Licensing Back to the Future:  
*Understanding Option Licenses to Advance Developments Today While Preserving Rights Tomorrow*

Bio International Convention

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Panelists

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Funding Trends: Challenging Environment for Early Stage Funding

Life Sciences Funding by Stage 2009-2011

Why Did Your Company Delay R&D in 2011?

- Funding not available: 40.2%
- Regulation (FDA, EPA, SEC): 27.8%
- Change in corporate priorities or strategy: 25.8%
- Other: 7.2%
- Layoffs: 4.1%
- Closed facility: 0%

Source: PricewaterhouseCoopers, “Zigzagging upward,” February 2012

Source: California Biomedical Industry 2012 Report
The Rise and Fall of Option-Based Licensing

Percentage of Licenses Including An Option

25%
20%
15%
10%
5%
0%

2007 2008 2009 2010 2011 2012
(up to June 11, 2012)

Pharma and Biotech Licensing Deals (*)
Pharma Licensing Deals (**)
2011 Early Stage Deal Activity

Collaborations by Stage, 2011

- Discovery: 17%
- Preclinical: 7%
- Phase 3: 18%
- Regulatory: 9%
- Phase 1: 6%
- Phase 2: 4%
- Marketed: 4%
- Formulation: 35%

Source: Drug Discovery & Development Magazine, November/December 2011
Option-Based Deals

- Option to Manufacture
- Option to Expand Territory
- Option to License
- Option to Co-Promote
- Option to Acquire
- Option to Finance
CONNECT. PARTNER. INNOVATE.
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- Funding/Resources
- Expertise
- Control
- Endorsement

Company
Drivers for the Company

Funding/Resources
- Expertise
- Control
- Endorsement

Downsides
- No Long-Term Commitment
- Development Risk
- Locking Up Too Early?
- Increased Transaction Costs
Drivers for the Partner

Diversification/Risk Sharing

Expertise

Control

Exclusivity

Downsides

- Less Control Over Development
- Deal Terms Set Early
- Easier for Competitors to Match Option
Protecting IP Assets: Drivers for Company

- Maintain Full Rights to Pre-Existing IP
- Extend Limited License for Evaluation Only
- Own Company Developed Option Period IP
- Keep License Narrow and Protect Next-Generation Technology
Protecting IP Assets: Drivers for Partner

Pre-Existing IP

Protect Your IP

Post-Option IP

Option Period IP

Partner

✓ Obtain Broad Research License to Pre-Existing IP
✓ Own Partner Developed or Funded Option Period IP
✓ Take Opportunity to Seek Broad License
✓ Seek Right to Expand License and Access Improvements
Negotiating Option Deals: Secondary Protections of IP

- Mitigate Development Risk
- Maintain Control During Option Period
- Mitigate Termination Risk
- Plan for the Future
Negotiating Option Deals: Mitigate Development Risk

**Plan**
- Create a Concrete Development Plan including Goals, Contributions, Timelines and Budget

**Control**
- Maintain Control or Veto Rights over Changes to Development Plan

**Precision**
- Option Trigger Event Should be Well Defined
- Rapid and Streamlined Dispute Resolution
- Determine Appropriate Deadlines and Extensions
Negotiating Option Deals: Maintain Control During Option Period

Joint Steering Committee

Value
- R&D Guidance
- Communication Plan
- Collaborative Spirit
- Availability of Support

Risk
- Administrative Cost
- Partner Access to IP
- Claims to Joint Ownership of IP
Negotiating Option Deals: Mitigate Termination Risk

- What if Without Cause vs. Termination for Breach
- Options and Licenses Terminate Unless Option Exercised
- Consider How to Allocate IP at Outset
- Grantback of IP Upon Termination Where Appropriate
- Termination Fees or Payments
Negotiating Option Deals: Plan for the Future

Confidentiality Provisions Matter

**Announcements**
- Timing
- Content

**Disclosures**
- Advisors, Directors, Business Partners
- Investors and Acquirers

**Publications**
- Review and Input
- Exclusion of IP
Negotiating Option Deals: Plan for the Future

Assignment Provisions

**Company**
- Plan for Strategic Alternatives
- Maintain Exit Opportunities
- Provisions Often Reciprocal

**Partner**
- Protect Against Company Acquisitions by Competitors
- Assets Should Remain with the Company
Discussion

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Q&A