[B8746]: Investing in Medical Technologies
Fall 2013 (B-Term)
Monday 5:45 – 9:00pm Uris 331

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Course Overview

This course focuses on the critical factors and approaches that senior managers and sophisticated investors use to identify and value attractive business opportunities and investments in the medical technologies sector. It will provide students with an understanding of the current economic and competitive environment for the development and commercialization of new medical devices, including regulatory, pricing, and reimbursement factors. It will highlight new emerging technologies in the field, and how to assess such novel technologies and build commercial models for valuation purposes. Guest speakers from the medical device industry (company executives, physicians/surgeons, investors) and investment case studies will be used to provide students with practical insight into this complex sector. Critical issues to be examined include:

- Strategies and process of discovering, developing, and the approval of new medical technologies, including impact of government oversight and regulation;
- Pricing and third-party reimbursement of medical devices;
- Health policy/legislative matters impacting this sector;
- Keys to evaluating novel medical technologies and analyzing business drivers and future performance of medical device companies (public and private);
- How to build commercial models, including valuation methodologies that successful investors use to value/price companies in this sector.
- Considerations in taking long and short investment positions in this sector.

The course is cross-functional in its approach, and focuses on “real-world” problems currently facing senior managers and investors in this sector. This course will be useful for students interested in careers in the life science and healthcare services sectors, as well as healthcare consulting, investment banking, equity research, venture capital, private equity, and investment management given the large and growing healthcare practices of such firms. Some understanding of, or experience in, the healthcare/medical technologies sector will be highly valuable.

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>
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<tbody>
<tr>
<td>Corporate Finance</td>
<td>1. Time Value of Money</td>
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<td>2. Risk</td>
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<td>3. Firm Valuation Model</td>
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<tr>
<td>Decision Models</td>
<td>1. Decision Making Under Uncertainty and Risk</td>
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<td>2. Sensitivity Analysis</td>
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<td>3. Modeling Competitive Effects</td>
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<td>4. Modeling in Practice</td>
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<tr>
<td>Managerial Economics</td>
<td>1. Analyzing Complex Decision-making Under Uncertainty</td>
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<tr>
<td>Managerial Statistics</td>
<td>1. Modeling Uncertainty: Random Variables, Distributions,</td>
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<tr>
<td></td>
<td>Making Decisions Under Uncertainty</td>
</tr>
<tr>
<td>Marketing Strategy</td>
<td>1. Company analysis</td>
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<td>2. Competitive Analysis</td>
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<td>3. Market Penetration and Marketing Strategy</td>
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**Format and 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. Prominent guest speakers from the medical device industry, and investors and analysts that focus in this sector, will provide additional real-world insight on key industry challenges and trends.

**Materials**

Certain readings will be distributed on the first day of the course. Additional readings will be handed out in class as needed, or posted on Canvas.

**Course Requirements and Evaluation**

**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.

**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).
Final Paper/Presentation (50%): There will be a final (individual) paper (3-4 pages, excluding exhibits), together with short group presentations in the final class session focused on a sub-sector of the medical device sector that each group will select and follow throughout the course.

Class Schedule and Topics

The following is the schedule of topics (note: specific case studies, companies, and speakers may vary depending on schedules/availability).

Section I: Understanding Key Characteristics and Business Drivers of the Medical Devices Sector

Introduction/Overview
- Environmental assessment and summary of key challenges and opportunities in the global medical device sector.
- Overview of major sub-sectors, emerging technologies, prominent companies, customers, and other key stakeholders.

Regulatory, Intellectual Property/ Patents, Health Policy
- Key regulatory issues shaping the environment.
- Patents on medical devices and related intellectual property issues.
- Health policy issues impacting the medical device sector.

Clinical Development & Approval Process for Devices– Interactions with the FDA
- Clinical development process and strategies.
- Review of device approval process – U.S. and selected int’l markets (how compares with drugs).
- Balancing safety and efficacy; examples of cost effectiveness data.
- Working with the FDA in the current regulatory environment.

Commercialization/Pricing & Reimbursement Considerations
- Customer analysis; pricing/reimbursement; adoption/ utilization; product life cycle, etc.

Section II: Commercial/ Financial Modeling and Valuation Methodologies for New Medical Technologies

Building Commercial Models – the Basics
- Essential tools in building models.
- Modeling out revenue and expense drivers – understanding what is important.
- Stress-testing models.
- Reviewing different valuation methodologies relevant to this sector.
Conducting Primary Research and Effective Analyses
- How to conduct primary research in this sector.
- Determining customer preference.
- What to look for at medical meetings.
- Interpreting clinical data; incidence and prevalence.
- Risk adjusting; POS assumptions.
- Pricing and reimbursement assumptions.
- Examples of effective research and analyses.

Valuation Methodologies
- Common valuation methodologies used in the medical device sector.
- Unique issues in valuing, and investing in, private companies.

Other Investment Considerations – Long/Short
- Other considerations in taking long and short positions.

Section III: Investment Case Studies: Medical Technologies

Case Study: Insulet
- Insulin pump therapy
- Building the commercial model; levers and path toward profitability
- Reflections on valuation at different stages of the investment

Case Study – Boston Scientific (selected pipeline)
- Left Atrial Appendage
  - Overview of the data
  - Review of warfarin use
  - How does this translate into a market model
  - Risk adjusting as an input into the P&L
- S-ICD
  - Discussion of a typical ICD vs. S-ICD
  - Overview of ICD market and indications
  - Review of how it expands the market
  - Analyzing impact on market share
  - Risk adjusting as an input into the P&L

Case Study – Orthopedics
- Overview of the Orthopedic markets
- Examination of volume trends and demographics
- Review of pricing trends
- Discussion of changing landscape of ACO’s, Bundled Payment Initiative, and general price sharing information
- Generic competition? Review of Chinese entrants into Ortho
Case Study – Clinical diagnostics, patents and sequencing

- Myriad Genetics Supreme Court Case
  - Discussion points around the decision
  - Implications for clinical diagnostics

- Illumina - competitive landscape and the clinical opportunities
  - Examination of the competitive landscape
  - Look at the opportunities for clinical medicine
    - NIPT
    - Cancer
    - Neurological

Case Study – China – Opportunity for growth?

- Review of emerging markets for stents, ICDs, etc.
- Analysis of local Chinese manufacturers
- Review of multi-national companies into the Chinese stent market
- Overview of the CRM opportunity in China – is this an investment worth making?

- Course Wrap-up/ Student Presentations