CONNECT' FRAMEWORKS WORKSHOPS

Present

DRUG DEVELOPMENT in a Capital Constrained Economy

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Present

DRUG DEVELOPMENT

in a Capital Constrained Economy

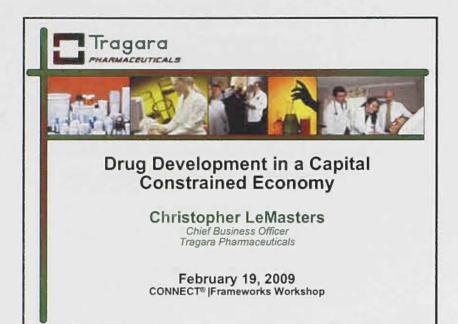
February 19, 2009 8:00 am - 11:00 am

AGENDA

7:30 – 8:00 am	Registration & Networking
8:00 – 8:05 am	Introduction: Bethany Kraynack, CONNECT
8:05 – 8:15 am	Introduction: David L. Johnson, BioCrossroads
8:15 – 8:45 am	Topic 1: How San Diego biotechs are adjusting to new funding environment Chris LeMasters, Tragara Pharmaceuticals
8:45 – 9:15 am	<u>Topic 2: How CMOs are partnering with biotechs to reduce cost and time to</u> <u>the clinic</u> Craig Davis, <i>Chao Center</i>
9:15 – 9:30 am	Break
9:30 – 10:00 am	Topic 3: How companies are sharing risk and reward with their CRO partners Lynn Lewis, Covance
10:00 – 10:50 am	Panel Discussion and Audience Q & A All Participants
10:50 – 11:00 am	Closing Remarks & Evaluations

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BioCrossroads[®] LINX Connections to Drug Development Resources



Capital Constrained Economy San Diego Life Sciences

- Nationwide Venture Funding
 Down 30% in last 3 months of 2008
- San Diego Venture Funding

 Down 57% in last 3 months of 2008
 - Life Science down 84%

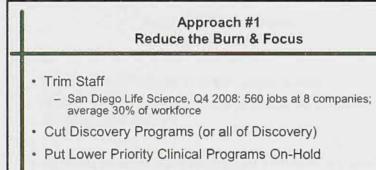
2008 Q4 Financing

Anaphore (protein therapeutics) - \$25M Series A (Dec '08) •5AM Ventures, Versant Ventures, Apposite Capital •5AM founded •First \$8M came in April

Source: Dow Jones VentureSource

Tragara

Dugan



- Lower Cost Clinical Development
 - NCI, ISPs, etc.

3

- Risk Sharing with CROs?

Focus spending on the Value Drivers of the business Focus employees on Cost Control

Malaise courtesy of the "San Diego Layoff Tracker" www.xconomy.com

Cost Cutting Impact on CROs & CMOs

Pressure on budgets & timelines

 From all levels of biotech employees

- · Heavy "Milestone-ing" of CRO/CMO contracts
- Consolidation of contracts under fewer CROs/CMOs
- More careful consideration of investor opinions of CROs/CMOs
- "De-linking" of CRO/Consultant relationships
- We are monitoring the health of our CROs & CMOs
- Cost Trap: "emergency" CRO/CMO relationships for biotechs that cut too deeply

T Tragara

Approach #2 Business Development Partner individual programs Raise Cash Reduce Expense Sell now: M&A

- BUT, Big Pharma is...
 - Busy buying each other
 - Told by bankers that "Every Biotech is for Sale...Today"
 - Searching for bargains, and everything is a bargain

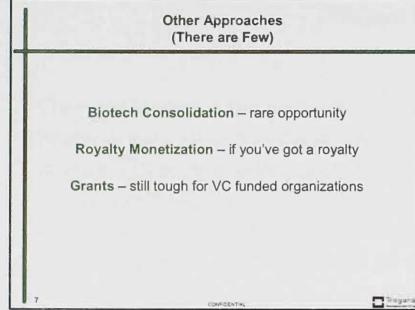
Big Pharma is Still Being Choosy Data Brings Them In and Quality Sells it

Dingers.

Business Development Impact on CROs & CMOs

- · Pressure on timelines, to obtain saleable data
- "Credible and Auditable" CROs & CMOs are crucial to the partnering process
- Business Development Trap: Deals take time, consume financing runway – may halt all development activity





Cautious Optimism

- · "There is no recession on innovation"
- "Getting more with less" is well received by investors
- VCs are looking closely for good investment opportunities within their existing portfolios
- Scarcity of quality therapeutics with POC data

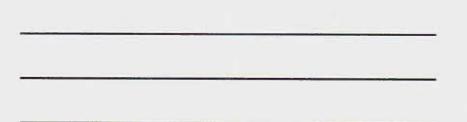
2009 Q1 Financing

Mpex (antibiotics) - \$27.5M of \$40M Series D (Feb '09) •Investor Growth Capital, RiverVest, SV Life Sciences, HBM BioVentures, Aberdare, Adams Street •Funding to complete Phase II for lead •Proven ability to enroll trials and produce quality data

Tragara



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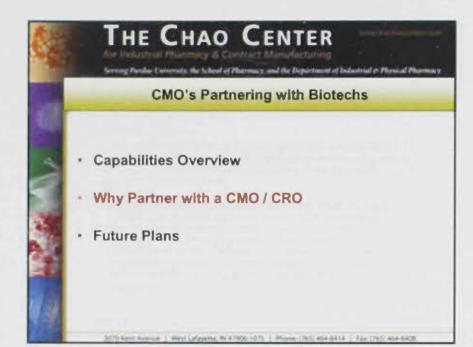
Chris LeMasters Chief Business Officer Tragara Pharmaceuticals

Chris LeMasters is the co-founder and Chief Business Officer of Tragara Pharmaceuticals in San Diego. At Tragara, he negotiated the company's founding license agreement with Daiichi Sankyo for the clinical-stage oncology drug Capoxigem® (apricoxib). He also negotiated the world-wide license to the company's preclinical-stage oncology compound, SB1317 (TG02), from S*BIO Pte Ltd of Singapore. At Tragara, LeMasters oversees the administrative and operational functions of the company, including finance and accounting, intellectual property, and corporate development.

Prior to Tragara, LeMasters was the co-founder and Chief Business Officer of Cabrellis Pharmaceuticals, where he was responsible for negotiating the \$104 million acquisition by Pharmion Corporation in November 2006. Previously, he served as Vice President, Business Development of Conforma Therapeutics where he was responsible for the in-licensing of Amrubicin from Dainippon Sumitomo and for negotiating the \$250 million acquisition by Biogen Idec in May 2006. LeMasters earlier worked for six years in Corporate Business Development at Eli Lilly and Company in Indianapolis. In that role, he was responsible for the successful negotiation of numerous partnerships and licenses across diverse therapeutic areas. LeMasters was also a management consultant with Coopers & Lybrand Consulting in Chicago for four years, where he led strategy consulting projects for Fortune 500 clients. He specialized in turn-around and profit improvement strategy and implementation. LeMasters began his business career as an operational auditor with Owens Corning Fiberglas in Toledo, Ohio, where he led formal assessments of internal organizations and manufacturing/distribution operations.

LeMasters has a B.A. in Finance from Indiana University and an M.B.A. with honors from the University of Chicago, and he is a Co-Founder and Board Member of Aarden Pharmaceuticals of Indianapolis, Indiana.

Chris LaMasters 10955 Vista Sorrento Parkway, Suite 120 San Diego, California 92130 (858) 350-6913 clemasters@tragarapharma.com



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Why CMO's (and what to look for)

Cost Control

- ...blotech firms have begun implementing cost-cutting measures that have reduced work forces and scaled back research and development efforts.
- Contract research organizations, or CROs, offer local biotech companies an attractive avenue for savings during these cash-strapped times.
- By outsourcing a bigger portion of their drug discovery and development work, smaller biotechs say they're able to save 30 to 40 percent of the typical costs involved in identifying potential new drug candidates.

Source: San Diego Business Journal, Dec 1, 2008 by Heather Chambers

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Why CMO's (and what to look for)

- Efficiency
 - CMO Held to a Contract



	Why CMO's (and what to look for)
Inf	frastructure
-	Smaller blotechs find it more practical to pay CROs for their internal expertise, laboratories and equipment to handle human and animal studies than to conduct the research themselves.
1	Although biotechs account for more than half of all molecules in development, many lack equivalent development infrastructure compared to their pharmaceutical counterparts. CROs act as a project manager of sorts, helping to oversee clinical trials, provide regulatory guidance to early-stage companies and, occasionally, helping to file patents or provide legal support

THE CHAO CENTER Versus Product Several to Color of Planmacy, and the Department of Industrial & Physical Planmacy Why CMO's (and what to look for)

Manufacturing Challenges

- Technical Expertise
- Capital Expenditure
- Equipment and Procedures In Place

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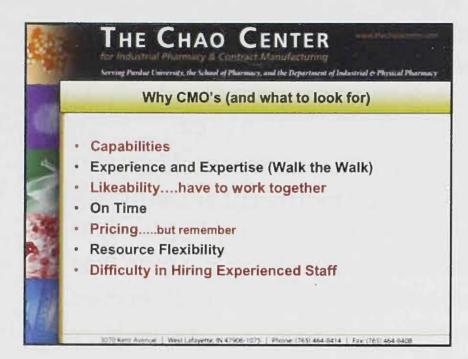
Why CMO's (and what to look for)

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- Quality Assurance
 - Quality Systems (Equipment History Binder, Logbooks, Notebooks, Sop's etc)
 - Technical Expertise
 cGMP Training
 - Comin Intaining
 - Training Records
- Regulatory Challenges
 - Technical Expertise
 - Positive Relationship with the FDA
 - Audit Experience
 - Submission Experience

CONTRACTOR (MILLION CONTRACTOR) Prove Discrete Arts (Sec. (19)) 454,043



THE CHAO CENTER Serving Purdue University, the School of Pharmacy, and the Department of Industrial & Physical Pha Mission: Preeminence in Pharmaceutical Education, Development, and Manufacturing Goals and Objectives: Education — Attain and preserve excellence in learning through programs of superior quality and value in Pharmaceutical Development and cGMP Manufacturing Training · Johnson & Johnson Summer Internship · Clerkships (6th Year Pharmacy Rotations) · High School Work Study Manufacturing - cGMP Manufacturing of both clinical and commercial product Formulation and Analytical Development – Effectively address the needs of healthcare and the pharmaceutical industry Faculty and Research Use - Access to a cGMP Facility for mutually beneficial research Create a positive impact on the local and state economy Revenues above operating costs are given back to the University cGMP Manufacturing Core with 7 Multi-purpose Production Suites Approximately 10,000 ft² - Non-sterile Production Area

- Multiple Dosage Forms
- Tablets, Capsules, Liquids, Semi-solids, Creams

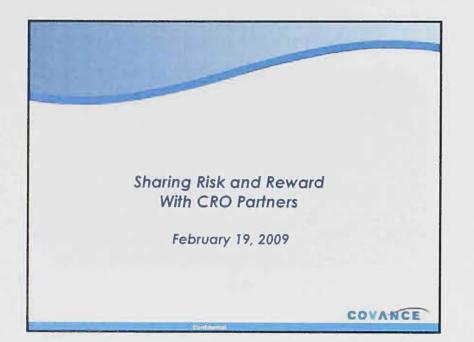
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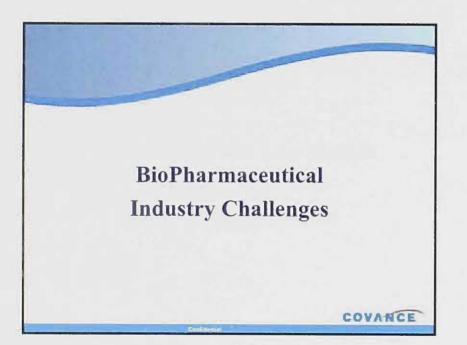


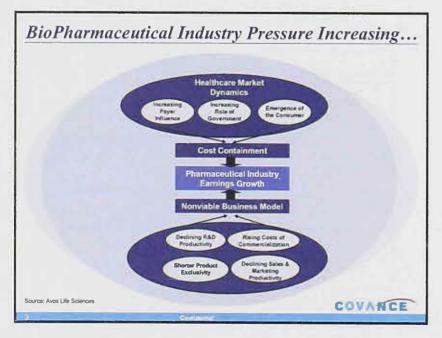
Craig W. Davis, PhD Executive Director The Chao Center for Industrial Pharmacy and Contract Manufacturing

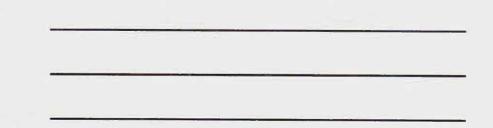
Craig Davis received his BS in Microbiology from Purdue University and his PhD from the Department of Industrial & Physical Pharmacy at Purdue University. During his nearly 14-year tenure at Burroughs Wellcome, he held positions of Group Leader of Sterile Products Development and Section Head of Liquid Dosage Forms Development & Physical Pharmacy. Davis worked at Bausch & Lomb Pharmaceuticals in Tampa, Florida, as the Director of Pharmaceutical Product Development before leaving to start a CRO that was later acquired by MDS to become the Vice-President of Pharmaceutical Development at MDS Pharma Services-Tampa.

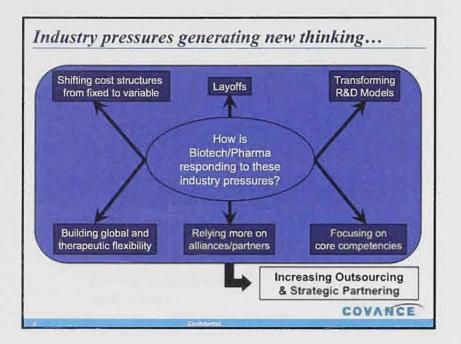
Craig Davis The Chao Center for Industrial Pharmacy and Contract Manufacturing 3070 Kent Ave West Lafayette, IN 47906-1075 <u>daviscw@thechaocenter.com</u> (765) 464-8414 www.thechaocenter.com



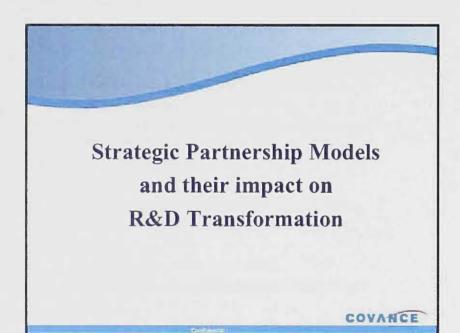


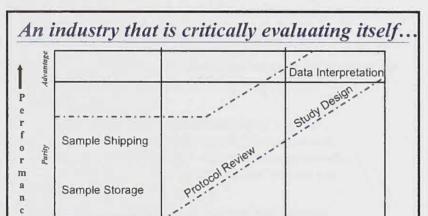


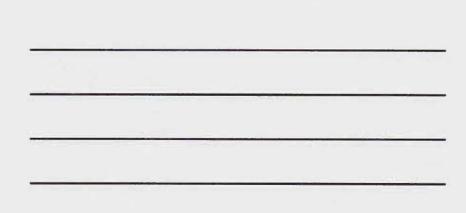


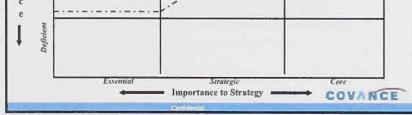


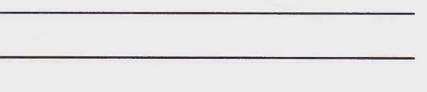


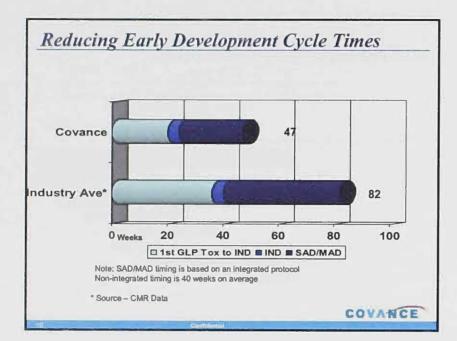


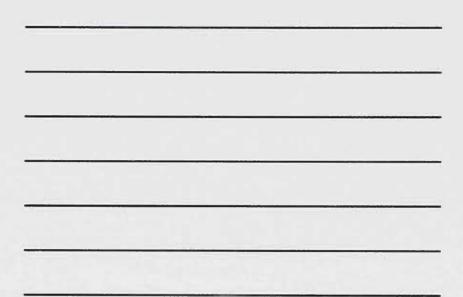












Other Ways to Partner & Share Risk

- Co-develop drug with CRO
 - Example: Takeda & PPD
 - PPD pays for much of the development; receives revenue stream when drug is launched
- CRO invests in drug
 - D Example: Daiichi-Sankyo & Quintiles
 - Quintiles pays for right to develop drug; receives revenue stream when drug is launched
- Risks:

Drug may never make it to market

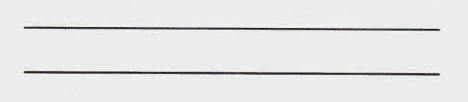
Conflict of interest for other clients' similar drugs?

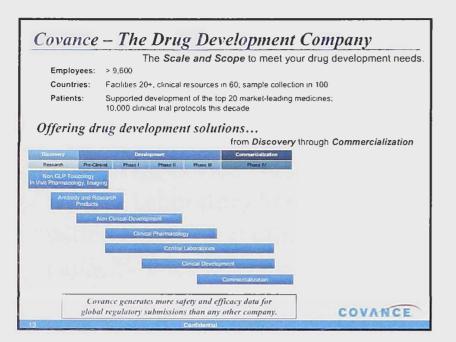
COVANCE

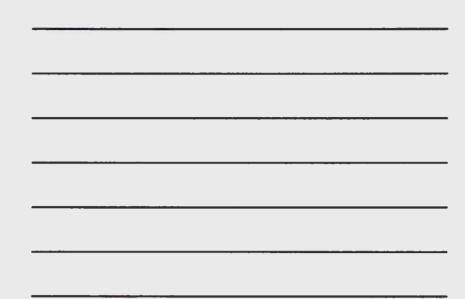
COVANCE

Keys for a Successful Partnership

- Active and visible Executive-level involvement and support
- Well-defined and rigorous Governance model
- Cultural alignment -
 - Solid cross-functional relationships based on trust
 - Executive, Scientific, Operational and Business levels
 - Candid and open dialogue...high levels of communication
 - Process improvement mentality...reduce time and cost
- Effective Escalation Process
- Performance-based, metric-driven environment
- Incremental value-creation with competitive pricing
- Focus on Total Cost of Outsourcing (TCO)
 - Cost, Quality and Delivery
- Commitment to the partnership







Lynn Lewis Vice President, Global Sales and Marketing Covance Central Laboratory Services

Lynn Lewis is Vice President, Global Sales and Marketing for Covance Central Laboratory Services. She is responsible for all commercial activities within the Central Laboratory division and has been with Covance in this capacity since January 2003.

Prior to joining Covance in 2003, Lewis worked for Eli Lilly and Company for 16 years. She held various positions in the sales, marketing, strategic planning, and general management areas of the company. Her last position was Product Team Leader for two of Lilly's osteoporosis compounds.

Lewis' background includes a MBA from the University of North Carolina – Chapel Hill, and a B.S. in Biology from Bucknell University.

Lynn Lewis Covance Central Laboratory Services 8211 SciCor Drive Indianapolis, IN 46214-2985 <u>llewis@covance.com</u> www.covance.com

THE CONNECT STORY

CONNECT is a non-profit organization dedicated to creating and sustaining the growth of innovative technology and life science businesses in San Diego. Serving as a proven neutral broker, CONNECT directly addresses the critical business needs of companies ranging from start-ups to large public corporations as well as university and research entrepreneurs.

Originally founded by the University of California San Diego at the urging of the business community, CONNECT is widely regarded as the nation's most successful regional program linking high-technology and life science entrepreneurs with the resources they need for success: technology, money, markets, management, partners, and support services.

CONNECT's services are tailored to meet the varying needs of San Diego entrepreneurs at all stages of their business life cycles and growth. CONNECT delivers more than 300 events and programs each year, that engage more than 1,000 CEOs and companies. Its programs serve as a catalyst for the development and exchange of ideas, a forum to explore new business avenues and partnerships, and an opportunity to network with peers.

CONNECT's success is directly attributable to the generous, unfailing support of its friends and supporters. Its multifaceted network of business and university resources form the platform for its award-winning programs and events. The active, hands-on participation by its premier partners, vendors, and providers from the areas of high technology, life sciences, law, accounting, investment banking, marketing, and communications brings invaluable expertise. The business professionals and capital providers who serve as CONNECT management fellows and form its various committees round out CONNECT's circle of resources. The result is an energetic, resource-rich environment for honing ideas, pursuing personal growth and professional development, and exploring innovative business opportunities.

CONNECT is entirely self-supporting. It is supported through membership dues, course fees, and corporate underwriting for specific programs.

For more information on CONNECT or its programs, contact us at (858) 964-1300 or visit www.connect.org.

Contact

CONNECT

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La Jolla, CA 92037

Phone: (858) 964-1300

Fax: (858) 964-1301

www.connect.org

FRAMEWORKS WORKSHOPS

Half-day professional development programs structured to provide attendees with an overview of business basics through our 'Core Curriculum': a vocabulary, foundation, and "framework" in which business leadership can be built around, and our 'Electives': a focused and detailed look at specialized and industry specific topics customized to fit the needs of a start-up company.

Core Curriculum (Business Basics)

Intro to business basics for scientists and engineers i.e. Accounting, Finance, Sales and Marketing, Org. Structure, HR, Finance, Legal, Business Plan Creation, etc.

Electives (InFocus Seminars)

Focused and industry specific subjects for start-ups such as Facilities, Regulatory affairs, Communications, Term Sheets, etc.

"As always, CONNECT finds the best speakers for the best topics. CONNECT does education on the cutting edge."

MARK LONG Founder, SuperLab

"I love these CONNECT sessions – I always take away a few big ideas to apply to my job and spread through my company."

DAVID SNYDER SAIC

"CONNECT FrameWorks Workshops are affordable and effective for the entrepreneur on a shoestring. I have taken away highly valuable concepts from every workshop I have attended."

ROBERT CASS

COO, Perminova

FRAMEWORKS COMMITTEE:

Ken Polin (Chair) Foley & Lardner LLP

Joe Davidson Allen Matkins

Sandy Ehrlich San Diego State University, Entrepreneurial Management Center

Julia Kellogg Cooley Godward Kronish LLP

Mark Nash Barney & Barney

Tyler Orion Board, CONNECT

Summer Rogers Tunnell Consulting

Dan Ruchman CONNECT EIR

David Snyder SAIC

Rose Thiessen Knobbe Martens

Denise Thompson KPMG

Dennis Zocco USD

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Bethany Kraynack

Program Director

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FRAMEWORKS WORKSHOPS CORE CURRICULUM

 THE COMPLETE BUSINESS PLAN Creating a technology strategy Business models Financial projection techniques 	TERMINOLOGY: Executive summary, Company & product overview, Market analysis, Marketing & sales plan, Operations plan, Management plan, Funds required & uses, Refine the plan
 STRUCTURING YOUR ORGANIZATION Board and officers' roles and responsibilities Directors or advisors Recruiting and retaining boards Compensation, salary scales and comparables Bonus and incentive plans 	TERMINOLOGY: D&O, Liability, Errors & Omissions, Indemnification, Annual Report, Minutes, Stock Option pool, 401K, W2, Vesting, Warrants, Deferred Compensation, Defined contribution plan, FICA, Deductions, Employer match
 START-UP ACCOUNTING & TAXES Budgeting & spreadsheets Financial infrastructure Projecting start-up and development costs Reporting and controls 	TERMINOLOGY: Pro Forma, EBITA, GAAP, Ratios, ROI, Valuation, Sarbanes Oxley, Balance sheet, Cash flow, Margins, Burn rate
 GETTING STARTED LEGALLY Legal issues of business formation Boards of directors and advisors Planning basics & terminology 	TERMINOLOGY: C-Corp, S-Corp, LLCs, Equity, Exits, Pro Forma, Milestones, Capital formation, Executive summary, Beta customers
 ESSENTIAL EMPLOYMENT LAW Overview of legal issues and compliance Basic labor & employment agreements Management issues and red flags Compliance and regulations Insurance and risk management 	TERMINOLOGY: EEOC, OSHA, Unions, Workers Compensation, Non-compete agreements, PPO, POS, PTO, PEO, HSA, Dependant care, FTE, PTE, Independent Contractor, 1099
 THE VENTURE CAPITAL PROCESS Structuring a company for investment Realistic expectations- for valuations and terms Developing a value proposition 	TERMINOLOGY: Angels, VCs, Bootstrapping, Strategic investor, M&A, ROI, IPO, Liquidity, Valuation, Term sheet, Series A/B/C, Syndication, Exit strategy
VALUATION & FINANCIAL ANALYSIS	TERMINOLOGY:

- Importance of accurate financial statements
- Creating projections
- Playing the VC game

Price earnings ratio, ROI, Cash flow, Book value, Liquidity, Replacement value, Internal Rate of return, Pre-Money, Post-Money, PPS, Equity, Marketability, Capitalization...

MARKETING, SALES, & BUSINESS DEVELOPMENT

- Identifying and entering a market
- Timing and tactics
- Building customer relationships

TERMINOLOGY:

Image, Branding, Messaging, Positioning, Competitive landscape, Market niche, Adopter, Differentiating, Collateral...

FRAMEWORKS WORKSHOPS ELECTIVES

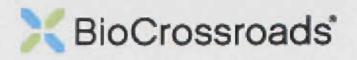
 THE FDA PROCESS The regulatory landscape Legal issues and compliance- at all stages Reimbursement issues 	 MERGERS & ACQUISITIONS What are they and how do they work Preparing for due diligence Exits and expectations 		
 ART OF THE TERM SHEET Critical issues for founders Understanding investors' concerns Protective provisions and investor rights 	 THE EMPLOYEE OWNERSHIP ALTERNATIVE Creating EO in your company Funding growth without VC Capital Building ownership culture 		
 LAUNCHING A WEBSITE Agreements with 3rd party vendors Protecting your on-line IP Marketing & advertising End user agreements 	 BUILDING YOUR IP PORTFOLIO Protecting your IP Building a strategic portfolio Identifying your value and competitive advantages 		
 NEGOTIATING A FLEXIBLE LEASE How to use commute/recruit studies Putting a relocation team in place Key lease or purchase agreement clauses 	 DOING BUSINESS IN CHINA & INDIA Macroeconomics of Asian markets Dealing with family-owned businesses Developing new competitive strategies 		
 INTRODUCTION TO IP The fundamentals of Intellectual Property What can you protect What are the critical issues Do's and don'ts of getting started 	 INTERNATIONAL DISTRIBUTION Utilizing a risk management approach Managing channel conflict Understanding governing law to resolve disputes 		
 PARTNERSHIPS & ALLIANCES Alliances in an overall business strategy Assessing your potential value Characterizing and evaluating potential partners Defining metrics and expectations 	 PROTECTING AGAINST PRODUCT LIABILITY Importance of labels, warnings, and instructions The differences between negligence, strict liability, or breach of warranty Consumer Product Safety Improvement Act 		
 ACCESSING GOVERNMENT GRANTS Finding the right programs Proposal writing 	 SOURCING ALTERNATIVE FINANCING Debt and venture debt Traditional bank financing 		

- Proposal writing
- Preparation, administration and regulations
- SBIR / STTR
- AVOIDING LICENSING PITFALLS
 - Why license
 - Identifying and targeting opportunities
 - Due diligence & avoiding pitfalls

- Traditional bank financing
- Vendor and purchase order financing
- Bootstrapping

EFFECTIVE PRODUCTION MANAGEMENT

- Prototyping and design
- Systems and quality controls
- Resource planning



BioCrossroads accelerates the growth of life sciences in Indiana by connecting ideas to resources. Whether providing funding or launching new businesses, BioCrossroads inspires progress, innovation and collaboration – working with entrepreneurs, research institutions, math and science educators, philanthropic organizations and global companies to build healthier communities and a healthier economy. We connect. We invest. We educate.

www.biocrossroads.com

Indiana is well-positioned to support pharmaceutical and biotechnology companies with its concentration of nearly 50 contract drug development service providers. From toxicology studies and pre-clinical services to formulation and manufacturing, more than 8,000 skilled workers help companies and universities to advance discovery and develop drugs around the world. By building regional collaborations and developing educational programs, **BioCrossroadsLINX** is connecting discovery and development.

www.biocrossroadslinx.com

For more information contact: Brian Stemme 317-238-2463 bstemme@biocrossroads.com

David Johnson President and CEO BioCrossroads

David Johnson is the President and Chief Executive Officer of BioCrossroads, a market-driven collaboration of Indiana's corporate, university, government and entrepreneurial leaders in the life sciences industry. BioCrossroads seeks to build upon the state's substantial life sciences strengths through the promotion of strategic partnerships, the sponsorship of new ventures and the assembly of seed and early-stage venture funding to commercialize the next generation of leading life science business opportunities.

A longtime business leader and finance lawyer, Johnson was one of the original four members of the community steering committee that advanced the BioCrossroads concept in early 2002. In 2003, he served as volunteer chair of a capital formation task force to develop the concept and, ultimately, the funding for the Indiana Future Fund LLC, a \$73 million pool of venture capital investments from many of Indiana's leading corporate, university and public pension fund institutions. Managed by the private equity group of Credit Suisse First Boston, the Future Fund is providing early-stage venture capital to emerging Indiana life sciences companies. Since assuming leadership of BioCrossroads in January, 2005, Johnson has continued, among other initiatives, to pursue further market-driven funding alternatives for emerging life sciences companies, including the \$6 million BioCrossroads-managed Indiana Seed Fund.

An honors graduate of Harvard University, Harvard Law School and Oxford University, where he studied as a Rhodes Scholar, Johnson was a partner in the law firm of Baker & Daniels from 1986 through 2004 (and today remains "of counsel" with the Baker & Daniels firm).

Johnson's active business and community board participation includes service on the board of directors of BioCrossroads; BioCrossroadsLINX; the Indiana Health Information Exchange, Inc.; the Fairbanks Institute for Healthy Communities, Inc.; Indiana University Research and Technology Corporation; CS-Keys, Inc.; and FlowCo, Inc.; and as a member of the Purdue Discovery Park Advisory Council; the Notre Dame Graduate Studies and Research Council; the Kelley School Center for the Business of Life Sciences Industry Advisory Board; the IU School of Medicine Dean's External Advisory Board; the IUPUI Community Advisory Board; the Indiana Translational Research Acceleration Corporation (ITRAC) Advisory Board; and the Indiana Clinical and Translational Science Institute External Advisory Committee (Chair). In his capacity as CEO of BioCrossroads, Johnson serves as Manager of the Indiana Seed Fund and Manager of the Indiana Enterprise Fund, as well as a member of the Advisory Committee for the Indiana Future Fund I, LLC.