WPI Venture FORUM℠

To inspire and facilitate technology-based entrepreneurship

Vantage℠

October 2007
VOLUME 17 • NO. 2

THIS MONTH'S MEETING

TUESDAY, OCTOBER 9, 2007

WPI, WORCESTER
Campus Center Odeum

NEW THIS FALL!
EXTENDED NETWORKING BEGINS AT 5:30 P.M.
MEETING: 6:30 – 9:00 PM

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Cooperation Key to BioPharma Growth

What are the characteristics of a successful biotech startup? And how can startups and established companies in the biopharmaceutical industry find ways to cooperate? Answering these questions at the October 9 WPI Venture Forum meeting will be keynote speaker Dr. Rainer Fuchs, Vice President of Biogen Idec and Executive Director of the Biogen Idec Innovation Incubator, Bi^3.

DR. RAINER FUCHS, *Vice President, Biogen Idec*

His talk will examine some of biotech's productivity issues and address established and novel models for cooperation between startups and established companies. According to Fuchs, compared with other high-tech industries, the biopharmaceutical industry has yet to establish a culture of "co-opetition" while retaining its reputation as a more prolific source of innovation. He will also discuss whether pre-money and seed stage companies are critical to the growth and success of biotech and pharma.

A molecular biologist by training, Fuchs has a PhD in biochemistry and a master's degree in microbiology. He has been with Biogen Idec since 2000 in various executive leadership roles, including co-head of Discovery Research and VP Informatics and Operations. In his new role at Bi^3, he oversees the company's efforts to provide facilities, space, money, and expertise to help scientific entrepreneurs develop new therapeutic candidates.

Before joining Biogen, Fuchs was Global Head of Lead Generation Informatics for Aventis Pharma. His experience in the biopharmaceutical industry includes senior leadership positions at Ariad Pharmaceuticals and Glaxo Wellcome. Prior to his work in industry, Rainer was staff scientist at the European Molecular Biology Laboratory (EMBL).

Case Presentation

Synscia, Inc.

Synscia, Inc. is a Boston-based biopharmaceutical company commercializing a novel product portfolio in ophthalmology. The company is targeting the chronic diseases of age-related macular degeneration (AMD) and proliferative diabetic retinopathy (PDR), both of which have rapidly growing patient populations and represent a market opportunity of $10 billion.

The company's strategy is to develop proprietary products based on proven drug entities with known safety and efficacy, and to apply them in the isolated environment of the eye. Focused expenditures allow the company to accelerate commercialization while lowering development and clinical risk. The company is currently seeking funding to complete devel-

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A Letter from a Committee Chair

Making Every Contact Count

The only way to really understand networking is to immerse yourself in the medium. Take Web 2.0, for instance, and the revolution we're seeing in social media. First popularized by our kids, sites like MySpace and Facebook have millions of users. And now adults are networking through these sites as they sport sophisticated interactive technologies, far beyond what is seen on sites like LinkedIn.

But technology rarely enhances the quality of interactions, it tends only to enhance the quantity. People often act differently when interacting with their computer screen. If you really want to make the most of a networking experience, nothing can replace the depth of a face-to-face experience.

This season, the WPI Venture Forum is planning several such events. We'll kick things off with a networking event at **BOSE** in Framingham on October 18, 2007. We're also going to try something a bit different with a networking event at the **Worcester Art Museum** on April 18, 2008. In between, we hope to be back at MBI for a tour of their new facilities and an update on what's new in biotech. Our special events committee is always looking for fresh ideas. If you'd like to join us, contact me at sharilee@telesian.com.

To prepare you for these events, we offer this networking checklist from former board member Alan Glou:

Planning

- Maintain a special briefcase or box in your car for access to your marketing material, including business cards and resumes.
- Keep your networking time focused on the kind of events that will attract prospective customers and/or the people they network with.
- Wear your nametag on the right side of your jacket for easy reading.
- Offer your card and ask for the other person's card when meeting.
- Write comments, key reminders about that person on the back of the card.
- Process cards and notes immediately upon returning to your office.
- Prepare and practice your "Elevator Speech" – a one minute overview of yourself and what you can do for someone.

Shari Worthington

Presentation

- Participate responsibly in at least one committee of every organization you join.
- Say "yes" if asked whether you will speak before a group.
- Freely share your good ideas with others. People will be inclined to share back.
- Use your ears more than your mouth. Listening, showing interest rewards more than dominating the conversation.
- Try to have someone introduce you; this breaks the ice much faster.

Happy networking!

Sincerely,
Shari Worthington
President, Telesian Technology

Ten Tips for Getting FDA Product Approval

Ensuring that your new medical products comply with FDA regulations can be daunting. Regulatory Affairs (RA) consultants can help you navigate the maze cost-effectively and improve your chances of funding. The key is to involve them "early and often" in the product development and commercialization process. Here are 10 tips to help make FDA clearance proceed smoothly:

1. Develop a regulatory submission strategy early in the game.
How early? Right from the start. Issues such as disposability, sterility, product classification, and clearance path must be defined and dealt with early on to avoid uninformed decision-making and significant delays later.

2. Include developing "product claims" with your regulatory strategy.
FDA clearance of your product is based on what you claim it does. An RA consultant can help your marketing staff develop appropriate claims that also meet broader company objectives. Establish a budget to benchmark competitive products, research the FDA regulations for your particular product, and develop suitable validation protocols that will support your claims.

3. Maintain a relationship with the FDA.
Our experience has proven that most FDA employees are helpful and want companies to successfully launch new products. Get to know the staffers in key offices and use the extensive online resources at www.fda.gov. An open line of communication with the FDA can resolve uncertainties and prevent major schedule delays later.

4. Respond promptly.
Often more information is needed after you submit a classification request, a product listing, or another document. Provide a complete answer, but don't offer more information than requested – it might raise questions about issues that were previously not a concern. Have another member of your team or your RA consultant review the correspondence before you send it to make sure it says exactly what it needs to say. Be sure to keep a regulatory correspondence file.

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by
RANDAL CHINNOCK
President, Optimum Technologies, Inc.

A Look at September's Meeting

Massachusetts Sees Growth

Keynote speaker Pat Larkin

Meeting attendees took advantage of networking before the speaker and during the break.

by

Mike Travis,
Travis & Company

On Tuesday, September 11, the WPI Venture Forum convened for the inaugural event of the 2007-2008 season. Attendees arrived to a campus abuzz with newly arrived students.

Patrick Larkin delivered the keynote address, "How Can Massachusetts Compete in the Global Economy?" Director of the John Adams Innovation Institute, the economic development division of the Massachusetts Technology Collaborative, Larkin's talk outlined the steps his organization is taking to make the Commonwealth a more competitive business environment.

As Larkin explained, the John Adams Innovation Institute is charged with:

- Growing the technology and innovation economy in Massachusetts;
- Growing and strengthening industry clusters;
- Leveraging Massachusetts' strength as a global knowledge center;
- Helping to make Massachusetts globally competitive;
- Facilitating the work of innovators by serving as "midwives to innovation."

Six industry sectors currently of investment interest in Massachusetts are: life sciences, enabling technology through nanotechnology, defense, IT, software and marine science.

To promote its objectives, the Institute has created the John Adams Innovation Institute Regional Fund, Larkin explained. The Fund makes awards between $150,000 and $500,000. Recent projects the Institute has awarded funding to include:

- A biosensor developer in Fall River;
- A supplier network to link plastics manufacturers in North Central Massachusetts to medical device companies;
- The Massachusetts Center for Biocomputing in Worcester; and
- The M2D2 medical device initiative at U-Mass Lowell.

Competition for federal research grants has become far more intense in recent years. Larkin explained that the Massachusetts Research Center created a matching program to help Massachusetts compete more effectively for federal money. Since the program's inception, it has facilitated approximately $260 million in federal and private investment,

Through Innovation

Panelists shared their wisdom with case presenter Bruce Ginsberg of MooBella.

including a recent $97 million grant to the Woods Hole Oceanographic Institute for an undersea laboratory.

Case Presentation

Moobella LLC

Bruce Ginsberg, President and CEO of MooBella LLC, presented the evening's case. MooBella has developed technology that can produce fresh ice cream to order in less than one minute. Interested audience members enjoyed MooBella's ice cream during Bruce's talk, thanks to a system that had been set up in the cafeteria especially for the event.

MooBella's story is a lesson in perseverance. The company was founded in 1992 as Turbo Dynamix. The early-stage start-up scored a coup when it inked a joint venture with General Mills in 1995, but by 1997 General Mills had changed directions and the joint venture was dead. Undaunted, founder Paul Kateman pressed on, and in 2000 he met Bruce Ginsberg, a 20-year veteran of the ice cream business. Ginsberg joined as president, and the company was reorganized as MooBella.

The company's big break came in 2006 when it introduced its technology at the DEMO 2006 conference. The product was a hit and generated an avalanche of PR from national media, along with interest from big money investors.

MooBella's technology has the potential to transform the ice cream business. While the first system will be deployed in cafeterias, the technology can be applied to systems for use in grocery stores and even in the home.

Ginsberg came to the Forum with two burning questions for the panelists. How could he expand and remake his board to better serve the business? And in the face of rapid growth, how should he build out his management team?

Tom Sherwin of CEO Resources fielded the first question. He offered the following insights:

- The current three-person board consists of two long-term investors, and a new director from the newest investor, Nestle; there is need for a culture change as the fourth director (one who is technically oriented and experienced in small private and larger public companies) is added.

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Cooperation Key to BioPharma Growth

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opment of the initial products and move them though Phase II clinical trials.

As President and CEO, Joe Straight brings to Synscia more than 26 years of operating experience in start-up entities, with the last 16 years in the biotechnology industry. Most recently he was co-founder and CEO of Verax Biomedical Inc., where he raised $24 million in financing. Prior to co-founding Verax, Straight served as CFO of the biotechnology firm ZymeQuest, Inc., and as VP of finance at Hybridon, Inc. He also has experience in the high tech sector, serving as VP of finance for SIS Corp., and in several financial and operating positions with GTE. He received a BA in business administration from the University of Washington and is a Certified Public Accountant.

Ten Tips for Getting FDA Approval

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5. Follow FDA guidelines for design controls.
As you go through the product development process, be sure you comply with your own Quality Manual and that it complies with FDA guidelines for design controls and manufacturing. Key elements include design reviews, risk analysis, design verification, maintaining a design history file, and design & process validations. Most (but not all) FDA guidelines now conform to ISO standards; your RA consultant should periodically review your compliance to make sure you're not missing key steps.

6. Conduct appropriate testing to demonstrate biocompatibility.
Most medical devices must demonstrate no carcinogenic, mutagenic, toxic, or other negative effects on live human tissues. Such testing is often performed by outside labs and can take weeks or even months to complete. Allow enough time and money to perform it properly. Work with your RA consultant or lab to determine the sample sizes required, which can be quite large. Also, you may have to develop and complete product cleaning and/or sterilization validation protocols as part of the biocompatibility testing.

7. Follow your clinical trial protocols.
Certain devices require clinical studies to demonstrate safety and efficacy. These trials must comply with the GCP (Good Clinical Practice) standards, which cover how the trial is designed and controlled and how data is collected, analyzed, and reviewed. Protocols must generally have FDA approval before starting the trials. Once you and the FDA agree on the protocol, follow it. Many companies have had product submissions denied because they deviated from their protocol without FDA approval.

8. Don't forget CE marking.
CE marking is generally required for sales into the European Union. If you intend to market your product in the EU, include CE marking tasks in your regulatory plan and submit your listing request at the appropriate time.

9. Consider the regulatory consequences of device modifications.
Once your pre-market clearance is complete, you're not done. Significant changes to the device's design, manufacturing processes, product claims, or indications may require additional activities. Minor changes may only require a "letter to file". Major changes may require updates to the labeling, review by the FDA, or even a new device listing. The FDA requires a system in place to determine whether changes to the product require action, what the actions must be, and who will conduct them. Failure to comply can result in the FDA removing the product from the market.

10. Hire a Regulatory Affairs pro.
A RA pro – either an employee or consultant – can help you plan, execute, and review all aspects of your regulatory plan. Outsourcing these tasks to a full-service firm avoids additional overhead expense and may help minimize complications. The consultant or firm should have experience in your types of devices and be able to demonstrate a track record of successful product commercialization.

Optimum Technologies, Inc. is a full-service product development, early-stage manufacturing, and product commercialization firm specializing in the use of light to diagnose and treat disease. The firm offers consulting services in the areas of FDA product clearance and other regulatory matters. Contact Paul White, Sales Manager, 508.765.8100 x203, www.optimum-tech.com.

WPI Venture FORUM

CALENDAR OF EVENTS

OCTOBER 9
From Concept to Product in Biotech
OCTOBER 18
Networking Event, Bose Corporation
NOVEMBER 13
Business Plan Contest
DECEMBER 11
Build Business by Networking
JANUARY 8
Going Green, Growing Green
FEBRUARY 12
Valuation, Funding, Scaling Up and Exit
MARCH 11
Manufacturing Goes High Tech
APRIL 8
Marketing a High Tech Enterprise
APRIL 18
Networking Event, Worcester Art Museum
MAY 13
Profits Come from People
JUNE 10
The Five Minute Pitch Contest

A Look at September's Meeting

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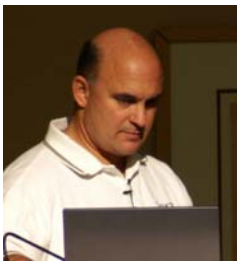

Bruce Ginsberg

- Ginsberg has expressed an interest in adding a board member with the technology expertise he lacks;
- An expanded board could offer better guidance to Ginsberg, and get the board structure closer to what might be required for an equity event;
- The two long-term board members will need to move away from involvement in operational matters and develop a more arm's length relationship with the company;
- Ginsberg should consider joining a board himself so he can learn to see the world from a board member's perspective;
- He might also consider forming an advisory board. However, Sherwin cautioned that these take a long time to yield useful guidance. If the liquidity event is less than three years away, there is no time to build an advisory board.

Carol Bergeron of Bergeron Associates addressed Ginsberg's questions on immediate human resource needs, team building, and incentive compensation. She made the following suggestions:

- Given the workforce will double in size each year and MooBella is a hot company, build a robust recruiting and new hire on-boarding function to efficiently manage the volume of applicants and the hiring of top talent;
- Hire the leadership team first then get them to hire their staffs;
- Charter the leadership team to define the core values of the organization and help design management practices and tools they'll use in recruiting, new hire on-boarding, compensation design, etc. Getting them involved in the design will be a team-building activity resulting in heightened commitment, practices that are compatible with the culture and keeps everyone moving in the same direction;
- On incentive compensation, link incentive pay to achievement of company goals. Consider what work needs to get done, how it gets done and who does it when designing. Develop the incentive plans so that targets are measurable, challenging and achievable to maximize employee motivation. A big benefit from incentive plans designed and communicated well is that every employee understands the company goals and how they contribute to achieving them;
- Create a workforce strategy, analogous to a marketing or product development strategy but it's for people, once some of the strategic partner and outsourcing arrangements are more solidified. Companies are only as good as the people they hire, and that takes deliberate planning and action.

Judging by the positive reviews from those who tried the ice cream, MooBella is poised for phenomenal success. It was a delicious start to the WPI Venture Forum's new season.

Mike Travis is a Principal at Travis & Company, an executive search firm focused on recruiting for medical device, biotechnology and pharmaceutical companies. For more information visit www.travisandco.com.

Spotlight on Entrepreneurs

GENIUS! INNOVATION & ENTREPRENEURSHIP GROUP

Paul Kassebaum, Co-founder, Executive Tactician

Product: Student club established as a safe environment for students to collaborate on intellectual property projects to make their ideas sustainable business concepts or products, then take advantage of Genius!'s ties with investors and other successful business leaders. Includes WPI and Holy Cross students to date. Intends to become a 501(c)3 organization. Benefits students, alumni and local industries.

Seeking: Mentors and $2,500 for start up funding

Phone: 917.538.7055

Email: genius@wpi.edu

Web: www.beagenius.org

The WPI Venture Forum invites entrepreneurs to make a one-minute practice elevator pitch at monthly programs.Content is limited to seeking investors or potential partners, but not customers. Overhead slide allowed and one pitch per season, per business idea. For a helpful template and submission criteria, please visit:
www.wpiventureforum.org/Programs/spotlight.html

Networking Event – Save the Date!

WPI Venture Forum Networking at Bose Corp.

Wednesday, Oct 18, 2007 • 5:30–7:30pm

Event includes tour of Bose manufacturing facility

BOSE®

Bose Corp. ~ Park Place Facility ~ 1 New York Ave. ~ Framingham, MA

Registration is required. Limited to 100 people!!

Directions available on the registration page

www.wpiventureforum.org — click Programs, then Networking Events

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