

THE WHARTON SCHOOL
University of Pennsylvania
HEALTHCARE ENTREPRENEURSHIP
HCMG 867-401
SPRING 2014
Wednesdays 4:30-6:30 PM – JMHH Room 255
Syllabus Date: 01/08/2014

INSTRUCTORS

Gary J. Kurtzman, MD
Managing Director, Life Sciences
Safeguard Scientifics
o: 610.975.4929
c: 610.716.3337
gkurtzman@safeguard.com
kurtzman@wharton.upenn.edu

Jeffery P. Libson
Partner/Head of Life Sciences Practice
Pepper Hamilton LLP
o: 610.640.7825
c: 610.517.0167
libsonj@pepperlaw.com
libson@wharton.upenn.edu

TEACHING ASSISTANTS

Sri Kotte skotte@wharton.upenn.edu
Steve Sweeny ssweeny@wharton.upenn.edu
Dalton Wright daltonwr@wharton.upenn.edu

OVERVIEW

The goal of the course is to give students the hands-on experience of establishing a healthcare or life sciences business by, among other things, working as part of a mentored group to craft and defend a business plan based on an actual technology or service in the space (defined as therapeutics, diagnostics, medical devices, or healthcare IT services). 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, therapeutics, device/diagnostics, health IT and investor communities, as well as service providers, will present relevant major themes in life sciences/health care 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, DVM, PhD candidates and 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 responsibilities of students taking the course for credit.

BUSINESS PLAN AND PRESENTATION

The primary deliverables are a pitch to a panel of investors (to include a PowerPoint presentation) and a written business plan highlighting the essential features of the business, market, competition, operating plan and financial projections, etc. and a separate executive Summary of the business plan. **The Executive Summary and the Investor PowerPoint presentation are due on April 23, 2014 and the final Business Plan is due on April 30, 2014.** 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 29, 2014).** Course instructors, TAs, staff and mentors will assist student in selecting their projects, where needed, through relationships with Penn, Penn Medicine and HUP, other technology transfer offices, as well as through other support organizations and 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 business plan or of significance to a life sciences or health care 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 mandatory and monitored.** 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: 30%; Class and team participation and interim deliverables: 30 %. *Notes: (1) Students will also evaluate their own 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.* Grading on a pass-fail basis is discouraged and will only be permitted with the consent of the professors.

ENROLLMENT:

Enrollment will be by application.

Class Schedule and Assigned Readings

Class 1– January 22, 2014 - A Venture Story (Part 1)

On the path from inception to successful product/service commercialization, there are many more stories to be told than there are companies that have been formed. The instructors have selected examples (one at the beginning and one at the end of the semester) from the life sciences and health services communities and have invited the founders or other principals to 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 the creation and execution of their ventures. We will also discuss how these examples may be illustrative of entrepreneurship in the life sciences and health services industries, and their relevance to the student projects.

Speaker: **Eric Heil**
 President & CEO
 RightCare Solutions, Inc.

Class 2 – January 29, 2014 – The Health Care Ecosystem

Based on the ~\$3 trillion that the U.S. spends on health care, the U.S. health care system would rank as the 6 largest economy in the world based on spend. Uncontrolled growth is not sustainable, and we can neither spend nor save our way out of this predicament. We need to find practical as well as innovative solutions that improve quality and save money. The entrepreneur's dilemma is to develop those innovative products and services within a rapidly shifting environment for customers. This lecture will serve as an overview of the perspectives and needs of the customers today and how these may change in the future. Case studies will be discussed.

Speaker: **Gary Kurtzman**
 Ming Fang WG'09

Deliverable: Project/Technology Summary

Class 3 – February 5, 2014 – IP – Branding and Patent Basics

Every start-up needs to consider what barriers to entry it can erect to deter competition. For a therapeutics start-up, this can include intellectual property, regulatory exclusivity, and trade-secrets/know how. On the health IT and services side, barriers can be softer or even non-existent, and often the only advantage is branding, critical mass, or being the first mover. Intellectual property rights can create barriers to entry that may affect 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 session, student teams will discuss their IP issues, along with possible strategies and tactics with our guest lecturer.

Speaker: **Joe Guagliardo, Esq. - Partner**
 John Zurawski, Esq. - Associate
 Pepper Hamilton LLP

Deliverable: One page project description including value proposition.

Class 4 – February 12, 2014 - Regulatory Influences

Many life sciences/healthcare businesses, whether active in a more traditional therapeutics role or pursuing healthcare IT products, are directly regulated or heavily influenced by government entities such as the FDA and CMS. In this lecture, we will provide an overview of the FDA's policies, regulations and practices with respect to product/service development and commercialization.

Speaker: **Janice Hogan, Esq.**
 Partner
 Hogan Lovells

Deliverable: List of key IP and/or licensing issues

Class 5 – February 19, 2014 – Team Building - Board and Management Relations

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. Creating and nurturing the right culture, building the management team, developing a board, and evolving an HR strategy are critical for a focused life science/health services start-up.

Speaker: **Jeff Libson**

Deliverable: If relevant to project, one-page summary of expected regulatory process; groups must define the predicted regulatory pathway for their venture, including what trial data or outcome research will be required to successfully launch their product.

Class 6 – February 26, 2014 - Market Analysis and Reimbursement

Many companies fail because they do not fully understand the true (“addressable”) markets for their products, who the customer is and who will pay for the product or service. In this lecture, we will present and discuss the factors that go into determining the appropriate market elements and reimbursement issues; along with what potential investors will expect to see.

Speakers: **Eric Stone and Pitou Devgon**
Entrepreneurs
Creative Vascular, Inc.

Deliverable: What does your organization look like now and over the next couple of years? What skill sets do you need? Which of these skill sets needs to be employed by your company, and which can be accessed through consultants, advisors, etc. Propose a “value statement” for your organization.

Class 7 – March 5, 2014 – Finance

There are different strategies for financing life sciences and health services ventures. In this lecture, we will present and discuss the continuum of financing for 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.

Speakers: **Richard Kollender**
Partner
Quaker Partners

Deliverable: Draft market model. Include one-page summary of what channels will drive commercialization initially, and what channels represent opportunities for future growth. Who is the customer and payer? How do or will you make money? How much could you make?

Class 8 – March 19, 2014 – The Patient/Consumer

Today, the provider is still the focus of the healthcare universe. Patients still defer most of the decisions about health and wellness to physicians and other healthcare professionals. As the cost burden and decision making is being rapidly shift to patients as “consumers” of healthcare, they need the tools to make decisions about their healthcare. This shift is also leading to an increasing emphasis on wellness. A number of tools and services are coming to market to help patients avoid unnecessary interactions with the healthcare system. In this lecture, the class will gain some perspective on this shift and how it will give rise to new business models and opportunities.

Speaker: **Michael Sturmer**
Consumer Health Engagement
CIGNA

Deliverable: What is the financing path for the company and an estimate of the magnitude of funding required at each step of the companies development or product path. Who are the likely sources of capital at each stage?

Class 9 – March 26, 2014 – Payment and Reimbursement

Private and public payers are critical stakeholders in the healthcare continuum, and the ultimate customers for a large portion of the products and services sold by life sciences and health IT companies. In this lecture, we will provide insights into payer interests and issues and how the goals of payers need to be considered in crafting a business plan, as well as the target profile of your product or service. We will also attempt to give you a sense of the shifting landscape and changing models for healthcare payment going forward

Speaker: **Marc Samuels**
President and CEO
ADVI

Deliverable: How will your product or service be affected by decisions made directly by patients or consumers?

Class 10 – April 2, 2014 – Pharma

The pharma model, business practices, finances, and cost of capital are in a state of flux. Pharma has been an important partner or acquirer of biopharmaceutical companies and/or products. While pharma has been focused on the lifecycle management of drugs, they are moving into an era that includes lifecycle management of patients. Pharma is also becoming an increasingly important customer for health IT and services focused in areas such as data analytics and physician and patient engagement. In this lecture, you will hear pharma’s perspective on the types of products and services that are under consideration, and where pharma perceives value.

Speaker: **Ad Rawcliffe**
SVP Finance North American Pharmaceuticals
GlaxoSmithKline

Deliverable: How will your product or service be affected by decisions made by payers? When and how do you plan to engage payers about your product or service? From the payer’s perspective, what is new, relevant and important about your product or service? What will Payers gain or lose from your innovation? What substitutes do payers currently consider? What will you need to prove to attract payer interest, and how will you achieve those goals?

Class 11 – April 9, 2014 – Compliance Issues

Government laws, rules and regulations can have significant influence on the business/revenue model of the venture, as well as its operation. These laws, rules and regulations are applicable to (and can impose risk on) the entrepreneur, as well as the venture. In this lecture, we will provide an overview of the compliance landscape (HIPAA, data privacy, meaningful use, payer/pricing, reimbursement, and marketing), along with risk mitigation strategies.

Speaker: **Sharon Klein, Esq. and John Devine, Esq**
Partners
Pepper Hamilton LLP

Deliverable: None this week

Class 12 – April 16, 2014 – A Venture Story (Part 2)

See description for Class 1 – January 22, 2104

Speaker: **Josh Benner**
President & CEO
RxAnte, Inc.

Deliverable: If relevant to project, one-page summary of expected compliance issues.

Class 13 – April 23, 2014 – The Provider

The provider, whether it is a hospital, physician or another healthcare professional, makes decisions about what products and/or services get utilized. Providers make these decisions not only in the context of seeking to deliver quality care, but also in the context of actual business considerations (e.g., profit/loss). In this lecture, the class will hear the perspective of this important customer.

Speaker: **Ronald A. Paulus, MD MBA**
President and CEO
Mission Health System

Deliverable: *Executive Summary and PowerPoint pitch for the Investor Presentation*

Class 15 – April 30, 2014 – Course Synthesis – Preparation for Presentations

Speakers: Gary Kurtzman and Jeff Libson

Deliverable: Final Business Plan

*****Business Plan/Investor Presentations – May 2, 2014- All Day – Times TBD*****

Time will be set aside at the end of classes for teams to pitch their plans to investors and others from the venture capital/finance communities.