

Health Care Technological Innovation

From Idea to Commercialization



Course Syllabus

Day One: Sunday November 11, 2007	
Day's Theme: The Creative Process and Foundational Tools	
8:00 AM	Registration/Administrative Continental Breakfast
8:30 AM Plenary classroom	<p>Session 1: Welcome and Opening Remarks:</p> <p>Professor Zvi Galil, Ph.D, President, Tel Aviv University 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</p>

	<p>and Venture Partner, Burrill & Company</p> <p>Acknowledgement of Sponsors</p> <p>Course Infrastructure:</p> <p>Introduction to Program Structure Review of required assignments Formation of study teams</p>
<p>9:00 AM Plenary classroom</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: “Creating and Implementing Breakthrough Medical Technology”</p> <p>Elezar Edelman, M.D., Ph.D. The Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology at MIT and Professor of Medicine at Harvard Medical School. Director of Harvard-MIT Biomedical Engineering Center (BMEC)</p>
<p>10:00 AM Plenary classroom</p>	<p>Session 3: 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</p>

	<p>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 Tamir Fishman Ventures, Board Member ILSI & IVA Jeremy Levin, Senior Vice President, Bristol Myers-Squibb Stanton J Rowe, Corporate Vice President Advanced Technology, Edwards Lifesciences Morris Laster, CEO, BiolineRx Incubator Brent Ahrens, General Partner, Canaan Partners David Frank, Head of BD, Ortho Diagnostics, J&J</p>	
11:30 AM	<p>Break: Refreshments, Networking and Gathering in Student Team Rooms</p>	
<p>Noon</p> <p>Designated participant study rooms</p>	<p>Session 4A: Biotechnology Break Out for Case Discussion on Product Analysis</p> <p>Prior to the program, one participant will be asked to prepare, submit and present a real situation for group review; questions provided.</p>	<p>Session 4B: Medical Device Breakout for Case Discussion on Product Analysis</p> <p>Prior to the program, one participant will be asked to prepare, submit and present a real situation for group review; questions provided.</p>
<p>12:45 PM</p> <p>Designated break – out classroom</p>	<p>Session 5A: Group Presentations from 4A</p> <p>A course director and two faculty from plenary to supervise and comment.</p>	<p>Session 5B: Group Presentations from 4B</p> <p>A course director and two faculty from plenary to supervise and comment.</p>
1:15 PM	<p>Networking Luncheon</p>	

<p>2:15 PM</p> <p>Plenary classroom</p>	<p>Session 6: Essentials of Pricing and Reimbursement</p> <p>This session is comprised of a lecture by the former head of the US Food and Drug Administration and the US Medicare/Medicaid Program. It includes a lecture by an attorney specializing in CMS related law and relationships.</p> <p>Moderator: Stephen M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Peter Bach, MD, MAPP, Associate Attending Physician, Memorial Sloan Kettering Cancer Center</p> <p>Robert Wanerman, Partner, Epstein Becker & Green, PC</p>
<p>3:30 PM</p> <p>Plenary classroom</p>	<p>Session 7: Building an Entrepreneurial Management Team</p> <p>How do we manage cross –disciplinary team of scientists, engineers, lawyers and MBAs? Team building in life science companies is the most challenging task for entrepreneurs, and the backbone of venture capitalists’ decision to invest or not to invest. The session provides exploration of the issues in forming an entrepreneurial team of a start-up or early stage company and approaches to successful team formation and management of the team.</p> <p>Brief Introductory lecture and moderator: Stephen M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Benad Goldwasser MD, MBA, CEO, GI View Moshe Flugelman, M.D., CEO, M.G.V.S Brent Ahrens, General Partner, Canaan Partners Ruth Allon, General Partner, Pitango, Chairperson, ILSI</p>
<p>4:45 PM</p>	<p>Bio – Break</p>

<p>5:00 PM</p> <p>Plenary classroom</p>	<p>Session 8: 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. In addition, a corporate representative will discuss IP portfolio management methods and how an IP portfolio relates to corporate strategy. A VC will also provide an investor viewpoint.</p> <p>Moderator: Benny Zeevi, M.D., Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA David Johnson, Partner, Intellectual Property Section at Mintz Levin Stanton J Rowe, Corporate Vice President Advanced Technology, Edwards Lifesciences Brent Ahrens, General Partner, Canaan Partners</p>	
<p>6:00 PM</p> <p>Designated break – out classroom</p>	<p>Session 9A: Biotechnology Breakout for Case Discussion on Intellectual Property</p> <p>Prior to the program, one participant will be asked to prepare, submit and present a real IP situation for group review and discussion with panelists and participants</p>	<p>Session 9B: Medical Device Breakout for Case Discussion on Product Analysis</p> <p>Prior to the program, one participant will be asked to prepare, submit and present a real IP situation for group review and discussion with panelists and participants.</p>
<p>6:45 PM</p> <p>Designated participant study rooms</p>	<p>Session 10: Teams meet for preparation of Day 2 Assignments (distributed for reading prior to the program):</p> <p>Sessions 12 A & B: Review Regulatory Case Presentation Session 13: Prepare Business Model Case</p>	

8:00 PM

**Opening Dinner for Faculty and Participants
At the Green Vila, Tel Aviv University**

Day 2: Monday November 12, 2007

Day's Theme: Strategy and Execution

8:30 AM	Continental Breakfast	
9:00 AM Plenary classroom	<p>Session 11*: The Health Care Value Chain, Business Models and Strategy</p> <p>The session will describe the major business models and their strategic implications. These models have profound implications for stakeholder management, overall structure and strategy, team building, project selection and prioritization, and resource allocation. A "Personalized Medicine" case will have been provided for review prior to the Program, and will be dissected during the session. Personalized medicine represents a good fusion of biopharmaceuticals, diagnostics, devices and forward integration into health services.</p> <p>Stephen M. Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company</p> <p>Robert Goldberg, PhD, Vice President, Center for Medicine in the Public Interest</p>	
11:15 AM	Bio – Break	
11:30 AM Designated break – out classroom	<p>Session 12A: Biotechnology Regulatory Workshop</p> <p>Prior to the program, one participant will submit a case study and presentation on the regulatory</p>	<p>Session 12 B: Medical Device Regulatory Workshop</p> <p>Prior to the program, one participant will submit a case study and presentation on the regulatory</p>

	strategy and issues of their company for review by the panelists.	strategy and issues of their company for review by the panelists.
12:15 PM Plenary classroom	<p>Session 13*: Biotechnology and Medical device Regulatory Planning, Clinical Development and the Implications for Strategy and Financing</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. The session is sponsored by the Center for Medicine in the Public Interest, a non-profit organization focused on regulatory process efficiency and global harmonization of regulatory requirements and administration. The session also includes work relationships with CROs.</p> <p>Moderator: Peter J. Pitts, President, Center for Medicine in the Public Interest, former Associate Commissioner, FDA</p> <p>Daniel Troy, former general counsel FDA and partner Sidley Austin</p> <p>Hugo Stephenson, M.D. President, Quintiles Strategic Research Services</p>	
1:15 PM	Networking Luncheon	
2:15 PM Plenary classroom	<p>Session 14: Keynote lectures</p> <p>1. “In cardiovascular medicine, everything that can be invented, has been invented”? – Stanton J Rowe, Corporate Vice President Advanced Technology, Edwards Lifesciences</p> <p>2. A Global Perspective on Emerging Market Activity in the Life Sciences: Implications for Israeli Companies</p> <p>Steve Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture</p>	

	Partner, Burrill & Company: Global financial trends in biotechnology and medical devices
3:30 Plenary classroom	<p>Session 15: Value Inflection Points, Milestones and Capital Requirements</p> <p>Unfortunately, life sciences CEOs and their teams will postulate a strategy independently of identifying critical milestones and the specific financial requirements for meeting each of these milestones. This session describes where VCs and prospective partners perceive inflection points in value, how these relate to milestone development and the related staging of capital requirements.</p> <p>Moderators: Benny Zeevi, M.D., Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Simon Benninga, Ph.D. Max and Steffi Perlman Professor of Financial Economics, Visiting Professor of Finance, Wharton School, University of Pennsylvania, Dean, Faculty of Management, Tel-Aviv University, Israel (Lecture) Jeremy Levin, Senior Vice President, Bristol Myers-Squibb Stanton J Rowe, Corporate Vice President Advanced Technology, Edwards Lifesciences Brent Ahrens, General Partner, Canaan Partners</p>
5:00 PM	Bio-Break
5:15 PM Plenary classroom	<p>Session 16: The Business Plan and the Pitch Book</p> <p>Experienced entrepreneurs and their investors openly recognize that within a year of operating, few companies resemble their original business plan. Business plans and the accompanying pitch, however, provide the starting point of a shared vision and evidence that the founding team can reach a consensus in the business and technology development planning process and the resources required to meet critical milestones. The session provides a framework for developing a</p>

	<p>pitch and the essentials of a business plan. The session is structured in a novel way. An entrepreneur will present the pitch for his company to a panel of early stage biotechnology venture capitalists who will share real-time critique and recommendations. Boot Camp participants will be invited to share their own views as well.</p> <p>Steve Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company- "The Business Plan and the Pitch Book"</p> <p>Kim Cooper, C.E.O, Kim Cooper Associates, a communications consulting company: "The Persuasive Pitch: Presenting Your Idea (and Yourself) with Purpose, Clarity, and Power"</p> <p>Brent Ahrens, General Partner, Canaan Partners</p>
<p>7:00 PM</p> <p>Designated participant study rooms</p>	<p>Teams meet for preparation of Day 3 Assignments (distributed for reading prior to the program):</p> <p>Sessions 18 A & B: Review Partnering Case Presentation Sessions 19 A & B: Prepare Market and Competitive Analysis Case Sessions 23 A & B: Review Capitalization Case Presentation</p>
<p>8:00 PM</p>	<p style="text-align: center;">Adjourn for day</p>

Day Three: Tuesday November 13, 2007

Day's Theme: Building Value and Corporate Responsibility

8:30 AM	Continental Breakfast
9:00 AM Plenary classroom	<p>Session 17: 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, M.D., Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA</p> <p>Session Keynote: Jeremy Levin, Senior Vice President, Bristol Myers-Squibb</p> <p>Panelists:</p> <p>Stanton J Rowe, Corporate Vice President Advanced Technology, Edwards Lifesciences Maya Netzer, Adv, Partner, Licensing Practice, Herzog, Fox & Neeman Hezi Himelfarb, CEO, Remon-Medical Technologies Ltd</p>
10:30 AM	Bio – Break

10:45 AM Designated break – out classroom	Session 18 A: Biotech Partnering Presentation Critique Biopharmaceutical Partnering Presentation by a company for real time analysis and critique by panel and the participants (who will have reviewed the material the previous evening).	Session 18 B: Device Partnering Presentation Critique Device Biopharmaceutical Partnering Presentation by a company for real time analysis and critique by panel and the participants (who will have reviewed the material the previous evening).
11:45 AM Plenary classroom	Session 19 A: Biotechnology Market Analysis and Competitive Analysis Case Discussion Prior to the program, one participant will submit a case study and presentation on the marketing strategy and competitive issues of their company for review by the faculty and participants.	Session 19 B: Medical Device Market and Competitive Analysis Discussion Prior to the program, one participant will submit a case study and presentation on the marketing strategy and competitive issues of their company for review by the faculty and participants.
12:45 PM Plenary classroom	Session 20: Pre-lunch Keynote: The Issues and Challenges of Global Health: Opportunities for Israeli Companies Steve Sammut, Senior Fellow, Wharton Health Care Systems and Entrepreneurship and Venture Partner, Burrill & Company	
1:30 PM	Luncheon	
2:15 PM Plenary classroom	Session 21: Post-luncheon Keynote Building a Large Global Israeli company Moderator: Benny Zeevi, M.D., Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA Israel Makov, the Chairman of Given Imaging, former CEO of Teva Pharmaceutical Industries Ltd.	

	<p>Brent Ahrens, General Partner, Canaan Partners Ruth Alon, General Partner, Pitango, Chairperson, ILSI</p>
<p>3:15 PM Plenary classroom</p>	<p>Session 22: Capitalization of the Venture – Working with Venture Capitalists CEOs of life science companies spend as much time raising capital as managing their company. Life science companies have unique issues in raising capital because their risk profiles differ from companies in most other industries. Risk is often managed by a sequential accomplishment of negotiated milestones. Capital tends to be rationed into companies on the basis of milestone completion. Life science entrepreneurs and their venture capitalists, therefore have a unique relationship and dynamic. Entrepreneurs, therefore, must turn to a variety of creative</p> <p>Pros and cons of angel financing: what to do and not do Presentation of needs and milestones The Capitalization Table Approaches to Valuation Term sheet provisions Working with legal counsel Legal documentation of the deal IPO: Is it an exit? Exit via trade sale: strategy and implications</p> <p>Moderators: Simon Benninga, Ph.D. Max and Steffi Perlman Professor of Financial Economics, Visiting Professor of Finance, Wharton School, University of Pennsylvania, Dean, Faculty of Management, Tel-Aviv University, Israel - Lecture</p> <p>Benny Zeevi, M.D., Managing General Partner, DFJ Tamir Fishman Ventures, Board Member ILSI & IVA Alon Sahar, Adv., Partner, Herzog, Fox & Neeman Brent Ahrens, General Partner, Canaan Partners</p>
<p>5:00 PM</p>	<p style="text-align: center;">Bio – Break</p>

<p>5:15 PM</p> <p>Designated break-out classroom</p>	<p>Session 23 A: Biotech VC Presentation Critique</p> <p>Biopharmaceutical Partnering Presentation by a company for real time analysis and critique by panelists from Session 23 and the participants (who will have reviewed the material the previous evening).</p>	<p>Session 23 B: Medical device VC Presentation Critique</p> <p>Device Presentation by a company for real time analysis and critique by panelists from Session 23 and the participants (who will have reviewed the material the previous evening).</p>
<p>6:15 PM</p> <p>Designated participant study rooms</p>	<p>Session 24 A: 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>	<p>Session 24 B: 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>
<p>7:00 PM</p> <p>Plenary classroom</p>	<p>Session 25: Reconvene for presentations of Take Away Exercise and "Words of Wisdom" from faculty at large</p>	
<p>7:30 PM</p>	<p style="text-align: center;">Program Adjournment</p>	

* Changes in curriculum may occur