Biotechnology Entrepreneurship Boot Camp Agenda Planning for 2022

Course will begin at 9:00 am Sunday, June 12, 2022 and 8:00 am Monday, June 13, 2022

Sunday, June 12, 2022 Pro	ogram Schedule	Start Time	Time
Opening Remarks, Program Overview of Program	National Co-Chair:	9:00 am	30
and Sponsor Acknowledgments	<u>James Jordan, MBA, CHT</u>		minutes
SESSION 1: Jessica Gibson, Co-Founder & CEO,	Introduced by:	9:30 am	45
Ariel Precision Medicine in conversation with Moira	<u>James Jordan, MBA, CHT</u>		minutes
Gunn, Host, NPR/BioTech Nation & Director, Bioentreprenuership, University of San Francisco			
SESSION 2: Project, Product or Platform:	Moderator and Lecturer:	10:15 am	60
Assessment and Qualification of Technologies as			minutes
a Basis for a Business Startup	<u>John M. York, PharmD, MBA</u>		
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.	John is going to use a case study and discussion format versus our typical panel.		
This session will provide the tools and framework to determine if your company is a project, product or platform.	<u>Dennis Abremski</u>		
 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. 			
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.			
SESSION 3: Reimbursement & Pricing Strategies	Moderator and Lecturer:	11:15 pm	60
The gap between revenue and cost determines your ventures profitability, and thus your ability to attract funders.	Robert Wanerman, JD, MPH		minutes
Price analysis is the major step to understanding the potential profitability of your venture.			
Life Sciences consists of the categories of biotechnology services, biopharm, diagnostics, medtech and health IT.			
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.			

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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.			
Break-out for panel discussion followed by group	recommendations	12:15 am	15 minutes
Lunch		12:15 pm	60 minutes
SESSION 4: What Every Investigator Must Know about IP in Biotechnology Startups Investors fund unfair advantages. An unfair advantage is a combination of unique personnel, proprietary relationships, know-how, assets and IP that are delivered in a not easily replicated, repeatable and scalable business model. Intellectual property (IP) is one of the strongest unfair advantages. The goal of the session is to provide information on the concepts, patent office processes and implications of	Moderator and Lecturer: Stephen M. Sammut, DBA	1:15 pm	60 minutes
certain decisions. SESSION 5: Regulatory Planning for the U.S. & Global Market - Implications for Strategy and Financing 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 most costly activities of a life sciences startup. 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?		2:15	60 minutes
Break	I	3:15 pm	15 minutes
SESSION 6: The R&D - Marketing Interface 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.	Moderator and Lecturer: Thanigavelan Jambulingam, PhD	3:30 pm	60 minutes

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This session provides the format and walks the student			
how to prepare one for their firm.			
SESSION 7: Is your IP is impervious to	Moderator and Lecturer:	4:30 pm	30
competitive advancement?			minutes
	<u>James Jordan, MBA, CHT</u>		
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.			
This session provides a tool called the Intellectual			
Property Pyramid [™] where startups can run their own			
exercises to ensure that their patents maximizes 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.			
SESSION 8: Building and working with the Board	Moderator and Lecturer:	5:00 pm	30
			minutes
Building and working with a board is a key element for	<u>James Jordan, MBA, CHT</u>		
success in entrepreneurial companies. Better boards			
make better companies.			
This consists will consider the book one skills and consists of			
This session will cover the best practices and successful			
principles of a great board and sound corporate			
governance processes.			
SESSION 9: Building an Entrepreneurial	Moderator:	5:30	60
Management Team		3.30	minutes
	Jessica Gibson, MBA		minaces
Team building in biotechnology companies is the most	<u> </u>		
challenging task for entrepreneurs, and the backbone			
of venture capitalists' decision to invest or not to	Presenters:		
invest.			
	Sam Ellis		
The session provides an exploration of the issues in	Chairman of the Board		
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the various start-up phases.			
	Julie Collens, PhD		
The panelists represent the perspective of a CEO and a			
venture capitalist who built the management team of a			
local company			
Faculty Office Happy Hours - this section provides th	e opportunity of participants to	6,20	
interact and ask questions of the panelists		6:30	
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Monday, June 13, 2022 Pro	ogram Schedule	Start Time	Time
SESSION 10: The Business Plan and Pitch in the Fund-Raising Process 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. Your investor pitch is the 10-20 slide hook to get investors interest in reading your business plan. Experienced entrepreneurs and their investors openly recognize that within a year of operating, few companies resemble their original business plan. 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. The session provides a framework for developing a pitch to investors/partners, and the essentials of a business plan.	Moderator and Lecturer: Benjamin Chen, PhD	8:00 am	45 minutes
SESSION 11: Accelerating Creditability and Valuation by Leveraging Partners 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. 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 also reduce capital requirements for the firm as it evolves through the commercialization, testing, and go-to market phases. This session will provide a working model to consider which elements of your business model may be best served with leveraging partners.	Moderator and Lecturer: James Jordan, MBA, CHT	8:45 am	30 minutes

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Break-out for case discussion followed by group	recommendations	9:15 am	15 minutes
SESSION 12: Group & Presentations	Moderator:	9:30 am	30 minutes
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.	Stephen M. Sammut, DBA		Timidee3
Two volunteers will take 15 minutes each to discuss their strategies.			
SESSION 13: Building Your Capitalization	Moderator:	10:00 am	60
Strategy	Thanigavelan Jambulingam, PhD		minutes
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.	Faculty: Steven M. Ferguson, MBA, CLP David Smith, JD		
This discussion will center around the customer (who in this case is the investor) so students can understand their needs, timing, and investment criteria.	James E. Foley, PhD Vivian Lee		
 Non-Dilutive Funding – NIH Angels Corporate Venture Capital Venture Capital Corporate Partners 	Richard Lin Rupak Doshi, PhD		
SESSION 14: Pre-seed/Seed Funding Pitch	Moderator:	11:00 am	60
The facilitator will give a brief introduction on the phases of private equity funding. In this segment, two companies will present their investor pitch and receive feedback appropriate to their investment phase.	David Smith, JD Company Presenters: Beth Hoffman Founder, CEO & President Origami Therapeutics Tia Lylos-Williams		minutes
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.			

Lunch		12:00 pm	60 minutes
SESSION 15: Defining your Exit Triggers	Moderator and Lecturer:	1:00 pm	30
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.	James Jordan, MBA, CHT		minutes
SESSION 16: Early-Stage Funding Pitch	Moderator:	1:30 pm	60
The facilitator will give a brief introduction on the phases of private equity funding.	Stephen M. Sammut, DBA Presenters:		minutes
In this segment, 1-2 companies will present their investor pitch and receive feedback appropriate to their investment phase.	Mya Thu CEO & Co-Founder VisiCELL Medical		
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.	Cari Health Panel: James E. Foley, PhD Bo Peng, M.D		
	Richard Lin Kristina Zakurdaeva, M.D., PhD		
Break-out for case discussion followed by group	recommendations	2:30 pm	15 minutes
SESSION 17: Group & Presentations	Moderator:	2:45 pm	30
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.	Stephen M. Sammut, DBA Kristina Zakurdaeva, M.D., PhD		minutes
SESSION 18: Working with the Media: Thoughts for Bio-Entrepreneurs	Moderator and Lecturer: Moira A Gunn, PhD	3:15 pm	60 minutes
Media coverage for bioenterprise is important in a number of ways: from raising money, to educating the market, to influencing company/product perception, to countering negative impressions, and more. While traditionally the sole province of BioIndustry Media and Financial Markets, bioenterprise has entered both Mainstream Media and Social Media. Whether developing a biomedical device, a diagnostic, or a biopharmaceutical, the need for explaining your bioenterprise in everyday terms has becoming essential.	Moira Gunn, Host, NPR/BioTech Nation & Director,		

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