# THE WHARTON SCHOOL

University of Pennsylvania

# HEALTHCARE ENTREPRENEURSHIP

HCMG 867 SPRING 2017

Tuesdays 4:30-6:30 PM – JMHH Room 245

**Syllabus Date: 11/3/2016** 

## **INSTRUCTORS**

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**TEACHING ASSISTANTS** 

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**OVERVIEW** 

The goal of the course is to give students the hands-on experience of establishing and operating an early-stage 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 digital health 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, craft a business plan and pitch presentation, and read "The Hard Things About Hard Things" by Ben Horowitz. Class discussions, led by course instructors as well as individuals drawn from the entrepreneurial, therapeutics, device/diagnostics, digital health and investor communities, as well as service providers, will present relevant insights impacting strategic, execution, and financing risks for early stage healthcare ventures.

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**

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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 Business Plan and the Investor PowerPoint presentation are due on April 29, 2017. 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 24)**. Course instructors, TAs, staff and mentors will assist student in selecting their projects, where needed, through relationships with Penn, Penn Medicine and 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 who will have a relevant technical background. In addition, members of the Penn Biotech Group, other groups and 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 "LUNCH & LEARNS"

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 digital health 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.

In addition, we are planning to provide background on some core areas such as intellectual property, compliance, etc. through "lunch and learn" programs that will be recorded and then made available to students through Canvas for subsequent viewing. To be respectful to the speakers, we are asking that students attend at least one of these lunch and learns.

#### 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**

# Class 1- January 17, 2017 - Healthcare Venture Lifecycle

Considering starting a company or joining an early-stage start-up in healthcare? Where and how to get started? Healthcare ventures go through a number of phases from idea generation, proof of

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concept, initial market traction, expansion, and exit. In the case of a life sciences or digital health venture, the phases are more often characterized as research/design, proof of concept, clinical development and approval, and commercialization with exit a possibility at an inflection point, usually stage changes, influenced by market dynamics. Hybrids between the two also exist. In this lecture, we will discuss these phases, business models (including B2B, B2C, solutions, platforms, etc.), and key attributes to consider before getting started. The goal is to provide context for crafting your plans and to set the stage for the rest of the course.

There are different strategies for financing life sciences and digital health 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. We will also talk about "pitching" to funding sources and include a live pitch for the class.

A portion of this class will also be dedicated to a course introduction and to assisting students select group projects.

Speaker: Gary Kurtzman, Jeff Libson, Eric Heil

## Class 2 - January 24, 2017 - Market Need & Strategic Risk

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. Uncontrolled growth is not sustainable, and neither spending nor cost-cutting will help us find our way out of this predicament. We need to find practical, as well as innovative, solutions that help achieve the Triple Aim – increase access, improve quality and lower costs. The entrepreneur's dilemma is to develop those innovative products and services, in a highly regulated industry, within a rapidly shifting environment for customers. This lecture will serve as an overview of the perspectives and needs of one customer today and how these may change in the future.

Speaker: TBD (KEYNOTE)

Deliverable: Problem and Unmet Need Overview and Product Description

Read: Chapter 1 & 2 - From Communist to VC, "I Will Survive", p1-38

# Class 3 - January 31, 2017 - Start Up Space - Product Design - MVP

"How can we walk away from requirements that we know to be true to pursue something that we think will help?" It turns out that is exactly what product strategy is all about—figuring out the right product is the innovator's job, not the customer's job. The customer only knows what he/she thinks they want based on their experience with the current product. The innovator can take into account everything that's possible, but often must go against what she knows to be true. As a result, innovation requires a combination of knowledge, skill, and courage. Sometimes only the founder has the courage to ignore the data. In this lecture, we will discuss various product design concepts, development methodologies for various types of healthcare solutions, and scaling challenges. In addition, the lecture will identify and address the risks and issues that often arise in this setting and will discuss strategies for mitigating the risks and overcoming the obstacles.

Speaker: Roy Rosin, Chief Innovation Officer, Penn Medicine

Deliverable: Define Minimally Viable Product (MVP) outline and timeline

READ: Chapter 3 - This Time with Feeling. p39

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# Class 4 – February 7, 2017 – The Tough Stuff, When Things Go Wrong, & Execution Risks

"It's the moments where you feel most like hiding or dying that you can make the biggest difference as a CEO." When you are building a company, you must believe there is an answer and you cannot pay attention to your odds of finding it. You just have to find it. It matters not whether your chances are nine in ten or one in a thousand; your task is the same. In this lecture, we will go behind the closed doors with CEO(s) and discuss the tough times along their journey, what happened, and what worked to get through them.

Speaker: TBD CEOs

READ: Chapter 4 - When Things Fall Apart, p57

## Class 5 - February 14, 2017 - Team Building

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.

Speakers: TBD

READ: Chapter 5 - Take Care of the People, the Products, and the Profits-In that Order, p93

#### <u>LUNCH & LEARN #1</u> - February XX, 2017 - <u>Regulatory Compliance</u>

Similar to data privacy and security, other significant federal and state regulations can influence the business/revenue model of the venture, as well as its operation. Likewise, these laws, rules and regulations are applicable to (and can impose risk on) the entrepreneur, the venture and the exit. In this lecture, we will provide an overview of the regulatory issues that arise in connection with payer/pricing, reimbursement, and marketing. Regulatory schemes discussed will include self-referral (Stark), anti-kickback and fraud & abuse.

Speaker: TBD

# Class 6 - February 21, 2017 - Hospitals & Health Systems and Post Acute Providers as a

The provider, whether it is a healthcare system, hospital, physician or other 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 other business considerations (operating efficiencies, resource optimization, profit/loss and risk mitigation). In this lecture, the class will hear the perspectives of this important customer, learn about typical sales cycles, hurdles, and processes.

Speakers: TBD

Read: Chapter 6 - Concerning the Going Concern, p143-169

Class 7 – February 28, 2017 – Pharma as a Customer

#36282479 v1 4 The business model of "big pharma" is under pressure as company's struggle with the issues of product pipeline, patents and patent expiration, the regulatory environment affecting clinical development and product approvals, as well as pricing and reimbursement. Pharma companies are increasingly looking to information technologies, data and digital health technologies to identify issues and formulate solutions. In this lecture, we will discuss the industry (internal and external forces) and the strategies and tactics for doing business with them.

Speakers: TBD

Read: Chapter 6 - Concerning the Going Concern, p170-196

#### Class 8 - March 14, 2017 - Payers as a Customer

Many entrepreneurs, when talking about their customers, often speak of payers and provider organizations rather generically. As the adage goes, "if you understand how to sell to one provider, you understand how to tell to one provider." The same goes for payers. In reality, these are complex organizations containing many potential points of contact each with their own motivations, budgets and priorities. The goal of this lecture will be to highlight the various constituencies and stakeholders within these organizations to better understand how to approach them with a product or service offering

Speakers TBD

Read: Chapter 7 - How to Lead Even When You Don't Know Where You are Going, p197-223

#### **Class 9 – March 21, 2017 – Pitch Day**

Review interim plans including elevator pitches and discussion. Bring in entrepreneurs to discuss. Consider having a few entrepreneurs come in and pitch their companies

# Class 10 – March 28, 2017 – Patients as a Customer

The healthcare industry is shifting to a more customer-focused culture not only because of healthcare reform provisions, but also because patients themselves are changing and forcing providers to respond. There is a "rising tide of consumerism" in which patients are becoming more demanding of providers, payers, med device, and pharma organizations.

Speakers TBD

Read: Chapter 7 - How to Lead Even When You Don't Know Where You are Going, p224-242

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# LUNCH & LEARN #2 - March XX, 2017 - Data Privacy and Security

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 fast-moving regulatory landscape of data privacy and data security.(HIPAA, data privacy, meaningful use, payer/pricing, reimbursement, and marketing), along with risk mitigation strategies.

Speaker: Sharon Klein, Esq., Pepper Hamilton LLP

# Class 11 - April 4, 2017 - Digital Health

The next three lectures will be devoted to the stories of entrepreneurs and entrepreneurial organizations in sub-segments relevant to the theme of this course. The emphasis will be on experiences that highlight the practical, and often emotional, journey of launching and scaling the entrepreneurial venture.

Eric Topol, cardiologist and author of The Creative Destruction of Medicine, defines as digital technologies, social networking, mobile connectivity and bandwidth, increasing computing power and the data universe converging with wireless sensors, genomics, imaging, and health information systems to creatively destroy medicine as we know it. Digital health seed fund Rock Health further explains that digital health encompasses both Health 2.0 (B2C) and Digital health (B2B). This lecture will help further define digital health and discuss the issues in launching digital health tools into the healthcare ecosystem.

Speakers: TBD

Deliverable: Interim project progress report/needs assessment/Business Plan Outline Read: Chapter 8 – First Rule of Entrepreneurship. There are No Rules, pg243

# LUNCH & LEARN #3 - March XX, 2017 - IP & Branding

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 digital health 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 <u>can</u> 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, our guests will provide background information and developing an IP strategy.

 ${\bf Speakers:} \qquad {\bf Joseph~Guagliardo, Esq~and~John~Zurawski, Esq,}$ 

Pepper Hamilton LLP

# Class 12 – April 11, 2017 – Medtech Stories

Medtech is defined as medical devices and diagnostics. While some of the products in this space can be developed rapidly and without a cumbersome regulatory process, others are more complex with paths more akin to biopharmaceutical products. As a result, the journey for a medtech

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venture is quite diverse and can be exceedingly complex. In this lecture, we will explore that journey and its drivers.

Speakers: TBD

Deliverable: Wireframe of investor pitch

Read: Chapter 9 -The End of the Beginning, p265

# Class 13 - April 18, 2017 - Seed/Venture Financing

There are different strategies for financing life sciences and digital health 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. We will also talk about "pitching" to funding sources and include a live pitch for the class.

Speaker: TBD

 $Class\ 14-April\ 25, 2017-\underline{Industry\ Trends\ and\ Course\ Reflection-Preparation\ for\ \underline{Investor\ Presentations}}$ 

Speakers: Gary Kurtzman, Jeff Libson, and Eric Heil

Class 15 – May 2, 2017- Final Pitch Day – All Day

**Business Plan/Investor Presentations - Group Times TBD\*\*\*** 

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