

Health Care Technological Innovation

From Idea to Commercialization

TEL AVIV UNIVERSITY  תל אביב-יפו
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

Second course:

Sunday, May 25 through Monday, Monday 26, 2007, Tel Aviv, Israel

Program Directors:

For the Recanati School

Professor Simon Benninga

Max and Steffi Perlman
Professor of Financial
Economics
Visiting Professor of
Finance, Wharton School,
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For Israel Life Science Industry Organization and Program Founder

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For International Institute for Biotechnology Entrepreneurship

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Senior Fellow, Health Care
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Company

For The Center for Medicine in the Public Interest

Robert Goldberg, Ph.D.
Vice President
CMPI

Second Course Syllabus (VERSION 10as of 3-30-08)

Day One: Sunday, May 25, 2008	
Day's Theme: Designing and Conducting Clinical Trials	
8:00 AM	Registration/Administrative Continental Breakfast
8:30 AM to 9:00 AM	<p>Session 1: Welcome and Opening Remarks:</p> <p>Professor Simon Benninga, Ph.D., Max and Steffi Perlman Professor of Financial Economics, Visiting Professor of Finance, Wharton School, University of Pennsylvania, Former Dean, Faculty of Management, Tel-Aviv University, Israel</p> <p>Dr. Benny Zeevi, Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Professor Stephen Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Dr. Robert Goldberg, Co-Founder and Vice President of the Center for Medicine in the Public Interest (CMPI)</p> <p>Acknowledgement of Sponsors</p> <p>Course Infrastructure:</p> <p>Introduction to Program Structure</p>

<p>9:00 AM to 10.00 AM</p>	<p>Session 2: Opening Keynote Address Introduction: Benny Zeevi, M.D. Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Keynote Theme: "Mergers and Acquisitions: Negotiations and Implementation"</p> <p>Israel Makov, Chairman of Given Imaging, Former President and CEO of Teva Pharmaceutical Industries</p>
<p>10:00 AM to 1 PM</p>	<p>Session 3: Demonstrating Quality and Value to Consumers: The Key to Reimbursement Success in the 21st Century, Implications for Clinical Trials Planning</p> <p>This session will be led by experts, including the former director of CMS and the leader of the largest patient advocacy organization in the United States, who are in the business of demonstrating quality and value to health care consumers. They will explain why this is more important than demonstrating cost-effectiveness for the success of a product in the marketplace. They will also describe ways start ups can inexpensively conduct research to show the value of to customers. Finally, the faculty will provide participants will tools and methodologies they can use for conducting their own assessments</p> <p>Moderator: Dr. Robert Goldberg, Co-Founder and Vice President of the Center for Medicine in the Public Interest (CMPI)</p> <p>Doug Badger, Partner, Nickles Group</p> <p>Bill Molmen, Co-Founder, Integrated Benefits Institute</p> <p>Ralph Snyderman, MD, President , Proventys Inc. and Chancellor Emeritus Duke University Medical Center</p> <p>Susan Horn, Ph.D. Senior Scientist, Institute for Clinical Outcomes Research</p> <p>Dr. Azin Parhizgar, former Vice President and COO of Conor Medsystems, Inc. and now an executive in J&J</p>
<p>1 PM to</p>	<p>Networking Luncheon</p>

1.45 PM	
1.45 PM to 2.45 PM	<p>Session 4: Clinical Effectiveness Case Studies</p> <p>Prior to the program, participants will be asked to prepare, submit and present a real situation for group review; questions provided.</p> <p>Faculty from previous sessions to serve as commentators.</p>
2:45 PM To 4.15 PM	<p>Session 5: Life Science industry Ethics, Social Responsibility and Global Health Needs</p> <p>This session will focus broadly on the initiatives addressing global health needs. The session will include a presentation of an actual project: an initiative to address and prevent asthma in India and the accompanying challenge: “What low cost diagnostics, devices etc can be developed so that families and non physicians can reduce emergence of certain parasites implicated in asthma.” He will be accompanied by a venture capitalist managing a global life science fund focusing on India and China. In addition the session will address changing diabetes as a global initiative – mobilizing forces at the local, regional and global level.</p> <p>Moderator: Professor Stephen M.Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Kanwarjit “KJ” Singh, MD, MBA Senior Program Officer Bill & Melinda Gates Foundation</p> <p>Leonard Bielory, M.D., Head of Allergy and Immunology at University of Medicine and Dentistry of New Jersey</p> <p>Dr. Alan Moses, Vice President and Chief Medical Officer Worldwide, NovoNordisk</p> <p>Gad Berdugo, Former Director and Sector Leader for global healthcare equity investment research at Lazard in New York</p>

<p>4:15 PM to 4.45 PM</p>	<p style="text-align: center;">Bio - Break</p>
<p>4:45 PM to 6:30 PM</p>	<p>Session 6: Intellectual Property</p> <p>The goal of the session is to provide information and insight into the specific issues confronting investigators, entrepreneurs, investors and their patent attorneys. The session will address the Current hot issues in biotech and devices, recent developments in US/PCT/TRIPS policies as related to biotech and devices, claims development strategy, managing the freedom to operate process, jurisdiction strategy and partnering implications</p> <p>Moderator: Dr. Benny Zeevi, Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Ivor Elrifi, Ph.D., LL.B. is Co-chair of the Intellectual Property Section and Member, Policy Committee Mintz Levin</p> <p>Brent Ahrens, General Partner, Canaan Partners (TBC) Critical Path Foundation, Former Head, US FDA, US Centers for Medicare and Medicaid Services</p>
<p>6:30 PM To 7:30 PM</p>	<p>Session 7: IP Case Studies</p> <p>Case analysis on issues provided by participants, Faculty to serve as commentators.</p>
<p>7:45PM</p>	<p style="text-align: center;">Opening Dinner for Faculty and Participants At the Green Vila, Tel Aviv University</p> <p style="text-align: center;">Keynote lectures: Tevi Troy, Deputy Secretary of the United States Department of Health and Human Services (HHS) , Prof' Manuel Trajtenberg, Head of the National Economic Council</p>
<p>Day 2: Monday, MAY 26, 2008</p>	

Day's Theme: Marketing, Partnering and Intellectual property	
8:30 AM	Continental Breakfast
9:00 AM to 12:30 PM Break at 10:30 AM	<p>Session 8: Designing and Conducting Clinical Trials: From Proof of Concept to Marketing Success</p> <p>This is a how-to guide for drug, device and diagnostic companies about how to use emerging tools, techniques and tips regarding the FDA's new approach to product development. The FDA is more than just a regulatory body, it is a agency the shapes policy based on new science. Start ups should be aware and part of this process, called the Critical Path, as much as possible. This session bring these two important trends to course participants. The current system will be contrasted with the critical path. Examples from pharmacokinetics, genetics/proteomics, medical devices etc.</p> <p>The session will also take a special look at applying technology to chronic disease with diabetes as a case example.</p> <p>Moderator: Dr. Robert Goldberg, Co-Founder and Vice President of the Center for Medicine in the Public Interest (CMPI)</p> <p>Hugh Rosen, (TBD)Raymond Woosley, MD, President and CEO, Critical Path Institute</p> <p>Daniel Troy, former general counsel FDA and partner Sidley Austin</p> <p>Dr. Alan Moses, Vice President and Chief Medical Officer Worldwide, NovoNordisk</p> <p>Dr. Azin Parhizgar, former Vice President and COO of Conor Medsystems, Inc. and now an executive in J&J</p> <p>Dr. Daniel G. Schultz, Director of FDA's Center for Devices and Radiological Health (CDRH).</p>
12.30 PM to 1.30 PM	Networking Luncheon
1:30 PM	Session 9: Creating Global Cross Border Collaborations and Knowledge Networks in the

<p>to 2.30 PM</p>	<p>Life Sciences: Practical Considerations for Emerging Israeli Companies</p> <p>The Israeli life sciences sector is poised for long-term growth and success; however, to achieve the economic promise of the life sciences industry, entrepreneurs need to consider targeted cross border research collaborations, joint business ventures and syndicated investments "from day one". This interactive session describes how to position your company to "think globally" and highlights the model of the Boston Haifa Life Sciences Initiative (BHLSI). In this session we will provide practical strategies to catalyze collaborations to facilitate angel and venture investments and alternative revenue streams, enhance opportunities for joint ventures and strategic alliances, and strategies to promote cross border research, clinical trials and strategic access to US markets.</p> <p>Moderator and Lecture: Robin JR Blatt, Director, Boston Haifa Life Sciences Initiative (BHLSI) Publisher, The Journal of BioLaw & Business, Adjunct Lecturer, Harvard School of Public Health Eisenhower Fellow (India and Singapore)</p> <p>Two Israeli CEOs will present their experience in working globally</p>
<p>2:30 PM to 3.00 PM</p>	<p style="text-align: center;">Bio-Break</p>
<p>3:00 PM to 4.15 PM</p>	<p>Session 10: Partnering in a Borderless World</p> <p>This session will address partnering strategy, planning, execution and management of the relationship.</p> <p>Moderator: Dr. Benny Zeevi, Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Jeremy Levin, Senior Vice President of External Science, Technology and Licensing, Bristol-Myers Squibb Company</p> <p>Amos Goren, Venture Partner (previously Head of European Healthcare team), Apex Partners</p> <p>John A. Dellapa, Of Counsel in the Corporate practice at Mintz Levin</p>

4.15 PM to 6.45 PM	<p>Session 11: 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: Professor Stephen M.Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Dr. Azin Parhizgar, former Vice President and COO of Conor Medsystems, Inc.and now an executive in J&J</p> <p>David Frank, Head of BD, Ortho Diagnostics, J&J</p> <p>Brent Ahrens, General Partner, Canaan Partners Amos Goren,Venture Partner (previously Head of European Healthcare team), Apex Partners</p> <p>An Israeli CEOs (TBD)</p>
6:45 PM to 7.45 PM	<p>Session 12: Marketing Workshop</p> <p>Case analysis on issues provided by participants Biotech/device breakout. Faculty to serve as commentators.</p>
7.45 PM	COURSE ADJOURNS

Take Away Exercise and "Words of Wisdom" from participants and faculty at large