B8746: Investing in Medical Technologies
Fall 2015 (B-Term); Monday 5:45pm – 9:00pm

Instructor: Efrem Kamen, Founder & Managing Member, Pura Vida Investments, LLC
Office: TBD
Email: ejk28@columbia.edu
TA: Sylvia Qiu
Email: sqiu16@gsb.columbia.edu

Course Overview

This course focuses on the critical factors and approaches that 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, investment bankers) 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 & diagnostic 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>
</tr>
</thead>
</table>
| Corporate Finance       | 1. Time Value of Money  
                          | 2. Risk  
                          | 3. Firm Valuation Model  |
| Decision Models         | 1. Decision Making Under Uncertainty and Risk  
                          | 2. Sensitivity Analysis  
                          | 3. Modeling Competitive Effects  
                          | 4. Modeling in Practice  |
| Managerial Economics    | 1. Analyzing Complex Decision-making Under Uncertainty  |
| Marketing Strategy      | 1. Company Analysis  
                          | 2. Competitive Analysis  
                          | 3. Market Penetration and Marketing Strategy  |

Format and Approach

Class participation is highly valued. The course will constantly seek to directly apply the information and ideas discussed in the classroom to issues currently confronting senior managers in this sector. These critical issues will be analyzed in considerable depth. Prominent guest speakers from the medical device industry, along with investors and analysts that focus in this sector, will provide additional real-world insight on key industry challenges and trends.

Materials

Readings and useful links will be posted on Canvas. Certain lecture notes will be distributed at the beginning of class sessions.

Guest Speakers

Rhonda Robb, Vice President and General Manager, Medtronic

Dr. Steven W. Boyce, MD, Cardiac Surgery, Washington Hospital Washington DC.

Michael Giaquinto, Managing Director, Greenhill & Co.

Dan Brennan, Boston Scientific Corp, Chief Financial Officer.

Timothy Ring, CR Bard, Chairman & CEO

Harold Swerdlow Ph.D., Vice President of Technology, Innovation at the New York Genome Center
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 (3-5 pages, excluding exhibits) analyzing a company in the medical technologies sector. Each student will select the company from a list provided by the professor, and write a short analysis (buy or sell recommendation).

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

Lecture #1 - October 26th

Introduction/Overview
- Course introduction and review of syllabus.
- “Big Picture” - key opportunities & challenges in the med. device sector.
- Leading geographic markets, med tech sub-sectors, companies, customers.
- Overview of medical device classifications and regulatory (FDA) review process & analysis for new products (e.g., 510k, PMA).
- Financial characteristics of the sector – margin analysis, growth, valuation.

Current Themes in Healthcare Investing
- Impact of the Affordable Care Act (ACA).
- Consolidation (providers, payers, suppliers).
- Pricing pressures.
- Integrated care/other.

Company viewpoint: Medtronic, Perspective on the Clinical Development and Adoption of Novel Cardiovascular Devices and Treatments
- Product development and going to market
• Market sizing
• What to look for at medical meetings.
• Risk adjusting; POS assumptions.
• Thinking about competition.
• Pricing and reimbursement assumptions.
• Guest speaker: Rhonda Robb, Vice President and General Manager, Medtronic

Lecture #2 - November 9th

Introduction to Session Two
• Recap/key takeaways from Session 1.
• Introduction to regulatory approvals of medical devices.
• How Medical Device approvals and reimbursement impact companies.

Clinical Development & Regulatory Approval Process for Devices
• Overview of clinical development process/strategies for new med. devices.
• 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.

Case study: HVAD Left Ventricular Assist Device

Future Outlook of the Medical Technologies Sector
• What new technologies are most promising?
• How will the regulatory environment change?
• What changes in the market structure & selling dynamics will take place?
• How large a role will emerging markets play?
• What margins and growth rates will the sector experience in 2020?
• Who are likely to be the “winners” and “losers” in the next ten years?
• Guest speaker: Dr. Steven W. Boyce, MD, Cardiac Surgery, Washington Hospital Washington DC.

Section II: Commercial/ Financial Modeling, Valuation Methodologies, and M&A/Financing for New Medical Technologies

Lecture #3 - November 16th

Healthcare Portfolio Management; Building Commercial Models; Valuation of Public and Private Companies

Overview: alternative approaches & strategies in investment management.

Conducting Primary Research and Effective Analyses:
• Determining customer preference.
• What to look for at medical meetings.
• Interpreting clinical data; incidence and prevalence.
• Risk adjusting; POS assumptions.
• Pricing and reimbursement assumptions.

**Building Commercial Models:**
• Essential tools in building commercial models in the healthcare sector.
• Modeling out key revenue and expense drivers.

**Case Study: Boston Scientific Cardiac Rhythm Management Business.**
• Valuation Methodologies: public and private companies.
• Other Considerations: long and short positions.

**M&A and Financing in the Medical Device Sector, including Deal Structures and Valuation Methodologies**
• M&A trends and medical device deal flow (recent past/current).
• Current healthcare/medical device financing environment – IPOs, acquisition financing.
• Valuation methodologies and deal structures in the space.
• Private equity’s role and focus in medical technologies sector.
• Deal analysis/examples - medical devices: 1-2 transactions TBD.
• **Guest speaker: Michael Giaquinto, Managing Director, Greenhill & Co.**

**Section III: Investment Case Studies: Medical Technologies**

**Lecture #4 - November 23rd**

**Case Study – Boston Scientific Corp. (BSX)**
• History and background of BSX.
• Acquisition of Guidant (2006) – rationale, look back/“lessons learned.”
• Current business profile (interventional cardiology, CRM, other).
• Key pipeline candidates and emerging technologies.
• Key regulatory, economic, and market factors impacting medical device companies and BSX future performance, including impact of ACA.
• Growth/turnaround strategy to grow top and bottom line.
• What can go right? What could go wrong?
• **Guest speaker: Dan Brennan, CFO, Boston Scientific Corp.**

**Pipeline analysis/models of BSX products**
• **Left Atrial Appendage**
  o Overview of the data.
  o Review of warfarin use.
  o How does this translate into a market model.
  o Risk adjusting as an input into the P&L.
• **S-ICD**
  o 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.

Modeling Exercise: Overview and Product Model – CR Bard
- Overview of the hospital supply business.
- Company history and background.
- Acquisition history
- Drug coated balloon review

Lecture #5 – November 30th

Review of Midterm Assignment

Modeling Review/Q&A

Case Study: CR Bard
- Drug coated balloon – competitive position.
- Building the commercial model: levers and path toward profitability.
- Reflections on valuation at different stages of the investment.
- Guest speaker: Timothy Ring, CR Bard, Chairman & CEO

Genomics, Sequencing and Diagnostics / Illumina Investment Example
- Understanding genomics, sequencing, bioinformatics analysis, high performance computing and data storage, etc.
- Sizing the market for next generation sequencing (NGS).
- Assessing the competitive landscape.
- Research applications vs. clinical applications.
- NGS vs. Molecular Diagnostics.
- Guest speaker: Harold Swerdlow Ph.D., Vice President of Technology, Innovation at the New York Genome Center

Lecture #6 - December 7th

Case Study: Nevro (NVRO)

Debate: High Frequency Spinal Chord Stimulation vs. Low Frequency Spinal Chord Stimulation
- Sizing the market for SCS
- Understanding the benefits of high frequency SCS
- Comparing Senza to traditional SCS
• Guest speaker: Clinician 1
• Guest speaker: Clinician 2

The Company Perspective

• Guest Speaker: Michael DeMane, Nevro Corporation, Chairman & CEO.

Course Wrap-Up