THE WHARTON SCHOOL
University of Pennsylvania
HEALTHCARE ENTREPRENEURSHIP
HCMG 867-401
SPRING 2010
Thursdays 4:30-6:30 PM JMHH 255
Syllabus Date: 01/11/2010

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OVERVIEW

The goal of the course is to give the 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 21, 2010)**. Course instructors, TAs, staff and mentors will assist student in selecting their projects through relationships with Penn Medicine and HUP, local technology transfer offices as well as through organizations such as

BioAdvance, the University City Keystone Innovations Zone, the Science Center, and 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 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 14, 2010 Organizational Session/The Business Plan

The first course meeting will include (i) a discussion of course goals, (ii) the theory and practice of preparing a business plan and (iii) an organizational session to review teams and projects and to discuss the deliverables for the semester.

Speaker: **Jeff Libson**

Class 2 – January 21, 2010 Founding a Life Sciences Company – Class Discussion

Speaker: **David Scheer**
President
Scheer And Co.

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 28, 2010 <u>Company Presentations – Class Discussion</u>

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

Same class description as January 22, 2009

Class 4 – February 4, 2010 <u>Technology Sourcing</u>

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: **Louis P. Berneman, Ph.D.**
President and CEO
Texelerate, Inc.

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

Class 5 – February 11, 2010 <u>Patents – Importance to Life Sciences Ventures</u>

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 18, 2010 <u>Regulatory Influences</u>

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 25, 2010 <u>Clinical Development Strategy and Tactics</u>

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: **Gerri Henwood, Ph.D. -** Therapeutics focus
CEO
Garnet Biotherapeutics, Inc.

Jeffrey O'Donnell – Device focus
CEO
Embrella Cardiovascular

Deliverable: One-page summary of expected regulatory process

Class 8 – March 4, 2010 <u>Market Analysis</u>

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: **Christopher Bunting**
Vice President, Marketing and Sales
Avid Radiopharmaceuticals

Deliverable: One-page summary of expected clinical development plan

Class 9 – March 18, 2010 <u>Health Economics and Reimbursement</u>

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

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

Class 10 – March 25, 2010 <u>Management, Scientific Advisory Boards & Corporate Governance</u>

A team of Wharton students, engineers and scientists are a great start in the development of an early stage company, but investors may not be prepared to fund lightly experienced student entrepreneurs. Forming the management team, building a board, and developing a strategy for seeking funding are critical for a focused life science start-up.

Speaker: **Jeff Libson**

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

Class 11 – April 1, 2010 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: **Ron Spair**
Executive Vice President - COO and CFO
OraSure Technologies, Inc.

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

Class 12 – April 8, 2010 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: Preliminary budget and financial projections through exit.

Class 13 – April 15, 2010 Financing and Exits

There are different strategies for financing and exiting 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 through its complete life cycle. We will discuss founder/angel and venture capital and other sources of equity and non-equity funding. Finally, we will discuss different endpoints as a point of reference for crafting the early strategy of a company.

Speaker: **Richard Kollender**
Partner
Quaker BioVentures

Deliverable: Profile, and if possible, names of most likely development and/or distribution partners - with rationale

Class 14 – April 22, 2010 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.

Speakers: **Gary Kurtzman**

Deliverable: Summary of financing and exit strategy

Business Plan/Investor Presentations – April 30, 2010

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