



2023 Biotechnology Entrepreneurship Boot Camp

Boston Convention and Exhibition Center, 415 Summer Street, Boston, MA 02210

Two-Day Course Schedule

Sunday, June 4, 2023, 9:00 a.m.—6:30 p.m.

Monday, June 5, 2023, 8:00 a.m. – 5:30 p.m.

Complimentary breakfast will be served each morning, 7:30—8:30 a.m.

The Course Registration desk will open each morning at 7:30 a.m.

BIO thanks [MBHB](#) for their sponsorship support of this course.

Sunday, June 4, 2023, Program Schedule		Start Time	Time
Opening Remarks, Program Overview of Program and Sponsor Acknowledgments	National Co-Chair: James Jordan, MBA, CHT	9:00 am	30 minutes
SESSION 1: Keynote Speaker: Lessons Learned on the Leading Edge of Biotechnology	Kathy Bowdish, PhD	9:30 am	45 minutes
<p>SESSION 2: Project, Product or Platform: Assessment and Qualification of Technologies as a Basis for a Business Startup</p> <p>Forming a company around technology is only one part of commercializing a product, generating a profit, and crafting an exit to obtain a return for investors.</p> <p>This session will provide the tools and framework to determine if your company is a project, product or platform.</p> <ul style="list-style-type: none"> • A project may be an incremental improvement. • A product may provide material customer benefit. • A platform may be the basis for a continuous stream of products. <p>Although all three pathways can generate a profit, careful consideration of whether you are a project, product or platform is required before you build your commercialization and funding plans.</p>	Moderator and Lecturer: John York, PhD	10:15 am	60 minutes

<p>SESSION 3: Reimbursement & Pricing Strategies</p> <p>The gap between revenue and cost determines your ventures profitability, and thus your ability to attract funders.</p> <p>Price analysis is the major step to understanding the potential profitability of your venture.</p> <p>Life Sciences consists of the categories of biotechnology services, biopharm, diagnostics, medtech and health IT.</p> <p>The biopharma, diagnostics and medtech categories are regulated markets where pricing is determined by insurers and governments. These groups set the pricing and use the term reimbursement instead of pricing.</p> <p>This session addresses the fundamentals of regulated pricing/reimbursement. Using the biopharma segment as an example students will obtain an understanding of how this system works.</p>	<p>Moderator and Lecturer:</p> <p>Robert Wanerman, JD, MPH</p>	<p>11:15 am</p>	<p>60 minutes</p>
<p>Break-out for panel discussion followed by group recommendations</p>		<p>12:15 pm</p>	<p>15 minutes</p>
<p>Lunch</p>		<p>12:15 pm</p>	<p>60 minutes</p>
<p>SESSION 4: Maximizing IP Value in Bioscience Investment</p> <p>Developing intellectual property assets that provoke investor interest is critical to early-stage bioscience entrepreneurs. Every IP decision, especially decisions related to the company's patents and the potential patents of others, can impact the value of the assets and any investment in the company.</p> <p>The goal of this session is to highlight the important IP concepts, timelines, costs, and perils that confront the start-up and venture-backed company to maximize the first or next funding round.</p>	<p>Moderator and Lecturer:</p> <p>Patrick Gattari, JD</p>	<p>1:15 pm</p>	<p>60 minutes</p>

<p>SESSION 5: Regulatory Planning for the U.S. & Global Market - Implications for Strategy and Financing</p> <p>In regulated markets, FDA approval is needed to obtain a license to sell and may define the positioning of your product. Obtaining regulatory approval is one of the costliest activities of a life sciences startup.</p> <p>This session provides the specific insight into planning for U.S. and global regulations and clinical trials. What are the considerations and the challenges that startups might encounter?</p>	<p>Moderator and Lecturer: David T. Lin PhD</p>	<p>2:15 pm</p>	<p>60 minutes</p>
<p>Afternoon Break</p>		<p>3:15 pm</p>	<p>15 minutes</p>
<p>SESSION 6: The R&D - Marketing Interface</p> <p>The goal of drug development is commercial and investor success. 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, IP, marketing, and sales strategies are aided. The TPP ensures product strategy and commercialization plan details do not disconnect. This tool is applicable to all life science verticals.</p> <p>This session provides the format and walks the student how to prepare one for their firm.</p>	<p>Moderator and Lecturer: Thanigavelan Jambulingam, PhD</p>	<p>3:30 pm</p>	<p>60 minutes</p>
<p>SESSION 7: Is your IP impervious to competitive advancement?</p> <p>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.</p> <p>This session provides a tool called the Intellectual Property Pyramid™ where startups can run their own exercises to ensure that their patents maximize their market positioning. What you are trying to understand is the reason the patent exists (the problem it's solving), and then ask yourself if your patent is the only path to achieving that goal.</p>	<p>Moderator and Lecturer: James Jordan, MBA, CHT</p>	<p>4:30 pm</p>	<p>30 minutes</p>

<p>SESSION 8: Building and working with the Board</p> <p>Building and working with a board is a key element for success in entrepreneurial companies. Better boards make better companies.</p> <p>This session will cover the best practices and successful principles of a great board and sound corporate governance processes.</p>	<p>Moderator and Lecturer:</p> <p>Maria Shepard, MBA</p>	<p>5:00 pm</p>	<p>30 minutes</p>
<p>SESSION 9: Building an Entrepreneurial Management Team</p> <p>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.</p> <p>The session provides an exploration of the issues in forming and evolving an entrepreneurial team through the various start-up phases.</p> <p>The panelists represent the perspective of a CEO and a venture capitalist who built the management team of a local company</p>	<p>Moderator: Kristina Zakurdaeva, M.D. PhD</p> <p>Presenters:</p> <p>Third Pole Therapeutics Bill Athenson, CEO</p> <p>Cairn Surgical Dave Danielson, CEO</p> <p>Panelists:</p> <p>Jessica Gibson, MBA</p> <p>Sally Wang Liang, JD MPH Elmira Safarova, PhD</p>	<p>5:30 pm</p>	<p>60 minutes</p>
<p>Faculty Office Happy Hours - this section provides the opportunity of participants to interact and ask questions of the panelists</p>		<p>6:30 pm</p>	

— END OF DAY ONE —

Monday, June 5, 2023, Program Schedule		Start Time	Time
<p>SESSION 10: The Business Plan and Pitch in the Fund-Raising Process</p> <p>The business plan details your effective growth and market strategies, the soundness of your operational tactics, and understanding of funding needs and timing. Its conclusion should express why you are attractive to investors and how you plan to be sustainable and provide an investor return. An effective business plan drives your business model.</p> <p>Your investor pitch is the 10-20 slide hook to get investors' interest in reading your business plan.</p> <p>Experienced entrepreneurs and their investors openly recognize that within a year of operating, few companies resemble their original business plan.</p> <p>However, these documents provide the starting point of a shared vision and evidence that the founding team can reach a consensus in the business and technology and resource planning process to meet critical milestones.</p> <p>The session provides a framework for developing a pitch to investors/partners, and the essentials of a business plan.</p>	<p>Moderator and Lecturer:</p> <p>Benjamin Chen, PhD</p>	8:00 am	45 minutes

<p>SESSION 11: Accelerating Creditability and Valuation by Leveraging Partners</p> <p>The Business Model (which supports the business plan) contains all elements required by a firm to create, deliver, and capture value. In effect, the firm “rents” elements of the business model from others.</p> <p>In developing and validating the business model elements, the firm can leverage the resources and channels of partners across the value chain and share the value created and delivered with others. Creative partnering can be used to reduce the risk profile and reduce capital requirements for the firm as it evolves through the commercialization, testing, and go-to market phases.</p> <p>This session will provide a working model to consider which elements of your business model may be best served with leveraging partners.</p>	<p>Moderator and Lecturer: James Jordan, MBA, CHT</p>	<p>8:45 am</p>	<p>30 minutes</p>
<p>Break-out for case discussion followed by group recommendations</p>		<p>9:15 am</p>	<p>15 minutes</p>
<p>SESSION 12: Group & Presentations</p> <p>Utilizing the worksheet provided, students will discuss and identify the areas where partnerships could either accelerate, de-risk, or deepen domain relationships. Utilizing group discussions, gathering potential partners, and introductions.</p> <p>Two volunteers will take 15 minutes each to discuss their strategies.</p>	<p>Moderator: Kristina Zakurdaeva, PhD, MD</p>	<p>9:30 am</p>	<p>30 minutes</p>
<p>SESSION 13: Building Your Capitalization Strategy</p> <p>A start-up requires the continuous alignment of customer, investor, and acquirer’s objectives and concerns. Investors fund the journey, and a poorly planned and ill-provisioned journey increases the probability of failure.</p> <p>This discussion will center around the customer (who in this case is the investor) so students can understand their needs, timing, and investment criteria.</p> <ul style="list-style-type: none"> - Non-Dilutive Funding – NIH - Angels 	<p>Moderator: Thanigavelan Jambulingam, PhD</p> <p>Faculty: Steven M. Ferguson, MBA, CLP David Smith, JD James E. Foley, PhD</p>	<p>10:00 am</p>	<p>60 minutes</p>

<ul style="list-style-type: none"> - Corporate Venture Capital - Venture Capital - Corporate Partners 	Stephen Sammut, DBA Yury Kukushkin, PhD Julie Di Paolo		
<p>SESSION 14: Pre-seed/Seed Funding Pitch</p> <p>The facilitator will give a brief introduction on the phases of private equity funding.</p> <p>In this segment, two companies will present their investor pitch and receive feedback appropriate to their investment phase.</p> <p>The objective of this session is to witness real-life feedback and understand the expectations of investors for each investment phase. Students will 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 they are using the objection to avoid investing or providing feedback.</p>	Moderator: Kristina Zakurdaeva, PhD, MD Craniosense, Inc. Ryan Myers, CEO Rubik Therapeutics Murray Robinson, CEO Panel Members: Benjamin Chen, PhD Yury Kukushkin, PhD Elmira Safarova, PhD Jessica Gibson, MBA Vivian Lee, PhD	11:00 am	60 minutes
Lunch		12:00 pm	60 minutes
<p>SESSION 15: Defining your Exit Triggers</p> <p>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.</p>	Moderator and Lecturer: James Jordan, MBA, CHT	1:00 pm	30 minutes

<p>SESSION 16: Early-Stage Funding Pitch</p> <p>The facilitator will give a brief introduction on the phases of private equity funding.</p> <p>In this segment, 1-2 companies will present their investor pitch and receive feedback appropriate to their investment phase.</p> <p>The objective of this session is to witness real-life feedback and understand the expectations of investors at the early-stage valuation point. These 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.</p>	<p>Moderator: Maria Shepard, MBA</p> <p>Presenters:</p> <p>Cairn Surgical David Danielsen, CEO</p> <p>Cerberus Therapeutics Novalia Pishesha, CEO</p> <p>Panel:</p> <p>Stephen Sammut, DBA James E. Foley, PhD Yury Kukushkin, PhD Elmira Safarova, PhD</p>	<p>1:30 pm</p>	<p>60 minutes</p>
<p>Break-out for case discussion followed by group recommendations</p>		<p>2:30 pm</p>	<p>15 minutes</p>
<p>SESSION 17: Group & Presentations</p> <p>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.</p>	<p>Moderator: Maria Shepard, MBA</p> <p>Regional</p>	<p>2:45 pm</p>	<p>30 minutes</p>
<p>SESSION 18: Working with the Media: Thoughts for Bio-Entrepreneurs</p> <p>Media coverage plays a crucial role in various aspects of the bioenterprise, including raising funds, educating the market, shaping perception, and managing negative impressions. Previously limited to bioindustry media and financial markets, bioenterprise is now present in mainstream and social media. Therefore, it is important to communicate the value of biomedical products in simple language.</p>	<p>Moderator and Lecturer:</p> <p>Moira A Gunn, PhD Moira Gunn, Host, NPR/BioTech Nation & Director, Bioentrepreneurship, University of San Francisco</p>	<p>3:15 pm</p>	<p>60 minutes</p>

<p>SESSION 19: The Mechanics of Capitalizing Your Venture</p> <p>CEOs and CSOs may spend as much time raising capital as managing their company. What are the implications and risks associated with various decisions.</p> <p>The objective of this sessions, an attorney specializing in company formation and capitalization provide legal models and the risks associated with various decisions.</p> <p>It would be beneficial if you watched this video so you may ask more questions of our experts.</p> <p>Capitalization of the Venture: Founding & Funding</p>	<p>Moderator and Lecturer: David Smith, JD</p>	<p>4:15 pm</p>	<p>60 minutes</p>
<p>SESSION 20: Boot Camp Wrap-up, Acknowledgements, & Adjournment</p>	<p>James Jordan, MBA, CHT</p>	<p>5:15 pm</p>	<p>15 minutes</p>

— END OF DAY TWO —