Dive Deeper Into Due Diligence: Enhanced Value for Life Sciences Companies

Tuesday, December 4, 2007
Marriott San Mateo, San Mateo, CA

7:30 a.m. **Registration and Continental Breakfast**

8:15 a.m. – 8:30 a.m. **Welcome and Opening Remarks**
Gordon M. Saul, Executive-in-Residence, InterWest Partners

8:30 a.m. – 9:30 a.m. **Managing Your Due Diligence Process Throughout the Life Cycle of a Life Sciences Company**

Ensuring top value of a product throughout the lifecycle process involves managing issues related to evaluating a potential product; Identifying the best people for a project, recognizing key value factors of a product, and managing the size, flow and duration of a project. This panel will specifically address:

- How does your evaluation of a project differ in the big Pharma setting vs. a more entrepreneurial setting?
- What factors do you consider in determining whether their will be life after the patent on the active
- How have considerations changed in doing research (basic and developmental) in the last 10 years?
- What are some sources for evaluating the likelihood of success of a project?

Panelists:
Kim Graham, Former Director, Cambridge Antibody Technology Inc.
Ed LeFevre, Partner, Foley
Roberto Rosenkranz, Ph.D., Chairman and CEO, ROXRO PHARMA
L. James Strand, M.D., General Partner, Managing Director, Institutional Venture Partners (IVP)

9:45 a.m. – 10:45 a.m.

Track 1: (Synergy 2) **Finding Value in the Most Overlooked Elements of the Due Diligence Process**

Intellectual property rights, especially patents, frequently form the foundation of value in a life sciences company. If conducted with eventual commercial success in mind, a due diligence review of an IP portfolio can enable an investor to assess more accurately the present and future value of the technology and IP associated with an investment. Often times however, little thought is given as to how to leverage the harvested intelligence in the commercialization process of the acquired technology after the deal. This panel will discuss:

- The IP due diligence process - what to expect and preparing for the unexpected
- Working the IP - identifying and valuing know-how to execute the IP
- The technology factor - working with R & D during and after the diligence process

Panelists:
Antoinette Konski, Partner, Foley
Doris Spielthenner, Vice President of Business Development, FAS.research Inc.
Carol Stratford, General Counsel, KaloBios Pharmaceuticals, Inc.

Track 2: (Synergy 4) **"Do's and Don'ts" in Venture Funding: A Team Perspective**

How do you get your company ready for venture funding? What internal due diligence steps do you need to take? Bringing together both company and venture

perspectives, this panel will discuss the challenges of raising a venture equity round, as well as offering advice on due diligence issues ranging from IP to product development to the venture fundraising process.

Key areas to be covered include:

- What are the three things that every executive summary must have in order to get VC interest?
- The three most common questions that VCs will ask in a meeting that you better be ready to answer
- How important is the management team early in the development cycle of the company and what are the "must have" positions?
- How important is spending on IP, freedom to operate, and picket fence when you are pre-funded and have limited resources?
- How important is a warm introduction
- What are the alternatives to Sand Hill Road?

Panelists: **Avi Kulkarni**, COO, Aviir
Antoun Nabhan, CFO, Presidio Pharma; Principal, Sagamore BioVentures
Jonathan Norris, Managing Director, Private Equity Group, SVB Capital
Diana Villegas, CEO, Alpha Orthopaedics

10:45 a.m. – 11:05 a.m. **Coffee Break**

11:05 a.m. – 12:05 p.m.
Track 1: (Synergy 2)

Regulatory Due Diligence: Ensuring Full Term Investment Success
Transactions involving the acquisition of FDA-regulated firms and/or the licensing of products present unique challenges during the due diligence process. This session focuses on best practices and real-life examples of pitfalls that make or break the deal as they relate to intellectual property issues, clinical research, and regulatory requirements including:

- Projecting the scope of exclusionary rights on the product
- How the “useful” life cycle of a patent impacts transaction value and associated risks
- Evaluating the risks associated with patent litigation with respect to small molecules and follow-on biologics
- Understanding the clinical research and development program - how to maximize potential for success
- What can go wrong with clinical trials and practical suggestions to ensure compliance
- Identifying critical aspects of FDA regulatory authority relative to a diligence review
- Determining regulatory pathways towards product approval
- Prospecting opportunities to increase product life cycles

Panelists: **Doug Carsten**, Partner, Foley
Jeff Miller, VP, Regulatory Affairs and Quality Assurance, Icon Clinical Research
David Rosen, Co-Chair, Life Sciences Team, Foley

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Track 2 (Synergy 4) **M&A With Big Pharma: Due Diligence Issues That Can Affect a Deal**

The success of life sciences companies will depend on products and services not yet found in a companies offerings in the next decade. Much of those products will be brought to companies through the merger and acquisitions of small to mid-sized companies. This panel will discuss:

- When is the right time to get acquired?
- What is the survival rate of c-suite after an acquisition?
- Why is an acquisition better than a collaboration?
- What are the key issues in the due diligence process that can hurt the value of the deal?
- How does big pharma prepare for pricing negotiations and how can a smaller seller be prepared
- What types of steps can be taken to prepare a forecast that drives value negotiations
- How can this analysis be leverage in negotiating a collaborative or co-partner agreement

Panelists:
Ben Clark, Partner, Deloitte & Touche LLP
Jay Jesclard, Senior Manager, Deloitte Financial Advisory Services LLP
Linda Justice, Senior Manager, Deloitte Financial Advisory Services LLP
Ronda Sroka, Partner, Deloitte Tax LLP

12:05 p.m. – 12:30 p.m. **Lunch**

12:30 p.m. – 1:45 pm. **Ensuring Success From the Top**

In this interactive session, Life Sciences CEOs will explain what their concerns are while evaluating opportunities outside their organizations and maximizing the opportunities inside their organizations. Topics will include:

- How does a CEO incorporate shareholder valuation into the due diligence process?
- How do you measure acceptable risk?
- What due diligence factors do you use in selecting a partner for a collaboration agreement?

Panelists:
George Daniloff, CEO, Carbylan BioSurgery
Dinesh V. Patel, Ph.D.,
President and CEO, Arête Therapeutics
Tom Moran, Of Counsel, Foley
Jay Sheppard, President and Chief Executive Officer, Relypsa, Inc.
James A. D. Smith, President and Chief Executive Officer, Genelabs

2:00 p.m. – 3:00 p.m. **Key Indicators of Value and Success in a Life Sciences Company**

In any due diligence process, knowing the assumptions that drive the value estimate and the methodology used to balance anticipated investments, risks, and rewards will allow for a company to adjust the diligence review accordingly. This discussion will cover:

- Approaches for developing valuation and valuation assumptions for in-licensing, M&A, IPO, and R&D
- Evaluating the future impact of key items when reviewing a biotech IP portfolio

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- Identifying factors that executives use to arrive at a starting value, and then quantifying the deductions depending on the results of the IP due diligence
- Valuation methodologies used for early-stage vs. late-stage products

Panelists: **Gregg Alton**, Senior Vice President and General Counsel, Gilead Sciences, Inc.
Doug Crawford, Associate Executive Director, QB3
Doug Sheehy, Vice President & General Counsel, Codexis, Inc.
Paul Stewart, Partner, Foley

3:00 p.m. – 3:30 p.m. **Due Diligence in Light of New Rulemaking and Case Law**
Peter Milner, MD, President, ARYx Therapeutics

3:30 p.m. – 4:30 p.m. **Reception**