

Health Care Technological Innovation

From Idea to Commercialization

TEL AVIV UNIVERSITY  תל-אביב
FACULTY OF MANAGEMENT
THE LEON RECANATI
GRADUATE SCHOOL OF BUSINESS ADMINISTRATION



INTERNATIONAL INSTITUTE FOR
BIOTECHNOLOGY ENTREPRENEURSHIP
A Non-Profit Program offered by Burrill & Company



"Health Care Technological Innovation - From Idea to Commercialization"

An Executive Program for Biotechnology and Medical Device Entrepreneurs and Managers Offered by:
The Leon Recanati Graduate School of Business Administration, Tel Aviv University

In collaboration with

The Israel Life Science Industry Organization
The International Institute for Biotechnology Entrepreneurship
The Center for Medicine in the Public Interest

Monday, December 13 through Wednesday, December 15, 2010, Tel Aviv, Israel

Program Directors:

**For the Recanati
School**

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**For International
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**For The Center for
Medicine in the
Public Interest**

**Robert Goldberg,
Ph.D.**
Vice President
CMPI

**For Canaan
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Brent Ahrens
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Course Syllabus

Day One: Monday December 13, 2010	
Day's Theme: The Creative Process and building value	
8:30 AM	Registration/Administrative Continental Breakfast
9:00 AM	Session 1: Welcome and Opening Remarks: Prof' Asher Tishler, Dean Faculty of Management, Tel Aviv University Course Directors Acknowledgement of Sponsors Course Infrastructure: Introduction to Program Structure Review of required assignments Formation of study teams
9:30 AM	Session 2: Opening Keynote Address Introduction: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest Frank L. Douglas, Ph.D., M.D. President & CEO, Austen BioInnovation Institute in Akron "How To Move From Discovery To Commercialization"

10.30AM	<p>Session 3: The Persuasive Pitch, Part 1: Introduction of course participants</p> <p>Moderators: Kim Cooper , CEO, Kim Cooper Associates, Leadership & Communications</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>David Frank, Managing Director MEDX Associates LLC - Presentation Style from the Executive Technique</p> <p>In order to give participants a chance to learn more about their colleagues in the course, and as the first part of our special focus on presentations, we are asking each participant to prepare to deliver a 3-5 minute presentation, using 2-4 power point slides, to introduce yourself and your company to the group</p>
12:30 AM	<p>Networking Luncheon</p>
13.30 AM	<p>Session 4: Lessons learned from our experience: A panel of life science serial entrepreneurs</p> <p>In this session we will have several leading entrepreneurs in life science telling their experience</p> <p>Moderators: David Cassack, Managing Partners and co-founders of Windhover.</p> <p>Shimon Eckhouse, Co-founder and Chairman of Syneron Ltd. "Key success factors in new life science business ventures – a personal perspective"</p> <p>Frank L. Douglas, Ph.D., M.D. President & CEO, Austen BioInnovation Institute in Akron</p> <p>Ascher Shmulewitz, M.D., President Medegenesis</p>
3:00 PM	<p>Session 5: Value Inflection Points in a Life Science Venture</p> <p>When meeting with investors and prospective strategic partners, entrepreneurs will often hear</p>

	<p>questions that ask: Where are you in the value chain?" How does your business model reflect this?" "How do you describe your milestones and how are you managing towards them?" How do your milestones tie-in with your value inflection points?" This session will consist of a brief overview of typical value inflection points for each type of product. The participants will be divided into small work groups, based on the nature of their companies, to discuss the value inflection points for their development scheme and offer one another critique. The groups will then reconvene and one example from each of devices, drugs and diagnostics will be reviewed by the faculty</p> <p>Moderator: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania. Venture Partner, Burrill & Company</p> <p>Brent Ahrens, General Partner, Canaan Partners</p>
4.00PM	<p>Session 6 :Case Study</p> <p>Faculty led discussion of a case prepared by the INSEAD Israel Research Centre:</p> <p>"Deep Breeze Brings an Innovative Case to Market"</p> <p>With participation of: Doron Nahmias, managing Director INSEAD Israel , Dr. Paivi Jokola Researcher INSEAD Israel, Yoav Cheluoche, Managing Partner, Aviv ventures</p>
5.00 PM	<p>Bio – Break</p>
5.30	<p>Session 7: Keynote lecture:</p> <p>Introduction: Brent Ahrens, General Partner, Canaan Partners</p> <p>David Cassack, Managing Partners and co-founders of Windhover.</p> <p>An overview of the medical device market</p>

6:30 PM	<p>Session 8: Incorporating Reimbursement in the Company Development Strategy</p> <p>Moderator: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest</p> <p>Lambert Van Der Walde, Former CMS liaison to VCs, start ups and Wall Street</p> <p>Steve Peskin, MD, MBA, Executive VP and Chief Medical Officer, MediMedia, USA</p>
8:00 PM	Adjourn for day
Day 2: Tuesday December 14, 2010	
Day's Theme: Strategy and Execution	
8:30 AM	Continental Breakfast
9:00 AM	<p>Session 9: Lecture</p> <p>Developing consumer healthcare products: Proctor & Gamble, Develop and Connect Program</p> <p>Lital Asher, Israel Innovation Leader & External Relations Manager</p>
09:30AM	Session 10: Designing and Conducting Clinical Trials: From Proof of Concept to Marketing Success

	<p>This session provides an abbreviated view of the overall process and specific insight into planning for FDA regulations in light of strategy, financial needs, and the concerns of prospective partners and investors. Entrepreneurs need to understand that there is an increasing need to perform clinical studies to support medical device safety and performance claims. They also need to have a basic understanding of the activities, resources and costs associated with the design and conduct of clinical studies. The failure to incorporate an effective clinical strategy into new project planning can lead to significant project and funding delays or, worse, the failure of the project. This session will provide an overview of the increasing need for device clinical study data; key activities, resource needs and costs; and planning for the successful design and conduct of medical device clinical studies for acceptance in the United States and Europe, even when these studies are conducted outside of these regulatory jurisdictions.</p> <p>Moderator: Benny Zeevi, M.D., Managing General Partner, DFJ Tamir Fishman Ventures</p> <p>Dr. Dan Schultz ,M.D. Sr. Vice President, Medical Devices & Combination Products, Greenleaf Health, Former Director of FDA's Center for Devices and Radiological Health (CDRH)</p>
11.30	Bio Break
12.00	<p>Session 11: Emerging Markets – Opportunities for Life Science companies?</p> <p>Moderator: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania, Venture Partner, Burrill & Company</p> <p>Dr. Peter Lu, Partner, Infinity Private Equity Fund, China</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Gad Berdugo, Founder, Explorium Capital Former Director and Sector Leader for global healthcare equity investment research at Lazard in New York</p>
1:30 PM	Networking Luncheon

2:30PM	<p>Session 12: Keynote lecture</p> <p>Steve Peskin, MD, MBA, Executive VP and Chief Medical Officer, MediMedia, USA</p> <p>Digital and Social media (R)evolution: <i>How Digital Communication Platforms and Tools are Transforming Life Sciences</i></p>
3:15	<p>Session 13: Capitalization of a life science Venture –Terms, Rounds etc...</p> <p>Andrew Farquharson, Managing Director, DFJ InCube Ventures</p> <p>Gad Berdugo, Founder, Explorium Capital Former Director and Sector Leader for global healthcare equity investment research at Lazard in New York</p> <p>Alon Sahar, Adv., Partner, Herzog, Fox & Neeman- Terms and agreements</p> <p>Naomi Herman, General Manager, SVB Israel Advisors Ltd</p>
4.15	<p>Case Study:</p> <p>NanoPass</p> <p>Moderators: Steve Sammut, Benny Zeevi</p> <p>Presenter: Dr. Yotam Levin, CEO Nanopass</p>
5:00 PM	<p>Bio – Break</p>
5:30 PM	<p>Session 14: The Persuasive Pitch, Part 2: Presenting Your Idea—and Yourself—With Purpose, Clarity, and Power</p> <p>Kim Cooper , CEO, Kim Cooper Associates, Leadership & Communications</p>
6.30PM	<p>Session 15: Venture Capitalists and Entrepreneurs – A complex Relationship</p>

	<p>Benny Zeevi, M.D. Managing General Partner, DFJ Tamir Fishman Ventures</p> <p>Brent Ahrens, General Partner, Canaan Partners</p> <p>David Cassack, Managing Partners and co-founders of Windhover</p> <p>Andrew Farquharson, Managing Director, DFJ InCube Ventures</p>
8:00 PM	<p>Dinner for Faculty and Participants At the Green Vila, Tel Aviv University</p> <p>Courtesy of Mintz Levin Short lecture</p>
Day Three: Wednesday December 15, 2010	
Day's Theme: Bringing the product to the market	
8:30 AM	Continental Breakfast
9:00 AM	<p>Session 16: Biopharmaceutical and Medical Device Licensing, Partnering and Strategic Alliances</p> <p>Format: Brief lectures, panel discussion, Q&A</p> <p>Major practical issues in formulation of partnering goals and managing different types of strategic alliances, preparation for positioning for partnering, identifying and qualifying prospective partners, making the approach, negotiation, closing the deal, with special emphasis on how to design alliances and avoid many potential problems and complications in managing these relationship.</p> <p>Moderator: Benny Zeevi</p>

	<p>Session Keynote: Ellen A. Lubman, Group Director, Strategic Transactions Group, BMS</p> <p>Rob Pinnok, BSC, PhD, Director, Scientific Liaison, External Scientific Affairs, Merck Sharp & Dohme</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Ruben Krupik, CEO, Clal Biotechnology</p> <p>Dr. Leah Klapper, General Manager, BioLine Innovations</p> <p>Maya Racine - Netser, Adv, Partner, Head, technology licensing group in the High Tech Practice , Herzog, Fox & Neeman</p> <p>Discussion and Q&A</p>
11:300 AM	Bio – Break
12.00	<p>Session 17: Market Analysis and Competitive Analysis - Essentials of Marketing in Biotechnology and Medical Devices</p> <p>This session will focus on Market analysis, Clinical state of the art and product positioning: assessment of different applications for the same product (choosing the right application from commercial point of view), Determination of subgroup of patients most appropriate for the product, Competitive analysis, Pricing and reimbursement strategy, Importance of opinion leaders, patients groups, patients organization and Selling strategy.</p> <p>Moderator: Brent Ahrens, General Partner, Canaan Partners</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Steve Peskin, MD, MBA, Executive VP and Chief Medical Officer, MediMedia, USA</p>

	Talya Miron –Shatz, PhD, Head the Center for Medical Decision Making, Ono Academic College, Teaches Health Consumerism at Wharton.
1:30 PM	<p>Session 18: Case study</p> <p>David Naveh, Ph.D., MBA, Former, VP and Chief Technical Officer, Bayer Biological Products, Worldwide</p> <p>Title: Biological Drug Development: From Package Insert to the Bench</p> <p>This case study will take the package insert of a protein therapeutic blockbuster, and starting with the medical claims, reverse engineer the clinical development program, and derive branding. The exercise will use the technical process description in the package insert to reverse engineer the process and process development, derive the Cost of Goods, and compare to the current selling price (\$5million per gram) of this multibillion dollar drug</p>
2:30 PM	Luncheon
3.15PM	<p>Session 19: The Impact of the US Health Care Reform on Technological Innovations.</p> <p>Health Care IT</p> <p>Moderator: Robert Goldberg, PhD, Vice President, CMPI</p> <p>Mark Leahey, CEO MDMA (By phone)</p>
4.00 PM	Bio – Break
4:20PM	<p>Session 20: The Persuasive Pitch, Part 3: Presentations Workshop</p> <p>Moderator: Kim Cooper , CEO, Kim Cooper Associates, Leadership & Communications</p>

	Three participants will present revised versions of their introductions from Sunday, and will receive feedback on both the written and spoken aspects of their presentations.
6.00 PM	Program Adjournment Session 21: Teams gather for "Take-aways Exercise" Each participant will receive at registration a work-sheet to record for each session one major lesson or "take-away." Teams will gather to discuss, compare notes, and develop one major take away for three sessions that will be assigned. Participants will have reviewed take-aways from Days 1 and 2 at the end of each day.
6.30PM	Program Adjournment

* Changes in curriculum may occur