אוניברסיטת תל-אביב
TAU Recanati
הפקולטה לניהול ע"ש ליאון רקנאטי

Israel Advanced Technology Industries

INTERNATIONAL INSTITUTE FOR BIOTECHNOLOGY ENTREPRENEURSHIP

להב
להוביל חדשנות בניהול

CMPI
Center for Medicine in the Public Interest

"Health Care Technological Innovation - From Idea to Commercialization"
The Sixth Course

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, November 26 through Wednesday, November 28, 2012, Tel Aviv, Israel

Program Directors:

Program Founder	**For the Recanati Business School**	**For International Institute for Biotechnology Entrepreneurship**	**For The Center for Medicine in the Public Interest**	**For Canaan Partners**
Dr. Benny Zeevi Managing General Partner DFJ Tel Aviv Venture Partners	**Prof. Simon Benninga** Faculty of Management Tel-Aviv University, Israel	**Stephen M. Sammut** Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania	**Robert Goldberg, Ph.D.** Vice President CMPI	**Brent Ahrens** General Partner

Course Syllabus

Day One: Monday November 26, 2012	
Day's Theme: The Creative Process and Technology Assessment	
8:30 AM	**Registration/Administrative** **Continental Breakfast**
9:00 AM	**Session 1: Welcome and Opening Remarks:** Prof. Moshe Zviran, Vice Dean Faculty of Management, Tel Aviv University **Course Directors**: Introduction to Program Structure Review of required assignments
9:30AM	**Session 2: The Persuasive Pitch, Part 1: Introduction of course participants** Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners David Frank, Managing Director MEDX Associates LLC – "Making YOUR Pitch Persuasive" 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
11:20AM	**Session 3: Keynote Address – Innovation and the Israeli Life Sciences Induartry** Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners

12:00PM	**Bio Break**
12:15PM	**Session 4: Project, Product or Company?: Assessment and Qualification of Technologies as a Basis for a Startup** The successful translation of discoveries from the lab to the market is the greatest challenge facing an entrepreneur. Many companies are formed on technologies emanating from university laboratories and spinouts from major corporations as well as life science companies themselves. Many healthcare innovations fall because they neither integrate with existing clinical practice nor are successful in creating new ones. Forming a company around a technology is relatively easy. Staffing and capitalizing it is another story. Savvy employees, astute venture capitalist and selective prospective strategic partners know that companies without technological critical mass sufficient to bring a series of product to the market are unsustainable. This session will provide tools and a contextual framework as to how technologies can be assessed by academic founders, top industry executives, CSOs, Incubators and VCs so that they can orient and characterize their business for capitalization and partnering. **Moderator**: Benny Zeevi, M.D., Managing General Partner, DFJ Tel Aviv Venture Partners Stephen M. Sammut**,** Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania David Frank, Managing Director MEDX Associates LLC Tamara Mansfeld, Director, Strategy & Portfolio Management, Pfizer
1:50 PM	**Networking Luncheon**
2:40 PM	**Session 5: Lessons learned from our experience: A panel of life science CEOs and Entrepreneurs** In this session we will have several US and Israeli CEOs in life sciences sharing their experience. Specifically addressing issues: Building a management team, financing, collaborations, dealing with the board and more Moderator: Ruti Alon, General Partner, Pitango Venture Capital Fund

	Udi Cohen, CEO Biocontrol Ascher Shmulewitz, M.D., President Medegenesis
4:00 PM	**Session 6 : Case Study** **Given Imaging - The Quest for Quantum Leap** Faculty led discussion of a case Stephen M. Sammut**,** Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania
4:50PM	**Bio Break**
5.00PM	**Keynote Address:** Corie Bar Dea, Strategy Director, Designit "Innovation Strategy"
5:45 PM	**Session 7: Market Analysis and Competitive Analysis - Essentials of Marketing in Biotechnology and Medical Devices** 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. Moderator: Stephen M. Sammut**,** Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania David Frank, Managing Director MEDX Associates LLC Yael Glassman, Former VP Marketing, American Well
7:30 PM	**End of Day…**

Day 2: Tuesday November 27, 2012	
Day's Theme: Strategy and Execution	
8:30 AM	**Continental Breakfast**
9:00 AM	**Session 8: Biotechnology and Medical device Regulatory Planning, Clinical Development and the Implications for Strategy and Financing: From Proof of Concept to Marketing Success. Designing and conducting clinical trials** 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. Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest – "How to approach the FDA" Udi Cohen, CEO Biocontrol – The experience of a CEO in conducting multinational clinical trial
10:30AM	**Session 9: Lecture - US Healthcare – Opportunities for Innovation** Nigel Ohrenstein, Founder, Vice-President of Business Development and Strategy at Lumeris The US Healthcare system is in a state of crisis – it is bankrupting America. Today, healthcare

	spending is over 16% of the GDP and estimate to rise to 25% in the next 10 years. It is not sustainable. To tackle this problem, the health care system is attempting to transform itself from a system which pays providers of health care for volume to a system which pays for value. Payers and Providers are entering into new collaborations where they share risk and base payment on their ability to impact both quality and efficiency targets. This transformation is creating turmoil in the market and with it huge opportunities for companies to innovate, disrupt and deliver value to the market. In this session, the speaker will provide a brief overview of the current market and identify which types of companies are best placed to succeed in the changing market place and what they need to thrive.
11:00	**Bio Break**
11:30	**Session 10: Emerging Markets – Opportunities for Life Science companies** The growth of biotechnology and other health related industries in Brazil, China and India is taking place at a stunning pace. While this fact might appear to be a competitive threat to Israeli entrepreneurs, it is in fact an opportunity. Companies in these countries are eager to collaborate with Israeli companies. This session will describe the status of activity in the three most rapidly advancing countries and will also describe how Israeli firms can do business in these same countries. **Moderator:** Stephen M. Sammut**,** Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania**,** Venture Partner, Burrill & Company Gad Berdugo, Founder, Explorium Capital Former Director and Sector Leader for global healthcare equity investment research at Lazard in New York David Frank, Managing Director MEDX Associates LLC
1:00 PM	**Keynote lecture:** Evidence based medicine Debbie Garner EMEA Regional Director, ,Avalere
1:45	**Networking Luncheon**

2:30PM	**Session 11: Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc** Financing a life science venture is challenging. When meeting with investors and prospective strategic partners, entrepreneurs will often hear 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, classical and alternative ways of financing, terms of financing rounds and more Moderator: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners Ruti Alon, General Partner, Pitango Venture Capital Fund John R. Lieberman, CPA/PFS Managing Director Perelson Weiner LLP Gad Berdugo, Founder, Explorium Capital Former Director and Sector Leader for global healthcare equity investment research at Lazard in New York Alon Sahar, Adv., Partner, Herzog, Fox & Neeman- Terms and agreements Dan Sztybel, Manager Global Incentives Advisory (GIA) E&Y- "Government Incentives"
4:00 PM	**Session 12: Keynote lecture** Nir Nimrodi, Vice President and General Manager,Animal Health & Food Safety, Life Technologies "The expanding role of biology in applied markets"
4:45 PM	**Bio – Break**
5:15 PM	**Session 13: Incorporating Reimbursement in the Company Development Strategy** Moderator: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest Debbie Garner EMEA Regional Director ,Avalere

6:30 PM	**Session 14: Intellectual Capital Management** 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 formation of specific IP strategy and execution and using intellectual capital for competitive advantage. Content includes major issues confronting companies with US and filings in other jurisdictions related to biotechnology, e.g., patent ownership, non-obviousness rulings, the scope of what can be patented.. A VC will also provide an investor viewpoint. Moderator: Steve M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship Brian Hopkins, Member, Mintz Levin – IP Management John R. Lieberman, CPA/PFS Managing Director Perelson Weiner
8:00 PM	**End of the day….**

Day Three: Wednesday November 28, 2012	
Day's Theme: Bringing the product to the market and HCIT	
8:30 AM	**Continental Breakfast**
9:00 AM	**Session 15: Biopharmaceutical and Medical Device Licensing, Partnering and Strategic Alliances** Format: Brief lectures, panel discussion, Q&A 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. Moderator: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners David Frank, Managing Director MEDX Associates LLC Ruben Krupik, CEO, Clal Biotechnology Maya Racine - Netser, Adv, Partner, Head, technology licensing group in the High Tech Practice , Herzog, Fox & Neeman Claudio Yarza, Life Sciences practice leader, PwC Israel - Cross-Border Licensing Agreements Discussion and Q&A
11:30 AM	**Bio – Break**

12.00 PM	**Session 16: Healthcare IT and Mobile Health** Quality and efficient healthcare delivery is highly depended on information and communication, anytime anywhere.Despite Healthcare Delivery Industry having much to gain from Information and CommunicationTechnologies, it is the slowest from all industries in the adoption. There are many reasons for IT failures in healthcare environment, but the single most important cause is the HIT capability mismatch to address work processes within healthcare service organization.HCIT investment will only be successful if the fit between IT and clinical processes will be close to matching, which will be reflected by the acceptance or rejection of end users. The emergence of new, disruptive technologies play a crucial role in closing the capability gap and gaining more acceptance from the main users. The latest innovations are changing not only how the medical care is organised, practiced and delivered but are also redefining host of other qualities including changing patient-physician model and facilitating the emergence of new industry players within the value chain. Mobile devices and services are transforming the way people all over the globe live, work, play and now also revolutionize the way they receive medical care. Mobile devices are the most personal technology that consumers and healthcare providers own, and allows consumers to be introduced to new services quickly and intuitively and establish personal preferences. mHealth enable health and wellness to be delivered through mass personalization anywhere and anytime, in the comfort of patients' own homes and during daily routines. Many new players are entering the mobile health industry; it is highly fragmented market worth several billion of dollars. The adoption and deployment of mHealth requires new regulatory clarity, standards and interoperability of devices and software, new viable business models, consumers and providers cultural changes and proven evidence –based outcome measures, clinically and economically. The potential applications of HCIT technologies and mobile health, it's role in global health, new business models, the use of social media by pharma and medical device companies as well as by healthcare providers and insurance companies and regulatory issues will be discussed. Moderator and introduction on Mobile Health: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners

	Prof. Shai Dekel, Chief Scientist Imaging Solutions, GE Healthcare IT Steve Peskin, MD, MBA, Senior Medical Director/Pilot Lead at Horizon Healthcare Innovations, a Horizon Blue Cross Blue Shield of New Jersey company , USA Yael Glassman, Former VP Marketing, American Well
2:00 PM	**Luncheon**
2:45 PM	**Keynote Lecture: "The changing world of medicines, economics, and its impact on Global pharmaceuticals manufacturing"** Benny Klener, Vice President , FIRST (Focussed Israel Respi Sterile Tech) OPS – Teva Generics System
3:45-4.30 PM	**Session 17: Keynote lecture:** Don't be the Bullseye: Anticipating and Avoiding Litigation in the United States... And How to Fight Back if Targeted" Litigation in the United States is fraught with peril for foreign corporate defendants, who, in addition to facing suits in unfriendly venues brought by plaintiffs' lawyers, are increasingly being targeted by aggressive government investigations that can lead to product recalls, enormous monetary fines, and even criminal charges brought against company executives. This presentation explores the key hallmarks of litigation in the United States of which foreign corporations should be aware, and provides strategies for corporations to avoid litigating in the U.S. The "three-headed monster" companies face from the plaintiffs' bar, federal regulatory agencies, and government criminal investigations is reviewed. Venues known as "judicial hellholes" that are extremely friendly to plaintiffs are discussed, as well as the perils of jury trials and punitive damages. You will also learn strategies that foreign corporations can use to avoid becoming a firm targeted by plaintiffs' lawyers and the government, as well as ways to avoid being brought into litigation in the U.S. The presentation also presents some key strategies for companies to successfully manage litigation when it becomes unavoidable, including methods for removing cases from state courts to federal courts, and ways to effectively use social media while selecting a jury.

	Lori Cohen, Shareholder; Chair, Pharmaceutical, Medical Device & Health Care Litigation Group; Co-Chair, Atlanta Litigation Practice, Greenberg Traurig, LLP
4:30 PM-5.30PM	**Session 18: Case study- American Well** Yael Glassman, Former VP Marketing, American Well Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners
5.30-6PM	**Bio Break**
6:00PM	**Session 19: The Persuasive Pitch, Part 2: Presentations Workshop** Moderators: Steve M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners David Frank, Managing Director MEDX Associates LLC Three to five participants will present revised versions of their introductions from Sunday before a panel of VCs and experts, and will receive feedback on both the content and spoken aspects of their presentations.
7.00 PM	**Program Adjournment** **Session 20: 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.

*** Changes in curriculum may occur**