MGMT B8536-001: Strategy and Competition in Pharmaceuticals and Biotechnology

Spring 2019 (B-Term); Tues/Thurs, 10:45am to 12:15pm; Room TBD

Professor: Cliff Cramer
Office: Uris 325C
Email: cc2663@gsb.columbia.edu
Phone: 212.854.2327
Office hours: by appointment

Robert Essner
Office: Uris 211
Email: re2222@gsb.columbia.edu
Phone: 212.854.6100
Office hours: by appointment

Course Overview

This course examines the strategic, technological, competitive, economic, organizational, and political challenges impacting the pharmaceutical and biotechnology industry. Critical issues to be examined include:

- Process of discovering, developing, and the approval of new drugs and biologics;
- Patents on pharmaceuticals and biologics; generics and “biosimilars”;
- Franchise/ R&D portfolio management;
- Sales and marketing objectives and practices;
- Review of oncology therapeutic category, including case study of global launch of novel oncology drug;
- Drug pricing and third-party reimbursement, including design of prescription drug plans and PBMs/contracting;
- Vaccines – development, regulatory, pricing, distribution;
- Orphan drugs – development, regulatory, pricing, patient advocacy;
- Health policy/reform impacting this sector;
- Mergers & acquisitions and licensing in the biopharma sector.

The course is cross-functional in its approach, focuses on “real-world” problems currently facing senior managers in this sector, and identifies emerging trends that will materially impact future performance of “Big Pharma” companies, as well as specialty pharmaceutical and biotechnology firms. This course will be useful for students interested in careers in pharmaceuticals, biotechnology, and health services, as well as management consulting, investment banking, equity research, venture capital, private equity, and investment management given the large and growing healthcare/pharmaceutical practices of such firms.

Connection to the Core

The learning in this course will utilize, build on and extend concepts covered in the following core courses:

<table>
<thead>
<tr>
<th>Core Course</th>
<th>Connection with Core</th>
</tr>
</thead>
<tbody>
<tr>
<td>Corporate Finance</td>
<td>1. Risk</td>
</tr>
</tbody>
</table>
2. Firm Valuation Model

<table>
<thead>
<tr>
<th>Decision Models</th>
<th>1. Decision Making Under Uncertainty and Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Managerial Economics</td>
<td>1. Analyzing Complex Decision-making Under Uncertainty</td>
</tr>
</tbody>
</table>
| Marketing Strategy | 1. Company Analysis  
| | 2. Competitive Analysis |
| Strategy Formulation | 1. Strategic Interaction Analysis  
| | 2. Diversification and Scope  
| | 3. Competing Firms  
| | 4. Global Strategy |

**Format, Approach**

We highly value class participation and will constantly seek to directly apply the information and ideas discussed in the classroom to issues currently confronting senior managers in this sector. We will pursue these critical issues in considerable depth. *Some understanding of, and/or experience in, the healthcare/pharma sector will be highly useful to understand course content and preparing writing assignments.* Prominent guest speakers from the pharmaceutical and biotechnology industry will provide additional real-world insight on key industry challenges and trends.

**Materials, Classroom, Ground Rules**

Certain readings will be distributed in class or posted on Canvas. We will try to have lecture notes available in advance of each class (subject to guest speaker preference). It is important that you attend all classes, arrive on time, and give speakers and your fellow classmates your full attention. If you cannot attend a specific class or have to arrive late let Prof. Cramer know in advance by email. Please refrain from using laptops, IPads, cellphones, etc. in class.

**Course Requirements and Evaluation**

**Class Participation (25%*):** Students will only get out of this course as much as they put in. It is therefore important that students take an active role in classroom activities and discussions and come fully prepared. The class participation grade will reflect class attendance and the quality of the student’s involvement in class discussion. *Note:* adhering to School guidelines, students who miss more than 33% of class sessions due to unexcused absences will receive a maximum grade of “P”; students who miss more than 50% of class sessions due to unexcused absences will receive a “F” in the course.

**Writing Assignment (25%):** For a mid-term writing assignment, students will be given a case study or series of questions for their written analysis and recommendations (2-4 page paper, excluding exhibits). This assignment will be due before class on Apr. 18.
Final Paper (50%): There will be a final paper (3-5 pages, excluding exhibits) on topics reviewed in class during the course. The final will be posted on or about Apr. 18, and be due May 6. Final grade distributions will be consistent with School guidelines for electives (no more than 50% of grades in “H” category; 5-10% in “P” category).

Class Schedule and Topics

The following is the schedule of topics (Note: specific dates, topics and speakers may vary depending on schedules/availability).

Mar. 26th (Tues.) Course Introduction and Industry Overview
- Course objectives, syllabus, readings, exams/grading.
- Environmental assessment and summary of key challenges and opportunities in the global pharmaceuticals business.
- Major strategic issues/alternatives facing executives at “Big Pharma”, specialty pharma, and early-stage biopharma companies.

Mar. 28th (Thurs.) Regulatory Environment, Intellectual Property/ Patents
- Forces shaping the environment (key players and issues)
  - Players: FDA, CMS, OIG, DOJ, States, etc.
  - Issues: safety, pricing, marketing practices, etc.
- Patents on pharmaceuticals and biologics; Hatch-Waxman; “biosimilars”.

Apr. 2nd (Tues.) Clinical Development and the Drug Approval Process – Interactions with the FDA
- Clinical development process and strategies
- Review of drug approval process – U.S. and selected int’l markets
- Strategies re: working with the FDA in the current regulatory environment
  - Guest speaker: Robert Ruffolo PhD, former president, Wyeth R&D

Apr. 4th (Thurs.) BioPharma CEO Perspective – Science, Regulation/Policy, Company Stakeholders
- Perspective on competitive and environmental issues facing BioPharma CEOs, including regulatory issues, impact of health policy/reform, drug pricing & reimbursement, Board and shareholder relations, etc.
- Unique issues of managing early-stage biopharma companies.
- Case study: Vertex Pharmaceuticals
  - Guest speaker: Jeffrey Leiden MD, PhD, Chairman and CEO, Vertex Pharmaceuticals

Apr. 9th (Tues.) Sales and Marketing Practices; Drug Pricing; Case Study: Rheumatoid Arthritis Category
- Goals of pharma marketing; role of sales reps; commercialization strategies - US and int’l; managed care; drug pricing, DTC advertising, etc.
- Who pays for drugs, and how are drug prices set (US, other markets).
- Debate on whether drug prices in US should be regulated similar to OUS markets and its potential impact on innovation.
- RA category: understanding the disease category, evolution of therapeutic agents, clinical development/ regulatory, competitive landscape, pricing & reimbursement, impact of biosimilars, etc.

Apr. 11th
(Thurs.)

**Oncology – Diagnostics and Therapeutics; Global Rx Launches; Case Study of Early-Stage Biopharma Company: Elucida Oncology**

- **Oncology**: Understanding the disease, evolution of therapeutic agents, clinical development/regulatory, competitive landscape, pricing & reimbursement, personalized medicine/ use of biomarkers, etc.
- **Global launches**: regulatory and commercial strategies of launch of a new oncology therapeutic (e.g., Ibrance).
- **Case study of early-stage biopharma company: Elucida Oncology**:
  - Review of cancer-targeting particle platform technology.
  - Uses in therapeutics, diagnostic imaging, surgical, etc.
  - Financing/capital formation strategies.
  - Corporate optimization/ longer-term objectives.
- **Guest speaker**: Geno Germano, President & CEO, Elucida Oncology; former Group President, Pfizer Innovative Pharma Business

Apr. 16th
(Tues.)

**PBM’s/Formulary Management**

- Role of Pharmaceutical Benefit Managers (PBMs); design of prescription drug plans; formulary management; utilization tools, etc.
- Evidenced-based payer value propositions; performance-based pricing and other risk-sharing arrangements.
- **Guest speaker**: Jeff Grosklags, CFO, OptumRx – tent.

Apr. 18th
(Thurs.)

**Corporate Strategy; Portfolio & Pipeline Management and Optimization**

- Portfolio advisory function to guide R&D investment decisions.
- Frameworks and related tools utilized in such analytics.
- Therapeutic category optimization (e.g., oncology platform).
- Other topics: TBD
- **Guest speaker**: Nate Russell, head of Corporate Strategy and Innovation, Pfizer - tent
Apr. 23rd
(Tues.)
Vaccines and HIV – R&D, Marketing, Pricing, Distribution

- Evolution of the vaccines and HIV businesses and franchises.
- Unique development, regulatory, manufacturing and distribution issues.

[Guest speaker: Emilio Emini Ph.D., HIV Program Director, Bill & Melinda Gates Foundation; former head vaccines research, Pfizer]

Apr. 25th
(Thurs.)
Review of Mid/Small Biotechnology Companies

- Current therapeutic focus areas (e.g., oncology, rare disease, etc.).
- Developing models for early-stage compounds (market sizing, probability of regulatory approvals, pricing/reimbursement assumptions, etc.).
- Review of selected biotechnology companies – examples of strong buy and hold rated companies.

[Guest speaker: [biotech equity research analyst]]

Apr. 30th
(Tues.)
Mergers, Acquisitions, and Partnering in the Pharma/Biotech Sector

- Considerations in pursuing and structuring mergers and acquisitions
- Partnering and licensing considerations.
- Outlook for future M&A activity in the industry (“Big Pharma”, specialty pharma/generics, small-cap biopharma companies).

May 2nd
(Thurs.)
Future Outlook of the Global Pharmaceutical Industry

- Will we see enhanced R&D productivity – which research targets are most promising – what are the prospects for “personalized medicine”?
- What changes in market structure and selling dynamics will take place?
- What legislative/policy changes might we see that will impact this sector?
- Will pharma companies become more diversified -- will we see more consolidation?
- Functional roles/career advancement in the biopharmaceutical industry.