- **Insistence on deal term flexibility**
 - Risk aversion (or at least containment)

Current Provisions: Risk Reduction in Economic Terms

- **Reduced “buy-in” fees**
 - Smaller up-front payments
 - Deficit made up by additional deferred milestones
 - Can be same net value, but spread out in more stages
- **More, but smaller, milestones**
 - Single milestone events split into multiple events
 - E.g., Phase IIa and IIb separate milestones
 - Milestones keyed to product achievement + 3P action
 - E.g., NDA or BLA *acceptance for filing*
- **Loans to fund biotech partner development activities**
 - Instead of funding FTEs, especially in deal with downstream participation
 - Instead of equity investment
 - Repayable from collaboration products or in equity
 - Forgiven if product is successful
 - In overall economics, in lieu of milestones or royalties

Current Provisions: Risk Reduction in Economic Protections

- **“Tail” payments**
 - Residuals upon termination
- **Reimbursement of up-front payments**
 - Negative clinical, regulatory or marketing trial developments
 - E.g., failure to meet endpoints
 - E.g., failure to achieve target labeling
 - E.g., failure to meet sales levels
 - Used to adjust economics, with termination or stand-alone
- **Cap on further investment in product development**
 - Agreed-to development budgets, with limits on unilateral increase
 - Separate funding responsibility for different indications
 - Halt further investment
 - Adjust decision-making powers

Current Provisions: Risk Reduction in Diligence Requirements

- **Biotech demand for partner's diligence**
 - Demand for continued focus and activity
 - Especially in view of reduced economic terms and greater protections
 - Leverage to make demands in late-stage product deals
- **More than “Commercially Reasonable Efforts”**
 - “CRE” can be modified to take into account many extraneous factors
- **Specific diligence requirements**
 - Timelines for clinical development, regulatory and marketing events
 - Can be date-specific, or keyed-off of prior accomplishments
- **Ramifications if not met**
 - Loss of specific rights to indication or product
 - Dispute resolution process, but carve-out from big pharma decision-power
- **“CRE” Boomerang**
 - In return, biotech may be held to “CRE” on its R&D activities
 - In addition to economic rewards being specific milestone-bases

Current Provisions: Risk Reduction in Product Rights

- **Ownership of pre-existing technologies**
- **License grant: exclusive? scope?**
- **Ownership of collaboration-based technologies and discoveries**
 - Sole or joint as per inventorship
 - Ownership by collaboration partner whose existing technology it “solely” or “primarily” relates to, or who is funding program
- **Criteria and decision-making process to select collaboration candidates for progression through development**
- **Back-ups dedicated or available to collaboration**
 - Distinction between back-ups and second generation technologies
- **Residual pool of collaboration candidates**
- **Ex-Program activities**
- **Quids**

Current Provisions: Risk Reduction in Termination Events

- **Failure to meet Phase IIb or Phase III clinical trial endpoints**
 - Investing partner wants to cut losses and further efforts
 - Innovator may not need partner's detailing
- **Delays beyond date-certain or timeline**
 - NDA acceptance
 - Marketing approval
 - First commercial sale
- **Failure to meet TPP**
 - Approval but with different labeling
 - Can impact managed-care reimbursement and sales projections
- **Negative FDA advisory panel recommendation**
 - But innovator wants partner's continued input and investment
- **Receipt of non-approval letter**
- **Big pharma partner failure to meet specific diligence requirements**