

COURSE SYLLABUS

15.363 Strategic Decision Making in the Life Sciences and Digital Health Industries

Professors:

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Wednesdays 5:30pm – 8:30pm E51-315 9 units (3-0-6)

Professor Fleming's Background

Mr. Fleming is currently the Chief Business Office and a member of the Board of Q-State Biosciences, a privately funded precision medicine for the brain company in Cambridge MA. Q-State uses its proprietary technology platform to enable the discovery of new medicines for diseases such as ALS, epilepsy, neurodevelopmental disorders and neuropathic pain. He is also a co-founder and Chairman of the Board of QurAlis – an ALS precision medicine company, and Enclear – developing a CSF dialysis therapy for neurodegenerative diseases. Since 1996, Mr. Fleming has been the Managing Partner of Oxford Bioscience Partners, an international venture capital firm specializing in life science investments, which raised over \$1 billion in early stage capital resulting in 21 IPOs and over 40 M&A transactions. Mr. Fleming has been a life science entrepreneur for more than 33 years, starting and financing growth companies in the United States, Europe, Israel and Asia. During his career Mr. Fleming co-founded several neuroscience companies that were later acquired including: Synaptic Pharmaceuticals (acquired by Lundbeck); Memory Pharmaceuticals (acquired by Roche); and Hynion Pharmaceuticals (acquired by Lilly). Mr. Fleming is currently a director of MIT spin-outs SQZ Biotech and Continuum Pharmaceuticals. He is the Chairman of the Board of a Cape Cod based commercial shellfish hatchery, Aquaculture Research Corporation. Since 2005 he has been on the executive board of a health care policy think tank based in Cambridge called NEHI. Mr. Fleming has been a Senior Lecturer at the MIT Sloan School of Management since 2002. He holds a MPA from Princeton University's Woodrow Wilson School of Public and International Affairs, and a BA from the University of California, Berkeley.

Professor Zarur's Background

Dr. Zarur is Co-Founder, Chairman & CEO of GreenLight Biosciences. His is also a co-founder and Chairman of the Board of Solid Biosciences (NASDAQ:SLDB). Dr. Zarur has been active in early stage life sciences companies for over 20 years, and has actively participated in the creation of over a dozen companies in the healthcare and clean energy sectors. He is also a partner at Kodiak Venture Partners, a venture capital firm specializing in the formation of early stage information and life technology investments. Prior to joining Kodiak Venture Partners, he was founder and CEO of BioProcessors (now part of Agilent Technologies). In addition to BioProcessors, he has led four life science companies from inception to exit. He is also a co-

founder and chairman of the board for Lumicell, and chairman of the board for Allegro Diagnostics. Dr. Zarur was named a Young Global Leader of the World Economic Forum in 2005, and he is an Overseer of the Museum of Science in Boston and a Senior Lecturer at MIT Sloan School of Management. Dr. Zarur holds Masters of Science degrees and a Ph.D. in Chemical Engineering from the Massachusetts Institute of Technology, and undergraduate degrees from the National University of Mexico. Dr. Zarur is the author of several peer-reviewed articles and holds close to 100 provisional and issued patents.

Aim: “Strategic Decision Making in Life Sciences” examines the key strategic decisions faced by entrepreneurs, managers and investors at each stage in the value chain of life science technology-based industries. The course aims to develop your ability to understand and effectively use analytical tools and industry knowledge to make good strategic decisions. Successful careers are based on good strategic decision making. The course will teach value creation in the life sciences industry for companies at various stages; from inception of a new company, through clinical development; from commercialization and reimbursement, through exit and value capture. The course will apply to strategic decision making in 4 different sectors within the life sciences: Drugs/biologics, next generation therapies, digital health, medical device/companion diagnostics. This course is intended for anyone interested in building a life science company or working in the life sciences industry as a founder/entrepreneur, senior industry executive, analyst/consultant or professional investor. It will also provide an analytical background to the industry for biological and biomedical scientists, engineers and physicians with an interest in understanding the commercial dynamics of the life sciences or the commercial potential of their research.

Course Description: The course is structured around the life sciences industry value chain from early stage scientific ideas, through licensing, financing and valuation, to discovery, clinical trials, production and sales. The foundations of the course provide a thorough understanding of the economics, risks and competitive dynamics at each of these distinctive stages of the value chain. It also highlights the critical problems and current issues at each stage. The two instructors combine to have over 50 years of experience in strategic decision-making in the life sciences industry. All of the case studies and examples are based on companies and transactions in which the professors were directly participating in some way. This series of structured, real-world problem-solving exercises will show the application of analytical tools for strategic decision making to a wide range of problems confronting the life sciences industry. Some of the tools used in the course include value chain decision trees, pipeline valuation, alliance valuation, drug adoption and lifecycle predictions, market assessments etc.

Course Organization: The course is held once a week on Wednesday evening from 5:30pm – 8:30pm in E51-315. Each week is organized into two periods. There will be 13 sessions in total.

Course Requirements: The course will center on analytical homework assignments, to be done in teams of (3-4), that will provide you with a chance to gain hands-on experience in using strategic decision-making methods. The homework and group projects are based on real life problems taken from life science firms. The mid-course project will consist of two phases: 1) a take-home team project and 2) an in-class negotiation between teams that will be prepared prior to class.

Dinners: The TAs will be ordering dinner that will be delivered during the break in each class.

15.363 COURSE DETAILS

Course Requirements & Grading

The course is intended to be a seminar with a lot of interaction as is reflected in the grading schema. Grades will be strongly determined by your class participation, which will depend upon thorough preparation, including relevant homework assignments. The grading schema is as follows:

a) Attendance & Class Participation (20%)

This class follows a seminar format with the discussion often built around case study material. It will therefore be impossible to understand the material if you do not come to class or if you do not participate. Skipping class will affect your grade - and, more importantly, - your own and your classmates' experience in the class. If you miss more than two sessions during the semester it will severely impact your class participation grade.

b) Homework Assignments (45%)

A significant portion of the grade is awarded to a series of homework assignments which will include a mix of both qualitative and quantitative analysis. Homework should be completed in groups of 3-4 people, and one copy of the homework should be submitted for each group. Groups must include at least one non-Sloan person (numbers permitting). The written analysis and spreadsheets are due in the Homework section of Stellar by 5:30pm on the designated due date.

c) Group Project (35%)

There will be one midterm group project requiring a more lengthy written analysis. This project should be completed in groups of 3-4. The groups will be asked to take the perspective of a seller or buyer in doing their analysis. In the first half of the project, the group will be responsible for only one perspective. For the in-class negotiation, the groups will be expected to understand the nuances of strategic decision making depending on the point of view of the decision maker.

Course Material

There will be some assigned readings posted on Stellar. These readings are intended to bring students with limited experience in the life sciences industry up to speed in order to allow for more advanced discussions during class sessions.

Course Norms and Expectations

Professional conduct is built upon the idea of mutual respect. Such conduct entails (but is not necessarily limited to the following):

Name cards: Please obtain a name card for yourself that contains your first and last name. We will eventually get to know all of your names but it will take us some time.

Arriving on time: Class starts at 5:35 PM. Because of the layout of our classroom, late arrivals are disruptive. Please try hard to be on time. If you know you are going to be late or will need to leave class early, please let us know in advance, if possible.

Minimizing disruptions: All cell phones and computers should be turned off during class. Please try to avoid engaging in side conversations after the class has begun.

15.363 COURSE READINGS

Required Readings:

The course is built around a series of analytical case studies and related homework assignments. In addition, there will be readings that include relevant articles and commentary from a combination of academic journals, the press and industry publications. These are intended to provide more in-depth analysis as well as relevant commentary or debate. Due to increasing concern about the environment and economy, we will not be creating a course reader this semester and will instead post all required readings and cases on Stellar.

Software:

One of the main goals of the class is to encourage the use of analytical and financial tools to enable solid decision making in life sciences. Decision trees are an invaluable resource for understanding and evaluating potential scenarios leading to desirable outcomes. Although conventional spreadsheet software tools, such as Microsoft Excel, can be used to construct decision trees, there are several dedicated software packages that facilitate their creation and understanding, and provide additional functionality in terms of statistical and sensitivity analysis. We have negotiated a special academic price (\$40 for a 6 month license) with one of the leading distributors of decision-making software called TreeAge Pro. Students are encouraged to obtain the software prior to the first lecture by logging into www.treeage.com/shop/ - under TreeAge Pro Suite, choose "Academic" and then "Student Course License."

15.363 Course Outline

Week	Class A	Class B	Assignments
MODULE I: TOOLS FOR STRATEGIC DECISION-MAKING			
1 Feb 6	<p>Class Introduction: Strategic Decisions in the Life Sciences Industry <i>Jonathan Fleming, Andrey Zarur</i></p> <p>The objectives of the class will be discussed. Key strategic decisions for life science and digital health executives and investors that determine success/failure are identified. The concept of The Value Chain will be introduced. The key to good decision making is understanding how the value of products and companies gets created as products move from concept through development, testing, approval and market launch. The problems of uncertainty of outcome and uncertainty of value are explained.</p>	<p>Analytical Decision-Making Tools – Decision Trees <i>Andrey Zarur</i></p> <p>This lecture will review the main tool used in this class: The Decision Tree. Based on our experience participating in hundreds of management team and board of directors meetings either as a founders, CEOs, VCs or independent directors we know the critical value of building accurate and sophisticated decision trees to help groups make good strategic decisions. An example of strategic decisions over the course of a biotechnology product launch will be covered in class.</p>	
2 Feb 13	<p>Perspective of the Analyst <i>Andrey Zarur</i></p> <p>Examples will be shown where the Perspective of the Analyst (Founder/CEO/Investor/Corp. Partner) affects the outcome of the strategic analysis. Understanding the different perspectives of the board members, investors, management team members and corporate partners in strategic discussion increases the chances of success in negotiations and decision making. Professor Zarur has played every one of these roles and knows that different perspectives generate different outcomes on the decision tree!</p>	<p>How cost and value is measured in health care. Rapid change creates opportunity and uncertainty <i>Andrey Zarur, Jonathan Fleming</i></p> <p>How is cost measured in healthcare system? What is the breakdown of costs in the system – where does the money get spent? How is value determined for products and companies in the life science and digital health space? What is the impact of recent regulatory and legislative changes on the value of healthcare products? What role is being played by value-based contracts? Why does this matter in strategic decision making in the life sciences?</p>	HW 1 Assigned
3 Feb 20	<p>Financial Analysis Tools and Fundamentals of Strategic Decision Making <i>Andrey Zarur</i></p> <p>The primer on strategic decision making will cover key concepts in strategic analysis and financial decision making. Strategy concepts covered will include the classic “Porters Five Forces” framework. Financial concepts covered will include cash flow analysis, “Net Present Value” and decision trees which account for the probability of different outcomes and different paths over the life of a project.</p>		HW 1 Due HW 2 Assigned
4 Feb. 27	<p>The Value Chain in the Pharmaceutical and Biotechnology Industry <i>Jonathan Fleming</i></p> <p>This lectures teaches the milestones in development of a life science product from Bench to Bedside and how value is calculated despite the lack of revenues or profits to use as the basis of value. Each step of the product development pipeline will be described and the amount of value it does or does not contribute to the enterprise or project.</p>	<p>The Value Chain for Next Generation Therapeutics <i>Andrey Zarur and Jonathan Fleming</i></p> <p>Gene therapy, ASO based therapies, other cell based therapies such as CAR-T are exploding in number, capital raised, number of clinical trials. These new products present quite different challenges and strategic decision making. The differences from traditional product Value Chains these new technologies create will be highlighted.</p>	
5 March 6	<p>Clinical Trial Strategies <i>Andrey Zarur</i></p> <p>Clinical trial strategic decisions are quite complex and involve trading off multiple uncertainties. Decision makers must optimize for time, cost, highest probability of success, patient recruitment and many other factors. The size and business strategy of the enterprise will also impact the strategic decision making for a clinical trial. The use of the course tools from the decision tree, the value chain, the financial modeling, the perspective of the analyst – all come together when making complicated clinical trial design decisions with huge uncertainty at every step of the process. Prof. Zarur has faced these decisions in his professional career many times. He will teach how to apply the tools of the course to this most critical strategic decision.</p>		HW 2 Due
6 March 13	<p>Capital Markets and Financing Strategies <i>Jonathan Fleming</i></p> <p>Life science companies require enormous amounts of capital to bring their products to market. Success for all players in the industry – from founders to entrepreneurs to CEOs to corp.</p>	<p>Pricing and Reimbursement Strategies <i>Jonathan Fleming and Andrey Zarur</i></p> <p>Pharmaceutical and medical device pricing has come under significant additional scrutiny in the past few years. In this class we will discuss how pricing is determined as well as innovative new pricing strategies</p>	Mid-term Assigned

	execs requires a sophisticated understanding of the wide variety of types of capital available and the cost and benefits of each type of capital. Professor Fleming has spent more than 30 years financing life science companies across the globe. Funds under his management made more than 100 investments in early stage life science companies.	that are being considered. The effect of the Affordable Care Act on reimbursement and the future of the healthcare industry will also be discussed. Examples of specific value based contracts will be analyzed and the strategic decision making behind them discussed.	
March 20	No Class - Sloan Innovation Period		
March 27	No Class - Spring Break		
7 April 3	In-Class Project Negotiation and Project Review <i>Andrey Zarur</i>		
8 April 10	The Value Chain in Digital Health Businesses <i>Jonathan Fleming and Andrey Zarur</i> <i>The broad spectrum of digital health businesses will be described, and some common strategic issues identified. The value chain for these types of business models will be analyzed and key milestones identified. The class will analyze several different types of digital health care business models and the strategic decisions required for success in those models</i>		HW 3 Assigned
9 April 17	The Value Chain in Digital Health Businesses <i>Jonathan Fleming and Andrey Zarur</i> This class will continue with the lecture of the previous week with a focus on different types of digital health business models with specific examples designed to demonstrate use of the strategic decision making tools for these types of strategic decisions	Commercialization and Partnership Strategies for Digital Health Businesses <i>Jonathan Fleming and Andrey Zarur</i> Professor Zarur and Fleming have been involved in numerous strategic decisions involving partnering and commercialization. Key strategic decisions face life digital companies as they go to market through partnerships or with their own sales force.	
10 April 24	Strategic Decision Making for Diagnostics and Personalized Medicine <i>Andrey Zarur and Jonathan Fleming</i> Both professor Zarur and Professor Fleming have been involved in bringing novel products and services to successfully to market in this field. Strategic decisions, financing and regulatory considerations for diagnostics will be discussed. The emerging market for and future of personalized medicine will be discussed.		HW 3 Due
11 May 1	Strategic Decision Making in the Medical Device Industry <i>Jonathan Fleming</i> Professor Fleming has made dozens of investments in this area. The Medical Device Industry will be described. The value chain for devices will be presented. Strategic decisions, financing and regulatory considerations for medical devices will be discussed – especially as to the differences with drugs.		HW 4 Assigned
12 May 8	Exit Strategies <i>Jonathan Fleming</i> Funds or companies managed by the professors have been involved in more than three dozen IPOs and more than 50 M & A transactions. Key considerations for exiting through M&A and IPO transactions will be discussed.		HW 4 Due
13 May 15	Course Keynote and Wrap & Up <i>Invited Speaker (TBD), Andrey Zarur and Jonathan Fleming</i>		