COURSE SYLLABUS

15.363 **Strategic Decision Making in Life Sciences**

Professors:
Jonathan J. Fleming, Andrey J. Zarur Ph.D.
jfleming@oxbio.com; azarur@kodiakvp.com

Professor Fleming's Contact: Kathleen Moeckel, kmoeckel@oxbio.com.
Professor Zarur's Contact: Laurie Jackson, ljackson@glbiosciences.com

Teaching Assistants:
Tiffany Kuo, Alaina Pleatman
tkuo@mit.edu; pleatman@mit.edu

Spring Semester
Tuesdays 5:30pm – 8:30pm • E51-315 • 9 units (3-0-6)

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 help you make good strategic decisions. The course will explore value creation and strategic decision making in 5 different sectors within life sciences: Therapeutics, Medical Devices, Diagnostics, Healthcare Management, and Novel Applications of Life Science Technologies. It is intended for anyone interested in building a life science company or working in the life sciences industry as a manager, consultant, analyst or 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. Through a series of structured problem-solving exercises you will learn analytical tools for strategic decision making and apply them 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. Critical to the course is the use of industry experts to compliment the analytical discussion and bring real world perspective to decision making under pressure.

Course Organization: The course is held once a week on Tuesday evening from 5:30pm – 8:30pm in E51-315. Each week is organized into two periods. There will be 11 sessions in total. There will also be a **MANDATORY** session on Financial Analysis Tools in week 2 or week 3 (same time, room TBA).

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. If you would like to participate in the class dinners, please bring a check for $100 on the first day of 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.

Background Reading:
There are several books that we recommend as background reading because they give particularly useful insights into the dynamics, politics, human aspects and ethics of the life science industry (especially for those of you who have little or no industry background). They describe the industry from the perspective of a particular company, patient or molecule:

Pisano, G., Science Business, (Boston: Harvard Business School Press, 2006).
Werth, B., The Billion Dollar Molecule, (New York: Simon & Schuster, 1994).

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-2	**Class Introduction: Strategic Decisions in the Life Sciences Industry** *Jonathan Fleming, Andrey Zarur* The objectives of the class will be discussed. The nature of strategic decisions in biomedical businesses will be explored. The concept of the Value Chain in life sciences will be developed. Different verticals within the life sciences industry will be discussed.	**Analytical Decision-Making Tools – Decision Trees** *Andrey Zarur* This lecture will review the main tool used in this class: The Decision Tree. An example of strategic decisions over the course of a biotechnology product launch will be covered in class.	**HW 1 Assigned**
2 Feb-9	**Perspective of the Analyst** *Andrey Zarur* Examples will be shown where the perspective of the analyst (Founder/CEO/Investor/Partner) affects the outcome of the strategic analysis.	**How cost and value is measured in health care?** *Andrey Zarur* How is cost measured in healthcare? How is value determined? Why does this matter in strategic decision making in the life sciences?	**HW 2 Assigned** **HW 1 Due**
TBA	**Mandatory Session – Financial Analysis Tools and Fundamentals of Strategic Decision Making** *Andrey Zarur*		
Feb-16	**President's Day – No Class – Monday Schedule**		
3 Feb-23	**The Value Chain in the Pharmaceutical and Biotechnology Industry** *Jonathan Fleming* A Value Chain describes milestones in development of a life science product from Bench to Bedside and how value is attributed to the project despite the lack of revenues or profits to use as the basis of value. In this lecture the specific milestones are detailed for the development of a therapeutic drug	**Financing Strategies** *Jonathan Fleming* Different sources of financing for life science projects will be described and their strategic implications will be explored. ***Mid-Term Project Assigned***	**HW 2 Due**
4 Mar-1	**Strategic Decision-Making for Pharmaceutical Products** *Jonathan Fleming and Andrey Zarur* Examples of Strategic Decisions for pharmaceutical and biotechnology drugs will be presented and analyzed. The influence of the current capital markets, the IPO window and regulatory changes on the pharmaceutical and biotechnology industries will be discussed.	**Clinical Trial Strategies** *Andrey Zarur* Based on the different goals of a company, the clinical trial design may be different. Different clinical trial design strategies will be discussed.	**Project Progress Report Due**
5 Mar-8	**In-Class Project Negotiation**	**Project Review** *Andrey Zarur*	**HW 3 Assigned**
Mar-15	**SIP WEEK – NO CLASS**		
Mar-22	**SPRING BREAK – NO CLASS**		
6 Mar 29	**Pricing and Reimbursement Strategies** *Jonathan Fleming and Andrey Zarur* 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 that are being considered. The effect of the Affordable Care Act on reimbursement and the future of the healthcare industry will also be discussed.		
7 Apr-5	**Strategic Decision Making for Diagnostics and Personalized Medicine** *Andrey Zarur and Jonathan Fleming* Strategic decisions, financing and regulatory considerations for diagnostics will be discussed. The emerging market for and future of personalized medicine will be discussed.		**HW3 Due**
8 Apr-12	**Commercialization and Partnership Strategy** *Jonathan Fleming and Andrey Zarur* Key strategic decisions facing life sciences companies as they go to market through partnerships or with their own sales force. Emerging importance of communication with multiple stakeholders during this process: regulatory, reimbursement, patient advocacy, physicians.		**HW 4 Assigned**
Apr-19	**PATRIOT'S DAY – NO CLASS**		
9 Apr-26	**Next Generation Therapeutics** *Andrey Zarur and Jonathan Fleming* Gene Therapy, cell based therapies and other next generation therapies will be discussed and the differences from traditional product Value Chains and Strategic Decisions will be discussed	**Strategic Decision Making for Medical Devices** *Jonathan Fleming* The Medical Device Industry will be described. Strategic decisions, financing and regulatory considerations for medical devices will be discussed.	
10 May-3	**Exit Strategies** *Jonathan Fleming* Key considerations for exiting through M&A and IPO transactions will be discussed.		**HW 4 Due**
11 May-10	**Course Keynote and Wrap & Up** *Invited Speaker (TBD), Andrey Zarur and Jonathan Fleming*		

Mandatory Session – Financial Analysis Tools and Fundamentals of Strategic Decision Making

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.