

Keck School of Medicine of USC

TRGN 543 Biotechnology Entrepreneurship and Commercialization I

No. of Units: 2
Term: Fall 2018
Date/Time: Thursday 10:00 am – 11:50 am
Location: NRT 2508

Instructor: Ron King, PhD, MBA
Office: NRT 2506
Office Hours: Thursday 9 – 10 am, or
by appointment
Contact Info: RKing@BioAccel.org
(323) 442-3237

Course Description

This is the first of two courses that examine the entrepreneurial process in biotechnology from idea generation through economic viability. Biotechnology companies are unique in that they often need a decades-long period of incubation prior to becoming self-sustaining. Topics of this course include an overview of the global biotechnology industry, idea generation, business plan formulation, intellectual property protection, funding, personnel management including board composition, regulatory body interaction and company exits.

This course is directed towards advanced students in biosciences or bioengineering. By starting their own virtual “BEEopoly” biotech company, students will be introduced to the steps needed to start and nurture a biotechnology company in the healthcare realm, and gain an ability to assess the health of potential collaborators, partners or employers.

Guests will be invited to join us for some sessions to help us better understand key issues covered in the course. We may have to reschedule some sessions in order to accommodate their schedules.

Learning Objectives

To familiarize students with the scope of issues and decisions that managers in biotechnology face as their company progresses from its earliest stages to self-sustainability, and give students the vocabulary to participate and contribute to the business side of scientific enterprises. This course also provides a general procedural road map for bioscience students who are interested in starting their own companies.

Suggested Readings and Supplementary Materials

- Steve Blank and Bob Dorf: *The Startup Owner's Manual: The Step-By-Step Guide for Building a Great Company*. K & S Ranch. ISBN-13: 978-0984999309
- Craig Shimasaki, ed.: *Biotechnology Entrepreneurship: Starting, Managing, and Leading Biotech Companies*. Elsevier Inc., 2014. ISBN: 978-0-12-404730-3. Reading list is noted within course schedule.
- Lawton Robert Burns: *The Business of Healthcare Innovation*. Cambridge University Press, Cambridge UK, 2005
- Burrill & Company Annual Biotechnology Industry Report
- William B. Bygrave and Andrew Zacharakis: *The Portable MBA in Entrepreneurship*. Wiley & Sons, Hoboken, NJ. 2009
- William B. Bygrave and Andrew Zacharakis: *Entrepreneurship*. Wiley, Hoboken, NJ, 2010.
- Steven A. Silbiger: *The Ten-Day MBA 4th Ed*. HarperBusiness, 2012
- Cynthia Robbins-Roth: *From Alchemy to IPO: The Business of Biotechnology*. Basic Books, 2001.
- Jeffrey A. Timmons, Andrew Zacharakis, Stephen Spinelli: *Business Plans That Work: A Guide for Small Business*. McGraw Hill, 2004.
- John A. Tracy: *How to Read a Financial Report: Wringing Vital Signs out of the Numbers*. John Wiley & Sons, Hoboken, NJ. 2009
- Barry Werth: *The Billion Dollar Molecule: One Company's Quest for the Perfect Drug*. Simon & Schuster, 1995.

Description and Assessment of Assignments

Students will be given assignments each week that will provide the basis for the following week's discussion or as assessment of prior content. Each week will begin with a short quiz or with several students (randomly chosen in class) presenting their work.

Grading Breakdown

45%	3 Quizzes
20%	Weekly Assignments
10%	Company Presentation
25%	Final Exam

Assignment Submission Policy

Unless otherwise specified, all assignments are to be submitted online. Late submissions incur grade penalties.

Course Website: Blackboard

Course Schedule:

		Topic	Reading
1	08/23	Introduction and Overview of the Biotechnology Industry Part I: translational biotechnology industry overview (include the commercialization pathways for drug, medical device, diagnostic companies) Part II: entrepreneurship/intrepreneurship Part III: Lean Launchpad (LLP) methodology Part IV: Commercialization Knowledge Survey (CKS)	chapters 1 - 4
2	08/30	Starting a Company Part I: formation of BEEenopoly companies Part II: team assessments Sample assignment: Come to week three prepared to deliver a 60 second pitch to a Venture Capitalist.	H/O
3	09/06	Business Model Part I: the business model canvas Part II: biotechnology business models	12
4	09/13	How to startup a Startup Part I: corporate structure (LLC, LLP, C-Corp, S-Corp, etc.) Part II: ownership/vesting Part III LLP check in (customer development) Sample assignment: be prepared to report on at least three customer interviews you conducted.	13, 16
5	09/20	Quiz 1 Business Basics Part I: accounting basics (financial statements) Part II: valuation (What's that company worth?) Part III: exit strategies (How do I get my ROI?) NIH SBIR Program Officer WebEx in to talk about SBIR/STTR funding opportunities at NIH. Additional Suggested Reading: The 10 Day MBA Day 3, Day 6	10 Day MBA
6	09/27	Funding Part I: the funding process Sample assignment: Students will consider funding strategy of their BEEenopoly company. On what basis should the company decide how often and when to raise money?	19, 21
7	10/04	Intellectual Property Part I: basic concept of intellectual properties (patents, Trademarks, Copyrights) Sample assignment: Find an example of an overturned drug patent. What was the basis of the claim? What was the process by which the patent was challenged? What benefit accrued to the challenger?	14, 15

8	10/11	Regulatory Strategies Part I: The FDA Part II: reimbursement Sample assignment: Come prepared next week to discuss your FDA strategy for your product and what data you have to validate it?	17
9	10/18	Quiz 2 Clinical Development Part I: pre clinical development (animal studies, admetox, etc.) Part II: clinical development, considerations for human experimentation. Part III: clinical trial design Sample assignment: LLP check in. Next week students will report on their customer development interviews and any changes to their customer profiles and value proposition	23
10	10/25	Industry Perspective and Experiences Guest Lecture (Investor) Further training of the other aspects of the LLP business model canvas. We will have guest lecturer(s) who can share their experiences with the class.	
11	11/01	Oversight/Governance Part I: Each BEEopoly company will nominate a slate of directors. Part II: staff needs as the company grows	16, 17
12	11/08	Industry Perspective and Experiences Guest lecture (Biotech Entrepreneur)	
13	11/15	Quiz 3 Course review Part I: LLP business model canvas check in Part II: extra focus on topics that class would like to spend a little more time covering	
	11/22	Thanksgiving	
14	11/29	Student Presentations Students will present their own revised business plans, demonstrating the model's evolution from week 1 to present.	
	12/06	Final Exam / CKS survey #2	

Statement on Academic Conduct and Support Systems

Academic Conduct:

Plagiarism – presenting someone else’s ideas as your own, either verbatim or recast in your own words – is a serious academic offense with serious consequences. Please familiarize yourself with the discussion of plagiarism in *SCampus* in Part B, Section 11, “Behavior Violating University Standards” policy.usc.edu/scampus-part-b. Other forms of academic dishonesty are equally unacceptable. See additional information in *SCampus* and university policies on scientific misconduct, <http://policy.usc.edu/scientific-misconduct>.

Support Systems:

Student Counseling Services (SCS) – (213) 740-7711 – 24/7 on call

Free and confidential mental health treatment for students, including short-term psychotherapy, group counseling, stress fitness workshops, and crisis intervention. engemannshc.usc.edu/counseling

National Suicide Prevention Lifeline – 1 (800) 273-8255

Provides free and confidential emotional support to people in suicidal crisis or emotional distress 24 hours a day, 7 days a week. www.suicidepreventionlifeline.org

Relationship and Sexual Violence Prevention Services (RSVP) – (213) 740-4900 – 24/7 on call

Free and confidential therapy services, workshops, and training for situations related to gender-based harm. engemannshc.usc.edu/rsvp

Sexual Assault Resource Center

For more information about how to get help or help a survivor, rights, reporting options, and additional resources, visit the website: sarc.usc.edu

Office of Equity and Diversity (OED)/Title IX Compliance – (213) 740-5086

Works with faculty, staff, visitors, applicants, and students around issues of protected class. equity.usc.edu

Bias Assessment Response and Support

Incidents of bias, hate crimes and microaggressions need to be reported allowing for appropriate investigation and response. studentaffairs.usc.edu/bias-assessment-response-support

The Office of Disability Services and Programs

Provides certification for students with disabilities and helps arrange relevant accommodations. dsp.usc.edu

Student Support and Advocacy – (213) 821-4710

Assists students and families in resolving complex issues adversely affecting their success as a student EX: personal, financial, and academic. studentaffairs.usc.edu/ssa

Diversity at USC

Information on events, programs and training, the Diversity Task Force (including representatives for each school), chronology, participation, and various resources for students. diversity.usc.edu

USC Emergency Information

Provides safety and other updates, including ways in which instruction will be continued if an officially declared emergency makes travel to campus infeasible. emergency.usc.edu

USC Department of Public Safety – UPC: (213) 740-4321 – HSC: (323) 442-1000 – 24-hour emergency or to report a crime.

Provides overall safety to USC community. dps.usc.edu