

# **Biotech Industry Innovators – Spring 2018**

## *Syllabus*

**Arts and Sciences: Biotech Industry Innovators L41 5014 Biol**

**Olin Business School: The Basics of Bioentrepreneurship B63 MGT 539**

**Dates and Time: 01/17/2018 – 05/02/2018 Wednesdays, 5:30 pm - 8:30 pm**

**Location: Farrell Learning and Teaching Center (FLTC) – Room 214 A & B**

### **Course Overview:**

"Bio-Entrepreneurship" investigates issues and decisions that inventor / scientists, investors, founders, business people, lawyers, and others might typically encounter when they are considering the application and commercialization of early stage scientific discoveries. This course is intended for anyone interested in working in the life sciences / biotech industry as chief scientists, entrepreneurs, managers, consultants, investors, analysts, technology transfer agents, or FD&C Act lawyers. It focuses on the issues and decisions that researchers typically face when considering how a discovery might be moved from a university laboratory to actual use. It also provides valuable background for career planning and choices in these and related industries.

Bio-Entrepreneurship is offered to PhD candidates, Post Docs, PhDs, master's level students, and undergraduates who have or are pursuing advanced degrees in science and business students. The course is taught on the medical school campus and has limited enrollment. About 1/3 of the class members are expected to come from other Washington University advanced degree programs, such as business, law, engineering, arts and sciences, and other areas. Students will receive academic credit that is equivalent to one full semester course.

This course will provide an overview of the scope of knowledge and range of skills needed. The goals of the course are to:

1. Introduce a framework for evaluating discoveries and ideas that might be commercially viable through licensing or partnership agreements and in some cases lead to high opportunity startup companies.
2. Develop an understanding of the biotech industry, its competitors, and how the industry is changing, including the role of large pharmaceutical companies, biotech firms, startups, universities, government, and other players.
3. Consider the implications of a researcher's or research team's personal motivations in choosing potential next steps for commercialization including the tradeoffs between scientific interests, reputation, personal time commitment, wealth creation, control, valuation, and access to resources.
4. Develop an appreciation for how basic discoveries are commercialized for use by mankind. This involves all options including the overall commercialization process. The course promotes learning in the areas of university resources, economics, intellectual property, competitive dynamics, and value milestones that impact various discoveries and the stages of monetizing different types of life and plant science discoveries.

5. Develop skills including idea evaluation, elevator pitching, intellectual property strategies, feasibility analysis, market assessments, regulatory approval, funding cycles, business planning, team formation, and financial planning.
6. The course will include examples and case studies from drug discovery, medical diagnostics, medical devices, scientific tools development, and other products.

**Course Structure:**

To accomplish these goals, the course will contain readings specific to the biotech industry, bio-entrepreneurship, lectures introducing basic concepts, and evaluation templates. The majority of the class discussion focuses on Harvard Business School and other case studies with learning being reinforced by practicing guest speakers. Preparation for classes will be done individually with all students completing readings prior to each class. Each student should be prepared contribute to the class discussion or to lead the class discussion of the assigned reading materials, if called upon to do so.

Each student will also complete project work in collaboration with other class members on an idea that they bring to class (a team project). Based on presentations ⅓ of the ideas will be selected, by the class members, for work by a team of students on a complete feasibility analysis including an idea description, executive summary, and poster board presentation. The purpose of this work is to apply learning in a small team setting. Teams will work together to make decisions and recommendations about their plan for commercializing **or** abandoning the idea. The culmination of each team's work will take the form of a final poster presentation to outside experts who will evaluate the quality of thinking that has been done. This hands-on experience will reinforce and help students develop a thought framework that will be useful as they encounter various opportunities throughout their careers.

The course is taught once a week for thirteen weeks with each session being three hours in length. Readings and course preparation will require approximately two to three hours outside of class. A summary outline and calendar are attached below:

1. **Section 1, Week 1 – Introduction to Course and Case Studies.** Presents an overview of topics that will be covered. Discuss case studies and how they will be used. Review course deliverables. Understand Non-Disclosure Agreements (NDAs) / Confidential Disclosure Agreements (CDAs). Learn the art of making effective elevator pitches.
2. **Section 2, Week 2 and 3 – Opportunity Evaluation Approach and Industry Overview.** Introduces an evaluation template for quickly assessing ideas. Provides an overview of the biotech industry including history. Reviews the role and strategic challenges of large pharmaceutical firms, biotechnology companies, startups, and university researchers. Provides context for industry change and the strategic position of various competitors.
3. **Section 3, Weeks 3 and 4 – Value Milestones and Feasibility Analysis.** Provides an overview of how the desires of individuals or teams of researchers might impact commercialization choices. Examples of “value milestone” based feasibility study. What to do when considering a promising opportunity.
4. **Section 4, Weeks 5, 6, and 7 – Sources of Capital.** Strategic Partnering, Venture Capital, Angel investors, SBIR / STTR funding, and other alternatives for acquiring

resources. How motivations, value milestones, resource needs, and investor expectations impact choices in pursuing opportunities.

5. **Section 5, Weeks 8 and 9 – Legal Issues, Intellectual Property, and University Support for Research Commercialization Activities.** Cover patents, legal entity choices, the role of a university in commercialization and how these factors relate to researcher motivations and choices. Relate opportunity to investment potential and options for resources.
6. **Section 6, Weeks 10, 11, and 12 – Medical Devices, Consumer Offerings, and Associated Regulatory Approval Issues.** Provides an overview of timing, costs and risks that different opportunities might encounter. Relate regulatory issues to value milestone concepts. Assesses how these differ with different types of discoveries and research commercialization choices.
7. **Final Presentations and Reception – Week 13.** Each student team will present a poster to a group of outside experts and receive comments about their commercialization plan. Each team member is expected to make about 1/3 of the presentation. A reception will follow the poster presentation allowing for additional discussion and feedback.

#### **Course Materials:**

There is a required course packet consisting of case studies, websites, and selected articles that illustrate particular features of the venture creation process. The course packet is available **only** at the Danforth Campus Bookstore in Mallinckrodt Hall.

#### **Also required:**

**Genentech: The Beginnings of Biotech (Synthesis)** by Sally Smith Hughes, PhD

ISBN-13: 9780226045511

Publisher: University of Chicago Press

Publication date: 4/9/2013

(available as an eBook for less than \$10 from either Kindle / Amazon or Barnes and Nobel)

Additional materials will be provided throughout the semester via e-mail.

#### **Course Structure and Format:**

The course relies heavily on case studies to illustrate various types of research and the companies that result from such research. These cases, readings, and website references allow students / teams to understand opportunity evaluation and feasibility analysis. It is vitally important that students read each case as well as the other assigned readings **prior to class**, and come prepared to discuss both the case and their application to their own or the team feasibility idea. In addition, there will be several outside expert speakers covering different aspects of the biotech industry.

#### **Requirements:**

The course requirements consist of:

- A feasibility study of an original business idea (the Student Business Opportunity).
- In-class participation

### **Student Business Opportunity Timetable**

A key requirement of the course will be for students to conduct a feasibility study of **an original business idea** that they either have or will develop. This work will be done in teams that are formed during the class.

### **Speakers**

A number of life science /pharma / biotech / business individuals donate their time to this class by providing timely lectures to the class. **Please:** 1. Arrive on time to class, 2. Read the bios of the speakers prior to class; where appropriate, look up their companies, 3. Give your undivided attention to the speaker, 3. Feel free to ask the speakers questions; some will entertain questions during their presentations, others prefer questions at the end of their presentations

The following describes the **key dates** and times for each of the deliverables for your feasibility study:

| <u>Date</u> | <u>Assignment</u>   |
|-------------|---|
| 1/30        | All students must submit a 1 page description of their business idea with a completed evaluation template. It should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm.  |
| 1/31        | All students will make a two minute presentation of their business opportunities to the class.  |
| 2/2         | Students will rank the ideas in descending order of preference by assigning dollar values to as many ideas as you like; the total "invested" in ideas must equal \$1000. Your rankings should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm. The ratings will be compiled and the top 1/3 of the ideas will be selected for feasibility study work and poster board presentations. |
| 2/5         | Votes tabulated and sent to all class members. Top projects based on student stack rankings will continue on to next stage. "Founders" must recruit 2 additional team members (other students; with no more than 1 MBA per team) to pursue work on their idea.  |
| 2/9         | "Founders" must submit list of team members. Each team must have 3 members. It should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm  |
| 3/16        | Complete public version of idea description and post public (non-confidential) idea description on <a href="http://www.IdeaBounce.com">www.IdeaBounce.com</a> . Due by 5:00 pm  |
| 3/30        | Hand In: First draft of three-page (maximum) written Executive Summary of Feasibility Plan including initial summary of value milestones, probabilities, cost estimates and other factors. Due by email; it should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm.  |
| 4/27        | Hand In: Final of five-page (maximum) written Executive Summary of Feasibility Plan including final summary of value milestones, probabilities, cost estimates and other factors. It should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm.   |

5/2 Business Opportunity Feasibility Study Presentations: Public Poster Board Session Invitation details and location TBD. Class speakers, former students, professors, and others will be invited to attend; refreshments will be provided. Please feel free to invite anyone that you would like to the event.

(NB. If there are any date conflicts between the above and the table below, **the table on pages 6 – 10 is considered the correct version**)

### **Grading**

Grades will be based on your performance in 3 aspects of the course:

- *Case Preparation and Class Participation:*

All students will be required to prepare all cases for class discussion and be prepared to discuss and lead the class discussion. This should include an outline of what points you wish to make as well as supporting spreadsheets or other work with quantitative analysis. Students will **not** be asked to hand in their work for grading.

- *Poster Board – on 5/2 and Written Executive Summary / Feasibility Study of Business Opportunity – due 4/27*

**50% of Final Grade (Team Grade)**

- *Class Participation – Based on performance during in-class case discussions*

**50% of Final Grade (Individual Grade)**

### **Communication:**

Although I have a Washington University e-mail address, communication is not seamless at all times, so please send all communications to: [PetePeters.class@sbcglobal.net](mailto:PetePeters.class@sbcglobal.net)

On all communications, include your name and / or the names of your team, as appropriate. Page numbering is preferred.

### **Attendance:**

Class attendance is not required; if you will be unable to attend, please let me know in advance as I do take attendance to help in determining class participation.

### **Confidentiality:**

The biotech / pharma / life sciences industries are built on novel ideas / intellectual property.

This course will require extensive discussion and analysis of classmates' business ideas. As such, absolute confidentiality of these ideas is required. A written confidentiality agreement will be reviewed in class and must be signed by all class participants.

**You may not use any of your classmates' ideas without written permission!!**

| Wk # | Date | Theme/Topics<br>General Objectives  | Case to be Discussed | Case Lessons   | Guest Speaker/Key Activities             | Assignments to be completed prior to class   |
|------|------|---|----------------------|--|--|--|
| #1   | 1/17 | <ul style="list-style-type: none"> <li>- Getting to know you</li> <li>- Getting to know me</li> <li>- Course overview</li> <li>- Housekeeping: (Grading, Attendance Other Policies)</li> <li>- Case preparation</li> <li>- Opportunity Evaluation Template</li> <li>- Nondisclosure agreement</li> </ul> <p>Innovation and Entrepreneurship</p> |                      | <ul style="list-style-type: none"> <li>-How will innovation impact the future and what is the relationship of innovation and entrepreneurship.</li> <li>-How do entrepreneurs solve problems?</li> </ul> | Discuss Individual Goals and Motivations | <p>Required Readings:<br/>Spend 30 minutes each on the following three items:</p> <p><b>The Entrepreneurs Guide to a Biotech Startup 4<sup>th</sup> Edition</b><br/> <a href="https://www.ctsi.ucla.edu/researcher-resources/files/view/docs/EGBS4_Kolchinsky.pdf">https://www.ctsi.ucla.edu/researcher-resources/files/view/docs/EGBS4_Kolchinsky.pdf</a><br/> (must connect thru Google Chrome)</p> <p><b>NIH Roadmap for medical research website, now part of NIH Common Fund.</b><br/> <a href="http://commonfund.nih.gov/">http://commonfund.nih.gov/</a></p> <p><b>Biotech Investor Blog site</b><br/> <a href="http://www.biotechindustrystocks.com/BIS/">http://www.biotechindustrystocks.com/BIS/</a></p> <p>Review:<br/> <b>Nondisclosure Agreement (NDA)</b> To be discussed and signed during first class (distributed via email)<br/> and<br/> <b>Opportunity Evaluation Template</b> (Read instructions and study template)</p> |

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| #2 | 1/24 | Biotech Industry Origins and Using the Opportunity Evaluation Template  | Genentech I           | -Overview of the Biotech industry  | Elevator Pitch Practice  | <p><u>Required Reading:</u><br/> <b><u><a href="#">Genentech: The Beginnings of Biotech (Synthesis)</a></u></b> by Sally Smith Hughes, PhD<br/> Chapters 1 - 3</p> <p><u>Required Readings:</u><br/> <b>Developing an Elevator Pitch for a New Venture</b></p> <p><b>How to Make Your Case in 30 Seconds or Less</b></p> <p><b>Prepare</b> an opportunity evaluation template of the idea that you will pitch to the class</p> |
| #3 | 1/31 | Biotech Industry Origins  | Genentech II          | -Partnering in the industry<br>-Industry historical view (1992)            | Student Presentations of Business Opportunity:<br>2 min. student presentations pitching your opportunities | <p><u>Required Reading:</u><br/> <b><u><a href="#">Genentech: The Beginnings of Biotech (Synthesis)</a></u></b> by Sally Smith Hughes, PhD<br/> Chapters 4 – 6</p> <p>Prepare: Written one page summary of your idea and send it to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> <b>prior to class.</b></p>  |
|    | 2/2  | Students will rank the ideas in descending order of preference by assigning dollar values to as many ideas as you like; the total “invested” in ideas must total \$1,000. Your rankings should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm. The rankings will be compiled and the top 1/3 of the ideas will be selected for feasibility study work and poster board presentations. |                       |  |  |  |
| #4 | 2/7  | Terms for an angel or VC or deal, equity, controlling a venture and entrepreneur’s disease.   | NanoGene Technologies | - Importance of Terms and Conditions in venture funded deal<br>-Term sheet | <b>Jim von der Heydt</b><br>Private equity and STL Arch Angels<br><br><b><u>Confirmed 5:30 pm</u></b>      | <p>Prepare Case: <b>NanoGene Technologies</b></p> <p><u>Required Readings:</u><br/> - <b>Angel Investing</b><br/> - <b>Jocelyn Chang</b><br/> - <b>A Note on Pre-Money and Post-Money Valuation (A&amp;B)</b></p> <p>-<b>Capital structure and Dilution template</b> (via email)</p>   |

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|    | 2/10 | "Founders" must submit list of team members. Each team must have 3 members with no more than 1 MBA per team. It should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm |  |  |  |  |
| #5 | 2/14 | Due Diligence   | Elliot Lebowitz  | Value Milestones<br>-How do your ideas compare?<br><br>Historical perspective. What has changed and what is the same?  | <b>Carl Siekmann</b><br>Seasoned Pharma and biotech licensing executive<br><br><b>Confirmed 5:30 pm</b>                  | Prepare Case: <b>Elliot Lebowitz</b><br>Prepare Case: <b>Biotransplant IPO</b><br><br><u>Required Readings:</u><br><b>What You Can Learn from Managers in Biotech</b><br><br><b>The Cagan Baranski Feasibility Study as an Example of Due Diligence</b>  |
| #6 | 2/21 | Venture Capital Firms   | Neurotherapy Ventures  | Understanding VCs<br>-Finding Money<br>-Evaluating financing alternatives<br>-Alternative money sources<br>- Hand out <b>Capital structure and Dilution template</b> | <b>Brian Clevinger</b><br>Founder / Managing Partner<br>– ProLog Ventures, a STL VC firm<br><br><b>Confirmed 5:30 pm</b> | Prepare Case: <b>NeuroTherapy Ventures: Catalyzing Neurologic Innovations</b><br><br><u>Required Readings:</u><br>- <b>How Venture Capital Works</b><br><br>- <b>SBIR and STTR Overview</b><br><a href="http://grants1.nih.gov/grants/funding/sbirstr_programs.htm">http://grants1.nih.gov/grants/funding/sbirstr_programs.htm</a>                             |
| #7 | 2/28 | Value Milestones and Strategic Partnering as a source of capital  | Millennium Pharmaceuticals (Value Milestones) (Partnering as a way to get resources) | Career Paths in the industry<br><br>-The search for an opportunity<br>-Evaluating how Millennium used strategic partnerships   | <b>Eric Miller,</b><br>Senior Analyst<br>BioGenerator<br><br><b>Confirmed 5:30 pm</b>                                    | Prepare Case: <b>Strategic Deal Making at Millennium Pharmaceuticals &amp; Millennium Pharmaceuticals (B)</b><br><b>Takeda Pharmaceutical Company (B): The Millennium Acquisition</b><br>Prepare Case: <b>Genzyme: Engineering the Market for Orphan Drugs</b><br><br><u>Required Readings:</u><br><b>Growth Strategies in the Pharmaceutical Industry (A)</b> |
|    | 3/7  | No Class – Travel Week  |  |  |  |  |
|    | 3/14 | No Class – Spring Break   |  |  |  |  |
|    |      | Complete public version of idea description and post public (non-confidential) idea description on <a href="http://www.IdeaBounce.com">www.IdeaBounce.com</a> . Due on 3/17 by 5:00.  |  |  |  |  |

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| #8  | 3/21 | Intellectual Property, Patents and Company Formation.<br><br>Forming a company and filing a patent | Comment and discuss student projects   | Intellectual property<br>-Innovation disclosures<br>-University Resources<br>-Licensing<br>-Creating a company<br>-Filing patents | <b>Dennis Donohue</b><br>CreativLaw<br><br><b><u>Confirmed</u></b><br><b><u>5:30 pm</u></b>                                      | <u>Required Readings:</u><br>- <b>Intellectual Property and Strategy</b><br><br>- <b>Strategic Management of Intellectual Property: An Integrated Approach</b><br><br>- <b>The Legal Forms of Organization</b>   |
| #9  | 3/28 | University support and responsibility for government funded or self-funded discoveries.            | Diagnostic Genomics  | -Converting ideas into business<br>-Validating business opportunity   | <b>Nichole Mercier,</b><br>Director, Office of Technology Management, WU<br><br><b><u>Confirmed</u></b><br><b><u>5:30 pm</u></b> | Prepare Case: <b>Diagnostic Genomics</b><br><br>Read:<br><b>Background on the Technology of Molecular Diagnostics</b><br><br><u>Required Readings:</u> Three websites<br>-Website review, 30 minutes<br><a href="http://otm.wustl.edu">http://otm.wustl.edu</a><br><br>Review drug discovery process regulation steps:<br><a href="http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm">http://www.fda.gov/Drugs/DevelopmentApprovalProcess/default.htm</a><br><br><a href="http://www.bio.org/">http://www.bio.org/</a> |
|     | 3/30 |  | Hand in: First draft of three-page (maximum) written Executive Summary of Feasibility Plan including initial summary of value milestones, probabilities, cost estimates and other factors. Due by email; it should be sent to <a href="mailto:PetePeters.class@sbcglobal.net">PetePeters.class@sbcglobal.net</a> by 5:00 pm. |   |  |  |
| #10 | 4/4  | Other Types of Business Models (Medical Devices)   | Endius, Inc.   | -Decision Making at Later Value Milestones<br>-Market Size and Risk   | <b>Hayley Johnston</b><br>GatewayVMS<br><br><b><u>Confirmed</u></b><br><b><u>5:30 pm</u></b>                                     | Prepare Case: <b>Endius Inc.: Alternatives for Developing a New Medical Device,</b><br><br><u>Required Readings:</u><br><b>Note on the FDA Review Process for Medical Devices</b>  |

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| #11 | 4/11 | Other Types of Business Models (Consumer product) and Opportunities                     | Medical Foods   | Applying the concept of Value Milestones How do business models differ?        | <b>Nick Goldner</b><br><b>Chris Bulow</b><br><b>Aki Kau</b><br>CEO, COO, and CSO<br>Viosera<br><br><u><b>Confirmed</b></u><br><b>5:30 pm</b> | Prepare Case: <b>Medical Foods, Inc.</b>  |
| #12 | 4/18 | Other Types of Business Models (Surgical Instruments) and What it is like after the IPO | Arthocare   | Medical Devices and leading a young public company. How might cultures change? | <b>Steve Trampe,</b><br>Chairman,<br>Sequoia<br>Sciences, Inc.<br>and<br>CFO Viosera<br><br><u><b>Confirmed</b></u><br><b>5:30 pm</b>        | Prepare Case: <b>Arthocare</b><br><br>Read:<br><b>Can Science be a Business? Lessons from Biotech</b> |
|     | 4/25 | No Class  |   |  |  |   |
|     | 4/27 |   | Hand In: Final (five-page maximum) written Executive Summary of Feasibility Plan including final summary of value milestones, probabilities, cost estimates, and other factors. It should be sent no later than 11:59 pm.   |  |  |   |
| #13 | 5/2  | Final Poster Presentations  | <b>Business Opportunity Feasibility Study:</b> Public Poster Board Session Invitation details and location TBD. eMail electronic copies (.pdf) of posters to <a href="mailto:petepeters.class@sbcglobal.net">petepeters.class@sbcglobal.net</a> prior to the beginning of the poster presentations. |  |  |   |
|     | 5/7  |   |   |  |  |   |