B40.3176: Topics in Investments - Financial Analysis in Healthcare

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Hours:	By appointment		

COURSE BACKGROUND

The course is taught by a mixture of lecture, discussion, and case method. Students will be taught a framework for critically evaluating and valuing healthcare businesses, with a focus upon drug and medical technology companies. The course will seek to sensitize students to common risks/pitfalls in life science investing. Issues that may impact the industry in the future will also be vetted through discussion. Students should be aware that there will be some limited reading of scientific literature for the class.

COURSE OBJECTIVES

- Acquire a framework to critically evaluate healthcare investment opportunities.
- Learn the basic structure of the US healthcare system and its history with regard to product regulation and payment.
- Evaluate science by understanding how to effectively apply an understanding of clinical context, regulatory requirements, and basic statistics.
- Understand the importance of intellectual property and the impact it has upon healthcare business models.
- Forecast income statements for various kinds of healthcare business models. Become thoughtful when faced with thinking about product pricing, market forecasting, reimbursement, patent expiration, litigation, competition, and operating expenses.
- Perform valuation analysis including basic DCF and comparables analysis. Appreciate the strengths and limitations of valuation approaches.
- Appreciate macroeconomic and industry challenges and be aware of how this may impact healthcare business models in the future.

COURSE REQUIREMENTS

Class Participation – 35% of the grade. Attendance is mandatory.

Written Work – 20% of the grade. 2 assignments.

- Assignment 1 – estimate likelihood of development success for a medical device
- Assignment 2 – build an operating income statement

Final Exam – 20% of the grade. Multiple choice exam covering lecture materials.

Final Paper – 25% of the grade. 5-10 pages, double-spaced. Students write an investment opinion of a publicly listed healthcare company, including the production of supporting materials such as product forecasts, financial model, and valuation analysis. The paper will be due _____.

COURSE POLICIES

Attendance. Attendance is mandatory at all regular class meetings. Exceptions for personal or family emergencies will be granted on a case by case basis.

Tardiness. No assignment will be accepted beyond the announced deadline. As with attendance, exceptions for emergencies will be granted on a case by case basis.

COMPANIES COVERED

- Abiomed (Medical Device)
- Alexion Pharmaceuticals (Biotech)
- Amgen (Biotech)
- Charles River Labs (Clinical Research Organization)
- Cigna (Managed Care)
- Intuitive Surgical (Capital Equipment)
- Masimo (Hospital Supplies)
- Myriad Genetics (Molecular Diagnostics)

SESSION / DATE

1	**Nov 10**	**Industry Overview**

Lecture – Introduce the scope and size of the various subsectors of healthcare and understand how they interact.

Discussion - Via discussion, the class will be introduced to a research framework that can be applied to a large proportion of science-based businesses.

Lecture – Review drug and device development and regulatory processes. Overview of history of government and private insurance market in the United States.

Pre-reading for this session:

Sisko, Andrea. "Health Spending Projections Through 2018: Recession Effects Add Uncertainty to the Outlook." Health Affairs Feb 24, 2009; 28:2 346-357.

http://www.fda.gov/CDER/HANDBOOK/DEVELOP.HTM (drug development path image)

Kaplan, Aaron. "Medical Device Development." Circulation 2004; 109:3068-3072.

2	Nov 17	Evaluating Science: Process and Pitfalls

Lecture – Introduction to scientific analysis and basic clinical trial statistics.

Case – Compare and contrast the clinical data from Eculizumab and Denosumab.
Questions for thought:

1. Which trial is stronger from a statistical perspective?
2. Which drug do you think is stronger from a clinical perspective?
3. What drug has a higher likelihood of ultimately being approved by the FDA?

Discussion – We will discuss the following issues:

1. How might the current and future state of science impact success probabilities in the future?
2. What influence does the FDA have upon success probabilities and how should this be incorporated in your analysis?

Pre-reading for this session:

Segreti, Anthony. "Biopharmaceutical Statistics in a Pharmaceutical Regulated Environment: Past, Present, and Future." Journal of Biopharmaceuticals Statistics 2001; 11:4 347-372.

Kola, Ismil. "Can the Pharmaceuticals Industry Reduce Attrition Rates?" Nature Reviews: Drug Discovery Aug 2004; 3 711-715.

Alexion/Amgen Resources:

- Hillmen, Peter. "Effect of Eculizumab on Hemolysis and Transfusion Requirements in Patients with Paroxysmal Nocturnal Hemoglobinuria." NEJM Feb 2004; 350:6.

- McClung, Michael. "Denosumab in Postmenopausal Women with Low Bone Mineral Density." NEJM Feb 23, 2006; 354:8.

Assignment due next class:

Read the paper discussing Abiomed's minimally invasive cardiac pump. Assign a likelihood of success for their ongoing clinical trial and ultimate regulatory approval.

Assignment materials:

- Abiomed US feasibility study presentation handout

3	Nov 24	Forecasting Revenue Ramps and Tails

Lecture – Introduction to intellectual property, generic drug regulation, and legal strategy.

Case – What might Amgen's denosumab revenue curve in osteoporosis look like for the life cycle of the drug? Questions for thought:

1. How would you approach estimating the size of the potential osteoporosis market?
2. How would you get a sense of how denosumab might fit into the treatment paradigm?
3. What will Fosamax's (a currently approved drug) revenue curve look like?

Discussion – Please be prepared to discuss the following issues:

1. How might different approaches to revenue forecasting differ in their reliability?
2. What role does regulation play in forecasting revenue curves (in particular tails) for small molecule drugs and biologics? How about for devices and services?
3. How is intellectual property law changing and how might it impact revenue curves in the future?

Pre-reading for this session:

Grabowski, Henry. "Generic Competition and Market Exclusivity Periods in Pharmaceuticals." Managerial and Decision Economics 2007; 28: 491-502.

Enthoven, Alain. "Employment-Based Health Insurance: Past, Present, and Future." Health Affairs Nov/Dec 2006; 25:6 1538-1547.

http://www.fda.gov/Cder/about/smallbiz/exclusivity.htm (new drug exclusivity faq)

http://www.fda.gov/cder/about/smallbiz/patent_term.htm (patent term restoration faq)
http://www.fda.gov/cder/regulatory/applications/ANDA.htm (anda process)

Amgen Denosumab Resources (please feel free to do additional research):

- Gass, M. "Preventing Osteoporosis-related Fractures: An Overview." American Journal of Medicine 2006; 119:4A 3S-11S.
- Handout showing historical osteoporosis product sales, pricing, and units.

4	Dec 1	Forecasting Costs and Profitability

Lecture – Framework for how to build up R&D and SG&A expenses for drug, device, tool, and diagnostic companies. Review benchmarks for partnership agreements. How to account for dilution during product development and commercialization.

Case - Compare and contrast Intuitive Surgical and Masimo's business models.

1. How might their revenue trajectories differ?
2. How do the risks to their business models differ?
3. Explain why their R&D as a percentage of revenue may be similar or different.
4. Explain why their SG&A as a percentage of revenue may be similar or different.

Discussion – We will spend some time discussing the following issues:

1. How might R&D as a percentage of sales for life science companies change over time?
2. How might deal structures between players in industry change over time?
3. Can we expect future estimates of dilution to look like past benchmarks?

Pre-reading for this session:

McCully, M. "Current Trends in Deals and Financing." Recombinant Capital.

DiMasi, JA. "The price of Innovation: New Estimates of Drug Development Costs." Journal of Health Economics 2003; 23 151-185.

Intuitive Surgical & Masimo Labs Resources:

- Investor Presentation
- 10K
- Sell-side initiations (will be handed out in class)
- American Hospital Association Factbook

Assignment due next class:

Build an operating income statement for Myriad Genetics assuming their only product is the BRACAnalysis molecular diagnostic. Forecast revenues and justify your assumptions. Also justify your assumptions for R&D and SG&A.

Assignment Resources:

- Handout of historical BRACAnalysis revenues, units, and operating costs to date.
- Your own web research on various ways to estimate revenue trajectory into the future.
- Your own estimates of future operating costs and justifications.

5	Dec 8	Valuation Approaches and Limitations

Lecture – Review key attributes of healthcare companies and how they are reflected by traditional valuation approaches. Within discounted cash flows; how to think about terminal value, scenario based analysis, discount rate, and dilution. Within comparables analysis; why companies with similar growth profiles trade at different multiples, and how to think about the 'appropriate' multiple. The practical use of real options analysis. How potential acquirers think about M&A valuation. Approaches for valuing technology platform companies.

Case – How much is Myriad Genetics worth? Questions to think about:

1. Review income statement together.
2. What valuation methods can be utilized here? What are their limitations?

Discussion – We will spend some time discussing the current valuation of various types healthcare companies and how this may change in the future. Some questions to think about.

1. What do you think about the implied terminal value of specialty pharmaceutical companies? Is this appropriate?
2. How should managed care companies be valued?
3. What are the key valuation drivers for clinical research organizations?
4. What factors are key for the future valuation of biotechnology companies?

Pre-reading for this session:

Bogdan, Boris. Valuation in Life Sciences: A Practical Guide. Berlin Germany: Springer, 2008. *Chapter on Project Valuation with DCF will be handed out in class.*

Villiger, Ralph. "Pitfalls of valuation in biotech." Journal of Commercial Biotechnology. April 2006; 12:3: 175-181.

Booth, Bruce. "Valuation with Cash Multiples." Nature Reviews: Drug Discovery July 2005, 4: 533-534.

Comparables valuation handout for various subsectors in healthcare.

6	Dec 15	Industry Challenges and Macroeconomic Issues

Final Exam – 45 minute multiple choice exam covering lectures.

Lecture – International healthcare markets and globalization. European and Japanese regulatory regimes and payment systems.

Discussion – In today's healthcare market, where might the most promising investment opportunities and largest risks exist?

		Additional Possibilities

Case – In 2007 Cigna reached a net operating margin of 8%. How should we think about the likely profitability of Cigna in the future? Questions for thought:

1. What trends are occurring in Cigna's mix of business?
2. How do these business lines differ in profitability?
3. How should we think of pricing in this sector?
4. How should we think about government's influence in this sector?

Case – What should Charles River' strategy be?

1. What areas of Charles River's business is most at risk? By who/what?
2. What service areas should Charles River pursue?
3. How will this industry evolve in the future?