

Health Care Technological Innovation

From Idea to Commercialization



Lahav Executive Education
Leading Excellence

INTERNATIONAL INSTITUTE FOR
BIOTECHNOLOGY ENTREPRENEURSHIP



"Health Care Technological Innovation - From Idea to Commercialization" The Seventh 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

Israel Advanced Technology Industries Organization
The International Institute for Biotechnology Entrepreneurship
The Center for Medicine in the Public Interest

December 9th-11th, 2013 - Monday through Wednesday, Tel Aviv, Israel

Program Directors:

Program Founder

Dr. Benny Zeevi
Managing General
Partner
DFJ Tel Aviv Venture
Partners
Co- Chairman, IATI

For the Recanati Business School

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Brent Ahrens
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Course Syllabus

Day One: Monday December 9th, 2013	
Day's Theme: The Creative Process and Technology Assessment	
8:30 AM	Registration/Administrative Continental Breakfast
9:00 AM	<p>Session 1: Welcome and Opening Remarks:</p> <p>Prof. Moshe Zviran, Vice Dean Faculty of Management, Tel Aviv University</p> <p>Course Directors:</p> <p>Introduction to Program Structure Review of required assignments</p>
9:30 AM	<p>Session 2: Opening Keynote Address - "Life Science Technology; The challenging landscape, from concept to commercialization"</p> <p>Introduction: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>Peter J. Fitzgerald, MD, PhD, FACC, Director, Center for Cardiovascular Technology, Stanford University</p>
10:10AM	Coffee break
10:20AM	Session 3: The Persuasive Pitch, Part 1: Introduction of course participants

	<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>Brent Ahrens, General Partner, Canaan Partners</p> <p>Ellen Lubman, Senior Vice President with Kadmon Pharmaceuticals</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 minute presentation, using 2-4 power point slides, to introduce yourself and your company to the group</p>
12:10 PM	Coffee break
12:20 PM	<p>Session 4: Project, Product or Company?: Assessment and Qualification of Technologies as a Basis for a Startup</p> <p>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.</p> <p>Moderator: Benny Zeevi, M.D., Managing General Partner, DFJ Tel Aviv Venture Partners Brent Ahrens, General Partner, Canaan Partners David Frank, Managing Director MEDX Associates LLC Tamara Mansfeld, Director, Strategy & Portfolio Management, Pfizer Ed Saltzman, President DefinedHealth</p>

2:00 PM	Networking Luncheon
2:45 PM	<p>Session 5: Lessons learned from our experience: A panel of life science CEOs and Entrepreneurs</p> <p>In this session we will have several US and Israeli CEOs in life sciences sharing their experience.</p> <p>Specifically addressing issues: Building a management team, financing, collaborations, dealing with the board, working with cross-border teams and more</p> <p>Moderators: Ruti Alon, General Partner, Pitango Venture Capital Fund</p> <p>Avner Halprin, CEO, Early Sense</p> <p>Udi Cohen, CEO Biocontrol</p> <p>Ascher Shmulewitz, M.D., President Medegenesis</p> <p>Frank L. Douglas, Ph.D., M.D. President & CEO, Austen BioInnovation Institute in Akron</p> <p>Bill Gerhart, Former CEO, Elevation Pharma</p> <p>Ori Hadomi, CEO Mazor Robotics</p> <p>Ed Saltzman, President DefinedHealth</p>
4:00PM	Coffee break

4:15 PM	<p>Session 6: Keynote Address</p> <p>Corie Chung- Bar Dea, Director of Strategy, Designit</p> <p>"Innovation Strategy"</p>
5.00PM-	<p>Session 7: 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, Importance of opinion leaders, patients groups, patients organization, Selling strategy, and Relationship Marketing: To build mutually satisfying long-term relationships with key customers in order to acquire and retain their business</p> <p>Moderator: Brent Ahrens, General Partner, Canaan Partners</p> <p>David Frank, Managing Director MEDX Associates LLC Yael Glassman, VP Marketing and Business Development, Sensible Mike Berman, medical device investor/entrepreneur, Former President of the Cardiology business of Boston Scientific Robert Barzelay, Marketing Consultants, Global Strategists Bill Gerhart, Former CEO, Elevation Pharma – CEO view</p>
6.15PM	<p>Coffee Break</p>
6:30-7 PM	<p>Session 8 : Licensing, Partnering and Strategic Alliances the Pharma perspective</p> <p>Ellen Lubman, Senior Vice President with Kadmon Pharmaceuticals</p>
7-7.45PM	<p>CEO Experiences... Bill Gerhart, Former CEO, Elevation Pharma</p>
7:45 PM	<p>Opening Dinner for Faculty, Participants and life sciences executives</p> <p>At the Green Vila, Tel Aviv University</p>

Day Two: Tuesday December 10th, 2013

Day's Theme: Strategy and Execution

8:30 AM

Continental Breakfast

9:00 AM

Session 9: 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.

Moderator: Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners

Susan Alpert, PhD, MD, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Vice President of Regulatory Sciences for C.R. Bard, Inc, previously worked at FDA where she held a variety of positions in the Centers dealing with drugs, devices and radiological health, and foods, including six years as the Director of the Office of Device Evaluation.

Udi Cohen, CEO Biocontrol – The experience of a CEO in conducting multinational clinical trial

10:20AM	Coffee break
10:30AM	<p>Session 10: Keynote Lecture Patrick Flochel, Partner, Global Pharmaceutical Sector Leader, Global Life Sciences Centre, EY "New business models in Life Sciences"</p>
11:35AM	Coffee break
11:45AM	<p>Robert Barzelay, Marketing Consultants, Global Strategists - Marketing</p> <p>***</p> <p>Session 11: Emerging Markets – Opportunities for Life Science companies</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>Moderator: Stephen M. Sammut, Senior Fellow, Health Care Systems and Entrepreneurial Programs, Wharton School, University of Pennsylvania, Venture Partner, Burrill & Company</p> <p>Gad Berdugo, Managing Director and Head of Life Sciences and Healthcare at Tegriss Advisors, Formerly Founder of Explorium Capital and Former Director and Sector Leader for global healthcare investment research at Lazard</p> <p>David Frank, Managing Director MEDX Associates LLC</p> <p>Patrick Flochel, Partner, Global Pharmaceutical Sector Leader, Global Life Sciences Centre, EY</p> <p>Pablo Halpern, CEO Atche Medical, Brazil- Opportunities in the Life Sciences Market</p> <p>Gil Kerbs, New Product Development Marketing manager, Covidien</p>

1:00 PM	<p>Session 12: Keynote lecture: Dr. Jeremy Levin, Former President & CEO Teva Pharmaceutical "The role of the company in society"</p>
1:45PM	<p>Networking Luncheon</p>
2:30PM	<p>Session 13: Capitalization of a life science Venture –Value inflection Points, Milestones and Capital Requirements, Alternative financing, Terms etc.</p> <p>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.</p> <p>Moderator: Brent Ahrens, General Partner, Canaan Partners</p> <p>Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p> <p>John R. Lieberman, CPA/PFS Managing Director Perelson Weiner LLP</p> <p>Gad Berdugo, Managing Director and Head of Life Sciences and Healthcare at Tegriss Advisors, Formerly Founder of Explorium Capital and Former Director and Sector Leader for global healthcare investment research at Lazard</p> <p>Dr. Ayal Shenhav, Shenhav & Co – Crowd funding for life sciences companies</p> <p>Hanan Haviv, Partner, Herzog, Fox & Neeman</p>
4:00 PM	<p>Session 14: Case study</p>

	Yotam Levin, MD, MBA,CEO, Nanopass Optimizing business models for a drug delivery Company
5:00 PM	Coffee break
5:15 PM	<p>Session 15: Intellectual Capital Management</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>John R. Lieberman, CPA/PFS Managing Director Perelson Weiner Medical device executive</p> <p>Brent Ahrens, General Partner, Canaan Partners – The VC perspective</p>
6:30 PM	<p>Session 16: Incorporating Reimbursement in the Company Development Strategy</p> <p>Moderator: Brent Ahrens, General Partner, Canaan Partners</p> <p>Reggie Williams, Vice President, Avalere Health</p> <p>Mike Berman, medical device investor/entrepreneur, past President of the Cardiology business of Boston Scientific</p>
8:00 PM	End of the day....

Day Three: Wednesday December 11th, 2013

Day's Theme: Bringing the product to the market and Health Care IT\Digital Health

8:30 AM

Continental Breakfast

9:00 AM

Session 17: 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

Ed Saltzman, President DefinedHealth

Mike Berman, medical device investor/entrepreneur, Former President of the Cardiology business of Boston Scientific

Maya Racine - Netser, Adv, Partner, Head, technology licensing group in the High Tech Practice , Herzog, Fox & Neeman

Discussion and Q&A

11:00 AM	Bio – Break
11.30 PM	<p>Session 18: Healthcare IT and Digital Health</p> <p>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 Communication Technologies; it is the slowest from all industries in the adoption. 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 plays a crucial role in closing the capability gap and gaining more acceptances 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 allow consumers to be introduced to new services quickly and intuitively and establish personal preferences. Digital health enables 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 provider's cultural changes and proven evidence –based outcome measures, clinically and economically.</p> <p>The potential applications of HCIT technologies and digital 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>Patrick Flochel, Partner, Global Pharmaceutical Sector Leader, Global Life Sciences Centre, EY</p>

	<p>Michal Geva, Co-Founder & Managing Partner, TriVentures</p> <p>Yael Glassman, VP Marketing and Business Development, Sensible</p> <p>Susan Alpert, PhD, MD, Former Senior Vice President, Chief Regulatory Officer of Medtronic, Former Vice President of Regulatory Sciences for C.R. Bard, Inc., previously worked at FDA- Are Digital and Mobile Health Tools Medical Devices? Who's Opinion Counts?</p>
2:00 PM	Luncheon
2:45 PM	Session 18 - continue
3:30PM	Coffee break
3:45-4.30 PM	<p>Session 19: Case Study Marketing case study Robert Barzelay, Marketing Consultants, Global Strategists</p>
4:30 PM-5.30PM	<p>Session 20: Case study- American Well</p> <p>Yael Glassman, VP Marketing and Business Development, Sensible</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p>
5.30-6PM	Bio Break
6:00PM -	<p>Session 21: The Persuasive Pitch, Part 2: Presentations Workshop</p> <p>Moderators: Steve M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship</p> <p>Brent Ahrens, General Partner, Canaan Partners</p> <p>Benny Zeevi, M.D. Managing General Partner, DFJ Tel Aviv Venture Partners</p>

	<p>David Frank, Managing Director MEDX Associates LLC</p> <p>Ellen Lubman, Senior Vice President with Kadmon Pharmaceuticals</p> <p>Ed Saltzman, President DefinedHealth</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>
7.00 PM	<p>Program Adjournment Session 22: Teams gather for “Take-aways Exercise”</p> <p>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.</p>

*** Changes in curriculum may occur**