
The Thirteenth Annual

Biotechnology Entrepreneurship Boot Camp

Sunday, June 18 and Monday, June 19, 2017 Special Session, Tuesday, June 20, 2017 San Diego, California

Rooms:

Sunday & Monday: 1B

Tuesday: Room 5B

National Co-Chair

Dennis Gross, MS, PhD

CEO Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center

National Co-Chair

James Jordan, MBA, CHT

President & CEO Pittsburgh Life Sciences Greenhouse

Distinguished Service Professor in Healthcare & Biotechnology Management Carnegie Mellon University

Local Co-Chairs

Steve Flaim, PhD, FACC, FAHA,

Chairman Emeritus, Tech Coast Angels, Director Angel Capital Association

Larry G Stambaugh

Founding Principal, Aperçu Partners Chairman, Molecular Assemblies, Inc. Chairman, MindXSciences, Inc. LifeTime Director, BioCom Chairman, ParaNetics

National Co-Chair Emeritus

Arthur A. Boni, PhD

John R. Thorne Distinguished Career Professor of Entrepreneurship Tepper School of Business Carnegie Mellon University

National Co-Chair Emeritus

Stephen M. Sammut, MBA

Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania

BIO-Coordinators

Sarah Arth, CAE

Vice President, Education Biotechnology Innovation Organization

Sarah Maki

Manager, Education Biotechnology Innovation Organization

Stephanie Haines

Coordinator, Education

Biotechnology Innovation Organization

History: The 2005 to 2017 Boot Camps

The Biotechnology Entrepreneurship Boot Camp was founded by Professors Arthur Boni of the Tepper School of Business at Carnegie Mellon, and Steve Sammut of the Wharton School, and by Jeffrey Libson, Partner, Pepper Hamilton LLP and Lecturer at Wharton School Health Care Management Program. The first Boot Camp was launched at the 2005 BIO Industry Organization's Annual Meeting in Philadelphia. The Boot Camp was originally designed as a program for CSOs but is now expanded in scope and design to address a broad range of issues for entrepreneurs more generally. The Boot Camp was created in response to the growing need in the managerial, scientific and academic community to learn about the necessary elements and skills to transform technology and invention into a viable company. The Biotechnology Innovation Organization through its BIO 2005 Academic-Industry Committee ("AI") worked with the founders to develop this unique program to fill this knowledge gap. The insight and energy required for entrepreneurial success can be developed by anyone motivated to think strategically, select projects and plan for expeditious and cost-effective management, understand the requirements of all the involved stakeholders, and oversee the essential components of the commercialization process.

The Boot Camp concept is Philadelphia's legacy gift to BIO and future annual meetings. The intention is that the Boot Camp will travel from year to year to each of the BIO International Convention venues – a veritable "moveable feast." Now in its twelfth year, the Boot Camp was offered at BIO International Convention's in Chicago in 2006, 2010, and 2013, Boston in 2007 and 2012, Philadelphia in 2005 and 2015, San Francisco in 2016, San Diego in 2008, 2014 and 2017, Atlanta in 2009 and Washington, DC in 2011. The creation of the syllabus, the recruitment of faculty, and the faculty's extensive preparation suggested that wherever possible there should be core faculty, i.e., a portion of the faculty from the Philadelphia Boot Camp who would volunteer from year to year. This approach has the added benefit of improving the presentations and the material from year to year as the faculty themselves identify what works, as well as how to teach together. Most of the faculty (and presenting companies), however, is recruited from the host region.

To facilitate and incorporate local participation, local co-chairs are recruited each year. In previous years, Local Co-Chairs were:

Chicago, IL, 2006:

- Panayiotis P. Constantinides, Ph.D, Principal, Biopharmaceutical & Drug Delivery Consulting
- Elsie Quaite-Randall, Ph.D., MBA Executive Director of the Office of Research Contracts and IP,
 McMaster University, formerly of Office of Technology Transfer, Argonne National Laboratory

Boston, MA, 2007:

• Robert Creeden, Partners HealthCare Systems, Inc., Managing Director, Center for Innovative Ventures

San Diego, CA, 2008

- Kurt A. May, MBA, Assistant Dean, Executive Development Center, Rady School of Management, University of California, San Diego
- Duane J. Roth, Chief Executive Officer and Member of the Board of CONNECT.
- Steve Flaim, PhD, FACC, FAHA, Chairman Emeritus, Tech Coast Angels, Director Angel Capital Association

Atlanta, GA, 2009

- Frank R. Hunt, MS MBA, President, SE bioStrategies, Inc., CEO, PNP Therapeutics, Inc.
- Dennis P. Schafer, CEO, Life Science Management

Chicago, IL, 2010

- Patrick G. Morand, Managing Director, SWMF Life Science Fund
- Charles B. Hoslet, Managing Director, UW-Madison Office of Corporate Relations
- Allen J. Dines, Assistant Director, Office of Corporate Relations, University of Wisconsin

Washington, DC, 2011

- Elana Fine, Director of Venture Investments, Dingman Center for Entrepreneurship, Robert H. Smith School of Business, University of Maryland
- Toby Gordon, Sc.D., Associate Professor, The Johns Hopkins Carey Business School
- Martha J. Connolly, Ph.D., Director, Maryland Industrial Partnerships, University of Maryland

Boston, MA, 2012

- Ashley J. Stevens, D.Phil. (Oxon), CLP, President, Focus IP Group, LLC and Lecturer, Strategy and Innovation Department, School of Management, Boston University
- Rekha Paleyanda, PhD, Sr. Business Strategy and Licensing Manager, Partners Healthcare

Chicago, IL, 2013

- Patrick G. Morand, Managing Partner, Open Prairie Ventures
- Allen J. Dines, Assistant Director, Office of Corporate Relations & Venture Designer Hybrid Zone X, University of Wisconsin-Madison

San Diego, CA, 2014

- Kurt A. May, MBA, Co-founder and Chairman, Psynomics Incorporated
- Larry Stambaugh, Founding Principal, Aperçu Partners
- Justin Chakma, Associate Director, Auspex Pharmaceuticals and Thomas, McNerney & Partners, LLC

Philadelphia, PA, 2015

- Dennis Gross, M.S., Ph.D., CEO, Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center
- James Jordan, MBA, CHT, Chief Investment Officer, Pittsburgh Life Sciences Greenhouse, Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University
- Alex B. Reitz, PhD., CEO, Fox Chase Chemical Diversity Center, Inc., The Pennsylvania Biotechnology Center

San Francisco, CA 2016

- Benjamin Chen, Ph.D. Managing Director, Ignatius Transaction Partners
- Moira Gunn, Ph.D. Host, NPR BioTech Nation, Director, Business of Biotechnology Program, Professor, School of Management University of San Francisco

San Diego, CA 2017

- Steve Flaim, PhD, FACC, FAHA, Chairman Emeritus, Tech Coast Angels, Director Angel Capital Association
- Larry Stambaugh, Founding Principal, Aperçu Partners, Founding Principal, Aperçu Partners, Chairman, Molecular Assemblies, Inc., Chairman, MindXSciences, Inc., LifeTime Director, BioCom, Chairman, ParaNetics

Convention Registration opens at 1:00 PM on Saturday, June 17. Participants in the Boot Camp should obtain their Convention Badges prior to the Boot Camp.

Sunday, June 18, 2016 Program Schedule			
8:00 AM - 8:30 AM	AM - Registration & Continental Breakfast		
8:30 AM - 9:00 AM	Opening Remarks, Program Overview and Sponsor Acknowledgments	National and Local Co-Chair: James Jordan, MBA, CHT	
9:00 AM - 9:45 AM	SESSION 1: Keynote Speaker Magda Marquet, PhD Chairman and Co-Founder Ajinomoto Althea, Inc.	Introduced by: James Jordan, MBA, CHT President & CEO Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management Carnegie Mellon University	
9:45 AM - 10:45 AM	SESSION 2: Project, Product or Company: Assessment and Qualification of Technologies as a Basis for a Business Startup Forming a company around a technology is relatively easy. Staffing and capitalizing it is another story. Savvy employees, astute venture capitalists 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 (the metaphor of a "project, product, or company") as to how technologies can be assessed for capitalization and partnering. The session includes a real-time review of the technology of a new company with intent of recommending commercialization and risk reduction strategies.	Moderator and Lecturer: Arthur A. Boni, Ph.D. John R. Thorne Distinguished Career Professor of Entrepreneurship Tepper School of Business Carnegie Mellon University Presenter: Michael J. Kamdar President, Chief Executive Officer & Board Member, Molecular Assemblies Commentators: Larry G. Stambaugh Steve Flaim Dennis Gross James Jordan, MBA, CHT	
10:45 AM - 11:00 AM	Break-out with refreshment for Case Discussion followed by Group Recommendations	Reconvene for Group Recommendations	

11:00 AM - 11:45 AM	SESSION 3: Reimbursement & Pricing Strategies It is never too early to assess how the market will respond to products, especially as it relates to pricing and reimbursement. Many companies do not address this issue and then run into problems (and potentially failures). This session will address the fundamentals of pharmaceutical pricing and reimbursement strategies.	Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania Faculty: Robert Wanerman, JD Partner, Epstein, Becker & Green, PC
11:45 AM - 12:30 PM	SESSION 4: Regulatory Planning for the Global Market - Implications for Strategy and Financing A global clinical trial is frequently used to obtain early first in human data and to reduce clinical trial costs. What are the other advantages of running trials internationally? What are the considerations and the challenges that sponsors might encounter?	Moderator: Dennis Gross, MS, PhD CEO Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center Faculty: Jim Ackland - International Managing Director, Global BioSolutions
12:30 PM - 1:00 PM	I	unch
1:00 PM - 1:45 PM	SESSION 5: Regulatory Planning for the U.S. Market - Implications for Strategy and Financing This session provides the specific insight into planning for FDA regulations in light of strategy, financial needs, and the concerns of prospective partners and investors.	Moderator: Dennis Gross, MS, PhD CEO Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center Faculty: David T. Lin, PhD - Domestic Senior Consultant Biologics Consulting Group, Inc.

1:45 PM - 2:00 PM	SESSION 6: What Every Investigator Must Know about IP in Biotechnology Startups The goal of the session is to provide information and insight into the specific issues confronting investigators, entrepreneurs, investors and their patent attorneys. Additionally, the speakers will describe the prevailing treatment by the PTO and the courts of specific issues and implications such as the doctrine of equivalents, gene sequencing, process patents, international issues, etc.	Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania Faculty: Kathryn Doyle, PhD, JD Partner Saul Ewing LLP	
2:00 PM - 2:45 PM	SESSION 7: Building an IP Pyramid impervious to competitive advancement A patent excludes others from replicating an approach; however, that may not equate to an exclusive market position. True exclusivity is creating a competitive position impervious to competitive advancement. The goal of the Intellectual Property Pyramid TM is to understand the exclusivity a patent provides matched with the desired result. What you are trying to understand is the reason the patent exists (the problem it is solving) and then ask yourself if your patent is the only path to achieving that goal.	Moderator: James Jordan, MBA, CHT Chief Investment Officer Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management, Carnegie Mellon University Faculty: Ray Miller, JD Partner Pepper Hamilton LLP	
2:45 PM - 3:00 PM	Bio	Bio-Break	
3:00 PM - 4:00 PM	SESSION 8: The R&D - Marketing Interface By expanding upon a strategic development tool based upon FDA Guidance called the target product profile (TPP), alignment of R&D, reimbursement, pricing, regulatory, label claim, I.P., marketing and sales strategies are aided. The TPP ensures product strategy and commercialization plan details do not disconnect as resource and technical constraints avail themselves during implementation.	Moderator and Speaker: James Jordan, MBA, CHT Chief Investment Officer Pittsburgh Life Sciences Greenhouse, Distinguished Service Professor in Healthcare & Biotechnology Management Carnegie Mellon University Faculty: Professor Thanigavelan Jambulingam, Ph.D. Thanigavelan Jambulingam Ph.D., Professor, Pfizer Fellow, Arrupe Research Fellow, Department of Pharmaceutical and Healthcare Marketing Haub School of Business Saint Joseph's University	

4:00 PM - 5:00 PM	SESSION 9: Building an Entrepreneurial Management Team Team building in biotechnology 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. The panelists represent the perspective of a CEO and a venture capitalist who built the management team of local company.	Lecturer and Moderator: Arthur A. Boni, Ph. D. John R. Thorne Distinguished Career Professor of Entrepreneurship, Tepper School of Business, Carnegie Mellon University Faculty: Larry G. Stambaugh Founding Principal, Aperçu Partners Chairman, Molecular Assemblies, Inc. Chairman, MindXSciences, Inc. LifeTime Director, BioCom Chairman, ParaNetics Presenter: Carol Gallagher Partner, New Enterprise Associates
5:00 PM - 5:45 PM	SESSION 9: Building and working with the Board Building and working with a board is a key element for success in entrepreneurial companies. Better boards make better companies. We will cover the best practices and successful principles of a great board and sound corporate governance processes.	Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania Presenter: Larry G. Stambaugh Founding Principal, Aperçu Partners Chairman, Molecular Assemblies, Inc. Chairman, MindXSciences, Inc. LifeTime Director, BioCom Chairman, ParaNetics Faculty: Steve Flaim, Ph.D. Chairman Emeritus, Tech Coast Angels Director, Angel Capital Association
5:45 PM - 7:00 PM	Networki	ing Reception

Monday, June 19, 2016 Program Schedule		
8:30 AM - 9:00 AM	Registration & Continental Breakfast	
9:00 AM - 9:40 AM	SESSION 11: The Business Plan and Pitch Book in the Fund Raising Process 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 pitch to investors/partners, and the essentials of a business plan.	Moderator and Lecturer: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Tepper School of Business Carnegie Mellon University
9:40 AM – 10:00 AM	SESSION 12: Open Innovation 101 Open innovation use both internal and external resources to accelerate a products path to market. Partnering with experienced providers also further de-risks the company to investors as partners have validated processes, scale, and deep domain relationships. In this session, a framework of aligning your partnership strategy to your business plan is offered. It is also important to note that this methodology is supportive of the Lean Startup discussions offered in the Supplemental Sessions.	Moderator and Lecturer: Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Tepper School of Business Carnegie Mellon University
10:00 AM- 10:15 AM	Break-out with refreshment for Group Discussions	
10:15 AM - 10:45 AM	SESSION 13: Group & Presentations Utilizing the work sheet provided, students will discuss and identify the areas of where partnerships could either accelerate, de-risk or deepen domain relationships. Utilizing group discussions gather potential partners and introductions.	Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania

	Two volunteers will take 15 minutes each to discuss their strategies.	
10:45 AM - 11:45 AM	SESSION 14: Capitalization of your Venture	Moderator:
	A start-up requires the continuous alignment of customer, investor and acquirer's objectives and concerns. Investors fund the journey and	Dennis Gross, M.S., PhD CEO Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center
	a poorly planned and ill-provisioned journey increases the probability of failure.	Faculty:
	This discussion will center around the customer (who in this case is the investor) so students can understand their needs, timing	Steve Ferguson, MBA, CLP Deputy Director Licensing and Entrepreneurship National Institutes of Health
	and investment criteria.	Benjamin Chen, PhD
	- Non-Dilutive Funding – NIH - Angels	Managing Partner, Ignatius Transaction Partners
	Corporate Venture CapitalVenture CapitalCorporate Partners	James Foley, PhD CEO Aqua Partners, former head of Business Development, Bristol Myers Squibb
		David Smith, Pepper Hamilton
11:45 AM - 12:30 PM	Lunch	Box in Room
12:30 PM – 1:30 PM	SESSION 15: Pre-seed/Seed Funding Pitch	Moderator:
	The facilitator will give a brief introduction on the phases of private equity funding.	Steve Flaim, PhD Chairman Emeritus, Tech Coast Angels Director, Angel Capital Association
	Companies need to be aware of the expectations of investors for each phase, and	Presenter:
	also learn to handle objections. For example, if a pre-seed funder is asking you for human data, they either aren't a pre-seed funder or	Jon Wilensky, MD Chief Executive Officer Braykion, Inc.
	they are using the objection to avoid investing or providing feedback.	Faculty:
	In this segment a company will present their investor pitch and receive feedback appropriate to their investment phase.	Benjamin Chen, PhD Managing Partner, Ignatius Transaction Partners
	appropriate to their investment phase.	James Foley, PhD CEO Aqua Partners, former head of Business Development, Bristol Myers Squibb
		Marc Malandro, PhD, CLP, RTTP Vice Chancellor for Technology Management and Commercialization University of Pittsburgh

1:30 PM – 2:00 PM	SESSION 16: Defining your Exit Triggers Running out of cash can be caused by a poorly planned and ill-provisioned journey. Startups frequently run out of cash when they mis-plan their exit. This discussion will offer you a tool to aid in your planning.	Moderator: James Jordan, MBA, CHT Chief Investment Officer Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management Carnegie Mellon University
2:00 PM – 3:00 PM	SESSION 17: Early-Stage Funding Pitch Early-stage valuation points are frequently aligned with Phase II clinical trial inflection points from an investor perspective. Additionally, the probability of strategic investors and a milestone based exit are available. This requires a pitch that satisfies a broader audience. In this segment, a company will present their investor pitch and receive feedback appropriate to their investment phase	Moderator: Steve Flaim, Ph.D. Chairman Emeritus, Tech Coast Angels Director, Angel Capital Association Presenter: Tom Hallam, Ph.D. Chief Executive Officer Leading Biosciences, Inc. Faculty: Rick Soni, CEO Cellular Logistics, Inc. Benjamin Chen, Ph.D. Managing Partner, Ignatius Transaction Partners James Foley, Ph.D. CEO Aqua Partners, former head of Business Development, Bristol Myers Squibb
3:00 PM - 3:15 PM	Break-out with refreshment for Group Discussions	
3:15 PM – 3:45 PM	SESSION 18: Group & Presentations Utilizing the feedback given during the two investor pitches, students will discuss and identify areas of improvement in their pitches. Two volunteers will take 15 minutes each to discuss their strategies.	Moderator: Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania
3:45 PM – 4:30 PM	SESSION 19: Working with the Media: Thoughts for Bio-Entrepreneurs	Moderator & Presenter: Moira A Gunn, PhD Host, NPR - BioTech Nation Director, Business of Biotechnology Program Professor, School of Management University of San Francisco

4:30 PM – 6:00 PM	SESSION 20: Capitalization of the Venture CEOs and CSOs of biotechnology companies spend as much time raising capital as managing their company. An attorney specializing in company formation and capitalization will join the panel to provide legal models.	Moderator: Dennis Gross, MS, PhD CEO Pennsylvania Drug Discovery Institute at The Pennsylvania Biotechnology Center Faculty: David Smith, JD Pepper Hamilton
6:00 PM	Session 21: Boot Camp Wrap-up Acknowledgements & Adjournment	Co-Chairs

BOOT CAMP SUPPLEMENTAL SESSION (90 MIN.)

Emerging Issues and Trends in the Business of Biotechnology Entrepreneurship

Tuesday, June 20, 2016 – 10:45 AM to 12:15 PM Room 5B

Session Organized and Moderated by Arthur A. Boni, Ph.D. and Stephen M. Sammut, MBA Panelists include Jim Jordan and Dennis Gross

Room 5B	Session Title: Emerging Biotechnology Business Models – disruption, open innovation, and building teams to transitions thru value inflection points	Discussion led by Art Boni Arthur A. Boni, PhD John R. Thorne Distinguished Career Professor of Entrepreneurship Tepper School of Business Carnegie Mellon University
Room 5B	Session Title: Pricing of Biotechnology Products	Stephen M. Sammut, MBA Senior Fellow, Health Care Management and Lecturer, Entrepreneurship, Wharton School, University of Pennsylvania
Room 5B	Session Title: Application of Principles of Lean and Agile Management to Biotechnology	Discussion led by Jim Jordan James Jordan, MBA, CHT Chief Investment Officer Pittsburgh Life Sciences Greenhouse Distinguished Service Professor in Healthcare & Biotechnology Management Carnegie Mellon University