

**THE WHARTON SCHOOL**  
**University of Pennsylvania**  
**HEALTHCARE ENTREPRENEURSHIP**  
**HCMG 867-401**  
**SPRING 2011**  
**Thursdays 4:30-6:30 PM JMHH 240**  
**Syllabus Date: 12/03/2010**

**INSTRUCTORS**

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**OVERVIEW**

The goal of the course is to give students the hands-on experience of establishing a life sciences business by, among other things, working as a “mentored” group to craft and defend a business plan based on an actual technology or service in the life sciences space (defined as therapeutics, diagnostics, medical devices, or technology platform). Healthcare services may be acceptable but will not be a focus of the course for this year. Students, ideally working in groups of 4-6, will select a technology and present a proposed project description to the course instructors prior to the second class meeting.

During the course of the semester, students will be expected to prepare certain group-specific deliverables and to craft a business plan and investor presentation. Class discussions, led by course instructors as well as individuals drawn from the entrepreneurial, biotechnology, biopharmaceutical and investor communities as well as service providers, will present relevant major themes in life sciences business strategy and tactics using current early stage ventures to illustrate these themes.

Non-Wharton Penn students or post-docs are welcome to take the class for credit or audit with permission from the instructors. If for credit, then students will need to make arrangements with their primary departments. Other Penn affiliates (e.g., MD candidates, faculty) or those not affiliated with Penn may also audit the course with permission from the instructors, and will be expected to fulfill all of the same responsibilities of students taking the course for credit.

**BUSINESS PLAN AND PRESENTATION**

The primary deliverable is a written business plan highlighting the essential features of the business, market, competition, operating plan and financial projections, etc. In addition, each team will prepare and deliver a PowerPoint presentation to a panel of investors. Teams will be required to provide certain deliverables with respect to their interim progress in the form of written work or presentations.

**PROJECT SELECTION – PRELIMINARY WORK**

Students will evolve their projects and deliverables during the fall semester, but no later than the second class meeting. **Teams are required to prepare and hand in an initial project description which is due by the second class (January 20, 2011).** Course instructors, TAs, staff and mentors will assist student in selecting their projects through relationships with Penn, Penn Medicine and HUP, other technology transfer offices as well as through organizations such

as BioAdvance, the University City Science Center, the Ben Franklin Technology Partners and local start-up and early stage companies.

### **TEAMS**

Teams will ideally include 4-6 students at least one of whom will have a relevant technical background. In addition, members of the Penn Biotech Group or other relevant individuals may act as consultants or participate as team members. With the prior approval of the instructors, non-Wharton technical members of the team will be permitted to participate in the class. The course instructors will assist each team in identifying an appropriate mentor to provide focus and to help identify appropriate resources within the life science community.

### **LECTURES AND READINGS**

Lectures will be held once each week and will deal with specific topics covered in a typical life sciences business plan or of significance to a life sciences venture. Lectures will include presentations by the instructors and experts on specific topics, with discussion facilitated by the instructors. **Since we are inviting experts from the outside, attendance at the lectures will be critical.** Prior to lectures, students will receive relevant reading in the forms of articles and case studies, among other materials.

### **GRADING**

Students will be evaluated on a combination of the final business plan, investor presentation and class participation, including the interim progress updates on the business plan in the following proportion: Business plan: 40%; Investor presentation: 20%; Class and team participation and interim deliverables: 40 %. *Notes: (1) Students will also evaluate their team members, with input factored into the participation grade. (2) The interim deliverables will count toward the participation grade and will be reviewed and returned with comments, but will not be evaluated on a graded scale.*

### **ENROLLMENT:**

Enrollment will be by application.

### **Class Schedule and Assigned Readings**

#### **Class 1 – January 13, 2011 Course Goals/The Business Plan**

The first course meeting will include (i) a discussion of course goals, (ii) the function of a business plan and (iii) the theory and practice of preparing a business plan.

**Speaker: Jeff Libson**

#### **Class 2 – January 20, 2011 Founding a Life Sciences Company – Class Discussion**

**Speakers: Eric Boutin**  
Founder and VP – Business Development  
Good Start Genetics

**Paris Wallace**  
Founder and VP – Finance and Operations  
Good Start Genetics

**Deliverable:** Project/Technology Summary

On the path from an invention to successful product commercialization, there are at least as many stories as there are companies that have been formed. The instructors will select examples from the life sciences community and invite the founders or other principals to come to class and tell their stories. The students will have the opportunity to review background materials prior to class

and will be encouraged to probe the presenters on the process of creation and execution of their ventures. We will also discuss how these examples are illustrative of entrepreneurship in the life sciences and their relevance for the student projects.

### **Class 3 – January 27, 2011 Company Presentations – Class Discussion**

**Speaker:**        **Daniel Skovronsky, M.D, Ph.D.**  
President and CEO  
Avid RadioPharmaceuticals, Inc.

Same class description as January 20, 2011

### **Class 4 – February 3, 2011 Technology Sourcing**

Biotech start-ups arise from a variety of sources of technology and products, including the solo inventor, academic technology transfer, and licensing/spin-outs from biopharma. In this lecture, speakers with experience in the process of accessing technology from academia and industry will give examples of strategies and models for sourcing technology.

**Speaker:**        **John Swartley, Ph. D**  
Deputy Executive Director  
Center for Technology Transfer - UPenn

**Deliverable:** Two minute elevator pitch from each team with one paragraph value proposition

### **Class 5 – February 10, 2011 Patents – Importance to Life Sciences Ventures**

Intellectual property provides the basis for the economic viability of a venture. Just as important as understanding some basic patent law, the successful entrepreneur needs to develop and implement a successful intellectual property strategy. In this lecture, we will discuss patents and their importance to the venture, as well as the decision making process that goes into formulating a strategy, including patent prosecution, licensing, and competitive analysis and the cost/benefit that underlies this analysis.

**Speaker:**        **Ray Miller, Esq.**  
Partner  
Pepper Hamilton LLP

**Deliverable:** None

### **Class 6 – February 17, 2011 Regulatory Influences**

Most life sciences businesses are regulated or at least heavily influenced by the FDA. In this lecture, we will provide an overview of the FDA's policies, regulations and practices with respect to a biopharma business and product development

**Speaker:**        **Janice Hogan, Esq.**  
Partner  
Hogan & Hartson, LLP

**Deliverable:** List of key IP and/or licensing issues

### **Class 7 – February 24, 2011 Market Analysis**

Many companies fail because they do not fully understand the true markets for their products. In this lecture, we will present and discuss the factors that go into determining the appropriate market elements and what potential investors will expect to see.

**Speaker:**       **Jerry McLaughlin**  
Vice President, Commercial Operations  
NuPathe, Inc.

**Deliverable:** One-page summary of expected regulatory process.

### **Class 8 – March 3, 2011 Clinical Development Strategy and Tactics**

Clinical development is not simply “checking the Phase 1, Phase 2, and Phase 3 boxes.” Companies must develop a viable strategy that matches the clinical endpoint to the available financial and other resources. In this lecture we will present and evaluate examples of clinical development strategies.

**Speakers:**       **Sunita Sheth, M.D.**  
Chief Medical Officer and VP-Clinical and Regulatory Affairs  
Tengion, Inc.

**Deliverable:** Draft of Excel market model (incidence/prevalence, addressable patients, etc.).

### **Class 9 – March 17, 2011 Health Economics and Reimbursement**

Just because your product gets approved by the FDA does not ensure that someone will pay for it. As a result of product pricing issues, the prospect of reimbursement often drives fundamental product development and investment decisions. This lecture will provide an overview of government and private reimbursement with a focus on its implication for an early stage life sciences venture.

**Speaker:**       **Stanford Miller**  
Vice President – Health Policy and Access  
Neuronetics, Inc.

**Deliverable:** One-page summary of expected clinical development plan.

### **Class 10 – March 24, 2011 Discussion of Course Themes and Team Progress/Issues**

This class period will be used to discuss major themes from the previous lectures and will allow for the discussions of issues confronted by the class teams.

**Speakers:**       **Gary Kurtzman and Jeff Libson**

**Deliverable:** One page summary of economic value proposition and reimbursement plan.

### **Class 11 – March 31, 2011 Budgets and Financial Projections**

In order to be successful, an entrepreneurial life sciences venture must efficiently use capital and ultimately provide a return on the invested capital. In this lecture, we will outline the elements of the budget and financial projections. It is intended that this lecture will dovetail with the lecture on Financing and Exits to provide a basic understanding of the financial planning for a life sciences company.

**Speaker:**       **Keith Goldan**  
Vice President and CFO  
NuPathe, Inc.

**Deliverable:** Management org chart including current members and key hires (positions – not actual names of personnel)

### **Class 12 – April 7, 2011 Financing and Deal Terms**

There are different strategies for financing life sciences ventures. In this lecture, we will present and discuss the continuum of financing for life sciences ventures and the implications of funding the company. We will discuss founder/angel and venture capital and other sources of equity and non-equity funding, as well as typical transaction terms.

**Speakers:**       **Richard Kollender and Jeff Libson**  
Partner  
Quaker BioVentures

**Deliverable:** Preliminary budget and financial projections through exit.

### **Class 13 – April 14, 2011 Collaborations/Business Development**

The reality is that just about every successful biotech venture is going to develop a relationship with a larger biopharmaceutical partner. This is increasingly true as large biopharmaceutical companies are looking upstream to biotech companies as a source of pipeline. In this class, we will discuss the business development ‘enterprise’ in a biotech venture.

**Speaker:**       **Ad Rawcliffe**  
SVP Worldwide Business Development  
GlaxoSmithKline

**Deliverable:** Summary of financing and exit strategy.

### **Class 14 – April 21, 2011 Reality**

Macro forces including the economy, capital markets, regulatory environment and healthcare expenditures are shifting more rapidly than perhaps anytime in the history of biotechnology industry. With particular attention to the current environment, in this lecture, we will discuss how entrepreneurs need to take this into consideration when crafting and pitching their plans.

**Speaker:**       **Gary Kurtzman**

**Deliverable:** Profile; and if possible, names of most likely development and/or distribution partners – with rationale.

**Business Plan/Investor Presentations – April 28 and 29 (possibly April 30), 2011**

Time will be set aside at the end of classes for teams to pitch their plans to individuals from the venture capital community.