

# Health Care Technological Innovation

From Idea to Commercialization



## **"Health Care Technological Innovation - From Idea to Commercialization" The Fifth 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, December 12 through Wednesday, December 14, 2011, Tel Aviv, Israel**

### **Program Directors:**

#### **Program Founder**

**Dr. Benny Zeevi**  
Managing General  
Partner  
DFJ Tel Aviv Venture  
Partners

#### **For the Recanati Business School**

**Prof. Simon  
Benninga**  
Faculty of Management  
Tel-Aviv University,  
Israel

#### **For International Institute for Biotechnology Entrepreneurship**

**Stephen M. Sammut**  
Senior Fellow, Health Care  
Systems and Entrepreneurial  
Programs,  
Wharton School, University of  
Pennsylvania  
Venture Partner, Burrill & Company

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

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

#### **For Canaan Partners**

**Brent Ahrens**  
General Partner

## Course Syllabus

Day One: Monday December 12, 2011	
Day's Theme: The Creative Process and building value??	
8:30 AM	<b>Registration/Administrative Continental Breakfast</b>
9:00 AM	<b>Session 1: Welcome and Opening Remarks:</b>  Prof. Asher Tishler, Dean Faculty of Management, Tel Aviv University Course Directors  <b>Acknowledgement of Sponsors</b>  <b>Course Infrastructure:</b>  Introduction to Program Structure Review of required assignments Formation of study teams
9:30 AM	<b>Session 2: Lecture</b> Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners "Innovations in Life Sciences, and Israel Life Science Industry"

10.15AM	<p><b>Session 3: The Persuasive Pitch, Part 1: Introduction of course participants</b></p> <p>Moderators: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>David Frank, Managing Director MEDX Associates LLC – "Making YOUR Pitch Persuasive"</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>
12:20 PM	<p><b>Networking Luncheon</b></p>
1:15 PM	<p><b>Session 4: Lessons learned from our experience: A panel of life science CEOs</b> <b>In this session we will have several US and Israeli CEOs in life sciences sharing their experience.</b> <b>Specifically addressing issues: Building a management team, financing, collaborations, dealing with the board and more</b></p> <p>Moderators: David Cassak, VP/Content, Elsevier Business Intelligence</p> <p>Andy Weiss, President &amp; CEO, CoAxia, former Vice President &amp; General Manager of Medtronic Neurological.</p> <p>Dr. Udi Cohen, CEO, BioControl Medical</p> <p>Hezi Himelfarb, CEO, IceCure Medical</p>

	<p>Sonny Vu, Founder of AgaMatrix</p> <p>Ascher Shmulewitz, M.D., President Medegenesis</p>
3: 00 PM	<b>Bio Break</b>
3:30 PM	<p><b>Session 5: Market Analysis and Competitive Analysis - Essentials of Marketing in Biotechnology and Medical Devices</b></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: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Andy Weiss, President &amp; CEO, CoAxia, former Vice President &amp; General Manager of Medtronic Neurological</p>

5:00 PM	<p><b>Session 6 :Case Study</b> "Deep Breeze Brings an Innovative Case to Market"</p> <p>Faculty led discussion of a case prepared by the INSEAD Israel Research Centre: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania</p> <p>With participation of: Doron Nahmias, Managing Director INSEAD Israel , Dr. Paivi Jokola Researcher INSEAD Israel, Yoav Cheluoche, Managing Partner, Aviv ventures</p>
6.00PM	<p><b>Keynote Address</b></p> <p>Introduction: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest</p> <p>Frank L. Douglas, Ph.D., M.D. President &amp; CEO, Austen BioInnovation Institute in Akron</p> <p>"Value Driven Engineering: A New Approach for Promoting Innovation"</p>
6:45 PM	<p><b>Session 7: Keynote lecture:</b></p> <p>Dafna Sheinwald, IBM Haifa Research Lab</p> <p>IBM Watson – A System Designed for Answers and its roll in healthcare.</p>
7:45 PM	<p><b>Dinner for Faculty and Participants At the Green Vila, Tel Aviv University</b></p> <p><b><u>Courtesy of Mintz Levin</u></b></p>

<b>Day 2: Tuesday December 13, 2011</b>	
<b>Day's Theme: Strategy and Execution</b>	
8:30 AM	<b>Continental Breakfast</b>
9:00 AM	<p><b>Session 8: Biotechnology and Medical device Regulatory Planning, Clinical Development and the Implications for Strategy and Financing: From Proof of Concept to Marketing Success</b></p> <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: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>Heather Rosecrans, Former FDA 510(k) Director, Senior Advisor, Regulatory Affairs Greenleaf Health LLC</p>

	<p>Estelle Geffard-Duchamp, Associate Director of Regulatory Affairs, MedPass International</p> <p>Andy Weiss, President &amp; CEO, CoAxia, former Vice President &amp; General Manager of Medtronic Neurological.</p>
10:30AM	<p><b>Session 9: Lecture</b></p> <p>Developing consumer healthcare products: Proctor &amp; Gamble, Develop and Connect Program</p> <p>Lital Asher, Israel Innovation Leader &amp; External Relations Manager</p>
11:00	<p><b>Bio Break</b></p>
11:30	<p><b>Session 10: Emerging Markets – Opportunities for Life Science companies</b></p> <p>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.</p> <p><b>Moderator:</b> Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania, Venture Partner, Burrill &amp; Company</p> <p>Lin Wang, Ph.D, Professor, Institute of Biophysics, CAS. CEO, Incubator for Protein Technology (Biotrand, Inc.), Executive Director, BioSino Bio-technology and Science, Inc</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>David Frank, Managing Director MEDX Associates LLC</p>

1:00 PM	<b>Keynote lecture: An overview of the Medical Device Market</b>  David Cassak, VP/Content, Elsevier Business Intelligence
1:45	<b>Networking Luncheon</b>
2:30PM	<b>Session 11: Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc</b>  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: Steve Levin, Editor-in-Chief/Medical Devices, Elsevier Business Intelligence  Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners  Andy Weiss, President & CEO, CoAxia, former Vice President & General Manager of Medtronic Neurological  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



4:30 PM	<b>Session 12: Venture Capitalists and Entrepreneurs – A complex Relationship</b> Benny Zeevi, M.D. Managing General Partner, DFJ Tamir Fishman Ventures
5:30 PM	<b>Bio – Break</b>
6:00 PM	<b>Session 13: Incorporating Reimbursement in the Company Development Strategy</b> Moderator: Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest Lambert Van Der Walde, Former CMS liaison to VCs, start ups and Wall Street Gaëtan Gicquel, Market Specialist Development, Reimbursement Department at MedPass Andy Weiss, President & CEO, CoAxia, former Vice President & General Manager of Medtronic Neurological.
7:15 PM	<b>Session 14: Case Study: Participant presenting his\her case study</b> <b>TBD</b>
7:45 PM	<b>Cocktail Reception - <u>Courtesy of Perelson Weiner LLP</u></b>

<b>Day Three: Wednesday December 14, 2011</b>	
<b>Day's Theme: Bringing the product to the market</b>	
8:30 AM	<b>Continental Breakfast</b>
9:00 AM	<p><b>Session 15: Biopharmaceutical and Medical Device Licensing, Partnering and Strategic Alliances</b></p> <p>Format: Brief lectures, panel discussion, Q&amp;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, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>Iddo Leshem, Country Manager Israel, BMS</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Ruben Krupik, CEO, Clal Biotechnology</p> <p>Fredric D. Price, Chairman of the Board of Directors and CEO of Chiasma</p> <p>Maya Racine - Netser, Adv, Partner, Head, technology licensing group in the High Tech Practice , Herzog, Fox &amp; Neeman</p> <p>Tom Duley, Of Counsel, DLA PIPER, concentrates on technology transactions for life sciences companies</p> <p>Discussion and Q&amp;A</p>

11:30 AM	<b>Bio – Break</b>
12.00 PM	<p><b>Session 16: Mobile Health</b></p> <p>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.</p> <p>Quality and efficient healthcare delivery is highly depended on information and communication, anytime anywhere. The potential applications of 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.</p> <p>Moderator and introduction: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>Claudio Yarza, Partner, PricewaterhouseCoopers   Kesselman &amp; Kesselman</p> <p>Sonny Vu, Founder of AgaMartrix</p> <p>Hanan Gelbendorf, Co-founder, Managing Director, 2Creative, Buzz Hunter, Using Social Research to shape your marketing strategy</p> <p>Talya Miron –Shatz, PhD, Founding director, Center for Medical Decision Making, Ono Academic College, Teaches Health Consumerism at Wharton, CEO CureMyWay - Global Opportunities with Mobile Health</p>

1:30 PM	<b>Luncheon</b>
2:30 PM	<p><b>Session 17: Case study</b></p> <p>AgaMatrix, Sonny Vu, Founder</p>
3:15 PM	<p><b>Session 18: Intellectual Capital Management</b></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 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.</p> <p>Moderator: Steve M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship</p> <p>Brian Hopkins, Member, Mintz Levin – IP Management</p> <p>Tom Duley, Of Counsel, DLA PIPER</p> <p>John R. Lieberman, CPA/PFS Managing Director Perelson Weiner</p>
4:30 PM	<b>Bio – Break</b>
5:00PM	<p><b>Session 19: The Persuasive Pitch, Part 2: Presentations Workshop</b></p> <p>Moderators: Steve M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners.</p> <p>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.</p>

6:30 PM	<b>Program Adjournment</b> <b>Session 20: Teams gather for "Take-aways Exercise"</b>
	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**