BIOTECHNOLOGY INDUSTRY, STRUCTURE & STRATEGY
SPRING 2015
NYU School of Medicine
Translational Research Building (227 E. 30th Street) Room 819
Friday 1:00PM – 4:00PM

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COURSE DESCRIPTION AND GOALS

Biotechnology started as a science, referring to the use of living cells as factories to produce protein through manipulation of genes. Yet today, biotechnology refers to an industry, with the top companies in the sector exceeding some of the major pharmaceutical companies in market capitalization. No longer are biotechnology companies constrained to using recombinant DNA technology alone, as the moniker is assigned today to any small company engaged in any life sciences-related research directed toward developing a commercial product, using any scientific means. Belonging to the sector usually also implies a culture – small, nimble, visionary but practical, cash constrained but willing to risk it all. While some of the above characteristics are more idealized than real, it is certainly the case that, while the key factors for success in a development stage company include the very same scientific, analytic, and/or managerial talents that reside in “big pharma”, the context is different, requiring the organization to incorporate some additional skills to ensure survival, and non-traditional systems to support success.

These systems are meant to reconcile the long product development cycles inherent to the industry with the shorter “survival index” supported by the available cash. In pharma in general, the long Product R&D cycles may minimize the rigor behind decision-making, since there is a long time lag between the action taken, and its ultimate impact. Moreover, paradoxically, there is a “comfort” to operating at a significant loss for many years, spending hundreds of millions of dollars of investors’ money, relieving the incentive to generate incremental revenue or savings that seem insignificant relative to the scale of the investment and the size of the opportunity. Finally, the need to constantly raise money sometimes favors promotion over analysis, and short-term impact on share price, rather than long-term creation of value.

We are going to try to avoid all of those traps, mindful that there is less margin for error built into the “biotech” business model. But we will superimpose a whole other set of considerations that make the industry different from just a smaller version of “big pharma”. Your ability to think across functions will be critical, as will your flexibility and ability to adapt the plan to changing circumstances. Finally, your own personal style will be more prominently displayed while swimming for survival in a small glass fish bowl, sharing the space with the occasional piranha.
COURSE FORMAT

My goal for the course is not to make you experts on the facts and figures of the industry. Instead, the goal is to teach you to identify issues, practice how to analyze and solve them, and then implement your solution from the perspective of a senior manager in a biotechnology enterprise. Most of the course will not be on starting a biotechnology company, but rather on running one. Therefore, the format will be primarily discussion rather than lecture, anchored around case studies of real situations faced by companies similar to those that you will (hopefully) found and/or join. Within the course, you will be exposed to all of the important functional areas: discovery, development, manufacturing, marketing, and sales. In addition, the more global topics of strategy, financing (including corporate deals), intellectual property, bioethics, and organizational behavior, will be addressed.

Our sessions are a three hours long but we have relatively few given the breadth of information to be covered, resulting in some compromises in course content. For example, while there will be some readings assigned and classroom discussion about medical devices and diagnostics, the major focus will be on pharmaceutical applications, as they tend to be more complex. However, there will be a full session dedicated to diagnostics, reviewing a case about Personalized Medicine in light of the increasing attention given to this field by drug developers and regulatory agencies. In additions, there will be a single medical device case which will provide a framework for comparing and contrasting drugs vs. devices from a clinical, regulatory, and reimbursement perspective. To minimize the need for starting from scratch with each case analysis, I have tried to carry companies and/or markets across multiple topics. For example, I have written three cases about my most recent company, Cypress Bioscience, Inc.– one covering clinical development, the second dealing with negotiating corporate deals, and the last with private and public financing. Given the length of each class, I will intersperse some alternative formats to maintain your interest, while saving my voice. One of these alternative formats, to be used frequently, will be our switching roles, with one or more of you taking on leadership of the class discussion. Other days may include team exercises, and/or videos. We will also have a guest at every session (except the first), typically a life science entrepreneur from the greater NYU community, so that you can hear from those that have successfully put the theory into practice. Many of the participating guests are already listed in the syllabus by session.

HOMEWORK AND GRADING

By way of philosophy, I come into the course with very high expectations of what each of you is capable of achieving, and will do my best to push you to realize that potential. As a result, the first session or two can be a little awkward, as we search to find a happy medium between what is possible and what is realistic. Based on past experience, the process, although perhaps frustrating in the very short term, yields large benefits, as we work together to tailor the rest of the quarter to meet the needs of the class as a whole, and of the individuals therein. My advice: hang in there, and provide me with feedback in real-time as to what works best, since the faster I know, the faster I can adjust.

A large component of your grade (50%) will be driven by the quality of your classroom participation. Please be sure to read and prepare the assigned cases to the best of your abilities. Depending on how many students we end up with in the class, I might suggest that you break up into teams so that the team members can work together to prepare the assigned case for the week.
The cases are listed below, and are all to be found on a “Course Pack” from Harvard Business School Publishing. To access the Course Pack use the following link: https://cb.hbsp.harvard.edu/cbmp/access/31888380.

When you open the course pack, you will find the cases listed in order, along with some additional required and optional readings for each session. You will also find the list of readings in the syllabus below, with those that are required highlighted in bold. You may also find a few articles listed that are not included in the Course pack, which can be accessed through the NYU library. Use of most of the readings requires a small fee, which you will be able to pay on the Harvard Business School site.

Remember, you are in the role of the CEO (or other key executive) in each case. You will be expected to have analyzed the situation, identified the key issues, and formulated a plan to address them. I am not looking for general platitudes by way of response. I want to hear the details of your analysis and the specifics of your plan. Perhaps different from the direction given to you in other classes, you are to strive to fully understand all of the available options, the trade-offs between the various solutions, and the implementation needs of the one that you choose. Do not confine yourself to the information included in the cases or the associated readings. You are encouraged to bring as much information as you can to each analysis, from other literature that you identify, company websites and/or public filings, or from discussion with those with relevant first-hand experience. Also, while the cases are meant to be analyzed, the readings are meant to be read, not studied or memorized. You will be evaluated based on your demonstrated problem-solving abilities, rather than on mastery of information. Consistent with this philosophy, no exams are planned.

The course will have a focus only on the Life Sciences industry. As the first few sessions introduce you to basic industry structure and strategy, each team will be asked to build an Excel spreadsheet of a “typical” pharmaceutical company P&L, and an “average” pharmaceutical product P&L. You will be provided with more detail when we meet.

In addition, all of you will be active participants in the two-part corporate partnering session (in which you will play the principals in a mock negotiation). For these exercises, we will merge whatever number teams that are formed into three. More details on the assignments for these sessions will follow. While, in general, your preparation for each session will be self-guided, you will be required to build a financial model (Excel) in preparation for the mock corporate partner negotiation session (case of “Cypress Bioscience, Inc. B: Finding Milnacipran’s Mate”). All of the above activities will be factored into the class participation component of your grade.

Since there are so few sessions, you must attend them all! If for some significant and unavoidable reason you must miss a class, please let me know in advance.

The remaining 50% of your grade will be based on a short paper to be submitted by our last session. The goal of this exercise is to have you apply what you have learned to the analysis of a local company. You choose the company, but it should be one with which you have no more than a passing familiarity. This is an exercise to be completed as an individual rather than as part of a team. Each of you needs to choose a different company. There will be a sign-up sheet at which you can “stake your claim.” Your task is to learn about the company from publicly available information. Your paper should include some company background (for my sake), but that piece need not be authored by you. You may use, for example, the executive summary from the company’s press kit, the business section from one of their public filings, or an analyst report initiating coverage on the company, that you will attach to your paper when you hand it in (preferably by e-mail). Your assignment is to identify a key issues faced by the company, based on what you have learned during the course. This issue should not be generic, but rather raised within the context of the company’s unique character – its technology, its people, its market, its investors, and the
like. Moreover, it may very well be issues that are different from those highlighted by the company within their public filings. After identifying the issue, I would like you to provide an analysis based on what you have learned in the course: Describe how the company has addressed the issue (if at all), along with a critique of their plan or actions: Do you agree with their approach to addressing this key challenge? Do you view the challenge and its solution differently than does the company? What action(s) do you think that the company should take to further analyze and/or overcome the challenge? The paper should run 3-5 pages, excluding the company background information. We will discuss this assignment further when we meet in person.

GENERAL BACKGROUND READING

BOOKS:


Keegan, Karl. Biotechnology Valuation: An Introductory Guide. Wiley (2009). For those of you with aspirations to work on Wall Street covering life sciences companies, this is a handy primer to the complex problem of trying to value biotechnology companies – especially early stage ones.

Robbins-Roth, Cynthia. From Alchemy to IPO: The Business of Biotechnology. Perseus Books Group (May 15, 2000). This book is similar to the Campbell reference above, but more specific to the small company biotechnology setting.

Werth, Barry. The Billion Dollar Molecule: One Company's Quest for the Perfect Drug. Simon & Schuster (1995). This is probably the best general interest book ever written about biotech. The book follows a company, Vertex Pharmaceuticals, from its inception through its “growing pains”, and ultimately to its success. Like a good thriller, it has it all – good guys versus bad guys, heart-stopping action, and pathos. Enjoy!
Below you will find a list of the planned sessions and dates. Do not be surprised if there are some changes along the way. In such case you will be notified with enough time in advance to prepare the appropriate assignment.

January 9, 2015: STRATEGY AND BUSINESS MODELS

During this first session, we will discuss the biotechnology industry's structure and strategies, in the form of examination of various business models – their rationale and sustainability. The session will also stress the economics of the industry as a whole, as well as of individual functions therein. To accomplish this goal, we will use two cases:

- one a recently written case about MorphoSys, a Germany based antibody company which must weigh the trade-offs of running their business as a “technology” business versus a “product” business, with the concomitant tradeoffs of risk versus return; and,
- a case about an earlier stage venture, Intellikine, and its “build to sell” strategy.

No need to worry for this first class about presenting; I will run the class for this session to give you a sense of how we go about analyzing and discussing cases. However, I do need you to read and prepare the two cases in advance.

CASES:


ARTICLES:


January 16, 2015: DRUG DISCOVERY

During this session, we will focus on options available to companies to generate a strong pipeline of novel drug candidates. The focus will be strategic, organizational, and operational, rather than technical. The first case (Wyeth) focuses on internal project prioritization while the second (Merck) raises the question of the efficiency of internal work versus accessing resources from outside of the company.

CASES:


NOTES:


ARTICLES:


INVITED GUEST: Mark Merrill, Principal – Griffin Securities
January 23, 2015: DRUG DEVELOPMENT
During this part of the session, we will discuss the clinical and regulatory processes. To those trained as scientists, clinical development seems so simple, yet it is the most complex, risky, and expensive part of the business. In this area, the company must make tradeoffs between rigor and practicality, in a process that is ultimately responsible for whether a company will succeed or fail. In development, outstanding execution is necessary but not sufficient for success. Strategic and tactical planning (in advance) is what separates the winners from the losers.

CASE:
A description of how a company took advantage of the inherent complexity of drug development to establish a competitive position.

NOTES:


INVITED GUESTS: Philip Band, CEO – Cytodel
Steve Isaacman, Ph.D., Founder & CEO, Nanometrics LLC
January 30, 2015: INTELLECTUAL PROPERTY

Today, you will be introduced to both legal and business elements of intellectual property (IP), and how company operations and strategy need to take IP into account. We will use the case of DiagnoFirst, which highlights the issue of whether genes are patentable, and its business implications.

CASES:


ARTICLES:


INVITED GUEST: Michael Kasdan – Partner, Wiggin and Dana
February 6, 2015: MANUFACTURING
Unlike in other industries, where manufacturing is all about lowering cost of goods, manufacturing plays a more strategic role in the pharmaceutical industry. It is the key element used by regulators to define and approve classic biotechnology products (biologics), and also is critical to establishing barriers to entry of others.

CASE:

INVITED GUEST: Dr. Bruce Cronstein, Director of the Clinical and Translational Science Unit, NYU Medical Center
DEALS: PARTNERSHIPS AND FINANCINGS
It takes years for most biotechnology companies to become profitable. It takes hundreds of millions of dollars of investment to get a company to that point. In this session, we will assume that the technology and/or product is financable. Yet, even though money may be available to a company, knowing when and how to collect it is a key decision for management. Today, we will discuss a common vehicle for raising money: corporate partnerships.

February 13 and 20, 2015: CORPORATE PARTNERING
This "hands-on" experience will be a 2-part session, as you will prepare for and participate in negotiating a corporate deal between four different parties, with different goals and conflicting needs.

CASE:
This case will serve as the basis for a mock negotiation, complicated by the typical need for a biotech company to renegotiate old agreements to form new ones.

NOTE::Hamermesh, Richard and Robert F. Higgins. "Note on Biotech Business Development."

INVITED GUESTS: Gordon Beck, VP – Business Development at AuraSense Therapeutics (2/13) and Frank Rimalovski, Director, NYU Entrepreneurial Institute (2/20)
February 27, 2015: FINANCINGS
Today, we will discuss the most common vehicles for raising money: private or public financings

VC’s, PIPE’s, IPO’s, Convert’s, Corporate deals – What to do?

CASES:
This case is all about the “who, what, where, when, how, and why” of raising money for an established biotechnology company.

Describes the mechanics of going public.

ARTICLES:

INVITED GUEST: Dr. Seth Orlow, Professor & Chair of Dermatology, NYU Medical Center, and Senior Advisor, Pharus Advisors; Former Co-Founder, Anaderm and Former Partner. Easton Capital Ptrs
March 6, 2015: SALES & MARKETING
If you love scandals, then this is the session that you have been waiting for! Pharmaceutical sales reps do not sell; they educate. Yet, lately, the press has vocally portrayed the industry's sale techniques as having undue influence on the prescribing habits of physicians. Are the cynics correct? If so, is it truly a problem?

CASE:
The anti-depressant market grew from a small “niche”, to its position today as the largest category in all of pharmaceuticals. This case will give us a chance to discuss how science and marketing came together to effect that transformation, and how the two continue to be used today to differentiate one anti-depressant from another.

NOTE:
Herzlinger, Regina E, Selin Gunal Tyler, and Charles C Huang. Social Media in Health Care Harvard Business School 311093.

INVITED GUEST: Jen van der Meer, Co-founder of Databetik
March 13, 2015: PRICING: The Interface of Economic Analysis, Public Policy, and Bio-ethics

Our prior sessions on sales and marketing and intellectual property provide a natural segue into a discussion of the inter-related topics of pricing and reimbursement, which, in turn, requires an analysis of the economic value of the product, tempered by a consideration of the ethical issues around access to care. While focusing on pricing, this session will also serve as an introduction toward the much broader fields of health policy and bioethics. Because of the breadth of today’s subject, we will be using two different cases – Metabical, to provide a little more practice on the process of modeling and analysis, and Gilead, to provide a more strategic perspective on pricing.

CASES:


NOTES:


INVITED GUEST: TBD:
March 20, 2015: PERSONALIZED MEDICINE
Today we will consider Genomic Health, one of the hottest companies in the “personalized medicine” space, to gain an understanding of the historical differences between the diagnostics and therapeutics industries, and to learn of the convergence now underway.

CASES:


NOTE:

ARTICLE:

INVITED GUEST: Dan Malamud, Professor of Dentistry, NYU, and Founder of TB Bioscience
March 27, 2015: MEDICAL DEVICES
We will close with a case on medical devices to compare and contrast with our therapeutics, such as drugs.

CASES:

NOTE:

INVITED GUEST: Andre Fenton, Professor Center for Neural Science, NYU and Co-Founder of BioSignal
GENERAL SOURCES

Journals:
- Nature Biotechnology; http://www.nature.com/nbt (especially the BioEntrepreneur column).
- Nature Reviews Drug Discovery; http://www.nature.com/nrd.
- New England Journal of Medicine; http://content.nejm.org (the most prestigious general medical journal, with frequent articles on policy issues).

Trade Publications:
- Chemical and Engineering News; http://pubs.acs.org/cen.
- In Vivo: The Business and Medicine Report; http://archive.windhover.com (the most sophisticated of all of the trade publications, with feature articles only, backed by detailed analysis).
- Medical Technology Stock Letter; http://www.bioinvest.com/FrontEnd. (biotechnology stock-picking advice by one of the best in the business)
- Modern Drug Discovery; http://pubs.acs.org/journals/mdd.
- Signals; http://www.signalsmag.com (on-line magazine with more of a financial bent. Edited by Recombinant Capital).

1. Free resources (of which there are not many) are noted in bold.
2. I will try to make sure that as many of the journals and books listed above as possible are available (in some form) at the Library.
3. ALL ARE OPTIONAL!

Data Sources:
- Analyst Reports from Investment Banks (only available to account holders)
- Ernst & Young Annual Reports on Life Sciences; http://www.ey.com (free to clients).
- Evelexa (advice for bioentrepreneurs); www.evelexa.com.
- IMS; http://www.IMShealth.com (the best source for data on markets).
- Medscape; http://www.medscape.com (general reviews and on-line continuing education on various medical topics, organized by specialty).
- Pharmaprojects; http://www.pipubs.com/pharmaprojects (lists status of all drugs in R&D).
- Recombinant Capital; http://www.recap.com (great data source on corporate deals. Some of the data is free).
- Think Pharm; http://www.thinkpharm.com (focuses on providing patent expiration dates).
Books:

- *Startup to IPO: How to Build and Finance a Technology Company*, Donald H Macadam. Xlibris (February 2, 2004).

Government / Industry Sites:

- BIOCOM; [http://www.biocom.org](http://www.biocom.org) (California regional biotechnology industry trade organization).
- FDA; [http://www.fda.gov](http://www.fda.gov).
- PhRMA.org; [http://www.phrma.org](http://www.phrma.org) (pharmaceutical industry trade organization).